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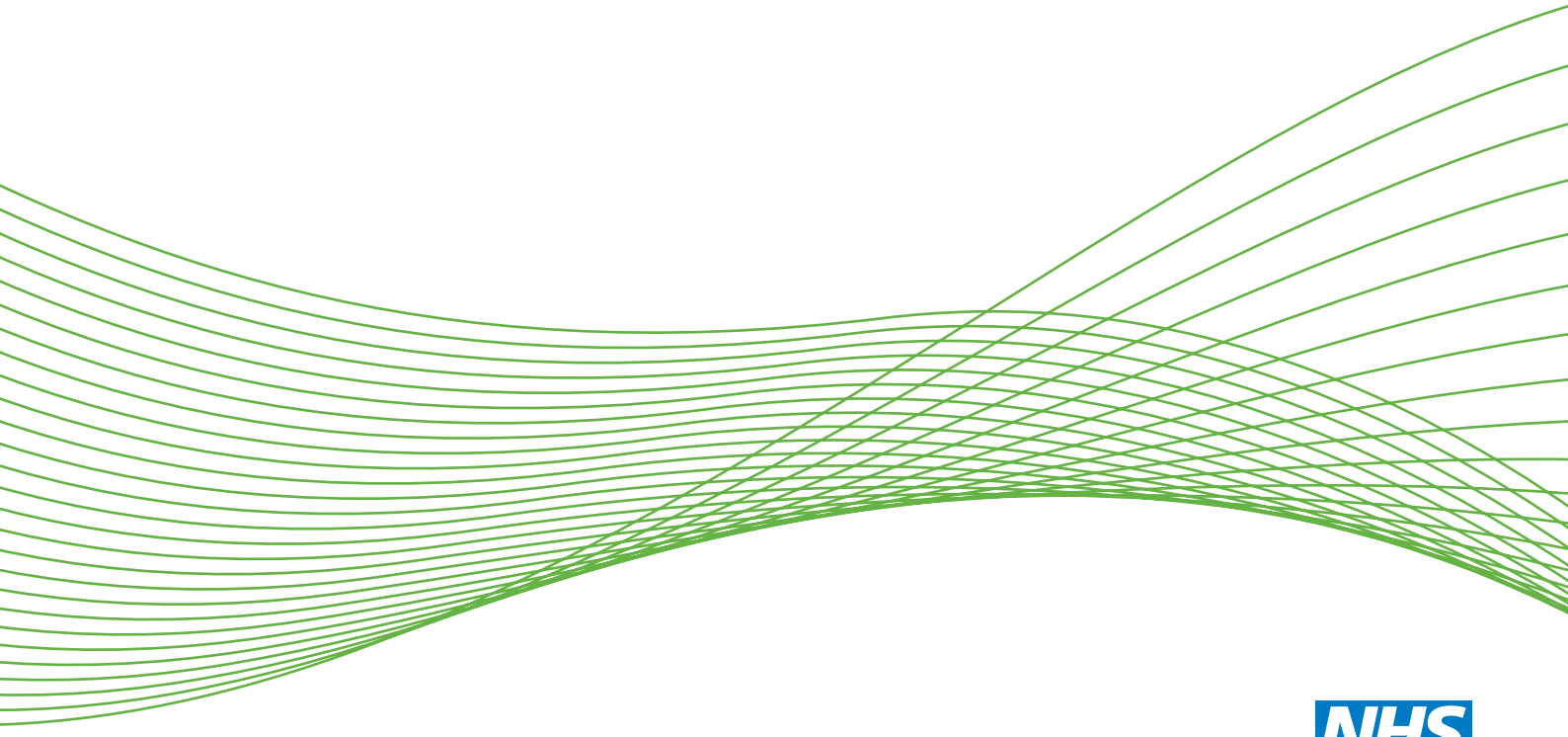

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Abstract

Cost and Outcome of BehaviouRal Activation (COBRA): a randomised controlled trial of behavioural activation versus cognitive–behavioural therapy for depression

David A Richards,[1]* Shelley Rhodes,[1] David Ekers,[2] Dean McMillan,[3] Rod S Taylor,[1] Sarah Byford,[4] Barbara Barrett,[4] Katie Finning,[1] Poushali Ganguli,[4] Fiona Warren,[1] Paul Farrand,[5] Simon Gilbody,[3] Willem Kuyken,[6] Heather O'Mahen,[5] Ed Watkins,[5] Kim Wright,[5] Nigel Reed,[7] Emily Fletcher,[1] Steven D Hollon,[8] Lucy Moore,[1] Amy Backhouse,[1] Claire Farrow,[2] Julie Garry,[1] Deborah Kemp,[2] Faye Plummer,[9] Faith Warner[1] and Rebecca Woodhouse[3]

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Background: Depression is a common, debilitating and costly disorder. The best-evidenced psychological therapy – cognitive–behavioural therapy (CBT) – is complex and costly. A simpler therapy, behavioural activation (BA), may be an effective alternative.

Objectives: To determine the clinical effectiveness and cost-effectiveness of BA compared with CBT for depressed adults at 12 and 18 months' follow-up, and to investigate the processes of treatments.

Design: Randomised controlled, non-inferiority trial stratified by depression severity, antidepressant use and recruitment site, with embedded process evaluation; and randomisation by remote computer-generated allocation.

Setting: Three community mental health services in England.

Participants: Adults aged ≥ 18 years with major depressive disorder (MDD) recruited from primary care and psychological therapy services.

Interventions: BA delivered by NHS junior mental health workers (MHWs); CBT by NHS psychological therapists.

Outcomes: Primary: depression severity (as measured via the Patient Health Questionnaire-9; PHQ-9) at 12 months. Secondary: MDD status; number of depression-free days; anxiety (as measured via the Generalised Anxiety Disorder-7); health-related quality of life (as measured via the Short Form questionnaire-36 items) at 6, 12 and 18 months; and PHQ-9 at 6 and 18 months, all collected by assessors blinded to treatment allocation. Non-inferiority margin was 1.9 PHQ-9 points. We undertook intention-to-treat (ITT) and per protocol (PP) analyses. We explored cost-effectiveness by collecting direct treatment and other health- and social-care costs and calculating quality-adjusted life-years (QALYs) using the EuroQol-5 Dimensions, three-level version, at 18 months.

Results: We recruited 440 participants (BA, $n = 221$; CBT, $n = 219$); 175 (79%) BA and 189 (86%) CBT participants provided ITT data and 135 (61%) BA and 151 (69%) CBT participants provided PP data. At 12 months we found that BA was non-inferior to CBT {ITT: CBT 8.4 PHQ-9 points [standard deviation (SD) 7.5 PHQ-9 points], BA 8.4 PHQ-9 points (SD 7.0 PHQ-9 points), mean difference 0.1 PHQ-9 points, 95% confidence interval (CI) –1.3 to 1.5 PHQ-9 points, $p = 0.89$; PP: CBT 7.9 PHQ-9 points (SD 7.3 PHQ-9 points), BA 7.8 PHQ-9 points (SD 6.5 PHQ-9 points), mean difference 0.0 PHQ-9 points, 95% CI –1.5 to 1.6 PHQ-9 points, $p = 0.99$}. We found no differences in secondary outcomes. We found a significant difference in mean intervention costs (BA, £975; CBT, £1235; $p < 0.001$), but no differences in non-intervention (hospital, community health, social care and medication costs) or total (non-intervention plus intervention) costs. Costs were lower and QALY outcomes better in the BA group, generating an incremental cost-effectiveness ratio of –£6865. The probability of BA being cost-effective compared with CBT was almost 80% at the National Institute for Health and Care Excellence's preferred willingness-to-pay threshold of £20,000–30,000 per QALY. There were no trial-related adverse events.

Limitations: In this pragmatic trial many depressed participants in both groups were also taking antidepressant medication, although most had been doing so for a considerable time before entering the trial. Around one-third of participants chose not to complete a PP dose of treatment, a finding common in both psychotherapy trials and routine practice.

Conclusions: We found that BA is as effective as CBT, more cost-effective and can be delivered by MHWs with no professional training in psychological therapies.

Future work: Settings and countries with a paucity of professionally qualified psychological therapists, might choose to investigate the delivery of effective psychological therapy for depression without the need to develop an extensive and costly professional infrastructure.

Trial registration: Current Controlled Trials ISRCTN27473954.

Funding: This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 21, No. 46. See the NIHR Journals Library website for further project information.

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List of abbreviations

AD-SUS	adult service use schedule
ADM	antidepressant medication
AE	adverse event
AfC	Agenda for Change
BA	behavioural activation
BADS	Behavioural Activation for Depression Scale
CBT	cognitive–behavioural therapy
CEAC	cost-effectiveness acceptability curve
CI	confidence interval
COBRA	Cost and Outcome of BehaviouRal Activation
CONSORT	Consolidated Standards of Reporting Trials
CSO	clinical studies officer
CTS-R	Cognitive Therapy Scale-Revised
DAS	Dysfunctional Attitudes Scale
DMC	Data Monitoring Committee
DSM-IV	*Diagnostic and Statistical Manual for Mental Disorders*-Fourth Edition
EQ-5D-3L	EuroQol-5 Dimensions, three-level version
GAD-7	Generalised Anxiety Disorder-7
GP	general practitioner
IAPT	Improving Access to Psychological Therapies
ICER	incremental cost-effectiveness ratio
ITT	intention to treat
MDD	major depressive disorder
MHW	mental health worker
MICE	multiple imputation by chained equations
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
PenCTU	Peninsula Clinical Trials Unit
PHQ-9	Patient Health Questionnaire-9
PM	process measure
PM1	process measure point 1
PM2	process measure point 2
PP	per protocol
PPI	patient and public involvement
PSS	Personal Social Services
PWP	psychological well-being practitioner
QALY	quality-adjusted life-year
RCT	randomised controlled trial
REC	Research Ethics Committee
RRS	Ruminative Response Scale
SCID	Structured Clinical Interview for DSM Disorders
SD	standard deviation
SEM	structural equation modelling
SF-36	Short Form questionnaire-36 items
SHAPS	Snaith–Hamilton Pleasure Scale
TMG	Trial Management Group
TSC	Trial Steering Committee

Plain English summary

Depression is a major health problem that causes severe hardship, distress and disability to many people. Cognitive–behavioural therapy (CBT), which works by helping people change the way they think, is an effective treatment for depression but its delivery requires a highly trained and professionally qualified workforce. Behavioural activation (BA), which works by helping people change the way they behave, may be an effective alternative to CBT and, because it is simpler, might be delivered more cheaply by less specialised health workers.

In this study, we directly compared CBT with BA, allocating people by chance, so that half of our 440 research participants received BA and half received CBT, to see if people receiving BA were no worse off than those treated with CBT. We also analysed cost-effectiveness – the differences in the costs of both treatments related to their effectiveness – and interviewed participants and therapists for their views on treatment.

We found that the people in both groups improved. We also found that at 6, 12 and 18 months after people were allocated to either treatment, those receiving BA were not worse off in terms of symptoms of depression than those receiving CBT, as measured by any questionnaires we used. We also found that the total costs of health and social care were lower for people treated with BA and that it was more likely that BA was cost-effective compared with CBT. Patients and therapists identified some challenges receiving and delivering treatment, but found BA and CBT to be acceptable overall.

In conclusion, our trial has shown that BA is a clinically effective and cost-effective alternative psychological therapy to CBT for the treatment of patients with depression.

Scientific summary

Background

Depression is a common, debilitating and costly disorder. Many patients request psychological therapy but the current best-evidenced therapy – cognitive–behavioural therapy (CBT) – is complex and costly. A simpler therapy, behavioural activation (BA), may be an effective alternative.

Objectives

1. To assess the clinical effectiveness of BA compared with CBT for depressed adults in terms of depression treatment response at 12 and 18 months.
2. To assess the cost-effectiveness of BA compared with CBT in terms of quality-adjusted life-years (QALYs) at 18 months.

We undertook a secondary process evaluation to investigate the moderating, mediating and procedural factors in BA and CBT that influence outcome.

Design

Randomised controlled non-inferiority trial.

Setting

Three English community mental health services.

Participants

Adults aged ≥ 18 years who met *Diagnostic and Statistical Manual of Mental Disorders*-Fourth Edition criteria for a major depressive disorder recruited from primary care and psychological therapy services in Devon, Durham and Leeds, excluding people who were receiving psychological therapy, were alcohol or drug dependent, were acutely suicidal or had attempted suicide in the previous 2 months, were cognitively impaired, had bipolar disorder, or who had psychosis or psychotic symptoms.

Randomisation

We randomly allocated participants in a 1 : 1 ratio to either BA or CBT arms stratified according to symptom severity on the Patient Health Questionnaire-9 (PHQ-9; < 19 vs. ≥ 19 points), antidepressant medication (ADM) use (yes/no) and recruitment site.

Allocation concealment

The registered Peninsula Clinical Trials Unit allocated participants remotely using a password-protected website after the researchers had collected and entered baseline data into a computer database.

Blinding

It was not possible to blind participants or clinicians. We ensured that research assessors were blind to participant allocation and we protected against assessment bias by using self-reported measures. We recorded instances where researchers were unblinded.

Interventions

After 5 days of training, NHS mental health workers (MHWs) and therapists delivered a maximum of 20 face-to-face weekly sessions of 1 hour duration of either BA or CBT, with the option of four additional booster sessions. MHWs and therapists received 1 hour of clinical supervision fortnightly from NHS psychological therapists clinically experienced in BA or CBT.

Behavioural activation

Behavioural activation, delivered by MHWs at NHS Agenda for Change (AfC) band 5 grade, was a structured programme increasing contact with potentially antidepressant environmental reinforcers and reducing the frequency of negatively reinforced avoidant behaviours. Specific BA techniques included the use of a functional analytical approach, self-monitoring, identifying 'depressed behaviours', developing alternative goal-orientated behaviours and scheduling. The role of avoidance and rumination was addressed through functional analysis and alternative response development.

Cognitive–behavioural therapy

Cognitive–behavioural therapy, delivered by NHS AfC band 7 therapists, was a structured programme to identify and modify negative automatic thoughts, maladaptive beliefs and, if indicated, underlying core beliefs. Specific CBT techniques included scheduling activity and mastery behaviours, the use of thought records and modifying maladaptive beliefs and rumination content. The behavioural elements in CBT focused on increasing activity with behavioural experiments to test specific cognitive beliefs rather than the contextual, functional analytical approach of the BA trial arm.

Measures

Baseline information

We collected demographic data at baseline on gender, age, ethnic origin, education level, employment, marital status, number of children, presence and duration of ADM treatment, previous history and age at onset of depression, and presence of comorbid anxiety disorder(s).

Primary clinical outcome

Depression severity (as measured via the PHQ-9) at 12 months.

Secondary clinical outcome

Major depressive disorder status; number of depression-free days; anxiety (as measured via the Generalised Anxiety Disorder-7 questionnaire); health-related quality of life (as measured via the Short Form questionnaire-36 items) at 6, 12 and 18 months; PHQ-9 at 6 and 18 months.

Economic outcomes

Cost per QALY at 18 months post randomisation, derived from the EuroQol-5 Dimensions, three-level version. We collected resource use data associated with delivery of BA and CBT from clinical records.

We measured all other health and social care services used, including medication prescription using the adult service use schedule. We measured productivity losses using the absenteeism and presenteeism questions of the World Health Organization's Health and Work Performance Questionnaire.

Process data

Behaviour (Behavioural Activation for Depression Scale); beliefs (Dysfunctional Attitudes Scale); rumination (Ruminative Response Scale); hedonic tone (Snaith–Hamilton Pleasure Scale); per protocol (PP) treatment adherence (from therapist case records); qualitative data via semistructured interviews to assess acceptability of BA and CBT for participants and clinicians.

Adverse events

Deaths from whatever cause and all self-harm and suicide attempts.

Sample size

We powered the trial at 90% ($\alpha = 0.05$) to detect a non-inferiority margin of 1.9 PHQ-9 points, inflating our sample size by 20% for participant attrition. Consequently, we needed to recruit 440 participants, 220 per arm, to detect a between-group non-inferiority margin of 1.90 in PHQ-9 points at one-sided 2.5% alpha.

Statistical methods and analyses

Clinical outcomes

We assessed equivalence of baseline characteristics and outcomes in the two groups descriptively. We analysed primary and secondary outcomes in accordance with Consolidated Standards of Reporting Trials guidelines for non-inferiority and equivalence trials, undertaking both intention-to-treat (ITT) and PP analyses. We compared observed primary and secondary outcomes between groups 12 months after randomisation using linear regression models adjusted for baseline outcome values and stratification/minimisation variables. We extended primary analysis models to fit interaction terms to explore differences in treatment effect from baseline symptom severity and ADM usage. We undertook secondary analyses to compare groups at follow-up across 6, 12 and 18 months using mixed-effects repeated measures regression. We ran sensitivity analyses for both primary and secondary analyses to assess the impact of missing data using multiple imputation models. We calculated the relative proportions of participants meeting criteria for 'recovery' (proportions of participants with PHQ-9 scores of ≤ 9 points) and 'response' (50% reduction in PHQ-9 scores from baseline).

Economic outcomes

We took the UK NHS and Personal Social Services perspective consistent with the UK National Institute for Health and Care Excellence (NICE)'s reference case and examined a broader societal perspective, adding productivity losses attributable to time off work, in a sensitivity analysis. We compared the costs and cost-effectiveness of BA and CBT at the final 18-month follow-up to capture the impact of events such as relapse, with unit costs from the 2013–14 financial year. We assessed cost-effectiveness in terms of QALYs using the net benefit approach. We analysed differences in mean cost per participant at 18 months using parametric *t*-tests, with the validity of results confirmed using bias-corrected, non-parametric bootstrapping. We calculated incremental cost-effectiveness ratios (ICERs) and constructed cost-effectiveness planes using 1000 bootstrapped resamples from regression models of total health- and social-care costs and outcome by treatment group, using these replications to calculate the probability that each treatment is the optimal choice for different values a decision-maker is willing to pay for 1-unit outcome of improvement. We

produced cost-effectiveness acceptability curves (CEACs) illustrating the probability that BA is cost-effective compared with CBT, which is dependent on willingness to pay per QALY. We controlled for stratification variables and baseline values of the variables of interest, truncating data to exclude influential outliers.

Process outcomes

Interactions between treatment allocation and each process covariate were investigated at 6, 12 and 18 months' follow-up for PHQ-9. A series of models were performed, adjusting for the stratification variables, trial site, baseline ADM use and baseline PHQ-9 score. Each model included the specific covariate being investigated as a potential moderator and its interaction with treatment allocation. For mediation, we used a structural equation modelling approach to evaluate the effect of each individual mediator at each follow-up time, on the primary outcome. We included all mediators measured at a specific follow-up time in an overall model for each follow-up point. Qualitative data were analysed using a framework analysis combining deductive themes from the topic guides and inductive themes emerging from the data. Transcripts were examined thematically across the whole data set as well as in the context of each interview, using constant comparative techniques.

Results

We recruited 440 participants, randomly allocating 221 (50%) to the BA group and 219 (50%) to the CBT group. Patient- and trial-level characteristics at baseline were well balanced between groups. Participants received a mean of 11.5 [standard deviation (SD) 7.8] BA sessions or 12.5 (SD 7.8) CBT sessions. We found that BA was non-inferior to CBT [ITT: CBT 8.4 PHQ-9 points (SD 7.5 PHQ-9 points), BA 8.4 PHQ-9 points (SD 7.0 PHQ-9 points), mean difference 0.1, 95% confidence interval (CI) –1.3 to 1.5 PHQ-9 points, $p = 0.89$; PP: CBT 7.9 PHQ-9 points (SD 7.3 PHQ-9 points); BA 7.8 PHQ-9 points (SD 6.5 PHQ-9 points), mean difference 0.0, 95% CI –1.5 to 1.6 PHQ-9 points, $p = 0.99$]. Between 61% and 70% of ITT and PP participants in both groups met criteria for recovery or response, with no difference in the proportions of patients in each group. We found no difference between groups on secondary outcomes at any time point. All findings were robust to sensitivity analyses.

Two (1%) non-trial-related deaths [one (1%) multidrug toxicity in the BA group and one (1%) cancer in the CBT group] and 15 depression-related, but not treatment-related, serious adverse events (three in the BA group and 12 in the CBT group) occurred in three (2%) participants in the BA group [two (1%) patients who overdosed and one (1%) who self-harmed] and eight (4%) participants in the CBT group [seven (4%) who overdosed and one (1%) who self-harmed].

We found a significant difference in mean intervention costs between the two groups, but no differences in other categories of cost or in total health- and social-care costs. As costs were lower and QALY outcomes better in the BA group than in the CBT group, this generated an ICER of –£6865, suggesting that BA dominates CBT (i.e. is both cheaper and more effective). The CEAC showing the probability of BA being cost-effective compared with CBT does not fall below 75% and is closer to 80% at standard NICE-preferred willingness-to-pay levels of £20,000–30,000 per QALY. All findings were robust to sensitivity analyses.

We found a weak moderating effect of baseline PHQ-9 score on treatment effect, with regard to PHQ-9 at 12 and 18 months' follow-up, indicating that BA may be a better choice of treatment for patients with higher baseline PHQ-9 scores. The only significant mediation effects were that overall treatment fidelity mediated the effect of treatment on PHQ-9 at 12 months' follow-up, with basic and overall treatment fidelity mediating the effect of treatment on PHQ-9 at 18 months' follow-up. Qualitative data showed that, despite being challenging at times, BA and CBT were acceptable and feasible for participants, MHWs and therapists, and effected changes in people's specific symptoms and in their lives more broadly. Despite experiencing initial difficulties that could be detected by some participants, with sufficient training, experience and supervision, junior MHWs could feel confident in delivering BA effectively.

Conclusions

Behavioural activation for depression is not inferior to CBT in terms of reduction of depression symptoms and is cost-effective compared with CBT against commonly applied decision-maker willingness-to-pay thresholds. We observed our results using both ITT and PP analyses, using a conservative non-inferiority margin. Our results in both groups compare favourably with a meta-analysis of the effects of CBT that estimate proportions of patients with remissions of around 50%. Our economic outcomes were driven by the lower costs of the MHWs who delivered BA, compared with the more experienced psychological therapists who routinely deliver CBT. Our study results, therefore, substantiate the hypothesis that BA is as effective as CBT and that BA's simplicity renders it suitable for delivery by junior MHWs with no professional training in psychological therapies.

Baseline PHQ-9 score had a weak moderating effect on depression symptoms at 12 and 18 months' follow-up, this interaction effect indicating that BA may be a better choice of treatment for patients with higher baseline PHQ-9 scores. We found that only treatment fidelity reliably showed an interaction with outcome, demonstrating the importance of MHWs and therapists adhering to clinical protocols. BA and CBT were both acceptable and feasible for participants, MHWs and therapists. Importantly, junior MHWs can deliver BA effectively, although they need training, experience and supervision to feel confident in delivering BA.

Strengths and limitations

To date, COBRA is the largest trial of BA and one of the largest psychological treatment trials for depression. We followed up participants for 18 months and our economic analysis is one of few in this field. Therapists and MHWs working in three different routine NHS settings delivered treatment, providing evidence of potential generalisability. We could not mask patients or clinicians to treatment allocation, but used self-reported outcome measures and robust researcher-masking procedures to reduce unmasking to $< 5\%$.

In this pragmatic trial many depressed participants in both groups were also taking ADM, although most had been doing so for a considerable time before entering the trial. Our levels of attrition and outcome loss to follow-up were low, similar to other trials in this area, but are still a limitation. However, our between-group inferences were robust to data imputation. Around one-third of participants chose not to complete a PP dose of treatment, a finding common in both psychotherapy trials and routine practice.

Implications

For years, CBT has been the foremost psychological therapy recommended by therapists, researchers and policy-makers. Our results challenge this dominance and suggest that BA could be a front-line treatment for depression. Our most striking finding is that BA leads to comparable clinical outcomes for patients with depression, but at a financial saving to clinical providers of 21% compared with the cost of provision of CBT, with no compensatory use of other health-care services by patients. There are substantial implications for the scalability of psychological treatment for depression in the UK and internationally, given the greater availability and ease with which a BA workforce could be trained than could a CBT workforce.

Although many obstacles exist to successful dissemination in addition to training of MHWs, our findings suggest that health services globally could reduce the need for costly professional training and infrastructure, reduce waiting times and increase access to psychological therapies. Our findings have substantial implications given the increasing global pressure for cost-containment across health systems in high-income countries, and the need to develop accessible, scalable interventions in low- and middle-income countries.

Our results, therefore, offer hope to many societies, cultures and communities worldwide, rich and poor, struggling with the effect of depression on the health of their people and economies.

Trial registration

This trial is registered as ISRCTN27473954.

Funding

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Chapter 1 Introduction

Scientific background and review of current literature

Clinical depression is one of the most common and debilitating of the psychiatric disorders. It accounts for the greatest burden of disease among all mental health problems, and is the second largest cause of global disability.[3] Lifetime prevalence has been estimated at 16.2% and rates of comorbidity and risk for suicide are high.[4–6] Depression is often recurrent, and without treatment many cases become chronic, lasting > 2 years in one-third of individuals. Over three-quarters of all people who recover from one episode will go on to have at least one more.[7] In the UK, depression and anxiety are estimated to cost the economy £17B in lost output and direct health-care costs annually, with a £9B impact on the Exchequer through benefit payments and lost tax receipts.[8] Globally, the economic impact of depression on aggregate economic output is predicted to be US$5.36 trillion between 2011 and 2030.[9]

Reducing these substantial costs is a key objective for low-, medium- and high-income countries alike. Antidepressant medication (ADM) and cognitive–behavioural therapy (CBT) are the two treatments with most evidence of effectiveness, both of which are recommended by the National Institute for Health and Care Excellence (NICE).[10] Problems with ADM include side effects, poor patient adherence and relapse risk on ADM discontinuation. Service user organisations and policy think tanks advocate greater availability of psychological therapies, which many people prefer.[11] CBT, which is of similar efficacy to ADM,[12] has several advantages: (1) it reflects the desire of many service users for non-pharmacological treatment; (2) it has no physical side effects; and (3) it modifies the illness trajectory in that benefits continue after the end of treatment, preventing recurrence.[13] However, CBT has several disadvantages: (1) its complexity makes it difficult to learn to implement in a competent fashion; (2) its efficacy is dependent on the skill of the individual practitioner; (3) patients are required to learn quite high-level skills; and (4) the high cost of training and employing sufficient therapists limits access to CBT.

As a consequence of the disadvantages above, many people do not receive adequate treatment, and, even when treatment is given, many respond only partially or not at all.[14] Despite the recent government initiative in England – 'Improving Access to Psychological Therapies' (IAPT; URL: www.iapt.nhs.uk/) – no more than 15% of people with depression will receive NHS-delivered CBT, and only 50% receiving CBT will recover.[15] It is therefore important to continue to test promising new treatments, especially if there are indications that such treatments reduce the risk of symptom return, are applicable to a wide range of depressed people including those with severe disease, are easy to implement in clinical practice and are therefore potentially more accessible,[16] and are a cost-effective use of resources.

Globally, health services require effective, easily implemented and cost-effective psychological treatments for depression that can be delivered by less specialist health workers in order to close a treatment gap that can be as much as 80–90% in some low-income countries.[17] The English NHS, in order to meet public and professional expectations, requires a simple, equivalently effective, easily implemented psychological treatment for depression which can be delivered by less specialist (albeit appropriately competent) junior mental health workers (MHWs) to treat many more people with depression in a more cost-effective manner.

Rationale for the research

Behavioural activation (BA) is a psychological treatment based on behavioural theory that alleviates depression by focusing directly on changing behaviour.[18–20] This theory states that depression is maintained by avoidance of normal activities. As people withdraw and disrupt their basic routines, they become isolated from positive reinforcement opportunities in their environment. The combination of increased negative reinforcement with reduced positive reinforcement results in a cycle of depressed mood, decreased activity and avoidance which maintains depression.[19] BA systematically disrupts this cycle, initiating action in the presence of negative mood, when people's natural tendency is to withdraw or avoid.[21,22] Although CBT incorporates some behavioural elements, these focus on increasing rewarding activity and initiating behavioural experiments to test specific beliefs. In contrast, BA targets avoidance from a contextual, functional approach not found in CBT (i.e. BA focuses on understanding the function of behaviour and replacing it accordingly). BA also explicitly prioritises the treatment of negatively reinforced avoidance and rumination. Furthermore, the BA rationale is easier to understand and operationalise for both patients and MHWs than CBT, which also focuses on increasing activity, but primarily on changing maladaptive beliefs.[23] Moreover, there is some evidence that CBT is less effective when delivered by less competent therapists.[12,24]

In the UK, CBT is delivered by professionally qualified senior MHWs (mainly clinical psychology, nursing, occupational therapy, social work or counselling), who have obtained a further 1-year, full-time postgraduate qualification in CBT. Their training is long and expensive and their employment grade is costly compared with junior MHWs, who deliver much of the routine mental health care in the UK. The relative simplicity of BA treatment may make it easier and cheaper to train junior MHWs in its application than CBT, the argument of 'parsimony' first advanced by one of the early proponents of this approach, Neil Jacobson.[19] However, this is appropriate only if BA delivered in this way is as effective as, and more cost-effective than, CBT.

Limitations of previous trials

A number of systematic reviews have attempted to address the more general question of BA effectiveness compared with CBT.[10,25–28] All have commented on the relatively poor quality of component studies. We conducted a meta-analysis of randomised controlled trials (RCTs) of BA,[25] and identified 12 studies with a total of 476 patients. At the primary end point we found no difference between the groups on depression symptom level [Hedges' $g = 0.102$, 95% confidence interval (CI) –0.122 to 0.326; $I^2 = 29\%$; $p = 0.372$] (*Figure 1*). At follow-up we found no difference between the groups on depression symptom level (Hedges' $g = 0.395$, 95% CI –0.032 to 0.822; $I^2 = 61\%$; $p = 0.070$).

In a subsequent update of this review[26] we found no additional trials comparing BA with CBT. Many of the trials included in our review were of limited methodological quality, all were underpowered for comparing treatments, and most did not utilise diagnostic interviews for trial inclusion. Treatments in many cases did not conform to modern clinical protocols for BA. Long-term outcomes were rarely reported, with average follow-up only to 4 months. These results have been replicated in two recent Cochrane reviews of behavioural therapies,[27,28] which concluded that there was only low- to moderate-quality evidence that behavioural therapies and other psychological therapies were equally effective and called for 'Studies recruiting larger samples with improved reporting of design and fidelity to treatment to improve the quality of the evidence'.[27]

Most significantly, NICE[10] reviewed the same evidence and regarded only a small subset of three trials[31,38,40] as of sufficient quality to be able to contribute evidence of effect (*Figure 2*). In those studies no difference was found between BA and CBT at primary end point (Hedges' $g = 0.139$, 95% CI –0.4.00 to 0.122; $I^2 = 1\%$; $p = 0.296$) or at follow-up (Hedges' $g = 0.135$, 95% CI –0.456 to 0.186; $I^2 = 0\%$; $p = 0.409$).

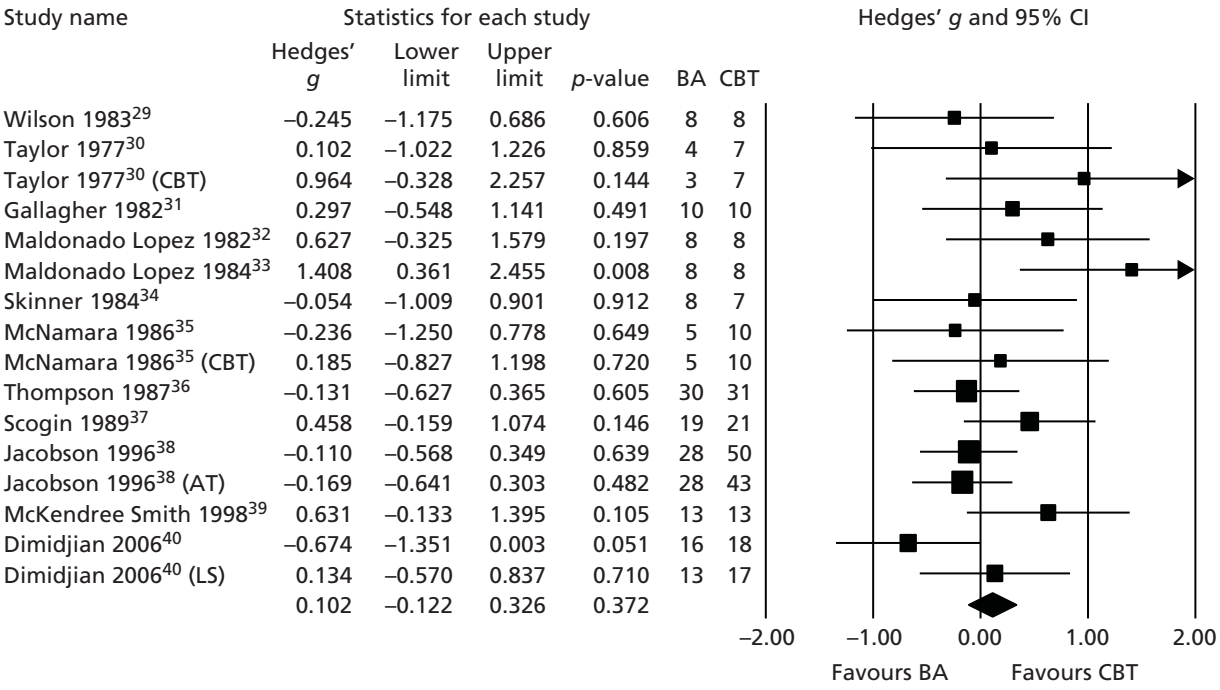

FIGURE 1 Meta-analysis of pre-COBRA (Cost and Outcome of BehaviouRal Activation) trial BA vs. CBT primary outcome point, all included studies. AT, automatic thoughts; LS, low severity.

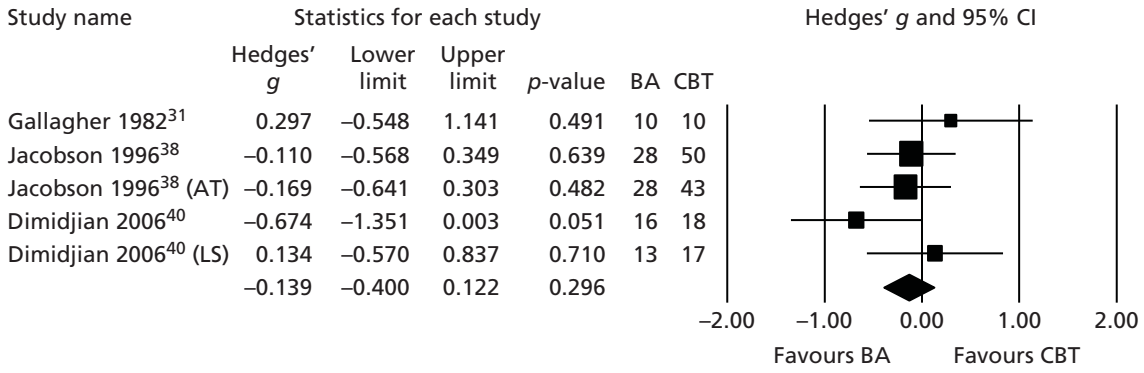

FIGURE 2 Meta-analysis of pre-COBRA (Cost and Outcome of BehaviouRal Activation) trial BA vs. CBT, subset of high-quality included studies in NICE review. AT, automatic thoughts; LS, low severity.

The conclusion of the NICE Guideline Development Group was that that the evidence base for BA was not 'sufficiently robust' for it to be recommended as an alternative to CBT. It was suggested that BA could be an option for clinicians, but the limited evidence base should be considered when making this treatment choice.[10] Consequently, NICE made a clear research recommendation 'to establish whether behavioural activation is an effective alternative to CBT' using a study which is 'large enough to determine the presence or absence of clinically important effects using a non-inferiority design' (p. 256).[10]

Pilot work preceding this trial

In order to test uncertainties around our main objectives, we piloted BA in a Phase II RCT to examine whether or not MHWs without previous specialist training in psychological therapy can effectively treat depressed people using BA.[41] We compared BA against usual care. Relatively junior NHS MHWs ('band 5' – equivalent to a basic grade, qualified mental health nurse) with no previous formal training or experience

in psychotherapy delivered BA. These workers received 5 days' training in BA and, subsequently, 1 hour of clinical supervision, fortnightly, from a clinical nurse consultant or trained psychotherapist. Intention-to-treat (ITT) analyses indicated a difference in favour of BA of −15.79 points ($n = 47$, 95% CI −24.55 to −7.02 points) on depression (as measured via the Beck Depression Inventory-II), an effect size of −1.15 standard deviation (SD) units (95% CI −0.45 to −1.85 units). We also found a quality-adjusted life-year (QALY) difference in favour of BA of 0.20 points (95% CI 0.01 to 0.39 points; $p = 0.042$), incremental cost-effectiveness ratio (ICER) of £5756 per QALY and a 97% probability that BA is cost-effective at a threshold value of £20,000.[41]

Conclusion

From our literature reviews and pilot work we concluded that BA was a potentially viable treatment for depression when delivered by junior MHWs, but that, as NICE had suggested, a non-inferiority trial of BA versus CBT was required to test whether or not BA was non-inferior to CBT and if BA could be a potentially cost-effective alternative to CBT for depression. We now report the results of this randomised trial to determine if BA is non-inferior to CBT in the treatment of patients with depression. This report is divided into chapters detailing the methods and results of our primary clinical effectiveness and cost-effectiveness questions followed by a chapter for our process evaluation. We conclude with a discussion chapter summarising our results and considering their implications for the treatment of depression in the UK and internationally.

Chapter 2 Methods

Research objectives

1. To assess the clinical effectiveness of BA compared with CBT for depressed adults in terms of depression treatment response at 12 and 18 months.
2. To assess the cost-effectiveness of BA compared with CBT in terms of QALYs at 18 months.

In addition, we undertook a secondary process evaluation to investigate the moderating, mediating and procedural factors in BA and CBT that influence outcome, the methods for which are covered in *Chapter 4*.

Study design

We undertook a research assessor-blinded, multicentre, two-arm, non-inferiority, patient-level RCT for people with depression, to test the effectiveness of a psychological intervention for depression, BA, against the current gold standard, evidence-based treatment, CBT. We included clinical, economic and process evaluations. The rationale for a non-inferiority trial is that we needed to establish whether or not the clinical effectiveness of BA is not substantially inferior to CBT. Therefore, we powered our trial on the basis of clinical non-inferiority, and analysed our data accordingly.[42,43]

Patient and public involvement

We involved patient and public involvement (PPI) representatives at all stages of the project. A PPI advisor (NR) was a full member of the Trial Management Group (TMG). He attended all meetings of the TMG and advised on patient-facing materials, including ethics materials and participant therapeutic manuals, and on the conduct of the trial including project management, questionnaire development, data collection and project dissemination. There was a PPI representative on the Trial Steering Committee (TSC) from a depression consumer advocacy group who provided important checks and balances as part of the independent TSC oversight of the trial.

All sites had excellent local PPI mechanisms. We followed national good practice guidance for researchers on public involvement in research and the paying of PPI representatives actively involved in research.[44] We also worked with our PPI representatives to ensure that our dissemination strategies were inclusive and accessible to other people who use services. In addition, the trial was co-ordinated from the University of Exeter's Medical School. The Medical School operates within a culture of PPI – guided by published theories of participation, empowerment and engagement – through the National Institute for Health Research (NIHR) Collaborations in Leadership in Applied Health Research and Care for the Peninsula Public Involvement Group.

Setting and participants

We recruited participants over a 20-month period from September 2012 to April 2014. Potential participants were identified by clinical studies officers (CSOs) or practice staff from the electronic case records of primary care and psychological therapy services in Devon, Durham and Leeds, indicating that the person had been identified as currently depressed at least once during the previous 2 months. Practices or services contacted patients to seek permission for researcher contact. The research team interviewed those who responded, provided detailed information on the study, took informed consent and assessed people for eligibility.

Inclusion and exclusion criteria

Inclusion

People aged ≥ 18 years with a major depressive disorder (MDD) as assessed by the Structured Clinical Interview for DSM Disorders (SCID) and *Diagnostic and Statistical Manual for Mental Disorders*-Fourth Edition (DSM-IV) were eligible to take part in the study.[45] Researchers were trained to administer the SCID using established training and inter-rater reliability procedures in use at the University of Exeter for all of our trials.

Exclusion

People who were alcohol or drug dependent, acutely suicidal or cognitively impaired, had bipolar disorder, psychosis or psychotic symptoms, ascertained at baseline by research interviews, were excluded. We also excluded people currently undergoing psychological therapy.

Randomisation, concealment of allocation and blinding

Following interview, participants were allocated in a 1 : 1 ratio to either the BA or CBT arm stratified according to their symptom severity on the Patient Health Questionnaire-9 (PHQ-9)[46] (PHQ-9 of < 19 vs. ≥ 19 points), ADM use (currently using ADM or not) and recruitment site. The registered Peninsula Clinical Trials Unit (PenCTU) allocated participants remotely after the researchers had collected and entered baseline data into a computer database to ensure researcher blinding and allocation concealment. Investigators were not informed of participants' allocations. The computer-based system allocated the first 20 participants to each arm on a truly random basis. For subsequent participants, allocation was minimised to maximise the likelihood of balance in stratification variables across the two study arms. Concealment was ensured by the use of a password-protected trial website and retaining a stochastic element to the minimisation algorithm. The computer-based allocation and website were set up and maintained by PenCTU, independent of the trial. The participant's details were then sent to the relevant MHW to alert them to contact this person and begin treatment. The general practitioner (GP) was then informed of their patient's involvement in the study.

In this type of trial, in which interventions are complex and clearly different from each other, it is not possible to blind participants or clinicians, so our procedures focused on helping to keep research workers blind to participant allocation and by protecting the study against assessment interpretation bias through the use of self-report measures. All research measures were applied to both groups, and researchers were instructed to maintain blindedness by reminding participants at follow-up of the need not to discuss their treatment with the researcher. We recorded instances where researchers were unblinded by patients disclosing their treatment during interviews.

Sample size calculation

We estimated the non-inferiority margin for the primary outcome (PHQ-9) using two potential approaches with reference to (1) the effect size of historical trials comparing BA versus control; and (2) the published minimum clinically important difference for the primary outcome (PHQ-9) of 2.59 to 5.00 points.[47] Based on our meta-analysis, BA was superior to control in depression score by a mean of 0.7 SD units (95% CI 0.39 to 1.00 SD units) or 3.8 PHQ-9 points (95% CI 2.1 to 5.4 PHQ-9 points) (assuming a SD of 5.4 from Lowe *et al.*).[47] It has been proposed that non-inferiority margins be taken as ≈0.5 × mean control effect size (i.e. 0.5 × 3.8 = 1.90 points) or as the lower 95% limit of the control effect size (i.e. 2.1 points).[48,49] To ensure the adequacy of this trial to test non-inferiority between BA and CBT, we therefore examined a number of potential scenarios taking into account the potential uncertainty in the non-inferiority margin for the primary outcome.

We selected a conservative non-inferiority margin of 1.90 points and power of 90%. As a consequence, we needed to recruit a total of 440 participants to detect a between-group non-inferiority margin of 1.90 points in PHQ-9 at one-sided 2.5% alpha, allowing for 20% attrition caused by dropouts and protocol violators. Furthermore, although previous trials of CBT have shown little or no effects of clustering in outcome by therapists, even when delivering group CBT,[50,51] if we were to assume a small therapist clustering effect (i.e. intracluster correlation coefficient of 0.01), this sample size would still have 80% power for a non-inferiority margin of 1.90 points on the PHQ-9 at one-sided 2.5% alpha, allowing for 20% attrition.

Our sample size was inflated by 20% for participant dropout to take account of participants who might exit the trial and refuse follow-up assessment, although our experience in running large primary care trials of depression treatment is that attrition rates would be less than this. Therefore, we planned to recruit 440 participants to the trial, 220 per arm. A summary of the sample size calculations is provided in *Table 1*.

Recruitment

Randomised controlled trials are vulnerable to selection bias and threats to external validity if there are systematic differences in behaviour between referring clinicians. We minimised this potential bias by recruiting participants through searching general practice records and referral logs from primary care to local depression and anxiety treatment services rather than by direct referral from GPs. We identified suitable participants by examining electronic case records for all patients in each general practice or treatment service. The search was conducted by practice staff or Clinical Research Network CSOs, identifying people

TABLE 1 Sample size calculation

Approach	MCID (points)	Power (%)	Attrition rate (%)	Sample size per group[a]
50% BA control effect size	1.90	90	20	220
50% BA control effect size	1.90	80	20	160
LCI BA control effect size	2.10	90	20	180
LCI BA control effect size	2.10	80	20	135
Lower MCID	2.59	90	20	120
Lower MCID	2.59	80	20	90

LCI, lowest confidence interval; MCID, minimum clinically important difference.
a Calculated assuming a PHQ-9 SD of 5.4 points[52] and a one-sided 2.5% alpha using nQuery v7.0 MTE0-6 (nQuery Statistical Solutions, Cork, Ireland).

with at least one identification code for depression recorded against their name in the last 2 months. In primary care practices we searched for the codes most widely used by GPs to classify participants as depressed. The list of potentially suitable participants was reviewed by GPs to identify any patients whom had known exclusion criteria. The remaining patients were written to, inviting them to take part in the study. For patients already referred to local psychological therapies services, we contacted those on the waiting list. Letters were sent with a short participant information sheet, stamped and addressed envelope and a 'Permission for Researcher to Contact' form to allow a researcher to contact them. If potential participants did not return the form, they were contacted by telephone by practice staff or practice-based Clinical Research Network CSOs to check that they had received the letter and asking them if they wished to participate in the Cost and Outcome of BehaviouRal Activation (COBRA) trial. Potential participants identified were interviewed by researchers on the telephone to confirm the presence of depressive symptoms and to explain the trial fully. If positive on the screen, potentially eligible participants were interviewed face to face by researchers to confirm eligibility, take consent, conduct a diagnostic interview and collect baseline measures. Eligible, fully informed and consenting participants were then entered into the study and randomised.

From our experience of previous trials, we calculated that 37% of potential participants interviewed at baseline would be likely to decline participation, would not meet our inclusion criteria or would meet one of the exclusion criteria. Therefore, we were required to interview 700 potential participants in order to induct our planned sample size of 440 eligible participants into the trial. Following random allocation of 440 participants, a maximum of 20% attrition would lead to our target sample size of 366 participants.

In order to identify 700 people for baseline interview, we planned to contact around 3400 potential participants through letter and/or telephone to inform them of the trial and offer them the chance to participate. In order to do so, we needed to identify 5300 potential participants from a sensitive coded search of practice case note records, as our existing data predicted that 1900 (approximately 36%) of these would be excluded by GPs against known trial exclusion criteria. Identifying 5300 potential participants was expected to generate at least 700 positive replies.

For an average-size practice of 7000 registered patients, we expected that searches would be likely to identify around 37 potentially eligible participants per search. Four searches per practice would, therefore, identify 148 potential participants per practice. Consequently, we planned to recruit at least 36 practices (12 per site) to identify sufficient potential participants to meet our target number of 5300.

Trial interventions

We developed our BA and CBT intervention protocols in line with (a) published treatment protocols,[19,21,22,40,53,54] including that developed for BA and CBT in our trials;[41,55] (b) advice from national and international collaborators (Martell, Dimidjian, Hollon); and (c) NICE recommendations[10] for duration, and frequency, of BA and CBT. To recognise realities of real-world clinical presentations, our protocols included behavioural and cognitive strategies for managing comorbidity, particularly anxiety, where this is present in addition to depression. Therapists were able to provide participants with a maximum of 20 sessions over 16 weeks with the option of four additional booster sessions.[10]

Behavioural activation

The overall goal of BA is to re-engage participants with stable and diverse sources of positive reinforcement from their environment and to develop depression management strategies for future use. MHWs delivering BA followed a written treatment manual. Sessions were face to face, of 1 hour duration, with the option of being conducted up to twice weekly over the first 2 months and weekly thereafter. The sessions consisted of a structured programme increasing contact with potentially antidepressant environmental reinforcers through scheduling and reducing the frequency of negatively reinforced avoidant behaviours. The central behavioural technique was a functional analysis of the participant's problems, based on a shared

formulation drawn from the behavioural model in the early stages of treatment, thereafter developed with the patient throughout their sessions. Specific BA techniques included the use of a functional analytical approach to develop a shared understanding with patients of behaviours that interfere with meaningful, goal-oriented behaviours and included self-monitoring, identifying 'depressed behaviours', developing alternative goal-orientated behaviours and scheduling. In addition, the role of avoidance and rumination was addressed through functional analysis and alternative response development incorporating recent trial evidence.[56]

We selected MHWs from NHS Agenda for Change (AfC) band 5 staff, such as mental health nurses and psychological well-being practitioners (PWPs),[52] who received 5 days' training in BA. In line with the programme developed and tested in our Phase II trial,[41] training focused on the rationale and skills required to deliver the BA protocol for depression and included sections on behavioural learning theory and its application to depression, developing individualised BA formulations and specific techniques used in sessions. Training was a mix of presentation and role-play with repeated practice and feedback. Workers were competency-assessed at the end of training using standardised marking criteria consistent with the BA protocol and further training was given if competency was not demonstrated in practical clinical exercises. BA workers received 1 hour of clinical supervision, fortnightly, from the three site leads or other members of the trial team who were clinically qualified in BA.

Cognitive–behavioural therapy

The overall goal of CBT is to alter the symptomatic expression of depression and reduce risk for subsequent episodes by correcting the negative beliefs, maladaptive information processing and behavioural patterns presumed to underlie the depression. Therapists delivering CBT followed a written treatment manual. Sessions were face to face, of 1 hour duration, with the option of being conducted up to twice weekly over the first 2 months and weekly thereafter. The sessions consisted of a structured, collaborative programme. Treatment began with agreeing a problem list and goals for therapy, participants learning the CBT model, behavioural change techniques, and moved on to identifying and modifying negative automatic thoughts, maladaptive beliefs and, if indicated, underlying core beliefs. In later sessions, learning was translated to anticipating and practising the management of stressors that could provoke relapse in the future. Specific CBT techniques included scheduling activity and mastery behaviours, the use of thought records and modifying maladaptive beliefs and rumination content. The behavioural elements in CBT focused on increasing activity with practical behavioural experiments to test specific cognitive beliefs. CBT did not take the contextual, functional analytical approach of the BA trial arm.

Cognitive–behavioural therapy was delivered by NHS AfC band 7 senior MHWs with a specialist postgraduate diploma in 'high-intensity' CBT from an accredited university course. The CBT therapists also received a 5-day orientation training to the specific COBRA trial CBT protocol, including its adaptation for comorbidities, cognitive theory of depression, developing individualised cognitive formulations and specific techniques used in sessions. Therapists were competency-assessed at the end of training using standardised marking criteria consistent with the CBT protocol and further training was given if competency was not demonstrated. CBT therapists also received a subsequent 1 hour of clinical supervision, fortnightly, from established supervisors in the three sites with advice from other members of the trial team who were clinically qualified in CBT.

Outcomes

An overview of our data collection timings is presented in *Table 2*.

TABLE 2 Timing of data collection

Data		Source of data	Timing of data collection			Months after baseline		
Baseline	Gender, age, ethnic origin, education level, employment, marital status, number of children, presence or absence of ADM treatment, previous history and age at onset of depression, duration of any ADM treatment, and presence of any comorbid anxiety disorder	CRF	Baseline					
Primary outcome	PHQ-9	CRF	Baseline			6	12	18
Secondary outcomes	DSM-IV depression status	CRF	Baseline			6	12	18
	Number of depression-free days	CRF				6	12	18
	SF-36	CRF	Baseline			6	12	18
Economic data	EQ-5D-3L	CRF	Baseline			6	12	18
	AD-SUS	CRF	Baseline			6	12	18
Process evaluation data	Age at depression onset	CRF	Baseline					
	Number of previous depression episodes	CRF	Baseline					
	BADS	CRF	Baseline	Therapy session 4	Therapy session 7	6		
	DAS	CRF	Baseline	Therapy session 4	Therapy session 7	6		
	RRS	CRF	Baseline	Therapy session 4	Therapy session 7	6		
	SHAPS	CRF	Baseline	Therapy session 4		6	12	18
	Acceptability of BA and CBT	Qualitative interviews	Patients: on completion of therapy					
			Clinicians: on completion of trial involvement					
	Treatment mechanisms and impact	Qualitative interviews	Patients: on completion of therapy					
			Clinicians: on completion of trial involvement					

AD-SUS, adult service use schedule; BADS, Behavioural Activation for Depression Scale; CRF, case report form; DAS, Dysfunctional Attitudes Scale; EQ-5D-3L, EuroQol-5 Dimensions, three-level version; RRS, Ruminative Response Scale; SF-36, Short Form questionnaire-36 items; SHAPS, Snaith–Hamilton Pleasure Scale.

Baseline information

We collected demographic data at baseline through a purposely designed form. We recorded data on gender, age, ethnic origin, education level, employment, marital status, number of children, presence or absence of ADM treatment, previous history and age at onset of depression, duration of any ADM treatment and presence of any comorbid anxiety disorder.

Clinical data

We conducted follow-up assessments at 6, 12 and 18 months post-baseline assessment. Our primary outcome was self-reported depression severity and symptomatology, as measured by the PHQ-9,[46] at 12 months. The PHQ-9 is a nine-item questionnaire that records the core symptoms of depression with established excellent specificity and sensitivity characteristics in a UK population.[57] Our secondary outcomes were DSM-IV MDD status and number of depression-free days between follow-ups, assessed by the SCID,[45] anxiety assessed by the Generalised Anxiety Disorder-7 (GAD-7) questionnaire[58] and health-related quality of life assessed by Short Form questionnaire-36 items (SF-36).[59] We also assessed the relative proportions of participants meeting criteria for 'recovery' (proportions of participants with PHQ-9 scores of ≤ 9 points) and 'response' (50% reduction in scores from baseline) on the PHQ-9. We also recorded the presence of DSM-IV anxiety disorders at baseline and follow-ups.

Economic data

We took the UK NHS and Personal Social Services (PSS) perspective consistent with the UK NICE reference case.[60] A broader societal perspective was explored in sensitivity analysis to capture the effects of productivity loss as a result of time off work due to illness, as depression is known to impact on an individual's ability to work and can result in substantial losses in the workplace.[61] In addition, the use of complementary therapies was included in a further sensitivity analysis following advice from the clinical team that such therapies are commonly used by adults with depression. Narrower perspectives of intervention and mental health care were also examined in sensitivity analyses.

We collected participants' use of BA and CBT from clinical records, with additional resource information (e.g. training, supervision and other non-face-to-face activities) collected from therapists and trainers. We measured all other health and social care services used, including medication prescription using the adult service use schedule (AD-SUS), designed on the basis of previous evidence of service use in depressed populations.[62] We measured productivity losses using the absenteeism and presenteeism questions of the World Health Organization's Health and Work Performance Questionnaire.[63] The AD-SUS and the Health and Work Performance Questionnaire were completed by patients in interviews with a research assessor at baseline and at the 6-, 12- and 18-month follow-ups. At baseline, participants were asked to report service use over the previous 6 months. At all follow-up points, participants were asked to report service use since the last interview, to capture service use for the entire period from baseline to follow-up, even if participants had missed intermediate interviews.

We measured effectiveness for the economic evaluation in terms of QALYs calculated using the EuroQol-5 Dimensions, three-level version (EQ-5D-3L), a non-disease-specific measure for describing and valuing health-related quality of life, at baseline and at the 6-, 12- and 18-month follow-ups.[64] The EQ-5D-3L consists of five dimensions in the domains of mobility, self-care, usual activities, pain/discomfort and anxiety/depression, each scored on three levels (no problems, some problems or extreme problems), and classifies individuals into one of 243 health states. Health states are converted into a single summary index utility score by applying weights to each level in each dimension derived from the valuation of EQ-5D-3L health states in adult general population samples.[65] QALYs were calculated as the area under the curve defined by the utility values at baseline and each follow-up. It was assumed that changes in the utility score over time followed a linear path.[66]

Process data

In addition to information on age at depression onset and number of previous episodes collected using the SCID,[45] we also collected data on changes in specific behaviour [as assessed via the Behavioural Activation for Depression Scale (BADS)],[67] changes in beliefs [as assessed via the Dysfunctional Attitudes Scale

(DAS)],[68] rumination [as assessed via the Ruminative Response Scale (RRS)],[69] hedonic tone [as assessed via the Snaith–Hamilton Pleasure Scale (SHAPS)],[70] acceptability of BA and CBT for participants and clinicians (assessed with qualitative methods), and per protocol (PP) treatment adherence (from therapist case records). We collected qualitative data via semistructured interviews to access participants', BA MHWs' and CBT therapists' accounts of the mechanisms and impacts of treatment. Interviews focused on acceptability, views of the role of cognitive and behavioural change strategies and broader impacts of treatment in participants' lives.

Intervention fidelity

We assessed the quality of, and adherence to, BA and CBT clinical protocols using audiotapes and written records of therapy sessions, which MHWs and therapists were instructed to take, with participant permission, for each clinical session. A random sample of tapes, stratified by therapist, therapy session and intervention, were sent to independent experts in both treatments for competency rating using the Cognitive Therapy Scale-Revised (CTS-R)[71] (range 0–78, competency cut-off score = 36) for CBT and the Quality of Behavioural Activation Scale[72] (range 0–84, competency cut-off score = 42) for BA. Independent rating of recorded therapy sessions was undertaken by the Oxford Cognitive Therapy Centre (Oxford Health NHS Foundation Trust) and Dr Christopher Martell of the University of Wisconsin–Milwaukee, for CBT and BA, respectively.

Therapy ratings were used for several different purposes:

1. to assess each therapist's competency, at the start of the trial, to deliver the interventions by rating the first two therapy sessions undertaken
2. to monitor whether or not levels of competence/adherence were maintained throughout the trial.

We asked all therapists in both treatment groups to record their in-session activity by completing specially designed therapy record sheets. These sheets included a list of therapeutic techniques specific to each type of therapy, with a tick box against each element. Therapists indicated which of the techniques they had used in each session.

Safety and adverse events

For adverse events (AEs), we recorded deaths from whatever cause, and all self-harm and suicide attempts. The independent Data Monitoring Committee (DMC) reviewed all AEs and made relevant trial conduct recommendations as a consequence.

Data analysis

We analysed and report primary and secondary outcomes in accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines for non-inferiority and equivalence trials.[43] All analyses were carried out using an a priori statistical analysis plan prepared in the first 6 months of the trial and agreed with the TMG, TSC and the DMC.

Equivalence of baseline characteristics and outcomes in the two groups were assessed descriptively. As differences between randomised groups at baseline could have occurred by chance, no formal significance testing was conducted. We also undertook a descriptive analysis of the baseline patient characteristics according to the recruitment method (recruitment from psychological therapies waiting list vs. GP case note review).

We undertook both ITT and PP analyses. PP analysis provides some protection for any theoretical increase in the risk of type I error (erroneously concluding non-inferiority).[73] The ITT population was defined as all randomised patients in the groups to which they were allocated with observed outcome data at follow-up. The PP population was predefined by the TMG as those patients who met the ITT definition and received eight or more treatment sessions for both groups. Although the CONSORT guidelines recommend a PP approach (i.e. analysis according to actual treatment received) as the conservative non-inferiority analysis option, given the potential biases of both PP and ITT analyses,[43] we took the approach of the European Medicines Agency, that security of inference depends on both PP and ITT analyses demonstrating non-inferiority of the primary outcome.[74] We, therefore, checked for non-inferiority in both the PP and ITT populations. In order to check the security of inference of non-inferiority, sensitivity analysis for the primary outcome was undertaken for the ITT imputed population and PP analyses based on different definitions of adherence/protocol adherence.

The TMG predefined our PP population. We also conducted sensitivity analyses using different definitions of PP adherence. We included varying proportions of PP participants in these sensitivity analyses populations, depending on how much of each therapy they had received, ranging from 40% to 100% of planned therapy sessions. Our analysis plan specified that, if non-inferiority was consistently shown by these analyses, we would proceed to assess superiority of CBT compared with BA (i.e. the CI lower bound lies above 0). If we found that conclusions were inconsistent across analyses, we planned to revert back to primacy of the PP analysis to confirm or refute the non-inferiority hypothesis.

Our primary analysis compared observed primary and secondary outcomes between BA and CBT groups at 12 months after randomisation using linear regression models that adjusted for baseline outcome values and stratification/minimisation variables (symptom severity, site, ADM use). Although we initially planned to include therapist as a random-effects variable in our models, given the low levels of observed clustering we took a parsimonious approach and fitted our models without inclusion of therapist. We also checked that there was no difference in inference with and without the inclusion of a random-effects therapist term.

We estimated that the one-sided 97.5% CI for the between-group difference and non-inferiority of BA compared with CBT was accepted (in a 0.025 level test) if the lower bound of the 97.5% CI lay within the non-inferiority margin of –1.90 points in PHQ-9 score. We checked for non-equivalence of the primary outcome at all follow-up points using the same approach. We extended the primary analysis models to fit interaction terms to explore possible differences in treatment effect in baseline symptom severity and ADM usage.

We undertook secondary analyses to compare groups at follow-up across 6, 12 and 18 months using a mixed-effects, repeated measures regression approach. We also ran sensitivity analyses for both primary and secondary analyses to assess the likely impact of missing data using multiple imputation models. We also calculated the relative proportions of participants meeting criteria for 'recovery' (proportions of participants with PHQ-9 scores of ≤ 9 points) and 'response' (50% reduction in the PHQ-9 scores from baseline). Between-group differences are presented for continuous outcomes as CBT versus BA (i.e. CBT minus BA) and for binary outcomes as BA relative to CBT (i.e. BA divided by CBT).

No interim inferential analyses were undertaken. However, the DMC requested (October 2013) a check of the statistical power of the trial for the PP analyses. This calculation used the assumptions of our original power calculation and was based on the observed level of attrition of the primary outcome at 12 months and the proportion of patients who fulfilled the PP definition (eight or more treatment sessions; as of January 2014). All analyses were undertaken using Stata v.14 (StataCorp LP, College Station, TX, USA).

Economic analysis

Although studies designed to test equivalence of effects are considered to be a legitimate situation in which a cost minimisation analysis (where costs alone are compared given equal outcomes) may be appropriate,[75] the same may not be true for non-inferiority designs. Even in situations where equivalence or non-inferiority are demonstrated, exploration of the joint distribution of costs and effects in a cost-effectiveness analysis is recommended to represent uncertainty[75] and to help interpret the economic results.[76] For these reasons, we prespecified that we would undertake a cost-effectiveness analysis irrespective of whether or not non-inferiority in the primary clinical outcome was demonstrated. We assessed cost-effectiveness in terms of QALYs using the net benefit approach.[77] We explored Bosmans *et al.*'s methods[76] for economic evaluations alongside equivalence or non-inferiority trials, which requires specification of non-inferiority margins for both costs and effects. However, as our prespecified method of economic evaluation was cost–utility analysis, using QALYs, rather than cost-effectiveness analysis, using the PHQ-9, which was the measure on which the hypothesis of non-inferiority is based, no non-inferiority margin for economic effects was specified. In addition, there is a general lack of guidance on how to define an economically unimportant difference in costs with which to estimate an appropriate non-inferiority margin for costs.

We compared the costs and cost-effectiveness of BA and CBT at the final, 18-month, follow-up to capture the economic impact of events, such as relapse with unit costs from the 2013–14 financial year.[78,79] We discounted costs and QALYs in year 2 at 3.5%.[60] We used complete-case analysis, with missing data explored in a sensitivity analysis using multiple imputation by chained equations (MICE). Our primary analysis took the NHS/PSS perspective preferred by NICE.[80] The impact of productivity losses as a result of time off work, known to be a substantial cost in depression,[81] were explored in sensitivity analysis. In addition, narrower cost perspectives were tested (e.g. an intervention perspective and a mental health-care perspective), to ensure that the NHS/PSS perspective had not captured irrelevant costs that may hide the true impact of BA and CBT on service use.

For each participant, a unit cost was applied to each item of service use reported to calculate the total cost for the duration of the trial. All unit costs are summarised in *Table 3*.

We estimated intervention costs using the bottom-up costing approach set out by the Personal Social Services Research Unit at the University of Kent.[82] We based BA MHW costs on NHS AfC salary band 5 (salary range: £21,909–28,462; US$31,662–41,130; €27,726–35,993) and NHS AfC band 7 (salary range: £31,383–41,373; US$45,350–59,786; €39,738–52,388) for CBT therapists, including employer's National Insurance and pension contributions plus capital, administrative and managerial costs.[79] We calculated a cost per hour using standard working time assumptions,[79] weighted to account for time spent on non-patient facing activities, which was estimated based on the results of a survey of trial therapists.

We costed hospital services using unit costs from the NHS *Reference Costs 2013–14*.[78] Unit costs for NHS primary care and social care services were taken from nationally applicable published sources.[79] Costs for complementary services were taken from the NHS Choices website.[83] The costs of medications were calculated based on averages listed in the *British National Formulary*[84] for the generic drug and using daily dose information collected using the AD-SUS.

We valued productivity losses as a result of time off work due to illness using the human capital approach, which involves multiplying the individual's salary by reported days off work due to illness.[85]

We report differences in use of services between randomised groups descriptively as the mean by group and as a percentage of the group who had at least one contact. We tested for differences in mean costs per participant between groups using standard parametric *t*-tests, with the results confirmed using bias-corrected, non-parametric bootstrapping.[86] This is the recommended approach, despite the skewed nature of cost data, as it allows inferences to be made about the arithmetic mean.[87]

TABLE 3 Unit costs applied to economic data

Service	Unit	Cost (£)
BA	Per hour	67.80
CBT	Per hour	86.20
Medication	Per daily dose	Various
Inpatient	Per night	527.17–602.52
Outpatient	Per appointment	49.00–411.00
Accident and emergency	Per attendance	108.96–266.85
Ambulance	Per attendance	231.00
GP surgery	Per minute of patient contact	2.90
Practice nurse	Per minute of face-to-face contact	0.73
Case manager	Per home visit minute	2.39
Community occupational therapist	Per minute of face-to-face contact	0.68
Social worker	Per minute	2.65
Advice service	Per minute	1.05
Chiropractic/osteopathy	Per minute	1.42
Homeopathy	Per minute	1.67
Acupuncture	Per minute	1.33
Massage therapy	Per minute	1.13

We explored cost-effectiveness using ICERs – the difference in mean cost divided by the difference in mean effect[88] – and cost-effectiveness planes constructed to show the probability that BA is more or less effective and more or less costly than CBT. As ICERs are calculated from four sample means and are therefore subject to statistical uncertainty, the planes were generated using 1000 bootstrapped resamples from regression models of total cost and outcome by treatment group. These were then used to calculate the probability that each of the treatments is the optimal choice, for different values a decision-maker is willing to pay for a unit improvement in outcome (the ceiling ratio, λ). Cost-effectiveness acceptability curves (CEACs) are presented by plotting these probabilities for a range of possible values of λ to explore the uncertainty that exists around estimates of mean costs and effects, and to show the probability that BA is cost-effective compared with CBT.[89]

All analyses were controlled for the following covariates: site, ADM use, symptom severity and baseline measurement of the variables of interest. Additionally, data have been truncated to exclude influential outliers (i.e. cases with total costs in the 99th percentile that make a significant difference to the results).[90] Between-group differences for costs are presented for continuous outcomes as BA versus CBT (i.e. BA minus CBT).

We carried out a number of independent sensitivity analyses to test assumptions made in the analysis:

1. the impact of including the use of complementary therapies
2. the impact of including productivity losses as a result of time off work as a result of illness
3. the impact of missing data, considered using MICE
4. the impact of taking an intervention perspective
5. the impact of taking a mental health-care perspective.

Process data analysis

A full description of the methods and analyses of our process data, including qualitative data, is presented in *Chapter 4*. Based on recent reviews,[91] exploratory analyses examined baseline variables that might moderate outcome at multiple time points (6, 12 and 18 months) across the two treatments, including depression severity, age at depression onset, number of previous episodes, and baseline levels of cognitive and behavioural dysfunction, using the approach set out by Kraemer *et al.*[92] Although the power to detect moderate subgroup interactions was low, we were primarily interested in exploring the possibility of large interactions that could inform subsequent clinical decision-making regarding treatment allocation.

Mediational analyses investigated the hypothesised mechanisms of change (for BA, changes in specific behaviour such as reduced avoidance and rumination, learned capacity to apply behavioural principles to modify the environment; for CBT, changes in beliefs and underlying information processing style), pretreatment to mid-treatment, mid-treatment to post treatment across the trial arms using approaches to testing mediation that allow multiple mediators in one model.[92] The effects of the mediators on outcome at 12 and 18 months were modelled. This approach to examining mediation ensures that changes in putative mediators temporally precede changes in the primary outcome and allow baseline to post-treatment change in symptoms to be statistically controlled, necessary to rule out reverse causality.[93]

Qualitative data analysis

Participant and therapist interviews were analysed using a framework approach[94] combining deductive themes from the topic guides and inductive themes emerging from the data. Some interviews were coded independently to assess the reliability of coding and meetings were held to discuss and refine emerging themes.[95] Transcripts were examined thematically across the whole data set, as well as in the context of each interview, using constant comparison techniques.[96] Data were indexed and sorted using the identified themes and subthemes, and were summarised in framework matrices.[94] In keeping with the framework approach, we interrogated the data, searching for comparisons and contradictions and keeping interpretive notes. Alternative explanations or negative cases were identified, discussed and a consensus reached.[95]

Ethics issues

We conducted the trial in such a way as to protect the human rights and dignity of the participants as reflected in the Helsinki Declaration.[97] Participants did not receive any financial inducement to participate. The study received National Research Ethics Committee (REC) approval from the South West REC in the UK (reference number 12/SW/0029). Local REC and NHS research and development approvals were also given for each recruitment site. To conform with data protection and freedom of information acts, all data have been stored securely and anonymised wherever possible. No published material will contain patient-identifiable information.

Obtaining informed consent from participants

We determined informed consent by a two-phase consent process. Participants received a study information sheet in the post and a form seeking their permission to be contacted by a member of the research team, not at this stage to give consent to trial participation. The information leaflets were produced using current guidelines for researchers on writing information sheets and consent forms[98] and informed by our consumer/lived-experience user representatives. Participants who wished to partake in the trial returned their initial written consent to be contacted form to the site research team. Full informed written consent was obtained through an interview by a researcher where the information sheet was fully explained and where the opportunity to ask questions was given. The opportunity to withdraw from the trial was also fully explained. Researchers seeking consent were fully trained and supervised by the chief

investigator and site leads. Communication and recording systems were set up to enable the trial team to monitor and act on participants' wishes to withdraw from the trial.

Anticipated risks and benefits

All participants received usual GP care and, therefore, no treatment was withheld from participants in this trial. Both arms were active psychological treatments with previously demonstrated efficacy and no known iatrogenic effects. This trial may have in fact benefited individual participants, as CBT is not generally available for the majority of people with depression. By participating in this trial, participants also received an intensive level of monitoring such that any participants with worsening symptoms or who were at suicidal risk were identified and directed to appropriate care. We recorded all instances of AEs as detailed earlier.

Informing participants of anticipated risks and benefits

Participant information leaflets provided potential participants with information about the possible benefits and known risks of taking part in the trial. Participants were given the opportunity to discuss this issue with their GP or the trial manager prior to consenting. The trial manager would have informed the participant if new information came to light that may have affected the participant's willingness to participate in the trial.

Management of suicide risk

Inherent in the nature of the population under scrutiny is the risk of suicide. We followed good clinical practice in monitoring for suicide risk during all research and clinical encounters with trial participants, developed for our previous trials.[55,99] Where any risk to participants attributable to expressed thoughts of suicide were encountered, we reported these directly to the GP (with the participant's expressed permission), or if an acute risk was present we sought advice from the GP immediately and followed locally established suicide risk management plans. Systems were put into place to ensure that the chief investigator, trial manager and researchers were informed if there were any risks to the participants' safety.

Trial Steering Committee and Data Monitoring Committee

A TSC was set up and included an independent chairperson, an academic GP and at least two other independent members, along with the lead investigator and some other study collaborators. The TSC met at least once a year. The DMC was set up and was composed of an independent mental health professional, statistician and clinician. The role of the DMC was to review serious AEs thought to be treatment related and look at outcome data regularly during data collection.

Execution dates

The preparatory period started in March 2012. Recruitment ran from September 2012 to April 2014. Follow-up lasted 18 months after randomisation and was completed by October 2015. Data analysis and reporting were completed 12 months after this (September 2016). The entire study period lasted 54 months (March 2012 to September 2016).

Chapter 3 Results of clinical and economic analyses

Participant flow and retention

Between 26 September 2012 and 3 April 2014, we recruited 440 participants, randomly allocating 221 participants (50%) to the BA group and 219 participants (50%) to the CBT group. We recruited to time and target and the majority of participants were recruited from primary care (87%). Progress over the course of recruitment and achievement of the target is shown in *Figure 3*. Participant recruitment and retention is shown for both the ITT and PP analyses in the trial CONSORT diagram (*Figure 4*). There were no protocol deviations.

Baseline characteristics of participants

Patient- and trial-level characteristics at baseline were well balanced between groups (*Table 4*). We also found no evidence of a difference in patient characteristics between recruitment methods (*Table 5*). The PHQ-9 primary outcome at baseline was negatively skewed, with a high proportion of participants scoring towards the upper end of the distribution (*Figure 5*), and scores were similar between groups [BA, 17.7 PHQ-9 points (SD 4.8 PHQ-9 points); CBT, 17.4 PHQ-9 points (SD 4.8 PHQ-9 points)] (*Table 6*).

Delivery and receipt of the interventions

Ten MHWs provided BA [median 22 participants each (interquartile range 19–25 participants each)] and 12 therapists provided CBT [median 21 participants each (interquartile range 13–23 participants each)]. MHWs had a mean of 18 months' mental health experience (SD 11 months' mental health experience) and CBT therapists had a mean of 22 months' experience (SD 24 months' experience) post CBT qualification. We removed one CBT therapist from the trial in the early stages who did not meet acceptable competency.

Participants received a mean of 11.5 BA sessions (SD 7.8 sessions) or 12.5 CBT sessions (SD 7.8 sessions). Three hundred and five participants (69%) completed the PP number of at least eight sessions [BA 147 (67%) participants, mean 16.1 sessions (SD 5.3 sessions); CBT 158 (72%) participants, mean 16.4 sessions (SD 5.4 sessions)]. Participants completing fewer than eight sessions {135 participants (31%) [BA 74 participants (33%) and CBT 61 participants (28%)] completed a mean of 2.5 BA sessions (SD 1.9 sessions) or 2.6 CBT sessions (SD 2.1 sessions)}.

Primary outcome: Patient Health Questionnaire-9 at 12 months

We present primary and secondary outcomes at 12 months in *Table 6*. We found no evidence of inferiority of PHQ-9 score at 12 months in either the ITT [CBT 8.4 PHQ-9 points (SD 7.5 PHQ-9 points), BA 8.4 PHQ-9 points (SD 7.0 PHQ-9 points); mean difference 0.1 PHQ-9 points, 95% CI –1.3 to 1.5 PHQ-9 points; $p = 0.89$] or PP [CBT 7.9 PHQ-9 points (SD 7.3 PHQ-9 points), BA 7.8 PHQ-9 points (SD 6.5 PHQ-9 points); mean difference 0.0 PHQ-9 points, 95% CI –1.5 to 1.6 PHQ-9 points; $p = 0.99$] populations. The

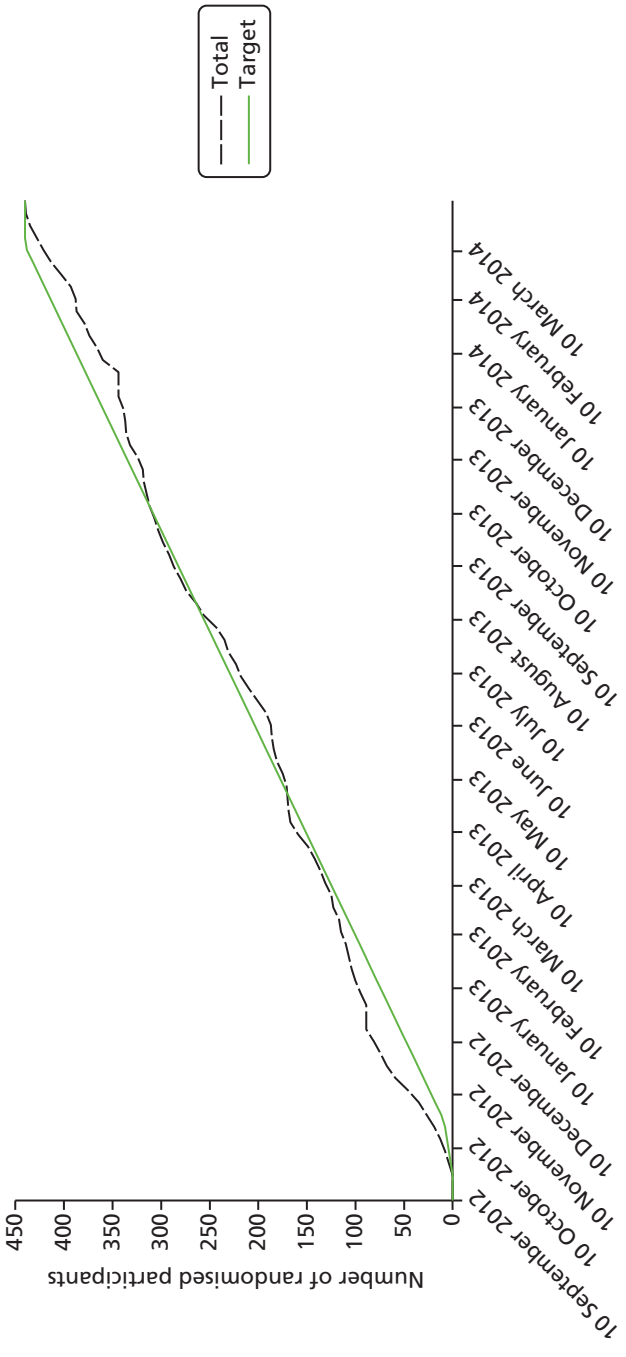

FIGURE 3 Trial recruitment. Solid line shows target recruitment and dashed line shows cumulative actual recruitment.

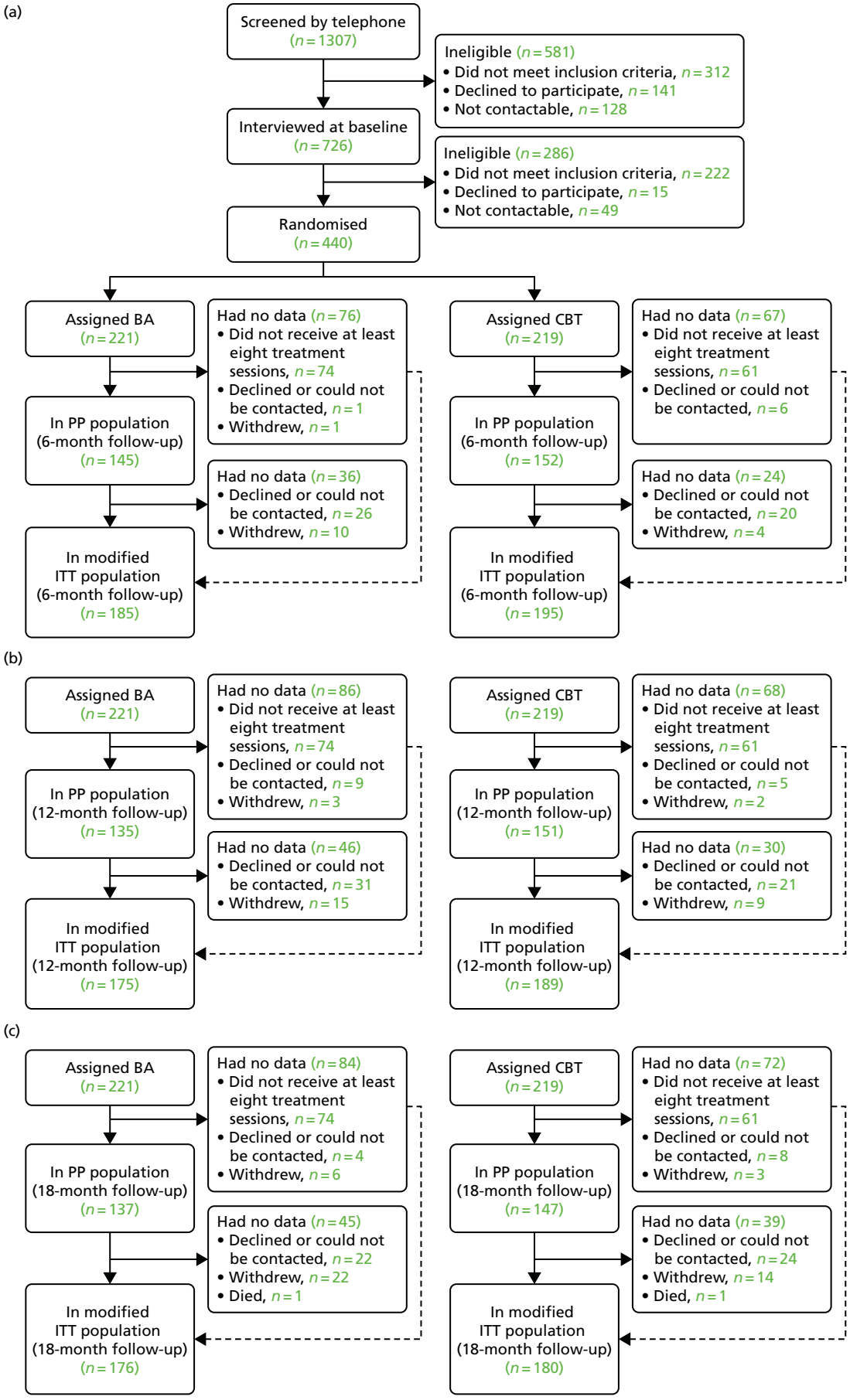

FIGURE 4 The trial CONSORT flow diagram. (a) 6-month follow-up, (b) 12-month follow-up and (c) 18-month follow-up.

TABLE 4 Baseline trial, patient and minimisation characteristics by group allocation

Characteristic	Trial arm		
	BA ($n = 221$)	CBT ($n = 219$)	All ($n = 440$)
Trial characteristic			
Method of recruitment, *n* (%)			
Case notes	192 (87)	190 (87)	382 (87)
IAPT	29 (13)	29 (13)	38 (13)
Patient characteristics			
Age (years), mean (SD) range	43.9 (14.1) 18–82	43.0 (14.1) 19–84	43.5 (14.1) 18–84
Gender, *n* (%)			
Male	79 (36)	71(32)	150 (34)
Female	142 (64)	148 (68)	290 (66)
Number of episodes of depression including current			
Mean (SD), *n*	7.0 (15.0) 192	6.3 (13.8) 192	6.7 (14.4) 384
Median (IQR)	3.0 (1–5)	2.0 (1–4)	3.0 (1–5)
First depression episode, age at onset (years), mean (SD)	27.2 (15.0)	26.3 (13.5)	26.7 (14.2)
Duration of antidepressant treatment (weeks)[a]			
Mean (SD), *n*	106 (210), 157	81 (164), 168	93 (188), 325
Median (IQR)	21 (10–71)	18 (7–51)	19 (8–66)
At least one comorbid anxiety disorder, *n* (%)	131 (59)	141 (64)	272 (62)
Marital status, *n* (%)			
Single	68 (31)	59 (27)	127 (29)
Cohabiting (not married)	29 (13)	25 (11)	54 (12)
Civil partnership	1 (1)	1 (1)	2 (1)
Married	84 (38)	92 (42)	176 (40)
Divorced/separated	39 (18)	42 (19)	81 (18)
Number of children, *n* (%)			
0	74 (34)	72 (33)	146 (33)
1	35 (16)	31 (14)	66 (15)
2	67 (30)	69 (32)	136 (31)
3	31 (14)	27 (12)	58 (13)
≥ 4	14 (6)	20 (9)	34 (8)
Level of education, *n* (%)			
No qualifications	25 (11)	30 (14)	55 (13)
GCSEs/O-levels	36 (16)	43 (20)	79 (18)
AS/A-levels	28 (13)	22 (10)	50 (11)
NVQ or other vocational qualification	54 (24)	71 (32)	125 (28)
Undergraduate degree	44 (20)	35 (16)	79 (18)
Postgraduate degree	28 (13)	14 (6)	42 (10)
Doctoral degree	2 (1)	1 (0)	3 (1)
Professional degree (e.g. MD)	4 (2)	3 (1)	7 (2)

TABLE 4 Baseline trial, patient and minimisation characteristics by group allocation (*continued*)

Characteristic	Trial arm		
	BA ($n = 221$)	CBT ($n = 219$)	All ($n = 440$)
Ethnicity, *n* (%)			
White British	204 (92)	197 (90)	401 (91)
Other	17 (8)	22 (10)	39 (9)
Stratification/minimisation variables			
PHQ-9 points category, *n* (%)			
< 19	118 (54)	118 (54)	236 (54)
≥ 19	103 (46)	101 (46)	204 (46)
Antidepressant use, *n* (%)			
Yes	172 (78)	175 (79)	345 (78)
No	49 (22)	46 (21)	95 (22)
Site, *n* (%)			
1	74 (33)	73 (33)	147 (33)
2	79 (36)	78 (36)	157 (36)
3	68 (31)	68 (31)	136 (31)

A-level, Advanced level; AS, Advanced Supplementary; GCSE, General Certificate of Secondary Education; IQR, interquartile range; MD, Doctor of Medicine; NVQ, National Vocational Qualification; O-level, Ordinary level.
a Twenty participants (BA, $n = 15$; CBT, $n = 5$) who reported that they were using ADM at baseline did not report duration of use.

TABLE 5 Baseline trial, patient and minimisation characteristics by recruitment method

Recruitment method	Recruitment method		
	Primary care ($n = 382$)	IAPT ($n = 58$)	All ($n = 440$)
Patient characteristics			
Age (years), mean (SD)	43.6 (14.2)	42.7 (13.4)	43.5 (14.1)
Gender, *n* (%)			
Male	122 (32)	28 (48)	150 (34)
Female	260 (68)	30 (52)	290 (66)
Number of episodes of depression including current			
Mean (SD), *n*	6.9 (15.3), 327	5.6 (7.2), 57	6.7 (14.4), 384
Median (IQR)	3.0 (1–5)	3.0 (2–5)	3.0 (1–5)
Age at onset of first depression episode (years), mean (SD)	27.0 (14.6)	25.6 (13.2)	26.7 (14.2)
Duration of antidepressant treatment (weeks)[a]			
Mean (SD), *n*	84 (165), 290	167 (313), 35	93 (188), 325
Median (IQR)	18 (8–64)	23 (15–108)	19 (8–66)
At least one comorbid anxiety disorder, *n* (%)	246 (64)	26 (45)	272 (62)

continued

TABLE 5 Baseline trial, patient and minimisation characteristics by recruitment method (*continued*)

Recruitment method	Recruitment method		
	Primary care ($n = 382$)	IAPT ($n = 58$)	All ($n = 440$)
Marital status, (%)			
Single	112 (29)	15 (26)	127 (29)
Cohabiting (not married)	45 (12)	9 (16)	54 (12)
Civil partnership	2 (1)	0 (0)	2 (1)
Married	149 (39)	27 (47)	176 (40)
Divorced/separated	74 (19)	7 (12)	81 (18)
Number of children, *n* (%)			
0	123 (32)	23 (40)	146 (33)
1	58 (15)	8 (14)	66 (15)
2	121 (32)	15 (26)	136 (31)
3	49 (13)	9 (16)	58 (13)
≥ 4	31 (8)	3 (5)	34 (8)
Level of education, *n* (%)			
No qualifications	50 (13)	5 (9)	55 (13)
GCSEs/O-levels	71 (19)	8 (14)	79 (18)
AS/A-levels	44 (12)	6 (10)	50 (11)
NVQ or other vocational qualification	106 (28)	19 (33)	125 (28)
Undergraduate degree	66 (17)	13 (23)	79 (18)
Postgraduate degree	36 (9)	6 (10)	42 (10)
Doctoral degree	3 (1)	0 (0)	3 (1)
Professional degree (e.g. MD)	6 (2)	1 (2)	7 (2)
Ethnicity, *n* (%)			
White British	353 (92)	49 (84)	402 (91)
Other	29 (76)	9 (2)	38 (9)
Stratification or minimisation variables			
PHQ-9 category, *n* (%)			
< 19 points	200 (52)	36 (62)	236 (54)
≥ 19 points	182 (48)	22 (38)	204 (46)
Antidepressant use, *n* (%)			
Yes	309 (81)	36 (62)	345 (78)
No	73 (19)	22 (38)	95 (22)
Site, *n* (%)			
Devon	145 (38)	2 (4)	147 (33)
Durham	157 (41)	0 (0)	157 (36)
Leeds	80 (21)	56 (97)	136 (31)

A-level, Advanced level; AS, Advanced Supplementary; GCSE, General Certificate of Secondary Education; IQR, interquartile range; MD, Doctor of Medicine; NVQ, National Vocational Qualification; O-level, Ordinary level.

a Twenty (primary care, $n = 19$; IAPT, $n = 1$) participants who reported that they were using ADM at baseline did not report duration of use.

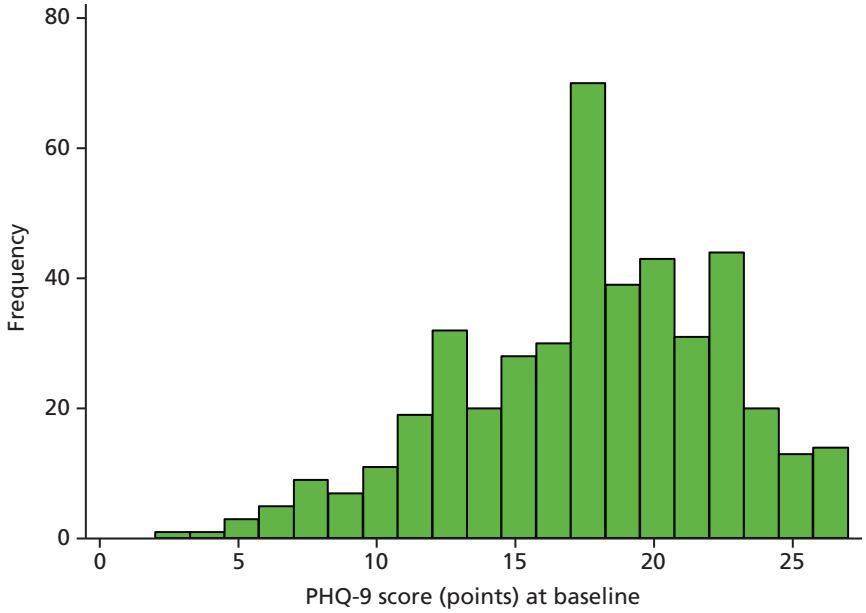

FIGURE 5 Distribution of primary outcome (PHQ-9 score) at baseline.

TABLE 6 Primary and secondary outcomes at 12 months

Outcome	Trial arm: *n*, mean (SD or %)		Between-group difference (CBT – BA) at 12-month follow-up: mean (95% CI), *p*-value	
	CBT	BA	Observed data only	Observed and imputed data
Primary outcome *PHQ-9*				
Baseline	219, 17.4 (4.8)	221, 17.7 (4.8)		
ITT 12-month follow-up	189, 8.4 (7.5)	175, 8.4 (7.0)	0.1[a] (–1.3 to 1.5), 0.89	0.2[a] (–1.1 to 1.7), 0.80
PP 12-month follow-up	151, 7.9 (7.3)	135, 7.8 (6.5)	0.0[a] (–1.5 to 1.6), 0.99	0.0[a] (–1.6 to 1.6), 0.99
Secondary outcomes *GAD-7*				
Baseline	219, 12.6 (5.1)	221, 12.7 (5.1)		
ITT 12-month follow-up	176, 6.3 (6.0)	161, 6.4 (5.9)	–0.1[a] (–1.0 to 1.3), 0.82	0.0[a] (–1.3 to 1.4), 0.96
PP 12-month follow-up	146, 6.0 (5.8)	129, 5.9 (5.5)	0.01[a] (–1.3 to 1.2), 0.95	–0.4[a] (–1.7 to 1.0), 0.60
SCID number of depression-free days				
ITT 12-month follow-up	160, 129 (58)	150, 120 (56)	9[a] (–3 to 23), 0.13	7[a] (–7 to 20), 0.27
PP 12-month follow-up	138, 132 (55)	125, 119 (55)	13[a] (0 to 26), 0.06	8[a] (–4 to 21), 0.21
SF-36 v2 PCS				
Baseline	65, 50.1 (13.1)	69, 51.4 (11.9)		
ITT 12-month follow-up	168, 48.1 (12.2)	150, 49.9 (11.6)	1.6[b] (–1.0 to 4.2), 0.22	–1.4[b] (–1.1 to 4.0), 0.27
PP 12-month follow-up	144, 48.0 (12.2)	125, 49.9 (12.0)	1.6[b] (–1.3 to 4.4), 0.28	–1.3[b] (–1.5 to 4.1), 0.36

continued

TABLE 6 Primary and secondary outcomes at 12 months (*continued*)

Outcome	Trial arm: *n*, mean (SD or %)		Between-group difference (CBT – BA) at 12-month follow-up: mean (95% CI), *p*-value	
	CBT	BA	Observed data only	Observed and imputed data
SF-36 v2 MCS				
Baseline	65, 23.2 (9.4)	69, 22.5 (7.8)		
ITT 12-month follow-up	168, 41.7 (14.1)	150, 41.6 (14.0)	0.0[b] (–3.0 to 3.0), 0.99	0.0[b] (–2.8 to 2.9), 0.97
PP 12-month follow-up	144, 42.9 (13.6)	125, 42.3 (13.3)	0.5[b] (–3.7 to 2.7), 0.77	0.6[b] (–3.8 to 2.7), 0.73
SCID depression	**n/N *(%)***	**n/N *(%)***	***Odds ratio (BA/CBT) (95% CI)*, p-value**	***Odds ratio (BA/CBT) (95% CI)*, p-value**
Baseline	219/219 (100)	221/221 (100)		
ITT 12-month follow-up	37/163 (23)	31/154 (20)	0.9 (0.5 to 1.6), 0.71	0.9 (0.5 to 1.6), 0.70
PP 12-month follow-up	30/141 (21)	24/128 (19)	0.9 (0.5 to 1.7), 0.80	0.9 (0.5 to 1.7), 0.75
Recovery[c]				
ITT 12-month follow-up	124/189 (66)	115/175 (66)	1.0 (0.6 to 1.5), 0.96	1.2 (0.7 to 1.9), 0.53
PP 12-month follow-up	104/151 (69)	94/135 (70)	1.0 (0.6 to 1.7), 0.96	1.2 (0.7 to 2.0), 0.47
Response[d]				
ITT 12-month follow-up	117/189 (62)	107/175 (61)	1.0 (0.9 to 1.1), 0.73	0.9 (0.6 to 1.4), 0.75
PP 12-month follow-up	100/151 (66)	87/135 (64)	0.9 (0.9 to 1.0), 0.64	0.9 (0.5 to 1.4), 0.55

MCS, Mental Component Scale; PCS, Physical Component Scale; v2, version 2.
a Models adjusted for baseline outcome score and stratification variables [symptom severity (PHQ score of < 19 points, PHQ score of ≥ 19 points), site (Devon, Durham, Leeds) and ADM use (currently taking ADM, not currently taking ADM)].
b Models adjusted for stratification variables, but not baseline outcome score.
c Participants with PHQ-9 scores of ≤ 9 points.
d Participants with a 50% reduction from baseline PHQ-9 scores.

non-inferiority of BA to CBT was accepted for both the ITT and PP populations, as the lower bound of the 95% CI (one-sided 97.5% CI) of the between-group mean difference lies within the non-inferiority margin of –1.9 PHQ-9 points (*Figure 6*). We ruled out superiority of CBT to BA as the lower bound of the 95% CI includes zero for the ITT and PP populations. The inference of non-inferiority was robust to sensitivity analysis across different PP definitions (*Table 7*). Our predefined stratification variable subgroup analyses (*Table 8*) showed no ITT or PP between-group difference by depression severity, ADM or site.

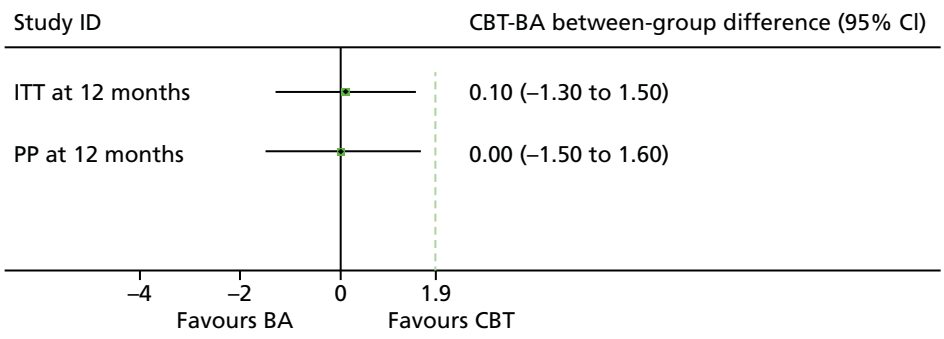

FIGURE 6 Mean difference and two-sided 95% CI for the primary outcome of PHQ-9 at 12 months and non-inferiority margin.

TABLE 7 Primary analysis on primary outcome (PHQ-9 score) at 12 months: sensitivity analysis across definitions of PP

PP definition	Time point, mean (SD), *n*				Between-group difference (CBT – BA):[a] mean (95% CI), *p*-value
	Baseline		12-month follow-up		
	CBT	BA	CBT	BA	
Standard PP definition[b]					
≥ 8 sessions attended	17.4 (4.9), 158	17.6 (4.6), 147	7.9 (7.3), 151	7.8 (6.5), 135	0.0 (–1.5 to 1.6), 0.99
Alternative PP definitions[b]					
≥ 0 sessions attended	17.4 (4.8), 219	17.7 (4.8), 221	8.4 (7.5), 189	8.4 (7.0), 175	0.1 (–1.3 to 1.5), 0.89
≥ 4 sessions attended	17.4 (5.0), 176	17.7 (4.6), 169	8.0 (7.4), 161	8.2 (6.8), 150	0.1 (–1.4 to 1.7), 0.86
≥ 12 sessions attended	17.8 (4.8), 115	17.7 (4.8), 109	8.6 (7.1), 112	7.6 (6.2), 105	–0.6 (–2.3 to 1.1), 0.52
≥ 16 sessions attended	17.8 (4.8), 83	18.3 (4.7), 77	8.8 (7.0), 81	8.6 (6.1), 75	0.2 (–1.9 to 2.3), 0.86
≥ 20 sessions attended	18.2 (4.7), 58	18.5 (4.6), 51	9.0 (6.7), 57	8.5 (6.1), 49	–0.4 (–3.3 to 2.5), 0.78

a All models adjusted for baseline outcome score and stratification variables [i.e. symptom severity (PHQ score of < 19 points, PHQ score of ≥ 19 points), site (Devon, Durham, Leeds) and ADM use (currently taking ADM, not currently taking ADM)].
b Based on observed data only.

TABLE 8 Predefined stratification variable subgroup analyses on the primary outcome at 12 months

Stratification variable	Population			
	ITT		PP	
	Between-group difference (CBT – BA):[a] mean (95% CI)	Interaction coefficient (95% CI), *p*-value	Between-group difference (CBT – BA):[a] mean (95% CI)	Interaction coefficient (95% CI), *p*-value
Depression severity				
PHQ-9 < 19 points	0.4 (–1.3 to 2.0)	1.1 (–1.8 to 3.9), 0.48	0.7 (–1.1 to 2.6)	1.9 (–1.2 to 5.0), 0.23
PHQ-9 ≥ 19 points	–0.6 (–3.5 to 1.8)		–0.9 (–3.5 to 1.7)	
Receiving ADM				
Yes	0.2 (–2.7 to 3.1)	0.2 (–3.2 to 3.7), 0.90	–0.4 (–3.5 to 2.7)	0.6 (–4.3 to 3.2), 0.74
No	–0.1 (–1.7 to 1.5)		0.2 (–1.6 to 2.0)	
Site				
Exeter	–1.2 (–3.6 to 1.1)	–2.1 (–5.5 to 1.4)	–1.2 (–3.9 to 1.5)	–1.7 (–5.5 to 2.1)
Durham	1.0 (–1.6 to 3.6)	–0.9 (–4.5 to 2.6)	0.6 (–2.2 to 3.4)	–1.3 (–5.3 to 2.6)
Leeds	–0.2 (–2.8 to 2.3)	0.49[b]	0.2 (–2.3 to 3.0)	0.64[b]

a All models adjusted for baseline outcome score and stratification variables [i.e. symptom severity (PHQ score of < 19 points, PHQ score of ≥ 19 points), site (Devon, Durham, Leeds) and ADM use (currently taking ADM, not currently taking ADM)].
b Global *p*-value.

Response and recovery at 12 months

Between 61% and 70% of ITT and PP participants in both groups met criteria for recovery or response, with no difference in the proportions of patients in each group who recovered or responded (see *Table 6*).

Primary and secondary outcomes at all follow-up points

Tables 9 and *10* show the repeated measures comparison of primary and secondary outcomes across time points for both ITT and PP populations. For the primary outcome, there was no evidence of difference

TABLE 9 Descriptive analysis of primary and secondary outcomes at 6, 12 and 18 months, and *p*-value for repeated measures analysis across all follow-up times: ITT analysis population

Outcome	Time point				Between-group comparison, *p*-value[a,b]
	Baseline	6 months	12 months	18 months	
Primary outcome					
PHQ-9, mean (SD), *n*					
CBT	17.4 (4.8), 219	9.7 (7.3), 195	8.4 (7.5), 189	8.5 (7.2), 189	0.95
BA	17.7 (4.8), 221	9.8 (6.9), 185	8.4 (7.0), 175	8.3 (7.1), 176	
Secondary outcomes					
GAD-7, mean (SD), *n*					
CBT	12.6 (5.1), 219	7.5 (6.0), 186	6.3 (6.0), 176	7.0 (6.2), 167	0.32
BA	12.7 (5.1), 221	7.5 (5.8), 176	6.4 (5.9), 161	6.4 (5.9), 165	
SCID number of depression-free days, mean (SD), *n*					
CBT	–	66 (41), 171	130 (58), 160	125 (60), 161	0.06
BA	–	70 (47), 164	120 (55), 150	129 (57), 153	
SF-36 v2 PCS, mean (SD), *n*					
CBT	50.1 (13.1), 65	48.4 (11.7), 107	48.1 (12.2), 168	48.8 (12.5), 167	0.64
BA	51.4 (11.9), 69	49.4 (12.1), 111	49.9 (11.6), 150	49.6 (12.5), 160	
SF-36 v2 MCS, mean (SD), *n*					
CBT	23.2 (9.4), 65	39.5 (12.4), 107	41.7 (14.1), 168	40.7 (14.4), 167	0.50
BA	22.5 (7.8), 69	37.5 (13.7), 111	41.6 (14.0), 150	42.3 (13.8), 160	
Other outcomes					
Recovery,[c] *n/N* (%)					
CBT	13/219, 6	111/195, 57	134/189, 66	127/180, 59	0.88
BA	208/221, 6	97/185, 52	115/175, 66	116/176, 66	
Response,[d] *n/N* (%)					
CBT	–	96/195, 49	117/189, 62	108/180, 60	0.94
BA	–	91/185, 49	107/175, 61	108/176, 61	

MCS, Mental Component Scale; PCS, Physical Component Scale; v2, version 2.
a Global *p*-value for treatment group–time point interaction.
b *p*-values for the SF-36 v2 outcomes were derived from the model that excluded baseline measurements.
c Recovery defined as follow-up score of ≤ 9 points on the PHQ-9.
d Response defined as a ≥ 50% reduction in the PHQ-9 score at follow-up compared with baseline.

TABLE 10 Descriptive analysis or primary and secondary outcomes at 6, 12 and 18 months, and *p*-value for repeated measures analysis across all follow-up times: PP analysis population

Outcome	Time point				Between-group comparison, *p*-value[a,b]
	Baseline	6 months	12 months	18 months	
Primary outcome					
PHQ-9, mean (SD), *n*					
CBT	17.3 (4.8), 158	9.1 (6.9), 152	7.9 (7.3), 152	8.0 (7.3), 147	0.51
BA	17.6 (4.6), 147	9.7 (6.7), 145	7.8 (6.5), 135	7.7 (6.7), 137	
Secondary outcomes					
GAD-7, mean (SD), *n*					
CBT	12.6 (5.2), 158	6.9 (5.8), 149	6.0 (5.8), 146	6.5 (5.9), 141	0.45
BA	12.5 (5.0), 147	7.1 (5.6), 140	5.9 (5.4), 129	6.0 (5.7), 132	
SCID number of depression-free days, mean (SD), *n*					
CBT	–	67 (40), 140	132 (55), 138	130 (59), 136	0.11
BA	–	68 (46), 137	119 (55), 125	130 (56), 123	
SF-36 v2 PCS, mean (SD), *n*					
CBT	50.3 (12.4), 51	49.9 (10.9), 90	48.0 (12.2), 144	49.0 (12.6), 141	0.60
BA	50.4 (12.1), 46	49.9 (11.8), 87	49.9 (12.0), 125	49.6 (12.7), 130	
SF-36 v2 MCS, mean (SD), *n*					
CBT	23.4 (9.3), 51	40.2 (12.2), 90	42.9 (13.6), 144	41.6 (14.6), 141	0.58
BA	22.9 (7.8), 46	39.0 (13.3), 87	42.3 (13.3), 125	42.7 (13.8), 130	
Other outcomes					
Recovery,[c] *n*/*N* (%)					
CBT	9/158 (6)	91/152 (60)	104/151 (69)	93/147 (63)	0.77
BA	7/147 (5)	75/145 (52)	94/135 (70)	96/137 (70)	
Response,[d] *n*/*N* (%)					
CBT	–	81/152 (53)	100/151 (66)	95/147 (64)	0.40
BA	–	67/145 (46)	87/135 (64)	88/137 (64)	

MCS, Mental Component Scale; PCS, Physical Component Scale; v2, version 2.
a Global *p*-value for treatment group–time point interaction.
b *p*-values for SF-36 v2 outcomes were derived from the model that excluded baseline measurements.
c Recovery defined as follow-up score of ≤ 9 points on the PHQ-9.
d Response defined as a ≥ 50% reduction in the PHQ-9 score at follow-up compared with baseline.

between the CBT and BA groups across observed or imputed outcomes over the period of the trial, as indicated by a non-significant time by treatment effect interaction. Although there was some weak evidence ($p = 0.06$) of a higher number of depression-free days at follow-up with BA than CBT in the ITT analyses, this difference was not apparent in the PP analysis ($p = 0.11$).

Primary and secondary outcomes and clustering by therapist

There was evidence of a small, negligible clustering of primary and secondary outcome scores at follow-up across therapists overall and within BA and CBT groups (intracluster correlation coefficient of ≤ 0.04).

Missing data

Of the 440 participants recruited, 76 participants (17%) had missing primary outcome data at 12 months' follow-up. The proportion of missing PHQ-9 data was higher in the BA than in the CBT group [46 (21%) vs. 30 (14%), ITT relative risk 1.15, 95% CI 1.0 to 1.32; $p = 0.044$]. Drop out from PP treatment was not significantly different (PP relative risk 1.13, 95% CI 0.98 to 1.30; $p = 0.84$). Imputation of data for primary and secondary outcomes at 12 months showed that, in accordance with the observed data analysis, no difference existed between groups (see *Table 6*), supporting our conclusion of non-inferiority. The odds of missing PHQ-9 data were higher for patients with increased baseline severity of depression (PHQ-9 $\geq$ 19, odds ratio 1.6, 95% CI 1.0 to 2.6; $p = 0.05$), and increasing age (in years) was associated with lower odds of missing PHQ-9 data (odds ratio 0.97, 95% CI 0.96 to 0.99). We found no evidence of an association between missingness and any other baseline characteristic.

Blinding

Outcome assessors reported having been unmasked for 16 (4%) participants [five (2%) in the BA group and 11 (5%) in the CBT group] as a result of participants informing assessors of their treatment allocation.

Safety and adverse events

Two (1%) non-trial-related deaths [one (1%) multidrug toxicity death in the BA group and one (1%) cancer-related death in the CBT group] and 15 depression-related, but not treatment-related, serious AEs (three in the BA group and 12 in the CBT group) occurred in three (2%) participants in the BA group [two (1%) patients who overdosed and one (1%) who self-harmed] and eight (4%) participants in the CBT group [seven (4%) who overdosed and one (1%) who self-harmed].

Intervention quality

Mental health workers and therapists met acceptable competency standards above our set thresholds, as judged by our independently rated tapes: mean Quality of Behavioural Activation Scale score for BA competence was 55 (SD 7.5) and mean CTS-R for CBT competence was 37.9 (SD 10.9).

Results of economic evaluation

Data completeness

At 18 months, full service use data for the entire follow-up were available for 159 (90%) of the 176 participants with outcome data in the BA group and 169 (93%) of the 180 participants with outcome data in the CBT group, which was 75% of the total number randomised. One participant was identified as an influential outlier in the CBT group and removed from the main analysis.

Service use

The use of most health services, social care services and complementary therapies was broadly similar across the randomised groups over the 18-month follow-up. Some services were used only by those in one group (case manager and homeopathy in BA; occupational therapist, community psychiatrist, advice service and acupuncture in CBT), but these were all services used by $< 2\%$ of the sample. Service use between baseline and the 18-month follow-up is detailed in *Table 11*.

TABLE 11 Service use (unit) between baseline and 18-month follow-up

	Trial arm					
	BA ($n = 159$)			CBT ($n = 168$)		
Service	Mean (SD)	Range	% using	Mean (SD)	Range	% using
Inpatient stay (nights), *n*	0.55 (2.13)	0–20	25.79	0.74 (2.96)	0–25	27.98
Outpatient appointments (contacts), *n*	3.45 (5.25)	0–4	66.67	3.48 (5.94)	0–58	58.33
Accident and emergency (contacts), *n*	0.55 (1.09)	0–6	30.82	0.44 (0.96)	0–7	25.00
GP surgery (contacts), *n*	6.67 (8.49)	0–42	51.57	5.96 (8.18)	0–55	51.19
GP telephone (contacts), *n*	0.67 (2.75)	0–21	8.18	0.67 (2.49)	0–17	8.93
Practice nurse (contacts), *n*	2.02 (8.04)	0–82	18.87	1.35 (3.57)	0–25	17.26
Case manager (contacts), *n*	0.09 (1.19)	0–15	0.63	0.00 (0.00)	0	0.00
Occupational therapist (contacts), *n*	0.00 (0.00)	0	0.00	0.32 (3.00)	0–34	1.19
Psychiatrist (contacts), *n*	0.00 (0.00)	0	0.00	0.03 (0.36)	0–5	0.60
Social worker (contacts), *n*	0.06 (0.71)	0–9	0.63	0.04 (0.54)	0–7	0.60
Advice service (contacts), *n*	0.00 (0.00)	0	0.00	0.47 (6.10)	0–79	0.60
Chiropractor/osteopath (contacts), *n*	0.27 (2.05)	0–18	1.89	0.47 (4.70)	0–59	1.79
Homeopath (contacts), *n*	0.03 (0.32)	0–4	0.63	0.00 (0.00)	0	0.00
Acupuncture (contacts), *n*	0.00 (0.00)	0	0.00	0.45 (5.86)	0–76	0.60
Massage therapy (contacts), *n*	0.97 (4.92)	0–53	8.18	1.29 (6.32)	0–54	7.14

Medication

The use of prescribed, psychotropic medication is summarised in *Table 12*. ADM was prescribed most frequently (around 80% of the full sample), followed by medication for anxiety or sleep (around 10% of the full sample). Mood stabilisers and antipsychotics were both prescribed for < 2% of the sample. There were no obvious differences in the proportion of participants in each group prescribed psychotropic medication.

Productivity losses

Of those in employment [BA, $n = 77$ (48%); CBT, $n = 71$ (42%)], over the 18-month follow-up the mean number of days off work did not differ between the groups (28.94 days in the BA group and 28.46 days in the CBT group).

TABLE 12 Use of prescribed medication at any time between baseline and 18-month follow-up

	Trial arm, % of sample using	
Medication type	BA ($n = 159$)	CBT ($n = 168$)
Antidepressants	79.87	82.74
Anxiety/sleep	10.06	11.31
Mood stabilisers	0.63	0.60
Antipsychotics	0.63	1.79

Total costs

Total costs over the 18-month follow-up period are summarised in *Table 13*, including a breakdown of costs by service-providing sector. We found a significant difference in mean intervention costs between the two groups, but no differences in other categories of cost or in total cost.

Outcomes

Health-related quality of life

We found that the mean health utility scores (as measured via the EQ-5D-3L) were slightly higher in the BA group than in the CBT group across the entire follow-up period, with resultant QALYs also higher for BA, but the QALY difference was not significant (*Table 14*).

Cost-effectiveness

As observed costs were lower and QALY outcomes better in the BA group than in the CBT group, this generated an ICER (the additional cost of one intervention compared with another divided by the additional effects) of –£6865, suggesting that BA dominates CBT (i.e. BA is both cheaper and more effective). The scatterplot of the bootstrapped cost and effectiveness pairs for BA versus CBT (*Figure 7*) illustrates dominance of BA over CBT, with the point estimate and two-thirds of the scatter points (66%) falling in the south-east quadrant of the cost-effectiveness plane, where BA replications are cheaper and more effective than CBT ones.

TABLE 13 Differences in costs (£) per participants between baseline and 18-month follow-up

Service	Trial arm, mean (SD)		BA – CBT, mean difference[a]	95% CI[a]	*p*-value[a]
	BA ($n = 159$)	CBT ($n = 168$)			
Intervention	974.81 (475.02)	1235.23 (610.03)	–262.29	–381.40 to –143.19	< 0.0001
Hospital	860.23 (1509.88)	927.26 (1975.64)	–75.67	–451.75 to 300.42	0.692
Community health and social care	644.36 (816.07)	944.25 (1726.17)	–15.14	–304.90 to 274.62	0.918
Medication	103.20 (197.92)	117.64 (265.92)	2.15	–39.83 to 44.13	0.920
Total	2596.62 (1846.72)	3250.74 (3040.99)	–343.24	–857.62 to 171.13	0.190

a Adjusted for site, ADM use, symptom severity and baseline covariates.

TABLE 14 Mean EQ-5D-3L utility score between baseline and 18-month follow-up and resultant QALYs

Time point/QALY	Trial arm				Mean difference[a] (BA – CBT)	95% CI[a]	*p*-value[a]
	BA		CBT				
	n	Mean (SD)	*n*	Mean (SD)			
Baseline	159	0.548 (0.307)	168	0.474 (0.317)			
6 months	153	0.683 (0.310)	151	0.677 (0.310)			
12 months	147	0.684 (0.341)	156	0.671 (0.348)			
18 months	152	0.670 (0.311)	157	0.624 (0.335)			
QALYs	152	0.985 (0.422)	157	0.935 (0.433)	0.050	–0.145 to 0.046	0.308

a Adjusted for site, ADM use, symptom severity and baseline covariates.

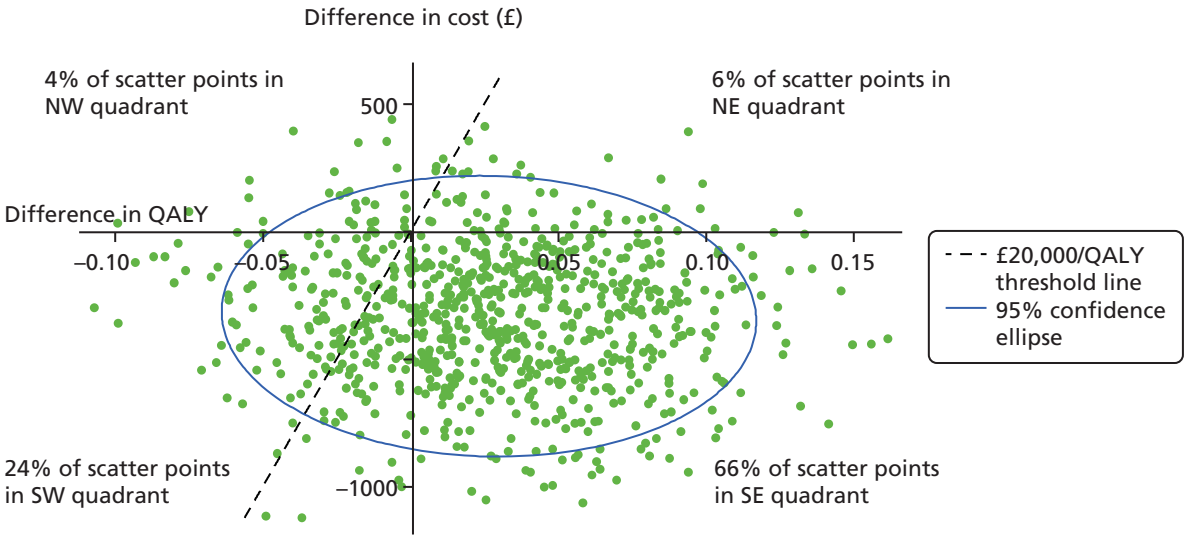

FIGURE 7 Scatterplot showing the bootstrapped mean differences in costs and effects of BA compared with CBT. NE, north-east; NW, north-west; SE, south-east; SW, south-west.

The CEAC showing the probability of BA being cost-effective compared with CBT does not fall < 75% and is closer to 80% at the standard NICE-preferred willingness-to-pay levels of £20,000–30,000 per QALY (*Figure 8*).

Sensitivity analyses

Inclusion of the costs of complementary therapies and productivity losses (*Table 15*) increased the overall mean difference in total cost between the two groups, making BA significantly less costly than CBT in both cases ($p = 0.039$ with the inclusion of complementary therapies and $p = 0.003$ with the inclusion of productivity losses). Narrower perspectives, focusing only on the cost of the interventions and the mental health service perspective, had the same effect ($p < 0.0001$ in both cases). *Figure 9* shows the CEACs for the inclusion of complementary therapies and productivity losses and *Figure 10* shows the CEACs for the two narrower cost perspectives. In all cases, BA continues to have a higher probability of being cost-effective compared with CBT at the NICE threshold of £20,000–30,000 per QALY.

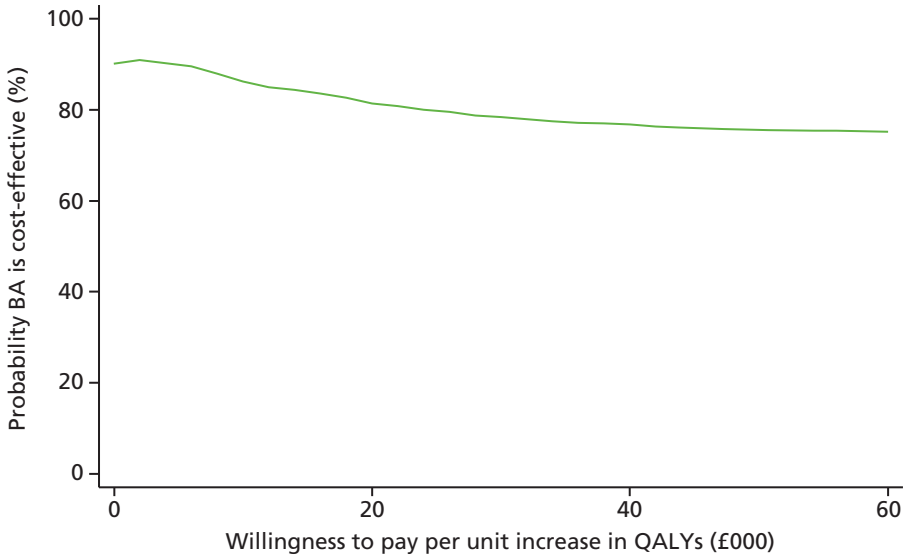

FIGURE 8 Cost-effectiveness acceptability curve showing the probability that BA is cost-effective compared with CBT for different values of willingness to pay per QALY.

TABLE 15 Results of the sensitivity analyses of economic data

Analysis type	Trial arm				Mean difference[a] (BA – CBT)	95% CI[a]	*p*-value[a]
	BA		CBT				
	n	Mean (SD)	*n*	Mean (SD)			
Impact on total costs (£)							
Main analysis	159	2596.62 (1846.72)	168	3250.74 (3040.99)	–343.24	–857.62 to 171.13	0.190
Inclusion of complementary therapies	158	2729.54 (2604.00)	168	3367.90 (3530.36)	–535.60	–1045.28 to –25.92	0.039
Inclusion of productivity losses	152	3305.91 (3410.20)	166	4937.92 (6367.92)	–1726.37	–2870.80 to –581.93	0.003
Intervention perspective	159	992.73 (60.54)	168	1255.03 (88.16)	–262.30	–381.40 to –143.19	< 0.0001
Mental health-care perspective	159	914.71 (67.86)	168	1253.85 (99.97)	–339.14	–472.64 to –205.64	< 0.0001
Imputation of missing data	221	1841.67 (287.97)	219	2282.40 (423.94)	–440.73	–1007.70 to 126.26	0.127
Impact on QALYs							
Main analysis	152	0.984 (0.422)	157	0.935 (0.433)	0.050	–0.145 to 0.046	0.308
Imputation of missing data	221	1.224 (0.043)	219	1.198 (0.061)	0.026	–0.058 to 0.109	0.546

a Adjusted for site, ADM use, symptom severity and baseline covariates.

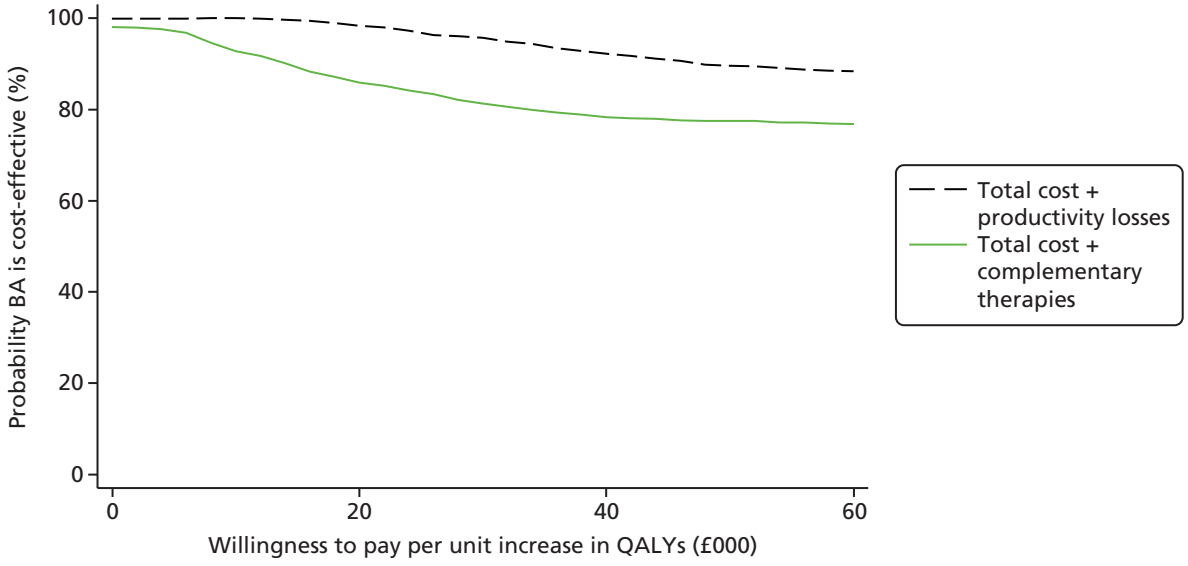

FIGURE 9 Cost-effectiveness acceptability curve showing the probability that BA is cost-effective compared with CBT for different values of willingness to pay for a QALY, including costs of complementary therapies and productivity losses.

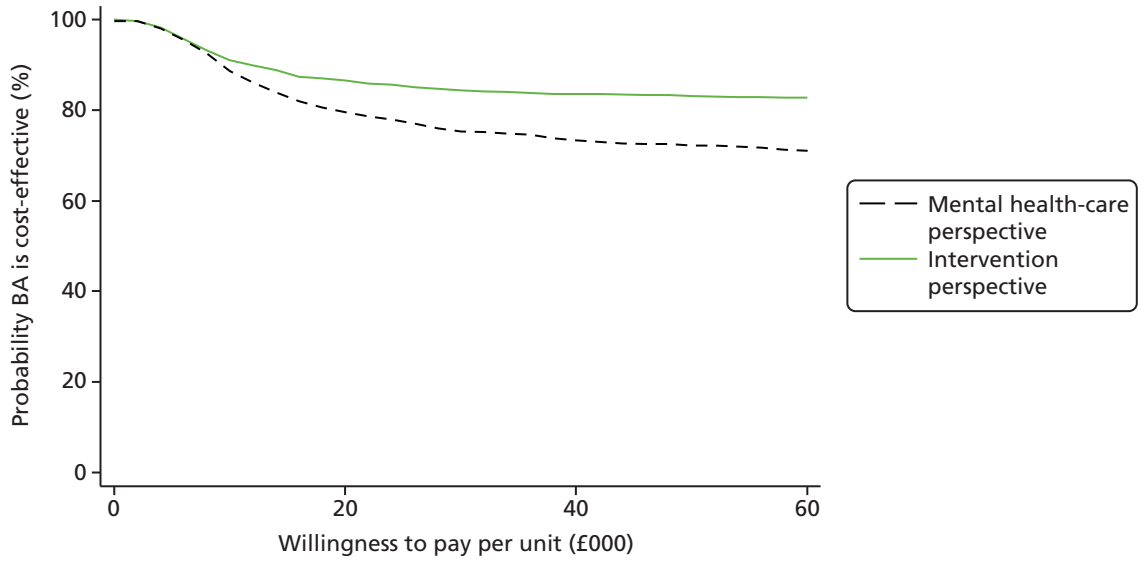

FIGURE 10 Cost-effectiveness acceptability curve showing the probability that BA is cost-effective compared with CBT for different values of willingness to pay for a QALY, from intervention and mental health-care perspectives.

Imputation of missing data increased the difference in total cost (£440.00 vs. £343.00 in the main analysis), but reduced the difference in QALYs (0.026 vs. 0.050 in the main analysis), increasing the ICER from –£6865.00 to –£16,951.00. *Figure 11* shows the CEAC for the missing data analysis, which again supports the likelihood that BA is cost-effective compared with CBT.

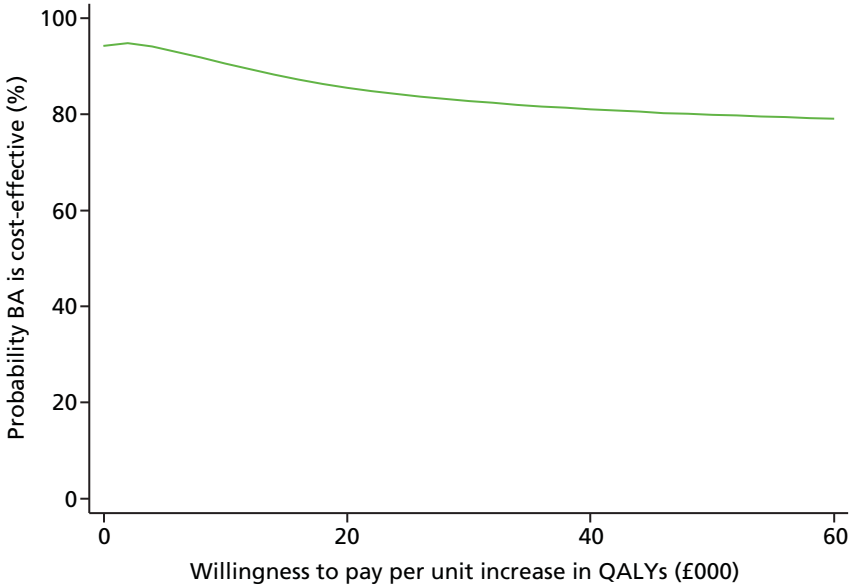

FIGURE 11 Cost-effectiveness acceptability curve showing the probability that BA is cost-effective compared with CBT for different values of willingness to pay for a QALY, including imputed missing data.

Chapter 4 Methods and results of the process evaluation

Introduction

Alongside the main clinical and economic evaluation, we undertook a process evaluation to investigate the implementation of the intervention, moderators of outcome and possible mechanisms of effect. This chapter consists of a description of our quantitative and qualitative methods, analyses and results.

Objectives

- To investigate factors that may moderate the effect of treatment allocation on outcome (PHQ-9 score), and mechanistic and procedural factors that may mediate the effect of treatment on outcome.
- To obtain a more in-depth understanding of the ongoing mechanisms and impact of treatment from participants and therapists including participants' views of the role of cognitive and behavioural change strategies and the broader impacts of treatment on participants' lives.

Quantitative process study

Moderators: identifying patient subgroups who may receive differential treatment effects

Having established no statistically significant difference in treatment effect between CBT and BA at any of the three follow-up points (6, 12 and 18 months), for the PHQ-9 score, a further issue of clinical interest is whether or not there are any specific subgroups of patients who would receive differential treatment effects (e.g. increased benefit from one treatment compared with the alternative treatment). In the event of identifying any such subgroups (defined by covariates that are known as moderators), these patients could be offered the treatment that would confer the strongest benefit, taking into account their own characteristics. To investigate this possibility, we extended the models used for the main analyses, by adding an interaction term between treatment allocation and the potential moderator of treatment effect.

The potential moderators of treatment effect that we investigated include indicators of depression severity: baseline PHQ-9 score, number of previous episodes of depression and age at onset of depression. We also included other psychological variables measured at baseline: total BADS score, DAS score and total RRS score. With regard to investigating whether or not patient preference for a certain treatment acted as a moderator, we used information elicited on whether or not the patient had a treatment preference, and if so whether the patient preferred CBT or BA, to derive three categories: (1) no treatment preference; (2) received preferred treatment; and (3) received non-preferred treatment.

Mediators: investigating potential mechanisms of therapy action

The traditional approach to causal mediation has followed the initial work of Baron and Kenny.[100] This approach is based on the existence of a significant effect of the independent variable on the mediator, and on the dependent variable, and also a significant effect of the mediator on the dependent variable, when the independent variable has been controlled for. However, this approach has received criticism, for example with regard to the possibility of potential confounders between the mediator and the dependent variable.[101] In addition, it has been argued that a significant association between the independent variable and the dependent variable is not required to demonstrate mediation.[102,103]

In a more complex situation, including more than one mediator in the structural model, such mediators could be conceptualised as exerting their effect between the independent and dependent variables either in sequence or in parallel to one another. In these analyses, all models that include multiple mediators are structured so that the mediators are acting in parallel. More recent methods for causal mediation analysis, for example using instrumental variables or potential outcomes (counterfactuals), have been developed,[101] but are not considered further, because of the difficulty in identifying a suitable instrumental variable.

We used four process measures (PMs) as potential mediators:

1. BADS
2. DAS
3. RRS
4. SHAPS.

The BADS comprises four subscales (activation, avoidance, work impairment and social impairment) that sum to give a total score. The RRS includes a subset of five items that consitute a reflection subscale. The SHAPS revised score (Franken) was used for all analyses, owing to increased granularity compared with the standard score, with each of the 14 items scored from 0 to 3, resulting in an overall score from 0 to 42. Each measure was calibrated such that a higher score indicated a more clinically negative outcome so that each measure was aligned with the directionality of the PHQ-9 primary outcome measure. Each mediation analysis included the baseline score for the relevant mediator(s) in the model.

We used three mediators based on participants' experience of their treatment:

1. proportion of sessions attended (out of a maximum of 24)
2. basic treatment fidelity
3. overall treatment fidelity.

Basic treatment fidelity was based on the proportion of core topics for the relevant therapy that were covered during all attended sessions. There were six core topics for BA and seven for CBT; hence, the number of topics was linearly rescaled on a score of 0–100. Inevitably, patients who received BA had a propensity for an increased proportion of core topics covered, owing to the smaller number of potential topics. The overall treatment fidelity was derived by linearly rescaling the proportion of mandatory topics covered during all attended sessions (two for BA and four for CBT) on a scale of 0–100, then combining with the score from 0 to 100 for basic quality therapy and dividing by 2 to produce a score from 0 to 100. For the mediation analyses, the scores for proportion of sessions attended and the treatment fidelity variables were reversed so that a low score indicated a more negative outcome. These measures were used as potential mediators for the 12- and 18-month PHQ-9 follow-up only, as 210 participants had not completed their final session at 6 months' follow-up. Analyses to evaluate the potential mediators of the treatment effect were performed for PHQ-9 measured at 6, 12 and 18 months; the potential mediators for each PHQ-9 time point are set out in *Table 16*.

TABLE 16 Variables investigated as potential mediators of the effect of treatment on PHQ-9 at the 6-, 12- and 18-month follow-ups

Outcome variable	Mediator variable	Time of measurement of mediator variable
PHQ-9: 6-month follow-up	BADS total score	PM1, PM2
	BADS activation	PM1, PM2
	BADS avoidance	PM1, PM2
	BADS work impairment	PM1, PM2
	BADS social impairment	PM1, PM2
	DAS	PM1, PM2
	RRS total score	PM1, PM2
	RRS rumination score	PM1, PM2
PHQ-9: 12-month follow-up	BADS total score	PM1, PM2, 6 months
	BADS activation	PM1, PM2, 6 months
	BADS avoidance	PM1, PM2, 6 months
	BADS work impairment	PM1, PM2, 6 months
	BADS social impairment	PM1, PM2, 6 months
	DAS	PM1, PM2, 6 months
	RRS total score	PM1, PM2, 6 months
	RRS rumination score	PM1, PM2, 6 months
	SHAPS	6 months
	Number of sessions	N/A
	Basic treatment fidelity	N/A
	Overall treatment fidelity	N/A
PHQ-9: 18-month follow-up	BADS total score	6 months
	BADS activation	6 months
	BADS avoidance	6 months
	BADS work impairment	6 months
	BADS social impairment	6 months
	DAS	6 months
	RRS total score	6 months
	RRS rumination score	6 months
	SHAPS	6 months, 12 months
	Number of sessions	N/A
	Basic treatment fidelity	N/A
	Overall treatment fidelity	N/A

N/A, not appropriate; PM1, process measure point 1 at treatment session 4; PM2, process measure point 2 at treatment session 7.

Having established that there is no evidence for a differential treatment effect between BA and CBT at any of the follow-up time points, but that both treatments are equally effective, the purpose of the mediation analyses is to investigate whether or not there are any differences in treatment mechanism between the two therapies.

Methods

Moderation analyses

Potential interaction effects between treatment allocation and baseline PHQ-9 score, age at onset of depression, number of past episodes of depression, baseline scores for BADS, DAS and RRS totals, and treatment were investigated. Participants who reported their age at onset of depression as < 10 years of age had their age at onset raised to 10 years, to bring them into alignment with the overall distribution of age at onset. Participants who reported having experienced > 50 episodes of depression had their number of episodes reduced to 50. The reported data on treatment preference were recombined into a categorical variable with three levels, using 'no treatment preference' as the default category, with two comparator categories: 'had a preference and did receive preferred treatment', and 'had a preference and did not receive preferred treatment'. For those participants who indicated a preferred treatment, no distinction was made in the analyses between a preference for CBT and a preference for BA.

Interactions between treatment allocation and each covariate were investigated at 6, 12 and 18 months' follow-up for PHQ-9. Separate analyses for the ITT and PP populations were performed. For the analyses of PHQ-9 data at 6 months' follow-up, the PP population was considered to be participants who had completed eight or more therapy sessions before the date of the 6-month follow-up. Only participants with observed data for all covariates included in each model were included within each analysis. A series of models were performed, each model adjusting for the stratification variables, trial site, baseline ADM use and baseline PHQ-9 score. Each model included the specific covariate being investigated as a potential moderator and its interaction with treatment allocation.

Mediation analyses

Mediation population

Mediation analyses were performed on a subgroup of participants that excluded seven participants whose process measure point 1 (PM1) and/or process measure point 2 (PM2) data were collected after 6 months' follow-up. Otherwise, all analyses were conducted using the ITT population, and included only participants with observed data.

Analysis methods

Unadjusted mean scores were reported for both treatment groups for PHQ-9 at all follow-up times, and for the mediator variables at all recorded follow-up times, for the mediation population. We also produced line plots to show the trajectories of individual participants by treatment group for PHQ-9 and each of the PM variables, and investigated whether or not there was any between-group difference over time for the PMs using a repeated measures model with adjustment for site, baseline PHQ-9 score and baseline ADM use. We also investigated whether or not there was any difference between groups with regard to proportion of sessions attended, basic treatment fidelity and overall treatment fidelity. Post hoc regression models were performed to investigate the effects of basic fidelity and overall fidelity on PHQ-9 score at 12 and 18 months' follow-up, with adjustment for treatment group, baseline PHQ-9 score, site and baseline ADM use. The interactions between fidelity and treatment group were also investigated.

For the mediation analyses we used a structural equation modelling (SEM; command sem in Stata v.14) approach to evaluate the effect of each individual mediator at each follow-up time, on the primary outcome, PHQ-9 score. We also included all mediators measured at a specific follow-up time in an overall model for each follow-up time for PHQ-9 measurement. All analyses adjusted for the stratification variables, baseline PHQ-9 (measured as a continuous variable rather than dichotomised as for the stratification process), trial

TABLE 17 Interactions between treatment allocation and baseline covariates

Interaction term[a]	PHQ-9: time point											
	6-month follow-up				12-month follow-up				18-month follow-up			
	ITT population		PP population		ITT population		PP population		ITT population		PP population	
	Mean difference (95% CI), *n*	Global *p*-value	Mean difference (95% CI), *n*	Global *p*-value	Mean difference (95% CI), *n*	Global *p*-value	Mean difference (95% CI), *n*	Global *p*-value	Mean difference (95% CI), *n*	Global *p*-value	Mean difference (95% CI), *n*	Global *p*-value
CBT/baseline PHQ-9 score	0.22 (–0.06 to 0.51), 380	0.128	0.21 (–0.11 to 0.53), 284	0.206	0.18 (–0.11 to 0.48), 364	0.226	0.28 (–0.05 to 0.61), 286	0.092	0.17 (–0.13 to 0.46), 356	0.274	0.29 (–0.03 to 0.62), 284	0.080
CBT/baseline BADS total score	0.01 (–0.07 to 0.08), 350	0.880	0.00 (–0.08 to 0.08), 263	0.983	0.01 (–0.08 to 0.06), 338	0.766	–0.01 (–0.09 to 0.07), 265	0.858	0.00 (–0.07 to 0.07), 331	0.990	0.00 (–0.08 to 0.08), 263	0.978
CBT/baseline DAS score	–0.02 (–0.05 to 0.02), 375	0.313	–0.01 (–0.05 to 0.03), 282	0.704	0.01 (–0.02 to 0.05), 361	0.508	0.02 (–0.02 to 0.07), 284	0.249	–0.02 (–0.06 to 0.01), 354	0.193	–0.02 (–0.06 to 0.02), 283	0.423
CBT/baseline RRS total score	0.07 (–0.06 to 0.21), 379	0.278	0.01 (–0.14 to 0.16), 284	0.907	0.08 (–0.06 to 0.22), 364	0.249	0.13 (–0.02 to 0.29), 286	0.097	0.08 (–0.06 to 0.22), 356	0.247	0.09 (–0.07 to 0.25), 284	0.268
CBT/age at onset of depression	–0.01 (–0.11 to 0.08), 371	0.774	0.01 (–0.09 to 0.11), 278	0.909	–0.03 (–0.13 to 0.07), 357	0.572	–0.07 (–0.18 to 0.04), 281	0.194	–0.02 (–0.12 to 0.07), 349	0.625	–0.05 (–0.15 to 0.06), 279	0.373
CBT/number of past episodes of depression	0.13 (–0.04 to 0.30), 333	0.141	0.09 (–0.11 to 0.29), 245	0.367	–0.02 (–0.21 to 0.17), 319	0.827	–0.09 (–0.31 to 0.14), 248	0.447	–0.05 (–0.22 to 0.13), 312	0.605	–0.07 (–0.27 to 0.13), 246	0.489
Treatment preference[b]	0.54 (–3.35 to 4.43), 378; 0.09 (–3.28 to 3.46)	0.963	1.70 (–2.35 to 5.74), 283; –0.57 (–4.28 to 3.13)	0.623	0.42 (–3.59 to 4.43), 363; 0.23 (–3.27 to 3.72)	0.976	1.35 (–2.93 to 5.63), 285; –1.28 (–5.16 to 2.60)	0.589	0.39 (–3.57 to 4.36), 353; 0.14 (–3.43 to 3.70)	0.981	0.62 (–3.71 to 4.95), 283; –1.26 (–5.21 to 2.69)	0.747

a All models include one interaction term between treatment group and the specified potential moderator, and adjustment for baseline PHQ-9 score, ADM use at baseline and trial site.
b Reference category for treatment preference: no preference. Interaction effects: CBT/received preferred treatment; CBT/did not receive preferred treatment.

site and whether or not the participant was using ADM at baseline. We also adjusted for age at onset of depression, as this was found to be a predictor ($p < 0.05$) of PHQ-9 score at all follow-up times. It was noted that none of the three potential mediator variables (BADS total, RRS, DAS) examined at baseline as potential predictors or moderators of PHQ-9 at any of the three follow-up times was significant. For the mechanistic mediators (BADS, DAS, RRS and SHAPS), we adjusted all analyses for the baseline score, but not for any other previous scores (if available). This approach takes account of both the participant's initial state and his/her change in state from baseline to follow-up. We report the total effect and indirect effect for each mediator, with 95% bias-corrected CIs[104] derived from bootstrapping with 5000 replications. All analyses were performed using Stata v.14.

Results

Moderation analyses

The results of the analyses investigating interactions between treatment effects and selected covariates are shown in *Table 17*. Across all three follow-up times, and in both the ITT and PP populations, there were no statistically significant interactions between treatment group and the specified covariates. However, in the PP population, at both 12 and 18 months' follow-up, there was weak evidence ($p < 0.1$) for an interaction between treatment group and baseline PHQ-9 score. This interaction was in the direction of participants with higher PHQ-9 scores at baseline, and receiving BA, having lower PHQ-9 scores at follow-up than with participants who received CBT. This treatment moderation effect of baseline PHQ-9 score is shown graphically in *Figure 12* for the 12-month follow-up. Weak evidence was found for a moderating effect of baseline total RRS score on the treatment effect for PHQ-9 at 12 months' follow-up, also in the PP population. However, this effect was not observed at any other follow-up time points.

Mediation analyses

Table 18 shows the unadjusted scores for PHQ-9 and all mediator variables at all time points at which the variable was recorded. *Figures 13–17* show the treatment group mean scores and *Figures 18–22* (see *Appendix 2*) show the individual participant scores, for all time points at which each variable was

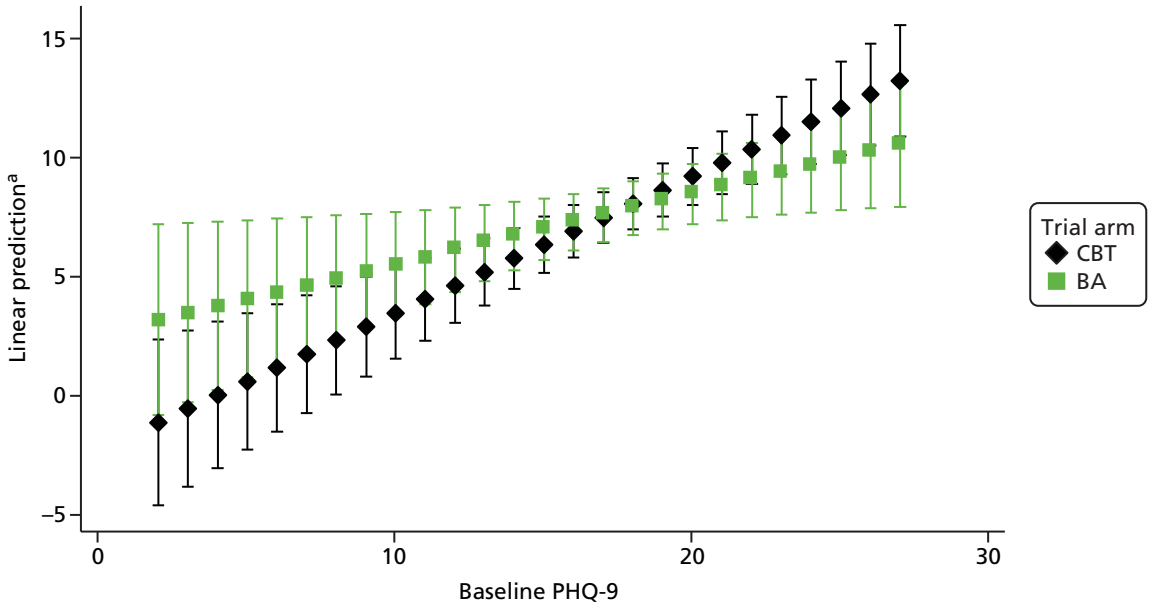

FIGURE 12 Margins plot of interaction, with 95% CIs, between the effect of treatment group and baseline PHQ-9 on PHQ-9 at 12 months' follow-up using the PP observed data sample only (with adjustment for site and baseline antidepressant use). a, Linear predictor of PHQ-9 at 12 months' follow-up.

TABLE 18 Unadjusted scores for PHQ-9 and mediator variables for mediation population

	Baseline		PM1		PM2		6-month follow-up		12-month follow-up		18-month follow-up	
Outcome variable	CBT	BA	CBT	BA	CBT	BA	CBT	BA	CBT	BA	CBT	BA
PHQ-9: mean (SD), *n*	17.39 (4.85), 214	17.69 (4.80), 219	DNC	DNC	DNC	DNC	9.41 (7.04), 190	9.72 (6.88), 183	8.20 (7.32), 184	8.34 (6.97), 173	8.39 (7.12), 176	8.32 (7.13), 174
BADS total: mean (SD), *n*	88.30 (19.98), 195	87.65 (21.32), 206	76.35 (24.46), 92	75.69 (27.10), 91	63.74 (27.76), 78	67.15 (27.56), 67	55.88 (29.65), 146	56.74 (30.18), 144	DNC	DNC	DNC	DNC
BADS activation: mean (SD), *n*	29.57 (7.21), 206	29.90 (7.67), 214	26.73 (7.86), 104	26.35 (7.97), 100	22.82 (8.28), 85	22.78 (9.48), 78	21.34 (9.24), 155	22.09 (9.90), 151	DNC	DNC	DNC	DNC
BADS avoidance: mean (SD), *n*	26.77 (9.47), 209	25.86 (9.31), 215	23.85 (10.54), 105	23.35 (10.03), 106	19.66 (10.14), 85	20.19 (9.39), 79	15.96 (11.25), 155	17.37 (10.72), 159	DNC	DNC	DNC	DNC
BADS work impairment: mean (SD), *n*	15.78 (6.24), 212	16.09 (6.43), 219	14.23 (6.38), 105	14.15 (6.97), 105	11.56 (7.20), 85	11.30 (6.07), 81	10.09 (7.08), 157	9.98 (6.99), 160	DNC	DNC	DNC	DNC
BADS social impairment: mean (SD), *n*	15.81 (7.23), 205	16.13 (7.77), 211	11.91 (7.53), 101	13.45 (8.39), 101	10.25 (8.14), 84	11.28 (8.27), 74	8.63 (8.02), 156	8.75 (8.06), 154	DNC	DNC	DNC	DNC
DAS: mean (SD), *n*	154.23 (38.35), 211	152.02 (38.67), 217	158.36 (40.04), 109	158.72 (40.65), 107	150.71 (41.98), 88	152.70 (41.38), 84	134.66 (41.95), 159	135.97 (42.15), 160	DNC	DNC	DNC	DNC
RRS total: mean (SD), *n*	60.28 (10.05), 213	59.61 (11.18), 219	58.29 (11.59), 109	58.18 (12.42), 111	52.22 (12.28), 88	53.45 (13.53), 85	48.27 (14.48), 159	49.95 (14.24), 160	DNC	DNC	DNC	DNC
RRS reflection: mean (SD), *n*	12.30 (3.12), 213	12.05 (3.41), 219	12.06 (2.99), 109	11.86 (3.35), 111	11.03 (3.00), 88	11.04 (3.59), 85	10.38 (3.44), 159	10.58 (3.37), 160	DNC	DNC	DNC	DNC
SHAPS: mean (SD), *n*	21.11 (2.37), 212	20.87 (2.43), 217	DNC	DNC	DNC	DNC	21.35 (3.16), 161	21.39 (3.02), 161	21.08 (2.31), 163	20.59 (2.75), 147	DNR	DNR
Proportion (%) of sessions attended:[a] mean (SD), *n*									52 (33), 214	48 (33), 219		
Basic treatment fidelity (scale 0–100):[a] mean (SD), *n*									73 (31), 213	86 (28), 218		
Overall treatment fidelity:[a] mean (SD), *n*									68 (31), 213	73 (33), 218		

DNC, data not collected; DNR, data not reported.
a Treatment fidelity outcomes measured across the full follow-up period, reported under 12 months' follow-up for convenience.

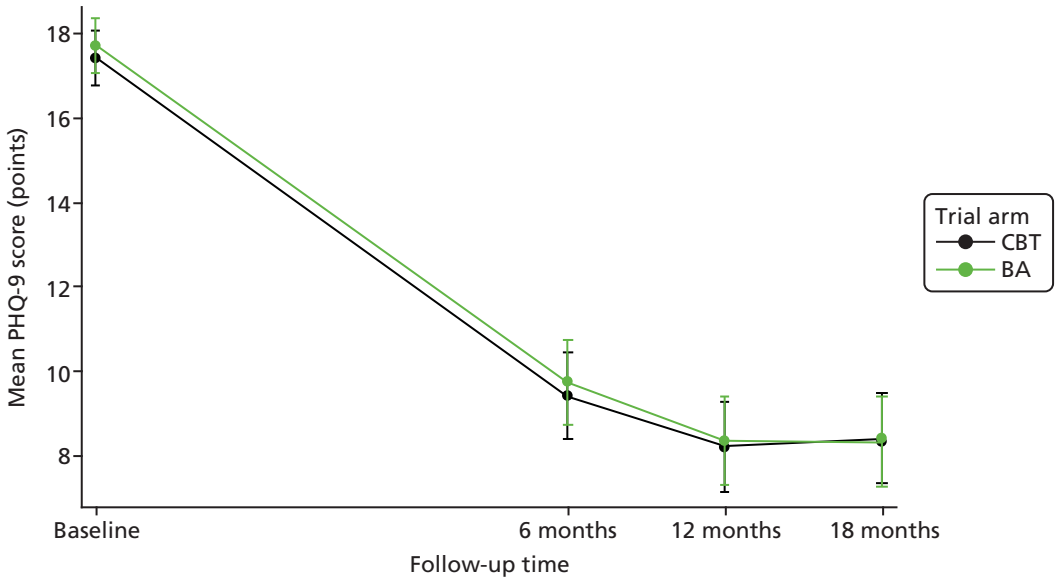

FIGURE 13 Mean PHQ-9 scores with 95% CI at baseline and at 6, 12 and 18 months' follow-up, by treatment group for the mediation population.

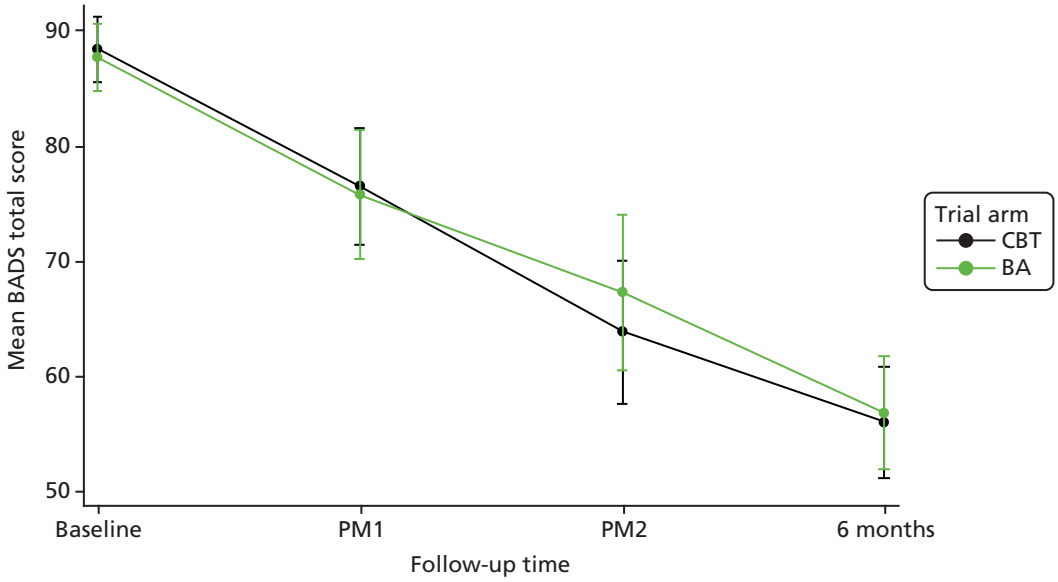

FIGURE 14 Mean BADS total score with 95% CI at baseline, PM1 (session 4), PM2 (session 7) and at 6 months' follow-up, by treatment group for the mediation population.

recorded. For PHQ-9, the greatest reduction in mean scores occurred between baseline and 6 months' follow-up, with a smaller reduction between 6 and 12 months' follow-up. Mean scores were stable between the 12- and 18-month follow-ups. On looking at the individual participant trajectories for PHQ-9 between the follow-up times, there was wide variation among participants with regard to their personal PHQ-9 trajectory. Some participants had an evident reduction in PHQ-9 score between baseline and 6 months' follow-up, which may be sustained in some cases but increased after the 6-month follow-up in others. A similar wide variation in individual participant trajectories was observed across all process mediator variables. No significant between-group difference across time points was found for any of the process mediators (*p*-values for interaction between group and time point were > 0.1 for all process mediators across all available time points). There was no significant difference between the treatment groups (CBT vs. BA) for percentage of sessions attended (mean difference 4.4 sessions attended, 95% CI –1.7 to 10.5 sessions

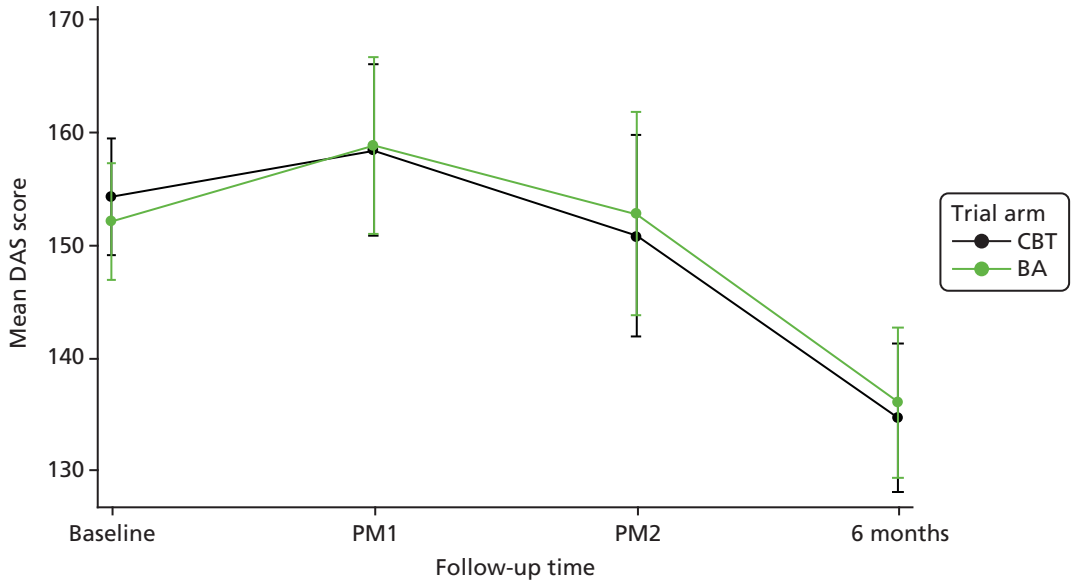

FIGURE 15 Dysfunctional Attitudes Scale total score at baseline, PM1 (session 4), PM2 (session 7) and at 6 months' follow-up, by treatment group for the mediation population.

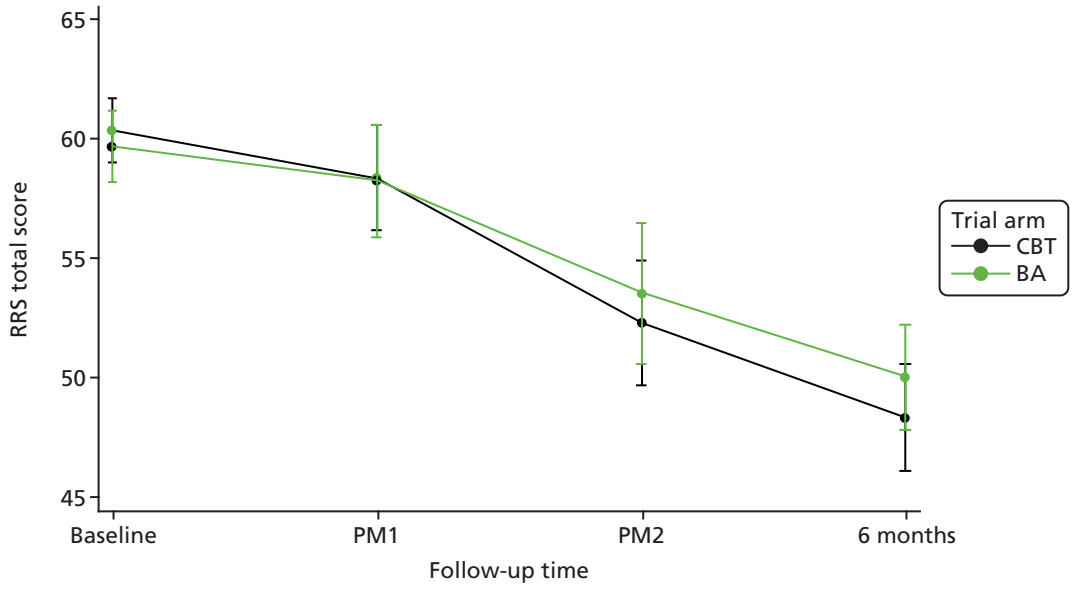

FIGURE 16 Ruminative Response Scale total score at baseline, PM1 (session 4), PM2 (session 7) and at 6 months' follow-up, by treatment group for the mediation population.

attended). For basic fidelity (on a scale of 0 to 100), there was evidence that the fidelity for CBT was lower than for BA (mean difference –12.1, 95% CI –17.6 to –6.7), although this may be artefactual because of the different numbers of topics for the two therapies. Among participants receiving BA, 158 out of 220 (71%) completed all six of the core topics, compared with only 70 out of 218 (32%) participants who received CBT completing all seven of the core topics, and only 132 out of 218 (61%) completed at least six out of seven core topics. For overall fidelity, there was no significant difference between the groups (mean difference –4.9, 95% CI –11.0 to 1.1), although again this may be arbitrary as a result of the weighting system used to weight core and mandatory topics.

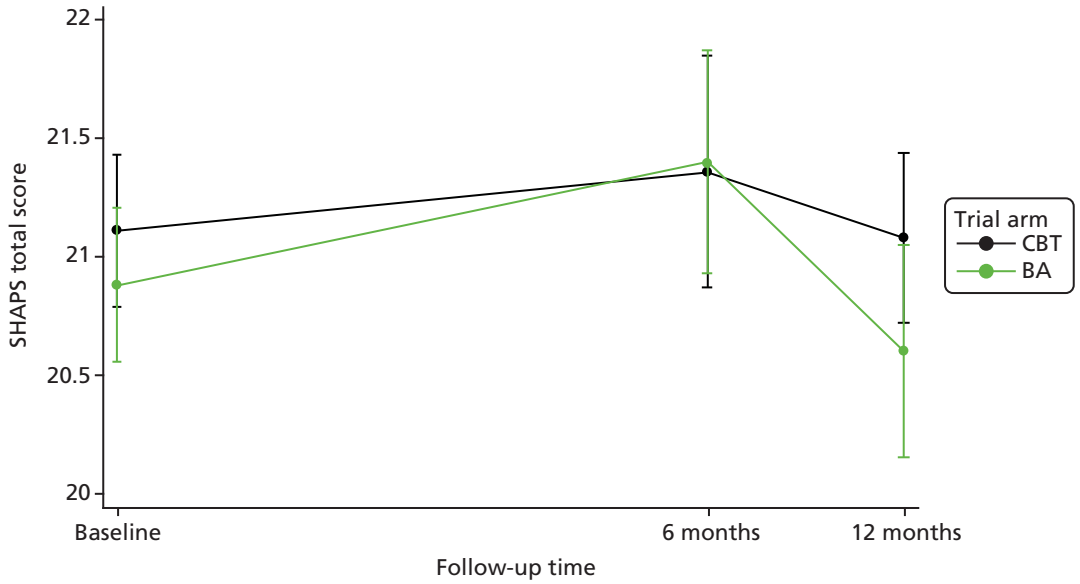

FIGURE 17 Snaith–Hamilton Pleasure Scale total score at baseline, and at 6 and 12 months' follow-up, by treatment group for the mediation population.

Using the SEM approach, at the 6-month PHQ-9 follow-up, when considered individually, each mediator measured at PM1 mediated only a small proportion of the total effect of treatment (*Table 19*). None of the mediators in the single mediator models or in the multiple mediator models was found to have a statistically significant indirect effect of treatment allocation acting via that mediator.

At the 12-month PHQ-9 follow-up, with mediators measured at PM1, again the BADS variables appeared to be the strongest individual mediators, with social impairment mediating 21% of the total effect of treatment, and the total BADS score mediating –18% (*Table 20*).

For the overall treatment fidelity, the indirect effect of treatment group acting via this mediator was statistically significant (–0.18, 95% CI –0.54 to –0.01), mediating –117% of the total treatment effect (see *Table 20*). In the multiple mediator model, however, none of the mediators was found to have a significant indirect effect. BADS avoidance, BADS social impairment, total RRS score, SHAPS, basic treatment fidelity and overall treatment fidelity were found to mediate at least 10% in magnitude of the total treatment effect.

At 18 months' follow-up, the indirect effect of treatment via basic treatment fidelity in the individual mediator model was statistically significant (observed effect 0.61, 95% CI 0.23 to 1.17) and associated with a proportion of total effect mediated of 610% (*Table 21*). In the multiple mediators model, with mediator variables measured at 6 months' follow-up, this effect was not statistically significant, but was associated with a proportion of total effect mediated of 77%. Similarly, the indirect effect via overall treatment quality was statistically significant (observed effect 0.24, 95% CI 0.03 to 0.65) in the individual mediator model, but this significant effect was not seen in the multiple mediators model.

Across the three PHQ-9 time points, the effects of the mediators varied considerably, with the proportions of total effect mediated increasing at later time points, possibly as a result of the mediator variables having a chance to stabilise at later measurement times, and also the PHQ-9 scores becoming more stable on progressing through the follow-up period. The only mediator that was statistically significantly different between the groups was basic treatment fidelity, which was a significant mediator of treatment allocation at 18 months' follow-up. Using individual regression models, both basic and overall treatment fidelity were associated with the 12-month PHQ-9 score, with poorer fidelity being associated with higher PHQ-9 scores (*p*-values 0.020 and 0.023, respectively). Similarly, both basic and overall treatment fidelity were significantly associated with the 18-month PHQ-9 follow-up, again with poorer fidelity being associated

TABLE 19 Results of the SEM analyses for mediation of treatment effect on PHQ-9 at 6 months' follow-up

	Model				
	Single mediator			Including all mediators	
Mediator	Indirect effect of treatment allocation acting through mediator (95% CI), *n*	Total effect of treatment allocation (95% CI)	Proportion of total effect mediated by indirect effect (%)	Indirect effect of treatment allocation acting through mediator (95% CI)	Proportion of total effect mediated by indirect effect (%)[a]
Mediators measured at PM1 (therapy session 4)					
				Total effect of treatment allocation –1.84 (95% CI –3.79 to 0.04), *n* = 158	
BADS total	0.18 (–0.34 to 0.91), 163	–1.52 (–3.43 to 0.34)	–12	Not included	Not included
BADS activation	0.12 (–0.51 to 0.75), 186	–1.52 (–3.45 to 0.32)	–8	0.13 (–0.11 to 0.81)	0.13 (–0.11 to 0.81)
BADS avoidance	0.11 (–0.17 to 0.71), 195	–1.34 (–3.14 to 0.51)	–8	–0.01 (–0.38 to 0.18)	–0.01 (–0.38 to 0.18)
BADS work impairment	0.10 (–0.45 to 0.69), 198	–1.45 (–3.24 to 0.42)	–7	0.05 (–0.10 to 0.65)	0.05 (–0.10 to 0.65)
BADS social impairment	–0.06 (–0.50 to 0.32), 184	–1.54 (–3.43 to 0.18)	4	0.04 (–0.12 to 0.52)	0.04 (–0.12 to 0.52)
DAS	0.13 (–0.26 to 0.71), 202	–1.73 (–3.46 to 0.16)	–8	0.18 (–0.12 to 0.84)	0.18 (–0.12 to 0.84)
RRS total	0.13 (–0.31 to 0.63), 206	–1.64 (–3.40 to 0.18)	–8	0.06 (–0.14 to 0.64)	0.06 (–0.14 to 0.64)
RRS reflection	0.04 (–0.09 to 0.39), 206	–1.60 (–3.36 to 0.21)	–2	Not included	Not included
Mediators measured at PM2 (therapy session 7)					
				Total effect of treatment allocation –2.63 (95% CI –4.87 to –0.32), *n* = 126	
BADS total	–0.23 (–1.45 to 0.89), 129	–2.52 (–4.94 to –0.35)	9	Not included	Not included
BADS activation	0.21 (–0.57 to 1.15), 153	–1.68 (–3.67 to 0.37)	–13	–0.01 (–0.47 to 0.19)	1
BADS avoidance	–0.05 (–0.84 to 0.72), 154	–2.26 (–4.42 to –0.12)	2	–0.01 (–0.48 to 0.30)	0
BADS work impairment	0.34 (–0.64 to 1.38), 160	–2.01 (–4.05 to –0.01)	–17	0.04 (–0.35 to 0.80)	–1
BADS social impairment	–0.29 (–1.29 to 0.56), 147	–2.33 (–4.46 to –0.23)	13	–0.19 (–1.19 to 0.19)	7
DAS	0.23 (–0.54 to 0.93), 166	–1.95 (–3.95 to 0.20)	–12	0.10 (–0.16 to 0.84)	–4
RRS total	–0.02 (–0.77 to 0.68), 167	–2.00 (–4.07 to –0.02)	1	–0.04 (–0.59 to 0.24)	2
RRS reflection	0.11 (–0.42 to 0.71), 167	–2.04 (–4.06 to –0.02)	–5	Not included	Not included

a Proportions of total effect mediated are not required to sum to 100%.

TABLE 20 Results of the SEM analyses for mediation of treatment effect on PHQ-9 at 12 months' follow-up

Mediator	Model				
	Single mediator			Including all mediators	
	Indirect effect of treatment allocation acting through mediator (95% CI), *n*	Total effect of treatment allocation (95% CI)	Proportion of total effect mediated by indirect effect (%)	Indirect effect of treatment allocation acting through mediator (95% CI)	Proportion of total effect mediated by indirect effect (%)[a]
Mediators measured at PM1					
				Total effect of treatment allocation –0.58 (95% CI –2.61 to 1.59), *n* = 154	
BADS total	0.09 (–0.78 to 0.81), 158	–0.49 (–2.55 to 1.41)	–18	Not included	Not included
BADS activation	0.01 (–0.69 to 0.61), 181	–0.79 (–2.74 to 1.09)	–1	0.08 (–0.27 to 0.69)	–14
BADS avoidance	0.02 (–0.47 to 0.49), 189	–0.82 (–2.76 to 1.14)	–3	0.01 (–0.20 to 0.45)	–3
BADS work impairment	0.03 (–0.69 to 0.61), 192	–0.56 (–2.51 to 1.35)	–5	0.08 (–0.26 to 0.79)	–15
BADS social impairment	–0.16 (–0.80 to 0.23), 179	–0.78 (–2.71 to 1.18)	21	0.00 (–0.24 to 0.24)	0
DAS	0.08 (–0.15 to 0.61), 198	–0.93 (–2.84 to 0.92)	–9	–0.18 (–0.90 to 0.13)	32
RRS total	0.09 (–0.41 to 0.66), 201	–0.98 (–2.88 to 0.83)	–9	0.10 (–0.09 to 0.73)	–17
RRS reflection	0.08 (–0.17 to 0.54), 201	–0.95 (–2.84 to 0.87)	–9	Not included	Not included
Mediators measured at PM2					
				Total effect of treatment allocation –0.84 (95% CI –3.23 to 1.58), *n* = 125	
BADS total	–0.29 (–1.40 to 0.64), 128	–0.53 (–2.98 to 1.74)	55	Not included	Not included
BADS activation	–0.09 (–0.73 to 0.84), 150	–0.27 (–2.29 to 1.69)	–33	–0.04 (–0.72 to 0.14)	5
BADS avoidance	–0.10 (–0.74 to 0.48), 150	–0.37 (–2.36 to 1.66)	26	0.00 (–0.38 to 0.52)	–1
BADS work impairment	0.14 (–0.76 to 1.10), 156	–0.47 (–2.58 to 1.67)	–31	–0.03 (–0.91 to 0.78)	4
BADS social impairment	–0.33 (–1.35 to 0.43), 145	–0.58 (–2.78 to 1.52)	57	–0.20 (–1.51 to 0.15)	23
DAS	0.11 (–0.42 to 0.67), 162	–0.57 (–2.58 to 1.49)	–19	–0.04 (–0.73 to 0.21)	5
RRS total	0.01 (–0.67 to 0.71), 163	–0.68 (–2.71 to 1.32)	–2	–0.03 (–0.63 to 0.43)	4
RRS reflection	0.20 (–0.23 to 0.90), 163	–0.72 (–2.73 to 1.28)	–28	Not included	Not included

TABLE 20 Results of the SEM analyses for mediation of treatment effect on PHQ-9 at 12 months' follow-up (*continued*)

Mediator	Model				
	Single mediator			Including all mediators	
	Indirect effect of treatment allocation acting through mediator (95% CI), *n*	Total effect of treatment allocation (95% CI)	Proportion of total effect mediated by indirect effect (%)	Indirect effect of treatment allocation acting through mediator (95% CI)	Proportion of total effect mediated by indirect effect (%)[a]
Mediators measured at 6 months' follow-up					
				Total effect of treatment allocation 0.30 (–1.37 to 1.95), *n* = 250	
BADS total	0.09 (–0.77 to 1.05), 258	0.27 (–1.33 to 1.93)	33	Not included	Not included
BADS activation	–0.05 (–0.82 to 0.68), 281	–0.22 (–1.73 to 1.31)	25	0.00 (–0.29 to 0.35)	2
BADS avoidance	–0.40 (–1.13 to 0.37), 285	–0.06 (–1.52 to 1.42)	720	–0.12 (–0.64 to 0.10)	–39
BADS work impairment	0.24 (–0.46 to 1.04), 294	–0.26 (–1.82 to 1.17)	–94	0.02 (–0.13 to 0.39)	6
BADS social impairment	0.26 (–0.52 to 1.09), 282	–0.06 (–1.58 to 1.53)	–463	0.06 (–0.11 to 0.52)	19
DAS	0.08 (–0.80 to 0.61), 296	–0.26 (–1.72 to 1.26)	33	–0.02 (–0.36 to 0.11)	–5
RRS total	–0.31 (–0.99 to 0.41), 297	–0.30 (–1.82 to 1.16)	105	–0.11 (–0.59 to 0.19)	–38
RRS reflection	–0.14 (–0.68 to 0.40), 297	–0.30 (–1.81 to 1.17)	47	Not included	Not included
SHAPS	0.02 (–0.04 to 0.22), 298	–0.09 (–1.70 to 1.41)	–20	0.05 (–0.03 to 0.33)	17
Treatment fidelity mediators[b]					
Proportion of sessions attended	–0.04 (–0.28 to 0.04), 350	–0.14 (–1.49 to 1.30)	29	0.01 (–0.12 to 0.24)	2
Basic treatment fidelity	0.33 (–0.03 to 0.83), 349	–0.15 (–1.55 to 1.27)	–216	0.07 (–0.79 to 0.76)	23
Overall treatment fidelity	0.18 (0.01 to 0.54), 349	–0.15 (–1.55 to 1.27)	–117	0.05 (–0.43 to 0.72)	17

a Proportions of total effect mediated are not required to sum to 100%.
b Treatment fidelity mediators included in model with mediators measured at 6 months' follow-up.

TABLE 21 Results of the SEM analyses for mediation of treatment effect on PHQ-9 at 18 months' follow-up

Mediator	Model: Single mediator: Indirect effect of treatment allocation acting through mediator (95% CI), *n*	Model: Single mediator: Total effect of treatment allocation (95% CI)	Model: Single mediator: Proportion of total effect mediated by indirect effect (%)	Model: Including all mediators: Indirect effect of treatment allocation acting through mediator (95% CI)	Model: Including all mediators: Proportion of total effect mediated by indirect effect (%)
Mediators measured at 6 months' follow-up					
				Total effect of treatment allocation –0.52 (95% CI –2.16 to 1.13), *n* = 248	
BADS total	0.06 (–0.76 to 0.96), 255	0.64 (–0.91 to 2.27)	9	Not included	Not included
BADS activation	–0.10 (–0.81 to 0.60), 278	0.14 (–1.42 to 1.64)	–75	0.00 (–0.15 to 0.22)	1
BADS avoidance	–0.38 (–1.05 to 0.25), 283	0.19 (–1.32 to 1.69)	–196	0.02 (–0.13 to 0.37)	3
BADS work impairment	0.17 (–0.52 to 0.90), 291	0.03 (–1.47 to 1.49)	653	0.11 (–0.07 to 0.64)	21
BADS social impairment	0.25 (–0.47 to 1.11), 278	0.56 (–0.88 to 2.14)	45	0.12 (–0.29 to 0.71)	23
DAS	–0.02 (–0.63 to 0.64), 294	0.03 (–1.44 to 1.52)	–76	0.00 (–0.23 to 0.21)	0
RRS total	–0.31 (–0.93 to 0.32), 294	0.02 (–1.43 to 1.49)	–1600	–0.06 (–0.47 to 0.08)	–12
RRS reflection	–0.09 (–0.51 to 0.35), 294	0.03 (–1.44 to 1.50)	–357	Not included	Not included
SHAPS	0.00 (–0.11 to 0.08), 293	0.01 (–1.50 to 1.48)	–9	0.00 (–0.11 to 0.13)	0
Treatment fidelity mediators[a]					
Proportion of sessions attended	–0.04 (–0.28 to 0.04), 343	0.12 (–1.29 to 1.53)	–36	0.04 (–0.08 to 0.45)	7
Basic treatment fidelity	0.61 (0.23 to 1.17), 342	0.10 (–1.28 to 1.54)	610	0.40 (–0.37 to 1.19)	77
Overall treatment fidelity	0.24 (0.03 to 0.65), 342	0.10 (–1.28 to 1.54)	237	–0.05 (–0.67 to 0.46)	–9
Mediators measured at 12 months' follow-up					
SHAPS	0.04 (–0.10 to 0.29), 291	0.34 (–1.16 to 1.96)	11	Not included	Not included

a Treatment fidelity mediators included in model with mediators measured at 6 months' follow-up.

with higher PHQ-9 scores (*p*-values 0.001 and 0.020, respectively), the basic fidelity remaining significant when included in a model with overall fidelity (*p*-value 0.007). No evidence was found for a significant interaction between treatment group and basic or overall fidelity, with regard to either 12 or 18 months' PHQ-9 follow-up.

Qualitative process study

Methods

Sample and design

At the baseline assessment all COBRA trial participants were asked whether or not they would be willing to complete an additional interview at a later date to discuss their experiences of therapy. Participants for the qualitative study were selected from those providing consent and were purposively sampled to ensure a selection of participants from each recruitment site, both trial arms, some who had fewer than eight sessions of therapy and some who had eight or more. Of those having eight or more sessions, we purposively sampled some who remained depressed and others who were no longer depressed according to the SCID[45] at 6 months' follow-up. Participants were invited to take part in the qualitative study via letter, followed up by a telephone call from a researcher. Interviews were conducted as soon as possible after therapy had ended and aimed to address the following research questions:

1. What are participants' views on the acceptability of BA and CBT?
2. What are participants' views on the role of cognitive and behavioural change strategies?
3. What are the broader impacts of BA and CBT on participants' lives?

In addition, all 22 therapists and MHWs delivering therapy in the trial were invited by e-mail to take part in an interview over the telephone with the trial manager to talk about their experiences of delivering therapy. Those who did not respond to the invitation were not chased further. Semistructured interviews were completed with six CBT therapists and seven BA MHWs.

Participant interviews were conducted over the telephone by Katie Finning (KF), and Rebecca Woodhouse (RW) and Faye Plummer (FP), who were researchers working on the COBRA trial in Devon (KF) and Leeds (RW and FP). All were given in-house training in qualitative interviewing, followed by assessment and feedback on their first interview from David A Richards (DAR), trial chief investigator experienced in qualitative interviewing. Interviews were completed across sites to ensure researcher blinding was maintained for main trial follow-ups (e.g. the researcher in Devon completed interviews with participants in Leeds). Participants therefore had no prior knowledge or relationship with their qualitative interviewer. A semistructured topic guide was developed by DAR and KF based on the study aims and previous literature. Interview topics included general experiences of treatment, acceptability and barriers to therapy, cognitive and behavioural change, and the impact of treatment. Probe questions were used where necessary to help participants elaborate on their responses. The topic guide was pilot tested on two participants and modified to include a question on important parts of therapy, and probe questions were refined.

Therapist interviews were conducted over the telephone by Shelley Rhodes (SR), the COBRA trial manager based in Devon, who was given in-house training in qualitative interviewing. A semistructured topic guide was developed by DAR and SR based on the study aims and previous literature. Interview topics included general experiences of delivering treatment, specific therapeutic strategies used, impact of treatment for participants, perceived reasons for participants who did not improve, how COBRA trial patients compared with patients seen in usual practice and the therapists' personal experience of taking part in the trial.

Participant and therapist interviews were audio-recorded with participants' prior consent and transcribed verbatim. Transcripts were not returned to participants or therapists for comment but were double-checked for accuracy by a second member of the research team. Participant interviews were conducted separately from the main trial follow-ups to avoid bias and encourage open communication.

Analysis

Participant transcripts were analysed by KF, Lucy Moore (LM) and DAR using a framework approach,[94] with the assistance of QSR International's NVivo 10 software (QSR International, Warrington, UK). Analysis began with familiarisation with the transcripts and the development of an initial thematic framework, combining deductive

themes from the topic guide and inductive themes emerging from the data. KF and LM coded three interviews independently to assess the reliability of coding[95] and meetings were held to discuss and refine emerging themes. Transcripts were examined thematically across the whole data set, as well as in the context of each interview, using constant comparison techniques.[96] Data were indexed and sorted using the identified themes and subthemes, and were summarised in framework matrices[94] with the original transcripts being frequently revisited to clarify contextual meaning. In keeping with the framework approach we interrogated the data, searching for comparisons and contradictions and keeping interpretive notes. Alternative explanations or negative cases were identified, discussed and a consensus reached.[95] In the final stage of analysis, KF and DAR met to discuss the findings in relation to the research aims and previous literature, focusing on drawing conclusions and synthesising the findings into the overarching themes presented here.

Therapist/MHW transcripts were analysed by KF using the framework approach described above. A second researcher independently coded three interview transcripts and provided an initial thematic framework, which was compared and combined with the framework developed by KF. In the final stage of analysis, KF and DAR met to discuss the findings and relate them to the research aims and previous literature, focusing on drawing conclusions and synthesising the findings into the overarching themes presented here.

Results

Results of participant qualitative interviews

Thirty-six interviews were completed between April 2014 and May 2015. Interviews lasted between 15 and 75 minutes and were completed, on average, 4 months after treatment ended (range 1–17 months). Participant demographics are provided in *Table 22* and the distribution of interviews across the purposive sampling frame can be seen in *Table 23*.

Results are presented under three main headings: acceptability of therapy, mechanisms of change and impact of therapy, reflecting our three research questions. Quotes are presented to support analysis and are labelled by participant ID number, therapy received, number of sessions, and for those who received eight or more sessions, depression status at 6-month follow-up (depressed or not depressed). Views were consistent across BA and CBT except where specified.

Acceptability of therapy

Participants' views about the acceptability of therapy could be understood in terms of three subthemes: elements of therapy, the therapist and barriers to therapy.

Elements of therapy

Many participants enjoyed therapy as an opportunity to learn about depression, themselves, and their thoughts and behaviour. A few participants expressed a preference for one-to-one, face-to-face therapy over alternative modes, and for many the length and regularity of treatment was considered beneficial:

> *It's had a lasting effect and I think that may be to do with it being really quite in depth as you're going for an hour week . . . going once a week is helpful, which had been much better than going once every 3 months for 6 years, it's like you're really working on it, like a car.*
>
> *28 – CBT 10 sessions, not depressed*

A small minority felt that therapy did not provide enough opportunity to talk about their feelings or the history behind their depression, but for others not having to focus on the past was considered helpful:

> *I really loved the fact that I didn't have to dwell on past experiences . . . I have seen therapists in the past and that but none of it's ever worked for me 'cos all they want to do is go over the past and I've never wanted to do that.*
>
> *4 – BA 17 sessions, not depressed*

TABLE 22 Demographics of qualitative participants

Participant	Therapy	Number of sessions attended	6-month depression status	Gender	Age group (years)
1	BA	1	N/A[a]	Male	55–64
2	CBT	3	N/A	Female	75+
3	BA	14	Not depressed	Male	35–44
4	BA	17	Not depressed	Female	45–54
5	CBT	24	Depressed	Female	45–54
6	BA	3	N/A	Female	25–34
7	BA	13	Depressed	Female	45–54
8	CBT	22	Depressed	Female	35–44
9	BA	9	Depressed	Male	35–44
10	CBT	20	Depressed	Female	75+
11	CBT	13	Depressed	Female	45–54
12	CBT	23	Not depressed	Female	55–64
13	BA	12	Depressed	Male	55–64
14	CBT	15	Not depressed	Female	18–24
15	CBT	14	Not depressed	Female	55–64
16	BA	13	Not depressed	Male	65–74
17	BA	2	N/A	Male	45–54
18	CBT	24	Depressed	Female	55–64
19	CBT	14	Not depressed	Male	35–44
20	BA	2	N/A	Male	45–54
21	CBT	19	Depressed	Male	55–64
22	BA	12	Not depressed	Female	45–54
23	BA	17	Depressed	Male	45–54
24	BA	8	Not depressed	Female	35–44
25	CBT	21	Not depressed	Female	55–64
26	BA	24	Depressed	Female	35–44
27	CBT	22	Not depressed	Male	35–44
28	CBT	10	Not depressed	Female	55–64
29	BA	24	Not depressed	Male	55–64
30	CBT	3	N/A	Female	35–44
31	BA	4	N/A	Female	35–44
32	BA	5	N/A	Male	18–24
33	CBT	1	N/A	Male	25–34
34	BA	8	Depressed	Female	65–74
35	CBT	10	Depressed	Female	35–44
36	CBT	6	N/A	Female	25–34

N/A, not appropriate.
a N/A: depression status at 6 months' follow-up was only included in the sampling frame for participants who had eight or more sessions of therapy.

TABLE 23 Number of qualitative interviews completed across the purposive sampling frame

	Trial arm, number of sessions attended; depression status at 6 months					
	BA			CBT		
Trial site	≥ 8; depressed	≥ 8; not depressed	< 8; N/A	≥ 8; depressed	≥ 8; not depressed	< 8; N/A
Devon	3	2	2	4	1	1
Durham	1	2	2	2	3	0
Leeds	2	2	2	1	3	3
Total	6	6	6	7	7	4

N/A, not appropriate.

A small number of participants in the BA group made additional comments that were not made by any of those receiving CBT. This included a resistance to the general BA approach, considering it simplistic, superficial and restrictive, and that it was a 'poorer cousin' of CBT because of its lack of consideration to thought processes:

> *I feel like your life's more complicated or more complex than that . . . I think if you don't actually kind of go a little bit deeper and underneath things, you're just sort of tinkering around with some of the superficial stuff on the top and rearranging the furniture.*
>
> *13 – BA 12 sessions, depressed*

In both treatments, experiences of homework were mixed. On the one hand, it could be difficult, bringing therapy into everyday life and having the potential to make mood worse. Some felt a pressure to complete homework, and felt that it could create feelings of fear and failure. But many others considered homework an important part of therapy, providing them with a feeling of owning their depression and gaining control over their feelings, and reported that having things written down was helpful. These views were not always distinct; some participants could recognise the benefits despite finding homework difficult:

> *People can give you information but you've got to put it into practice and act on it even if you might think 'Oh, this isn't going to really help me' . . . you've got to go through it and come out the other side, haven't you, to a certain degree?*
>
> *7 – BA 13 sessions, depressed*

The therapist

For many participants the therapist was a positive part of treatment: someone who was warm, patient and understanding. Participants in both treatments viewed their therapist as an expert who had the skills necessary to help them:

> *She was a lovely lady she gave me support when I needed it, she pushed me when I needed it . . . she could see when my mind was playing games with me where I was trying to ignore it or move around the situation, so for me she was very good.*
>
> *4 – BA 17 sessions, not depressed*

Some participants reported that the therapist played a particularly important role in helping them overcome difficulties in therapy. Being able to adapt treatment, offering reassurance and not putting pressure on participants were helpful skills when therapy was difficult, and addressing challenges with the therapist was largely seen as a helpful process:

> *Speaking to the counsellor and just being honest and open about what was, the fears or the barriers . . . because they were quite useful for her to understand, she could then fold that into the treatment as well.*
>
> *27 – CBT 22 sessions, not depressed*

A small minority of BA participants described their therapists as rigid, unauthoritative and lacking in confidence, comments that were not made by any of those receiving CBT. Although discussed only by a few participants in our sample, for those who did so it appeared to be a significant problem and was discussed at length:

> *It did feel like there was a bit of a confidence issue going on or a lack of confidence from the therapist's side in some way. 'Cos I sort of picked up that I needed to kind of make her kind of feel like she was doing a good job with me.*
>
> *13 – BA 12 sessions, depressed*

Barriers to therapy

Work and family were particular features of life that could make therapy difficult. Getting to sessions could be problematic, particularly for those with comorbidities, such as anxiety or chronic pain. A regular routine of appointments was considered to make attendance easier but flexibility was also welcomed (e.g. rearranging sessions or completing them over the telephone if particular barriers arose). There were also emotional challenges to therapy; it could be hard to open up and talk about personal things, especially in the beginning and for those who were not used to expressing their emotions. For some, depression itself made it hard to put things into practice and affected their ability to understand components of therapy:

> *The whole point about mood which makes it bad is the fact that it's impacting your ability to do . . . the depression itself is a barrier to doing it. I actually can't offer a solution that would make it easier, but I believe that it wouldn't work for everybody.*
>
> *33 – CBT 1 session*

Participants recognised the importance of their own attitude and commitment in helping them overcome barriers to therapy:

> *Hard as it was I was determined to do it because I knew I had to to make a difference in my life.*
>
> *4 – BA 17 sessions, not depressed*

Mechanisms of change

Participants' views about mechanisms of change could be understood in terms of three subthemes: behaviour change, cognitive change and talking versus doing.

Behaviour change

Changes to behaviour were considered important by many participants in both treatments, and this included avoidance, triggers, rumination and goal-oriented behaviour. Therapy enabled participants to understand and overcome avoidance behaviours, and this could reduce anxiety:

> *I felt like a weight had been lifted and I could, I was in a sort of procrastination phase where I couldn't make decisions and I was just puttin' things off . . . in gradual steps I started to be able to work my way through problems and being able to prioritise.*
>
> *19 – CBT 14 sessions, not depressed*

Therapy helped participants recognise triggers for low mood and understand the consequences of their response to triggers. Some described being able to choose different behavioural responses, control their feelings with actions and think differently about triggers, and these changes could reduce the power of depression. Therapy helped participants learn to set realistic, achievable goals and use behaviour to improve their mood, as well as encouraging them to reengage with positive activities and act when feeling low, helping to break the cycle of low mood:

> *When people are depressed I know it's a circle, you don't do anything, so you feel terrible, and then you don't do anything . . . this therapy forced me, pushed me to act, to do something. This is the first*

time that I've actually experienced that somebody tell me 'Well let's start doing this and you will feel better' and it happened.

24 – BA 8 sessions, not depressed

Both therapies encouraged participants to recognise the effect of rumination (i.e. repetitive unproductive thinking, especially about the experience of depression) and, for many, allowed them to manage and reduce time spent ruminating, which could improve mood and make life feel easier:

I care about people, my family and friends, now. As I say I didn't before, I didn't want to go anywhere, didn't want to see anyone, I just wanted to be left alone. And that's the ruminating time; she got me off that and I feel better for it.

23 – BA 17 sessions, depressed

Cognitive change

Cognitive change was discussed by some participants in both therapies, but was referred to more frequently by those who received CBT. This included having more self-belief, blaming themselves less when things go wrong and reduced beliefs of worthlessness:

It's given me a different way of looking at things and I suppose that's the way of believing in things, I have more belief in myself, that has helped a lot.

12 – CBT 23 sessions, not depressed

Participants in both therapies reported a more positive style of thinking, the ability to replace negative thoughts with positive thoughts and changing thoughts before entering a negative spiral. Other changes included a reduced tendency to overthink or ruminate, fewer self-critical thoughts and more balanced thinking. Some participants, particularly those who received CBT, described a sense of increased resilience, such as the ability to reason when things go wrong and taking things less personally:

I used to be a bit like a bull in a china shop if I was upset I would take it all very personally but now I'm more open minded . . . I think you don't take everything so personally, makes me think more rather than going to it head-long without thinking.

5 – CBT 24 sessions, depressed

Talking versus doing

This subtheme describes two typologies observed across both treatments, either prioritising opportunities to talk or using therapeutic strategies to bring about change. For several participants, having someone to talk to who was unbiased, non-judgemental and emotionally unconnected was the most important part of therapy, and problems from the week could be 'saved up' to discuss with the therapist:

Irrespective of what therapy it was, I think just the opportunity for an hour a week to talk about how you're feeling was in some way therapeutic, irrespective of the specific techniques of the BA.

9 – BA 9 sessions, depressed

In contrast, for many the 'doing' side of therapy was critical and the specific strategies of BA and CBT were considered helpful. The therapist was there not just to listen but to offer suggestions, and therapy was perceived to encourage participants to be proactive, finding a way to help themselves:

I think a lot of people need more input than just listening and what I liked about it is that they make very definite suggestions . . . you'd look for evidence and look at what is happening and then make goals to try and work towards.

28 – CBT 10 sessions, not depressed

Impact of therapy

Participants' views about the impact of therapy could be understood in terms of three subthemes: impact for self, impact for others and impact on the future.

Impact for self

In both therapies participants described no longer feeling depressed, enjoying life more and feeling like their old self again, and for some these improvements were longer lasting than they had experienced with other therapies:

> *Now I don't feel so full of despair as I used to be. Sort of, oh it's like taming the beast, really . . . it's given me the tools to get through day-to-day life and be more aware of moods and what effect they have on me and how to change that mood.*
>
> *12 – CBT 23 sessions, not depressed*

Other participants described themselves as happier, as a result of therapy, or feeling they have a different relationship with depression, leading to a feeling of acceptance. Several participants described therapy as having enhanced the way they feel about themselves, including increased feelings of self-compassion and improved self-esteem. Participants discussed positive influences of treatment leading to healthier lifestyles such as cooking better meals, exercising or seeking help for other problems such as pain or disability. Treatment was believed by some to have enabled them to get jobs, return to work after a period of being signed off, or perform better at work. For some, therapy enabled them to reduce or stop their ADM, and this could have further perceived benefits such as improved clarity of mind. Even those still meeting diagnostic criteria for depression could perceive a wide-reaching impact of therapy:

> *I would just say thank you very much for all the help you've given me and it's made an impact on my life that I never would have thought. I thought I was on my own, but evidently I'm not.*
>
> *23 – BA 17 sessions, depressed*

Impact for others

Participants in both treatments discussed ways in which therapy influenced those around them. Many perceived therapy to have helped their relationships and others described being more sociable or behaving more kindly towards others:

> *We talk, which has never happened before. We talk for like, hours. And we don't need to watch the telly or listen to music or anything . . . so I'm more interested in what's going on than the one-eyed god. The television!*
>
> *23 – BA 17 sessions, depressed*

Impact on the future

Many participants described therapy as providing them with a 'toolkit' to take away, teaching them skills that have enabled them to deal with life more effectively. For some these skills were becoming automatic as they continued to put them into practice. Relapse prevention work was important, helping participants learn to recognise the signs of depression and knowing how and when to ask for help. Having paper copies of therapeutic tools to take away was considered helpful and many participants revisit these when they feel low:

> *I think that this will probably be something I'll do for the rest of my life, 'cos I'm sure that for the rest of my life I'll have the ups and downs like everyone else does, but this will stop me going back to those dark places.*
>
> *11 – CBT 13 sessions, depressed*

Results of therapist qualitative interviews

Six CBT therapists and seven BA MHWs were interviewed in November and December 2015. Interviews lasted between 25 and 59 minutes (mean 40 minutes). Therapist demographics are provided in *Table 24*.

Data are presented under three overarching themes: the therapeutic model, confidence in delivery and the patients. Quotes are presented to support the analysis and are labelled by interview ID number, therapy delivered and recruitment site.

The therapeutic model

This theme illustrates therapists' views on the model of therapy that was delivered, including particular elements of therapy that were considered beneficial and their experiences of using the treatment manuals that they were trained to follow.

Elements of therapy

Mental health workers confirmed that, as intended, BA was an uncomplicated, logical and simple therapy that they believed made sense to patients, allowing them to make quick gains and encouraging a good therapeutic relationship. The majority of CBT therapists did not discuss the relative simplicity or complexity of therapy, but the one that did expressed a view that CBT is a complicated therapy that is difficult to deliver:

> *I think the fact that the behavioural activation model was quite simplified, it wasn't too complicated for people, so that helped with the therapeutic relationship as well. Yeah, it's an easy therapy to explain to patients.*
>
> *T10 – BA, Durham*

Many therapists, particularly those delivering BA, described working longer term with patients in the COBRA trial protocol than they would in usual practice, and this was seen as beneficial both for therapist and patient, and allowed for a better therapeutic relationship:

> *It was really good to get the chance to work with people over a much longer period and get to know them better . . . you form more of a relationship with them than you do when you're working with people for a shorter period of time, like six sessions.*
>
> *T12 – BA, Leeds*

TABLE 24 Demographics of therapists and MHWs who completed qualitative interview

Therapist characteristic	Number of interviews (n = 13)
Recruitment site	
Devon	5
Durham	3
Leeds	5
Therapy delivered	
BA	7
CBT	6
Gender	
Male	3
Female	10
Mean years since first qualified	
BA	3.0
CBT	12.4

Therapists in both treatments placed high value on relapse prevention. BA MHWs felt that it was useful for patients to reflect on what they had learnt and have a plan to recognise and respond to signs of depression in the future. Some BA MHWs commented that relapse prevention is not given a lot of attention in their usual practice in IAPT, and this was considered an important addition. Likewise, CBT therapists believed relapse prevention to be a core component of treatment that helped patients understand the changes made and encouraged them to continue implementing them. Therapists expressed a view that the aim of CBT is for patients to become their own therapist, and providing them with tools to take forward was important in helping them achieve this:

> *One of the aims of CBT is for people to become their own therapist . . . it gives people a bit of confidence and sense of hope for the future that there's stuff within their power and control that they can do to make changes.*
>
> *T08 – CBT, Devon*

For BA MHWs, another component of treatment considered particularly helpful, both for themselves and for patients, was rumination. MHWs believed that rumination is a key problem in depression, and it was therefore a frequently used technique that was considered to be applicable to many patients. It was noted that rumination was not taught when they trained as IAPT PWPs and that it was a helpful addition to their knowledge base, and something they continue to use in their clinical practice now:

> *Rumination, particularly, I think was quite helpful and very rarely is that used in standard step 2 practice, so I think that would be a really useful addition.*
>
> *T07 – BA, Devon*

Treatment manuals

Both BA MHWs and CBT therapists described the treatment manuals and patient worksheets as good, well structured, clear and concise. CBT therapists commented that it was helpful to have a manual to follow that could be taken off the shelf and used, providing useful and well-needed updates to the CBT model:

> *The COBRA manual itself was really kind of clear and concise and helpful as well . . . whereas Beck's original book on depression, it's very old, it really does need a bit of updating.*
>
> *T02 – CBT, Devon*

Therapists in both treatments described using the manuals flexibly, adapting therapy to meet individual needs. For the BA MHWs, there was a focus on using the optional modules in the manual to achieve this, whereas CBT therapists described a more core therapeutic skill of providing therapy using their own experience to gauge where to take each patient.

Despite recognising the ability of therapy to be adapted for individual needs, some therapists felt restricted by the treatment manuals and confused about how and when they could diverge from it. BA MHWs, in particular, expressed frustration at being unable to address negative thoughts and felt that some patients would have benefited from cognitive work. There was also anxiety about stepping outside the BA model and avoiding 'therapeutic drift' towards CBT:

> *We all had quite a lot of anxiety around following the protocol and making sure we didn't step outside that and 'Oh god don't mention thoughts when you're doing BA!'*
>
> *T13 – BA, Durham*

There was a view that the treatment manuals are not appropriate for everyone, and therapists could experience difficulty in treating patients whom they considered to have more complex problems, such as comorbid anxiety, personality disorders or a history of abuse, without working outside the treatment

manual. This could be particularly challenging when therapists felt that, in usual practice, a patient would have been referred to secondary care or more specialist services:

> *It impacted on the ability to follow the COBRA-specific protocol because it didn't feel appropriate if someone's main thing was anxiety to keep plugging a depression model, so to keep a therapeutic alliance going it was kind of necessary to focus on the anxiety.*
>
> *T08 – CBT, Devon*

Some patients were considered to struggle with the overall approach and structure of BA and CBT, and therapists also recognised that both therapies can be demanding of patients, particularly with regards to the requirement for homework:

> *Getting people to analyse what they're doing and getting people not just do more but start to look at activities and behaviours they can start to change. And I guess that's asking quite a lot of people, especially people on the severe end of depression.*
>
> *T06 – BA, Leeds*

Confidence in delivery

A common theme discussed by many therapists was how confident they felt in delivering COBRA trial therapy. This included discussion on things that were seen to challenge their confidence, as well as remarks about how confidence changed or improved, and the specific role of training and supervision in helping to build confidence.

Challenges to confidence

There was a clear distinction in the way BA and CBT therapists talked about how COBRA trial treatment compared with their usual practice. BA MHWs talked extensively about COBRA trial therapy as a new, different way of working, which could be challenging and overwhelming for them, especially in the beginning. BA was considered a big jump from their previous work and required learning lots of new skills and techniques:

> *It was quite overwhelming in some respects, I think I went into it thinking that there wouldn't be that much difference to what I was already doing, but actually once I did the training I realised that there was quite a big difference.*
>
> *T13 – BA, Durham*

A particular area in which BA MHWs lacked confidence was in making the transition from their prior role in guided self-help in which they considered themselves to be a 'coach' for patients, to becoming more collaborative in their relationship:

> *How you make that transition from just doing the kind of coaching style of PWP to this more therapeutic, collaborative, I mean it's still collaborative at PWP but it's a bit more in depth in the BA that we were doing, it was expected to be anyway.*
>
> *T12 – BA, Leeds*

For CBT therapists, however, COBRA trial treatment was considered familiar, and matched what they do in their day-to-day clinical work:

> *It was familiar for any cognitive therapist that's kind of like bread and butter really, the Beck model.*
>
> *T02 – CBT, Devon*

Other areas where therapists lacked confidence included working with patients with chronic conditions, and a CBT therapist who considered herself to be more of a behavioural worker struggled to work more cognitively.

Improving confidence

Therapists in both treatments felt that they had learned a lot from their involvement in the COBRA trial. BA MHWs described learning new skills and techniques, with particular references to formulation, rumination and functional analysis. They described feeling more capable of delivering behavioural therapy and continuing to use it now as an alternative to cognitive work. For those therapists who struggled with confidence initially, this was considered to have improved over time and with good-quality training and supervision:

> *We had really good supervision, so I think the training was really good to set you up for what was to be expected and then once you got into it I think my confidence just started to build a lot more with the actual techniques.*
>
> *T13 – BA, Durham*

Cognitive–behavioural therapy therapists, on the other hand, talked about the trial as an opportunity to consolidate old knowledge, build on previous learning and 'sharpen up' their skills. Some described feeling more confident in delivering cognitive therapy for depression now, as well as greater confidence in specific areas such as doing better behavioural experiments, dealing with difficult patients or improved flexibility as a therapist:

> *I've got more confidence now in being truly Socratic and curious and flexible in my approach, rather than just chugging along with things . . . it got me to really make sure that I'm connecting with people.*
>
> *T09 – CBT, Leeds*

Role of training and supervision

Training and supervision was discussed extensively by therapists in both treatments. Training was described as great, helpful and comprehensive, but was also hard work. For CBT therapists the training week was seen as a 'good refresher', whereas for those delivering BA the training taught them lots of new skills. Having a week of in-depth training on one therapy was considered a positive experience by both BA and CBT therapists:

> *I learned a lot from the training and just things like learning about rumination, functional equivalence, functional analysis, things like that that I hadn't learned about from the PWP course . . . having the chance to do a week in-depth about a particular treatment was really useful.*
>
> *T04 – BA, Leeds*

The training week, however, was also considered to be intense and overwhelming, particularly for those delivering BA. One BA MHW thought the training week would have benefited from more attention to core therapeutic skills such as collaborative working, which were considered to be a new way of working for them:

> *It was meant to be like proper therapy that's very collaborative and we spend a lot more time doing all that Socratic questioning, trying to get people to get the answer themselves and it's a different skill . . . maybe could have done more on that side of things in the training.*
>
> *T12 – BA, Leeds*

Supervision was described by therapists in both treatments as helpful, supportive and of high quality. Therapists described the supervisors as knowledgeable 'experts' and this was considered to be an invaluable experience which helped to build confidence:

> *Supervision from experts in the field as well . . . I've learned invaluable experience, I've sort of changed me as a practitioner as well.*
>
> *T10 – BA, Durham*

> *The quality of supervision was very good and so for me as a clinician that was very helpful I think, I certainly came out of the trial having felt a lot more confident and that still stays with me in providing CBT for depression.*
>
> *T05 – CBT, Leeds*

Having group supervision with other therapists was described as a beneficial process that allowed therapists to learn from each other. Taking audio-recordings of therapy sessions to supervision was a difficult experience for those in both treatments, but was also recognised as a useful practice from which a lot could be learnt:

> *In supervision, where our recordings are played out amongst the group of supervisees . . . I did find that difficult . . . but again, you can see how you can work through those things and I learned a hell of a lot in the supervision sessions because of that, and then it was great actually, I loved it in the end.*
>
> *T01 – BA, Devon*

The patients

This theme includes discussion of the patients treated in the trial, including how these patients compared with those they would see in usual practice, perceived cognitive and behavioural change for patients, and the broader impact of therapy on patients' lives.

Comparisons with usual practice

There were two distinct views about how COBRA trial patients compared with patients treated in usual practice. Therapists located in Durham, whether delivering BA or CBT, did not consider COBRA trial patients to be any different from those treated in usual practice; there was a range of complexity and willingness to engage, which mirrors usual practice:

> *At step 2 we see more complex people, I don't think for me there was any change with the COBRA people as such. Because some of them were mild to moderate but some of them were more complex.*
>
> *T13 – BA, Durham*

Therapists in Exeter and Leeds, on the other hand, tended to describe COBRA trial patients as having more complex difficulties and being more difficult interpersonally than patients seen in usual practice. No therapists described COBRA trial patients as being less complex than usual:

> *They were definitely more complex in terms of their history . . . some of them were quite different, I think, to what I'd usually be working with.*
>
> *T09 – CBT, Leeds*

Cognitive and behavioural change

Behavioural change was discussed extensively by therapists in both treatments. Therapy was believed to have led to significant changes in behaviour, and behavioural work was considered an important part of both BA and CBT. A common theme was that patients had increased their contact with pleasurable activities and re-engaged with the things they value:

> *You could actually see when they were talking about it how – oh, you know, it was just lovely to feel the water over her skin . . . some patients were very descriptive in explaining that positive reinforcing feeling of going back to an activity that they thought maybe they'd never try again.*
>
> *T01 – BA, Devon*

Cognitive–behavioural therapy therapists described many cognitive changes resulting from treatment, including overall changes to thinking style, less negative thinking and no longer predicting the worst to happen. Therapists described changes to patients' beliefs about themselves such as reduced feelings of worthlessness, as well as changes to beliefs about others such as believing the world is not out to get them. There were two distinct views from CBT therapists about the role of cognitive change. Some believed this to be a big turning point for many patients, leading to improvements in overall quality of life, and that behavioural change came as a result of cognitive change. The other view, however, was that cognitive work was less important than behavioural work, and one therapist felt it was hard to differentiate cognitive and behavioural change:

> *The whole treatment is about that really, it's trying to get people to change the way they think and get out of the kind of depressive thinking styles and then by doing that, that usually makes people more active and less avoidant.*
>
> *T08 – CBT, Devon*

Cognitive change was discussed much less frequently by BA MHWs than by those delivering CBT. For those who did discuss it, a common idea was that cognitive change came as a result of behavioural change:

> *When people start getting back to doing things that mean something to them and enjoying life, their cognitions naturally change . . . not always straight away, there was often a bit of a cognitive lag but it would catch up.*
>
> *T06 – BA, Leeds*

Patient outcomes

Therapists in both treatments considered therapy to have helped patients in broad and varied domains of life. Both BA and CBT were believed to have helped improve many patients' mood and other symptoms of depression, including motivation, concentration, energy, sleep and feelings about themselves.

Many therapists felt that therapy had helped improve patients' health and well-being. There was recognition that depression can have consequences for physical health, and a belief that BA and CBT could have a positive influence in this. Other improvements included patients taking better care of themselves, valuing themselves more and improvements to their overall appearance:

> *Some people reported feeling physically unwell as well as mentally unwell, and you could see a change in that, people's energy levels and things.*
>
> *T06 – BA, Leeds*

Both therapies were considered to have helped patients sleep, with behavioural work believed to be particularly important for this. Other improvements included eating better, exercising more and reduced alcohol consumption. Therapists in both treatments described improvements to patients' home and family lives as a result of therapy, as well as improved relationships with others:

> *People's home lives often, you know, depression can take its toll on everybody, so people often reported that things were better at home.*
>
> *T06 – BA, Leeds*

A common theme across both BA and CBT was increased social contact and reduced social avoidance as a result of therapy. Increased social contact was believed to have had a range of positive effects on patients including improving confidence and, for those in CBT, reinforcing positive beliefs about themselves:

> *For a lot of my patients who I saw they were all – they've all been sociable people, they're all from large families, they've enjoyed that and for whatever reason, they've lost it. And I think socialising reinforced to them that you are likeable, you do have a lot to contribute.*
>
> *T11 – CBT, Durham*

Therapists in both treatments also considered therapy to have helped patients at work, including getting back to work after a period of being signed off, getting a new job or being more productive at work:

> *One lady who struggled to get out of the door, over the doorstep, she actually, last year rang me to give her a reference to do some voluntary work . . . and that even now, it makes me feel really – 'cos it was just fantastic! It's life changing, isn't it?*
>
> *T11 – CBT, Durham*

The results of the participant and therapist qualitative interviews will be discussed and interpreted in *Chapter 5*.

Chapter 5 Discussion and conclusions

Summary of findings

We found that BA for depression is not inferior to CBT in terms of reduction of depression symptoms and is cost-effective compared with CBT against commonly applied decision-maker willingness-to-pay thresholds. We observed our results using both ITT and PP analyses, using a conservative non-inferiority margin. Our economic outcomes were driven by the lower costs of the MHWs who delivered BA, compared with the more experienced psychological therapists who routinely deliver CBT. Our study results, therefore, substantiate the hypothesis that BA is as effective as CBT and that its simplicity renders BA suitable for delivery by junior MHWs with no professional training in psychological therapies.[19]

Our process data found that, despite being challenging at times, BA and CBT were acceptable and feasible for participants, MHWs and therapists, and effected changes in people's specific symptoms and in their lives more broadly. Despite experiencing initial difficulties that could be detected by some participants, with sufficient training, experience and supervision, junior MHWs could feel confident in delivering BA effectively. We found weak evidence for an interaction between treatment and baseline PHQ-9 score on PHQ-9 at 12 and 18 months' follow-up, indicating that BA may be a better choice of treatment for patients with higher baseline PHQ-9 scores.

Summary of clinical outcomes

Both BA and CBT improved overall depression in the ITT and PP populations. At our primary end point of 12 months post randomisation, the mean PHQ-9 scores were 7.8 points (SD 6.5 points) in the BA group and 7.9 points (SD 7.3 points) in the CBT group, both below the commonly applied PHQ-9 threshold of 10 points associated with a diagnosis of MDD. At baseline, the mean PHQ-9 score for the BA group was 17.7 points (SD 4.8 points) and for the CBT group 17.4 points (SD 4.8 points), both groups being within the moderately severe depression range (15–20 points). Our results demonstrate the unequivocal non-inferiority of BA compared with CBT in both ITT and PP populations, as the between-group mean difference and 95% CIs lie firmly within our a priori non-inferiority margin of –1.9 PHQ-9 points (ITT mean difference: 0.1 PHQ-9 points, 95% CI –1.3 to 1.5 PHQ-9 points; $p = 0.89$; PP mean difference: 0.0 PHQ-9 points, 95% CI –1.5 to 1.6 PHQ-9 points; $p = 0.99$). Our results were robust to sensitivity analyses exploring the effect of different PP definitions, predefined subgroups and missing data.

In order to assist with clinical interpretation, we have also presented data that show there were no differences between groups in the proportions of participants responding to treatment or recovering from depression at 12 months post randomisation in either the ITT or PP analyses. In the PP population, 69–70% of trial participants were rated as recovered (PHQ-9 $\leq$ 9 points) and 64–66% as having responded to treatment ($\geq$ 50% reduction in PHQ-9 score from baseline). The equivalent figures for the ITT population were 66% and 61–62%. These outcomes were maintained at 18 months' follow-up. We observed very similar patterns for all of our secondary outcomes, including anxiety (as measured via the GAD-7 questionnaire) and health-related quality of life (as measured via the SF-36 questionnaire). We could not, therefore, detect any differential treatment effect on any clinical outcomes between BA and CBT as treatment for depression.

Summary of economic outcomes

We found that resource use and resultant costs were similar for both BA and CBT groups at our primary economic end point of 18 months. The only significant difference between groups was in mean intervention costs between the two groups. There were no significant differences in other categories of cost or in overall total cost. Although health-related quality of life was slightly higher in the BA group than in the CBT group across the entire follow-up period, with resultant QALYs also higher for BA, the QALY difference was not significant. Nonetheless, because observed costs were lower and QALY outcomes better in the BA group than in the CBT group, this generated an ICER of –£6865, suggesting that BA dominates CBT (i.e. BA is both cheaper and more effective). The probability of BA being cost-effective compared with CBT does not fall < 75% and is closer to 80% at standard NICE willingness-to-pay thresholds of £20,000–30,000 per QALY. Once again, these findings were robust to sensitivity analyses using both broader and narrower cost perspectives and analysing the impact of missing data. Our findings are therefore robust in suggesting that BA is cost-effective compared with CBT, driven principally by the lower costs of employing junior MHWs to deliver this simpler treatment.

Summary of process evaluation

Our process analyses indicated a moderating effect (statistically significant interaction) of baseline PHQ-9 score on treatment effect, with regard to PHQ-9 at 12 and 18 months' follow-up, although the evidence for such an effect was weak in both cases. Our analysis further suggested that BA may be a better choice of treatment for patients with higher baseline PHQ-9 scores. No significant differences were found between the BA and CBT groups with regard to the process mediators, proportion of therapy sessions attended and overall treatment fidelity, although basic treatment fidelity was found to be higher in the BA group. The only statistically significant mediation effects were that overall treatment fidelity mediated the effect of treatment (BA vs. CBT) on PHQ-9 at 12 months' follow-up, with basic and overall treatment fidelity mediating the effect of treatment on PHQ-9 at 18 months' follow-up. However, these statistically significant results were only seen in the models that included only one variable acting as a mediator of treatment effect (as opposed to models that included several potential mediators). In terms of the proportion of overall treatment effect mediated, basic treatment fidelity accounted for a high proportion of treatment effect mediated at both the 12- and 18-month follow-ups.

In terms of qualitative data, BA and CBT were considered acceptable by patients, MHWs and therapists. People liked the fact that the therapy offered them someone to talk to, gave them tools and techniques to enable them to help themselves and was an opportunity for them to learn. This is consistent with previous qualitative studies of change processes in cognitive therapy, which have found that patients value both specific cognitive techniques (such as changing negative thoughts), as well as general psychotherapy ingredients (such as a collaborative therapeutic relationship and the opportunity to learn).[105–107] Participants appreciated that therapy was long and regular and that they were not asked to spend a lot of time focusing on the past, although some would have liked more time to talk about their feelings. Homework was considered an important part of treatment for participants, allowing them to gain control of their feelings, but it could also be challenging. This is consistent with previous research in which patients receiving CBT for depression reported finding homework difficult for both emotional and practical reasons, but that they understood its necessity in the therapeutic process.[108] Therapists and MHWs, in particular, appreciated working longer term with patients than in usual IAPT practice and believed this to be beneficial both for themselves and for patients. Aspects of participants' personal lives, such as work and family, could make therapy challenging, and having other conditions like chronic pain or anxiety were considered by some to be a barrier to treatment. Depression itself could also be a barrier, impacting on participants' ability to 'do' and making it hard to focus or understand therapy.

Clinically, in some cases, both MHWs and patients expressed the opinion that MHW practice could appear to be somewhat rigid and that MHWs might lack confidence in their new BA role, although this had no impact on our main finding of clinical non-inferiority of BA compared with CBT. Furthermore, the finding that treatment fidelity mediated outcome suggests that adherence to the treatment protocol has more

beneficial than deleterious effects. Nonetheless, strategies to boost both the appearance and actuality of junior MHW practice will be considered later in this discussion.

Strengths and limitations

The COBRA trial is the largest trial of BA to date and is one of the largest trials of psychological treatments for depression. We followed up participants for 18 months and our economic analysis is one of few in this field. Therapists and MHWs working in three different routine UK care settings delivered treatment, providing evidence of potential generalisability. We assessed therapy quality using independent raters and ensured that treatment in both arms was delivered to the standard recommended in guidelines. Given the nature of the intervention and comparator we could not mask patients or the MHWs or therapists who were delivering the interventions to treatment allocation, but we used self-reported outcome measures and robust outcome assessor-masking procedures to reduce researcher unmasking to < 5%.

At 21% and 14% for BA and CBT, respectively at 12 months, our levels of attrition and outcome loss to follow-up were low at 12 and 18 months, similar to other trials in this area, but are still a limitation. Although we found a between-group difference in attrition for the ITT analyses, this was not the case for the PP analyses, suggesting that any differential attrition was an artefact of the trial and not of the treatments. Furthermore, our between-group inferences were robust to data imputation. Although participants in the PP population attended similar numbers of sessions to those in other CBT trials, 35% of participants overall chose to not attend a minimal number of sessions, a problem well known to routine psychological therapies services.

This pragmatic trial carried out in routine environments means we were unable to quantify or control for the contribution of ADM on outcomes. However, most participants who were taking medication had been doing so for a considerable time before entering the trial, making it unlikely that our results were driven by pharmacological treatment.

In terms of competency ratings, the ratings of our random sample of therapy tapes showed that both CBT therapists and BA MHWs were, on average, performing above competency thresholds. In terms of CBT, our mean sessional competency ratings (37.9) were very similar to the means reported in the CoBalT trial,[55] another significant and large recent UK trial of CBT – 38.8, demonstrating that our therapists were achieving competency levels consistent with other similar pragmatic effectiveness studies. However, on this random sample of tapes some therapists were scoring below the threshold of competence for that specific session as assessed by our external raters, although we would stress that all therapists had exceeded the competence threshold at the end of their COBRA-specific protocol training course.

We note that our CBT therapists had received 1 year of postgraduate training in CBT, had passed similar competency tests in order to qualify from these courses, had received an additional specialist training in the COBRA protocol and were supervised by CBT experts. Most importantly, they were NHS employees engaged in routine treatment for patients with depression in the UK NHS IAPT services; indeed they were working for the NHS alongside their trial duties. Finally, the competency ratings from the CBT arm in our trial are consistent with other research findings in the field.[12,40] Therefore, although it may be possible to train CBT therapists to achieve higher competency ratings, we suggest that these levels of competence are those actually seen in routine clinical practice in IAPT services in the UK, results achieved following substantial investment in therapists' clinical training, and appear unrelated to clinical outcomes.

Furthermore, although the measures of competence for the BA MHWs and the CBT therapists are not directly comparable, we note that the MHWs scored, on average, further above the competency threshold than the CBT therapists on the relevant competency measure. This provides some, albeit weak and indirect, supporting evidence for the proposition that it might be easier to train people to be competent BA workers than CBT therapists, although this is moderated by the difficulties with the unknown

psychometric properties of the BA competence measure in particular and we did not set out to test this proposal directly.

The period between baseline and the 6-month follow-up was the period in which the main treatment effect occurred; therefore, it is during this period that any mediation effect would be of greatest interest. However, there may be difficulties in assessing the effect of potential mediators during this period because of the variation in such mediators at the times when recorded during the first 6 months of treatment. Such variation may be attributable to differences in the pace of therapy in terms of how quickly the patients completed their sessions and engaged with the topics relevant to their therapy. At later stages of follow-up, with regard to both the outcome and the mediator variables, it may be the case that the mediator variables had become more stable and therefore better able to facilitate mediation analysis.

The wide variation among patients in their trajectories across time points within the follow-up period, with regard to PHQ-9 and each mediator variable, may also be an impediment to distinguishing possible mediation effects. However, little difference was noted between the CBT and BA groups in terms of the mediating psychological variables, possibly indicating little practical difference in how participants responded to the two forms of therapy. Owing to differences in the structure of therapy, the BA group scored more highly for measures of treatment fidelity, although the proportion of sessions attended was similar across the two treatment groups.

Considering differences in the pattern of mediation across outcome follow-up times, at the earlier follow-up time of 6 months, the indirect effects of the mediators appeared to be accounting for only small proportions of the total treatment effect. This may reflect lack of stability in the early phases of the trial, while many participants were still undergoing therapy, with regard to both PHQ-9 and mediator scores.

In terms of moderators and mediators, COBRA was a large study that incorporated the collection of several psychological variables that were potential mediators of treatment effect; these variables were collected at several time points during the follow-up period of the trial. Also, the primary outcome, PHQ-9, was collected at three time points (at 6, 12 and 18 months' follow-up). The collection of data for several psychological mediators at multiple time points has facilitated the comparison of how the two treatment groups progressed over the study period, at the group level and at the individual participant level. However, the large number of comparisons performed as a result of this brings about concerns regarding multiple testing and the possibility of finding statistically significant results by chance. With regard to the mediation analyses, only three statistically significant results were found when including a single mediator in each model, one relating to PHQ-9 measured at the 12-month follow-up and two at the 18-month follow-up. These results are consistent with the expectation of significant results occurring by chance. Therefore, these results should be viewed with caution.

Similarly, of the 42 inferential tests for moderation across the ITT and PP populations, and the three follow-up time points, none were found to be statistically significant at a p-value of < 0.05, although three moderation analyses yielded a p-value of < 0.1. In view of the low power to detect interaction effects, and in view of the number of tests performed, these possible interaction effects should also be viewed with caution.

The COBRA trial was the largest trial to date comparing CBT and BA and enabled an in-depth qualitative analysis of patients' and therapists'/MHWs' experiences of these treatments alongside the clinical effectiveness, cost-effectiveness and quantitative process analyses. To date, there have been very few qualitative studies of this. Our purposive sampling method for our participant interviews ensured diversity in our sample and we successfully interviewed participants from each recruitment site, both therapies, some who completed the full course/ended treatment early and some who were still depressed/no longer depressed, as well as both male and female participants across a range of ages. Similarly, we interviewed therapists/MHWs from both treatments, from all three recruitment sites and with a range of backgrounds and experience. However, the generalisability of our findings are limited to participants who were both eligible and willing to participate in the COBRA trial, and participants who declined to take part in the qualitative

study may also have had different views to those who agreed to be interviewed. Likewise, qualitative interviews were only completed with 13 of the 22 therapists/MHWs involved in the trial, and those who did not respond to the invitation to be interviewed may have had different experiences to those who did respond.

All interviews were carried out over the telephone as a result of the long-distance nature of cross-site interviewing. This maintained researcher blindness for participant quantitative follow-ups and was crucial for the integrity of the COBRA trial. Although some researchers have proposed that telephone interviewing may be less effective than face to face,[109] evidence suggests that telephone interviews yield the same number and quality of data as those conducted face to face,[110] and some argue that telephone interviewing may even be preferable when participants are discussing sensitive topics.[111] Finally, although we aimed to interview participants as soon as possible after completion of therapy, in practice this was difficult because of delays in obtaining information about therapy end dates, delays in the ability to recruit participants quickly after this time point, and an overall difficulty recruiting participants who had fewer than eight sessions of therapy, resulting in an extension of our qualitative recruitment period. A small number of participants commented that at the time of their interview they found it difficult to remember specific aspects of their treatment, and it is possible that participants who were interviewed soon after therapy completion may have had different reflections on their experiences from those interviewed some time later.

We recruited participants from primary care, rather than specialist settings. Our results are, therefore, applicable to the great majority of patients with depression in these settings. We excluded people who had other major psychiatric diagnoses, people who are most likely to be found in specialist mental health services. We did so because, notwithstanding their depression, people with diagnoses such as addictive disorders, bipolar disorder or psychosis require specialist treatment for these disorders as their primary psychiatric input. We excluded people with these conditions on the understanding that psychological treatment for their depression would not be the first line of treatment offered. Therefore, for this population, our results may not be generalisable.

Implications for health care

Our findings could have substantial implications for the scalability of psychological treatment for depression in the UK and internationally,[17] given the greater availability and ease with which a BA workforce could be trained than could a CBT workforce. For many years, CBT has been the foremost psychological therapy recommended by therapists, researchers and policy-makers. Our results challenge this dominance. Although more work needs to be done than has been undertaken so far to find ways to effectively treat the 20–30% of participants whose depression was unchanged by BA or CBT, our findings suggest that BA should be a front-line treatment for depression, with significant potential to improve reach and access to psychological therapy globally.

Our results in both groups compare favourably with a meta-analysis[112] of the effects of CBT compared with second-generation ADM. This analysis found no difference between ADM and CBT on rates of remission between 12 and 16 weeks post randomisation (ADM, 40.7%; CBT, 47.9%; risk ratio 0.98, 95% CI 0.73 to 1.32). For comparison purposes, our ITT recovery rates (synonymous with remission in the meta-analysis) at 18 months post randomisation were 66% for BA and 59% for CBT. Equally, in the meta-analysis referred to above, response rates were 44.2% for ADM and 45.5% for CBT (risk ratio 0.91, 95% CI 0.77 to 1.07); for comparison, 61% of our participants receiving BA and 60% of those receiving CBT had responded at 18 months. Thus, the proportion of participants in both treatment arms who experienced long-term positive clinical outcomes was higher in our study than in this recent meta-analysis.

Our cost-effectiveness analyses show the high probability that BA is cost-effective and affordable compared with CBT at standard willingness-to-pay thresholds. Our most striking finding is that BA leads to comparable clinical outcomes for patients with depression, but at a financial saving to clinical providers of 21% compared with the cost of provision of CBT, with no compensatory use of other health-care services by patients.

Driving these savings is the fact that BA can be delivered by inexperienced MHWs with no professional training in psychological therapies, with no lesser effect than that of more highly trained and experienced psychological therapists giving patients CBT. Although training of MHWs is only one of many obstacles to successful dissemination, our findings suggest that health services globally could reduce the need for costly professional training and infrastructure, reduce waiting times and increase access to psychological therapies.[17] Our findings have substantial implications given the increasing global pressure for cost containment across health systems in high-income countries, and the need to develop accessible, scalable interventions in low- and medium-income countries. Such countries might choose to investigate the training and employment of junior workers over expensive groups of psychological professionals. Our results, therefore, offer hope to many societies, cultures and communities worldwide, rich and poor, struggling with the effect of depression on the health of their people and economies.

The results of the moderation analysis did not provide any strong evidence for differential treatment effect across subgroups of participants, although there was some weak evidence for a stronger beneficial effect of BA among participants who were more severely depressed at baseline. This finding is consistent with a previous study,[40] and may indicate that, clinically, BA would be the preferred choice of therapy for more severely depressed patients.

The mediation analyses indicated that the quality of therapy, with regard to coverage of core topics, is the strongest mediator of treatment effect. Hence, this may provide guidance to therapists that they should concentrate on including the core topics within their therapy sessions. The mediation effects of the psychological mediators appear to be weaker than those of the mediators related to therapy fidelity, and clear findings with regard to the mediation effects of the psychological mediators were not observed.

Our qualitative findings suggest that, despite BA being non-inferior to CBT in terms of clinical outcomes, junior MHWs delivering BA could feel somewhat overwhelmed by the new skills they were learning and felt an initial lack of confidence in their ability to deliver therapy effectively. This lack of confidence was unique to BA, and was able to be detected by some patients. This is unsurprising given the new role that these workers were being asked to undertake, unlike CBT therapists, who had already been trained and were experienced in delivering CBT. BA delivered by therapeutically naive junior MHWs, therefore, requires good-quality training, time for therapists to build confidence through practice and ongoing supervision from experienced BA practitioners. Indeed, therapists/MHWs in both groups described training and supervision positively, and the model of support provided in the COBRA trial appears to be effective and well regarded by those delivering therapy. In particular, having a week of in-depth training, group supervision with peers and playing out of audio-clips from therapy during supervision were elements of the COBRA trial support model that were regarded as helpful, and should be considered for future implementation of BA and CBT for depression.

For CBT therapists, the COBRA trial treatment manual was generally considered to have been useful, although there was also anxiety about the lack of flexibility permitted. When training therapists to follow a therapeutic manual such as those used in the COBRA trial, therapists should not be too flexible in their clinical practice at the expense of overall treatment fidelity, since our quantitative process analysis demonstrated that fidelity predicts clinical outcomes. In addition, as outcomes for CBT in the COBRA trial were superior to those seen in IAPT services,[113] where therapists are not trained to follow a particular depression treatment manual, consideration should be given to whether or not it would be beneficial to routinely use such a treatment manual in IAPT.

Relapse prevention was an element of both treatments that was valued highly by therapists/MHWs and patients. This is important because research has shown that, even when patients make significant clinical improvements during therapy, they expect themselves to remain susceptible to depression and continue to implement techniques learnt in therapy as a way of managing what they consider to be a chronic condition.[114] Previous work has also suggested that the long-term effects of CBT are attributable to patients learning skills that they can continue to implement after therapy has ended.[115,116] Relapse prevention is therefore a crucial component of both therapy protocols, which should continue to be implemented.

Implications for future research

Despite the encouraging nature of both our overall treatment outcomes and the cost-effectiveness and non-inferiority of BA compared with CBT, there remain three issues that should be priorities for research. The first is how to engage the considerable number of people with depression who either do not start, or rapidly drop out of, psychological treatment. Neither treatment in our trial performed better than the other in terms of this engagement and retention. Multiple contextual, specific and common therapeutic factors may contribute to the hypothesis that some patients find psychological therapy either generically undesirable, impractical or specifically inappropriate to their needs. It is unlikely that there is one simple solution – for example, psychological treatments with a different theoretical orientation – that will overcome these diverse factors impeding patient engagement. Nonetheless, research into ways in which patients can be engaged more fully could be considered.

Second, even for the PP population, around 30% of people did not experience a clinically relevant change in their depression symptoms, whether they received BA or CBT. It remains a possibility that matching patients to treatments by specific patient-level moderator variables, as has been hypothesised by some researchers,[117] would lead to better outcomes. Unfortunately, in terms of depression severity, although a phenomenon previously observed,[40] our study has only provided weak evidence to support the hypothesis that BA has a stronger therapeutic effect for patients who are more severely depressed at the onset of treatment. In terms of potentially enhancing the mediating effect of a range of psychological variables, despite previous studies of CBT[55] reporting the mediating effect of changes in dysfunctional attitudes and metacognitive awareness, we were unable to demonstrate any substantial effect of psychological mediators on outcome. We are unable to recommend, therefore, that therapists enhance their therapeutic focus on these areas with any guarantee of improving outcomes for patients. Our only substantive finding that fidelity to a clinical protocol mediates outcome in both BA and CBT merely emphasises the importance for MHWs and therapists of following an evidence-based clinical treatment closely in their work. Much more prospective research using precision medicine approaches such as the Personalised Advantage Index[117] to test the potential of matching treatments to individual patient characteristics seems to be warranted.

Third, Kanter and Puspitasari[118] have noted that, 'now that we have support for BA as a treatment that is clinically effective and cost-effective, we can shift our efforts to focus on what is necessary to produce sustainable large-scale BA implementation across diverse geographical and cultural settings'.[118] The central rationale of BA, now supported by our COBRA trial results, is that it is also a simple treatment suitable for widespread dissemination beyond high-income countries. Knowledge for the sustainable dissemination and implementation of BA as an effective health technology to low- and medium-income countries remains suboptimal. Although there have been a number of studies in low- and medium-income countries, including India, Iran and Iraq,[119–121] the outcome data are equivocal as these studies either do not use an optimum clinical protocol tested in RCTs, are underpowered, incorporate BA as one part of a multicomponent complex intervention, or focus on very tightly defined populations. Nonetheless, these international studies do provide some evidence for the cross-cultural face validity of BA.[118] We now need to identify the low- and medium-income countries workforce best able and available to deliver this simple treatment. We need to determine if the face validity of BA can go some way to overcoming mental health stigma and people's reluctance to engage in treatment in different cultures. We need to engage with organisations and cultures unused to the concept of evidence-based mental health therapies. Finally, we need to apply our scientific methods in low and middle income countries contexts, not least our health economic methods, as these data will drive recommendations to implement BA widely or not.

In summary, future research should focus on strategies to improve the initial engagement of depressed people with psychological therapies, should examine ways to personalise and optimise the allocation of a range of evidence-based treatments, and should take an implementation science approach to dissemination and reach outside the high-income countries in which BA in particular has been developed and tested.

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Rebecca Woodhouse (Associate Research Fellow) contributed to data collection, and contributed to the writing and editing of the report.

All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

Publications

Rhodes S, Richards DA, Ekers D, McMillan D, Byford S, Farrand PA, *et al.* Cost and outcome of behavioural activation versus cognitive behaviour therapy for depression (COBRA): study protocol for a randomised controlled trial. *Trials* 2014;**15**:29.

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Data sharing statement

The authors confirm that all data underlying the findings are fully available without restriction. The authors have made the clinical and economic data set available through the University of Exeter's Institutional Repository – Open Research Exeter (see https://ore.exeter.ac.uk). Access to these data is permitted but controlled through requests made via the repository to the chief investigator (Professor Richards: d.a.richards@exeter.ac.uk). Although use is permitted, this will be on the basis that the source of the data is acknowledged (including the funder) and it includes reference to the data set 'handle'.

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Appendix 1 Qualitative interview topic guides

COBRA Qualitative Interview Topic Guide

1. General experiences of treatment

You recently received a course of CBT/BA as part of the COBRA trial. Please tell me about your experiences of receiving treatment.

Probe areas:

What it felt like receiving treatment
Anything in particular that they liked or found helpful
Anything they didn't like or found less helpful

2. Barriers to treatment

We are interested in reasons why people might decide to attend some or all of their therapy sessions, including completing some exercises and maybe not others. Please could you tell me about your reasons for deciding to continue with or stop therapy?

Probe areas:

Personal contextual factors
Specific therapy factors
Therapeutic relationship factors
Stages or exercises causing difficulty?
Anything (else) that could have been done to overcome these difficulties

3. Cognitive change strategies

We are interested in your views on the role of therapy in changing your beliefs or the way you think, and any impact this may have had on your mood. Did the therapy have any effect on your beliefs or the way you think?

Probe areas:

Underlying beliefs
Style of thinking
Influence of the changes in the way they think on mood/depression

4. Behavioural change strategies

We are interested in your views on the role of therapy in changing your behaviour, and any impact this may have had on your mood. Did the therapy have any effect on your behaviour?

Probe areas:

Changes in specific behaviour, e.g. avoidance, rumination
Recognising triggers and changing behaviour in response to them
Influence of behavioural changes on mood/depression

5. Most important part of therapy

What was the most important aspect of your therapy for you?

Probe areas:

Therapeutic relationship
Exercises/homework tasks

6. Broader impact of treatment

Please tell us about the impact the treatment had on you generally or in other aspects of your life.

Probe areas:

Thoughts and opinions on depression
The way they feel about themselves
The role of psychological therapies in the treatment of depression
Impact of treatment on any other areas of life

COBRA Therapist Qualitative Interview Topic Guide

Introduction

Experiences of delivering the treatment

Please tell me about your experience of delivering the COBRA therapy.

- What did you think of the COBRA therapy?

Probe: how acceptable?

- Tell me more about …

Therapeutic Strategies

The COBRA protocol contains certain therapeutic strategies and techniques.

- Which elements of the therapy did you use most?
- Why?

Probe: are there any other elements you used frequently or particularly liked?

- Were there any elements you didn't like?

Broader impact of treatment

Did you notice an impact, of the treatment, on patient's lives?

- Were there any particular things you noticed that changed regarding their cognitions or behaviours?

Probe: can you link that to a specific therapeutic strategy?

- Were there any particular things you noticed that changed for patients generally (anything you don't think is covered by cognitions or behaviours)?

Probe: can you link that to a specific therapeutic strategy?

- Did you notice a change in the patients' health and well-being?

Probe: can you link that to a specific therapeutic strategy?

People who stayed in therapy but didn't improve

Some people responded better to therapy than others. Why do you think that might be?

- Were there any characteristics of those people that affected their response to therapy?
- Were there any characteristics of the therapy that affected their response to therapy?
- Was there any part of the COBRA therapy that affected the therapeutic relationship?

Added after therapist 5:

Was there anything different about COBRA patients compared to the patients you usually treat?

Summarise

Thank you I will now summarise your answers…

Is there anything you would like to add to that summary something you may have just thought of?

Therapist's personal experience

The final part of the interview is to ask about your personal experience of working on the COBRA trial?

- Did the training help you?
- Do you do anything differently now?
- Do you have any suggestions for future trials?

Appendix 2 Individual participant Patient Health Questionnaire-9, Behavioural Activation for Depression Scale, Dysfunctional Attitudes Scale, Ruminative Response Scale and Snaith–Hamilton Pleasure Scale scores

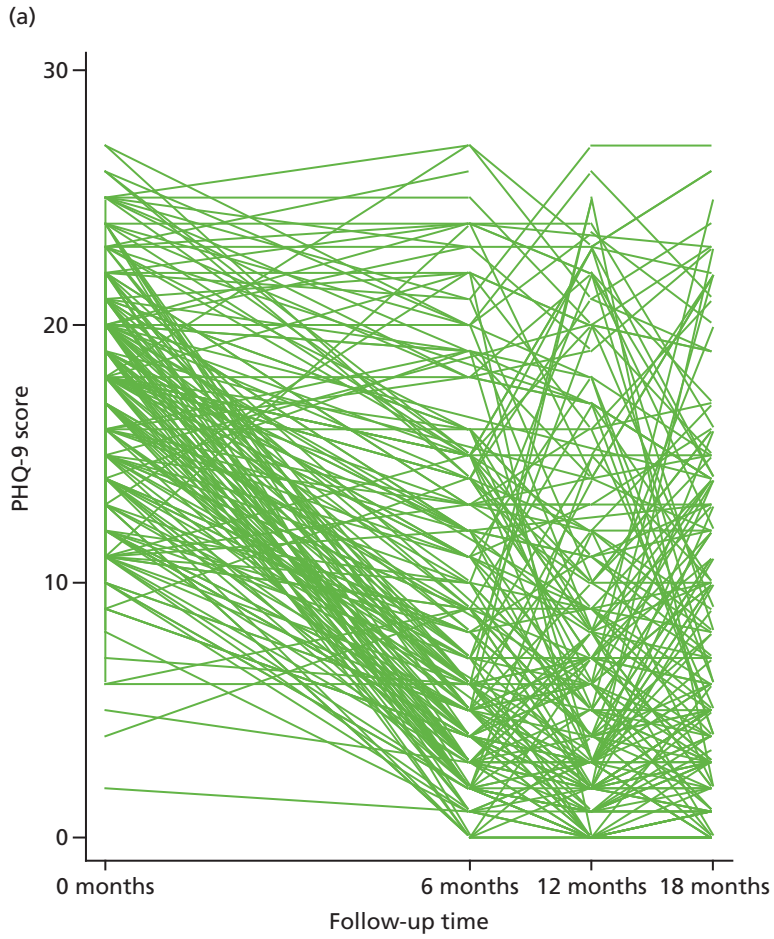


FIGURE 18 Individual participant PHQ-9 scores at baseline (0 months) and at 6, 12 and 18 months' follow-up for each treatment group for the mediation population. (a) CBT and (b) BA. (*continued*)

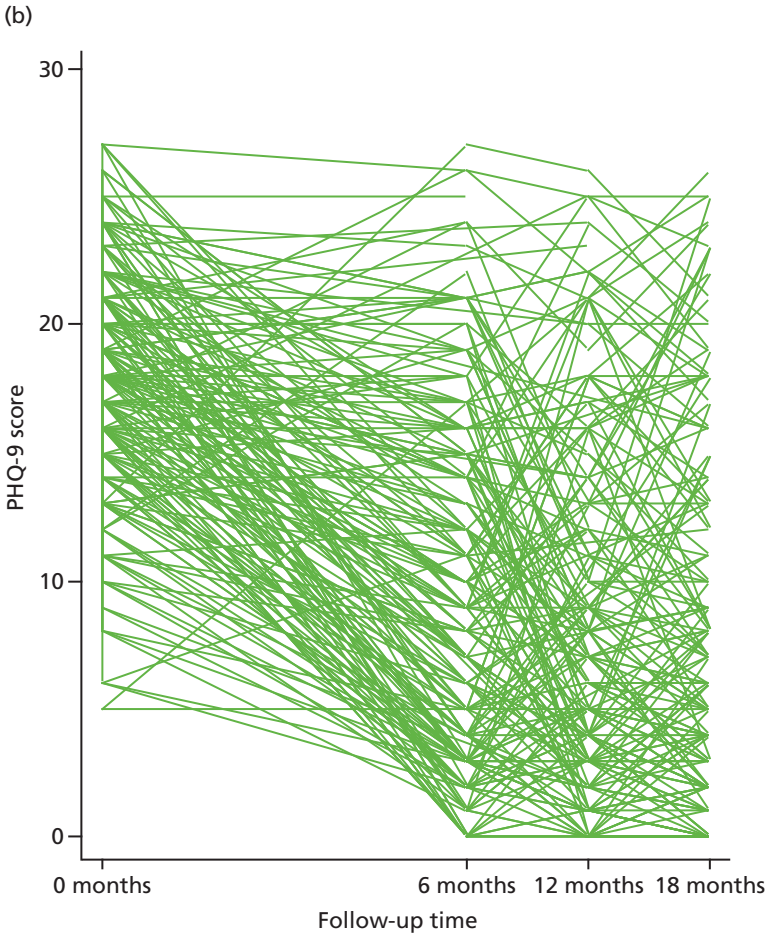


FIGURE 18 Individual participant PHQ-9 scores at baseline (0 months) and at 6, 12 and 18 months' follow-up for each treatment group for the mediation population. (a) CBT and (b) BA.

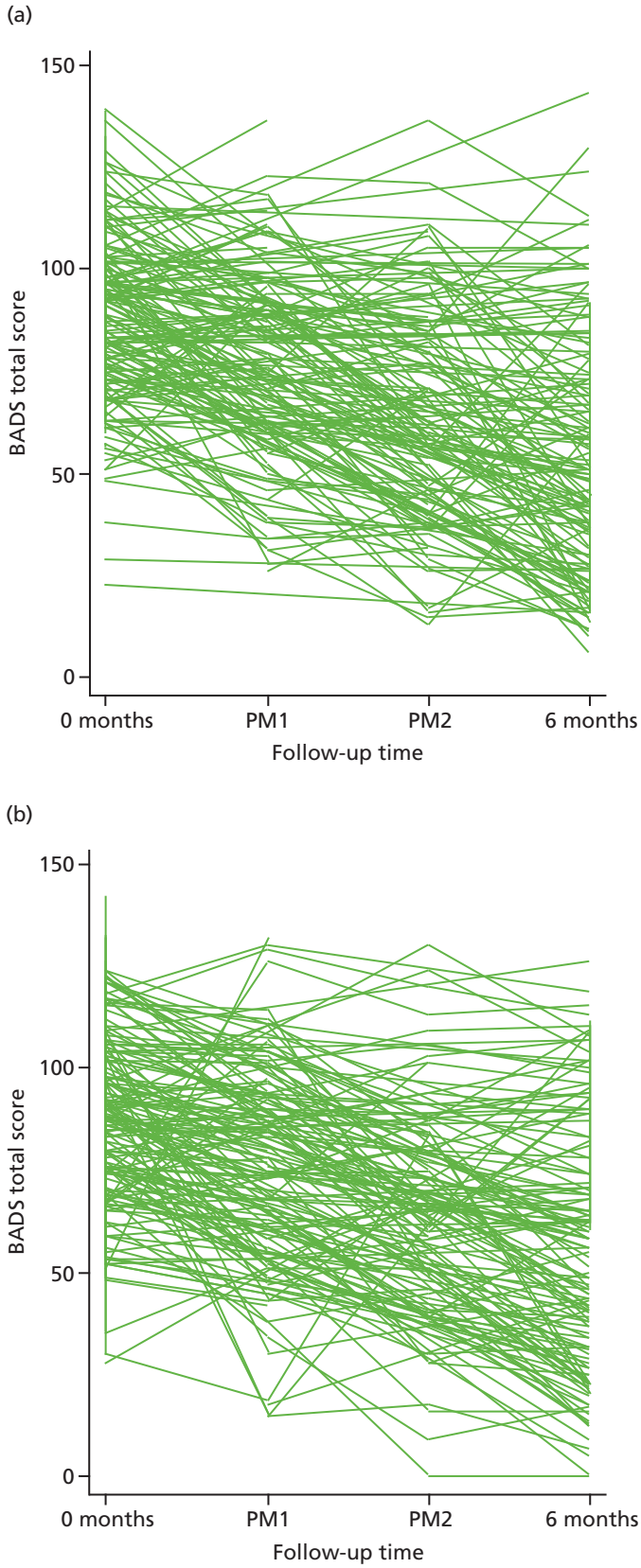


FIGURE 19 Individual participant BADS total scores at baseline, PM1, PM2 and 6 months' follow-up for each treatment group for the mediation population. (a) CBT and (b) BA.

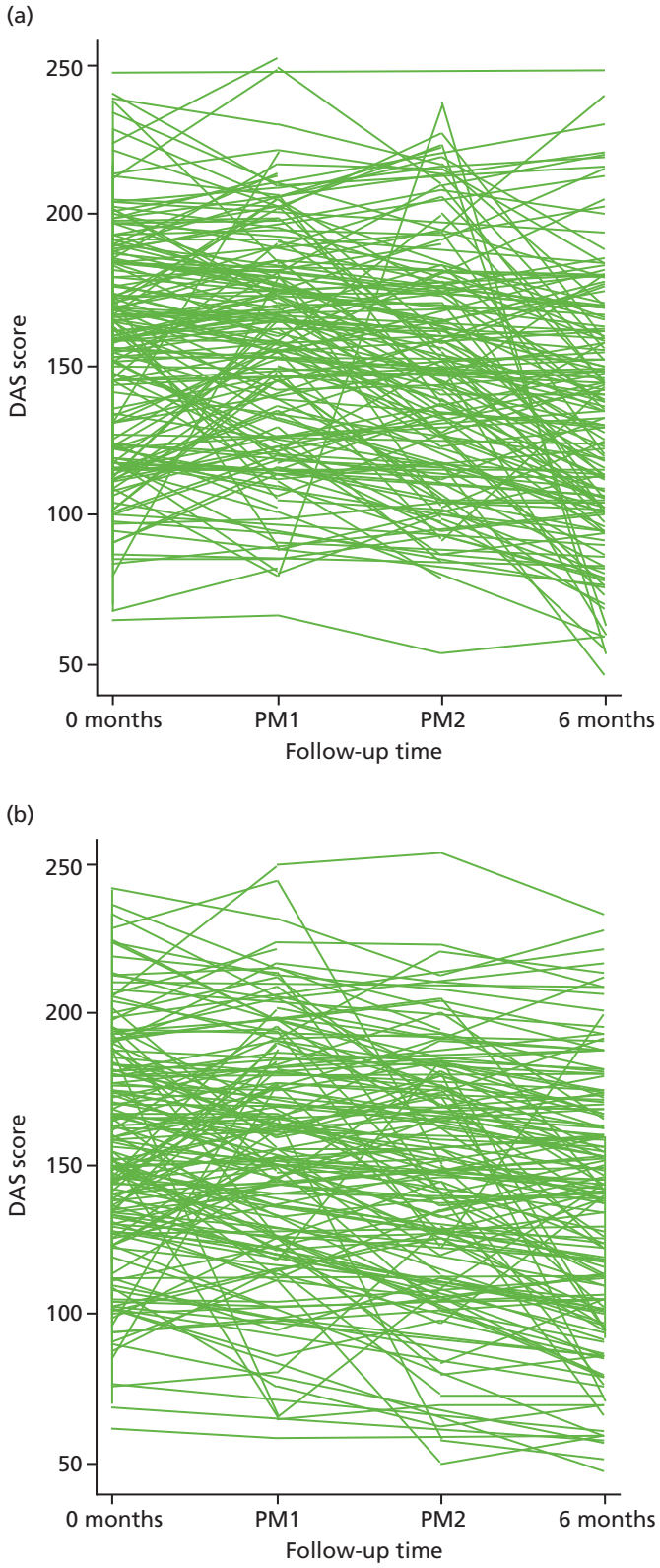


FIGURE 20 Individual participant DAS scores at baseline, PM1, PM2 and 6 months' follow-up for each treatment group for the mediation population. (a) CBT and (b) BA.

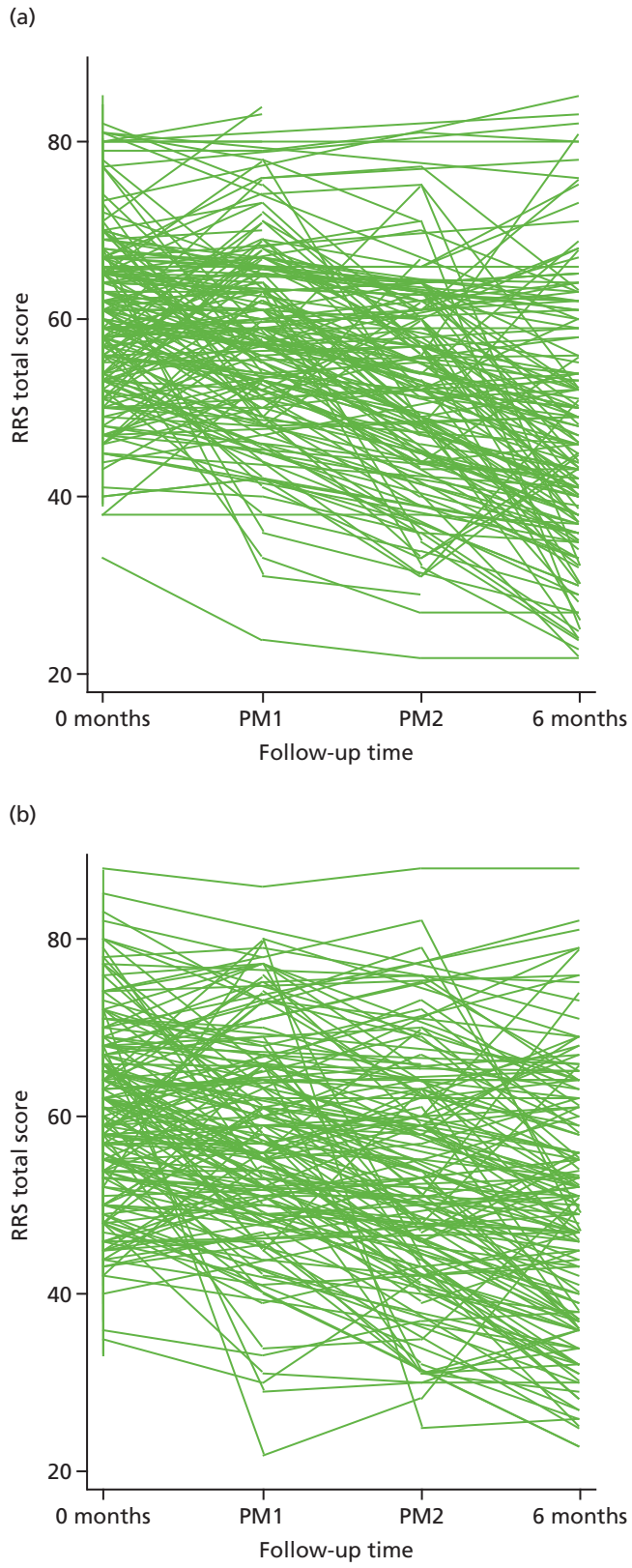


FIGURE 21 Individual participant RRS total scores at baseline, PM1, PM2 and 6 months' follow-up for each treatment group for the mediation population. (a) CBT and (b) BA.

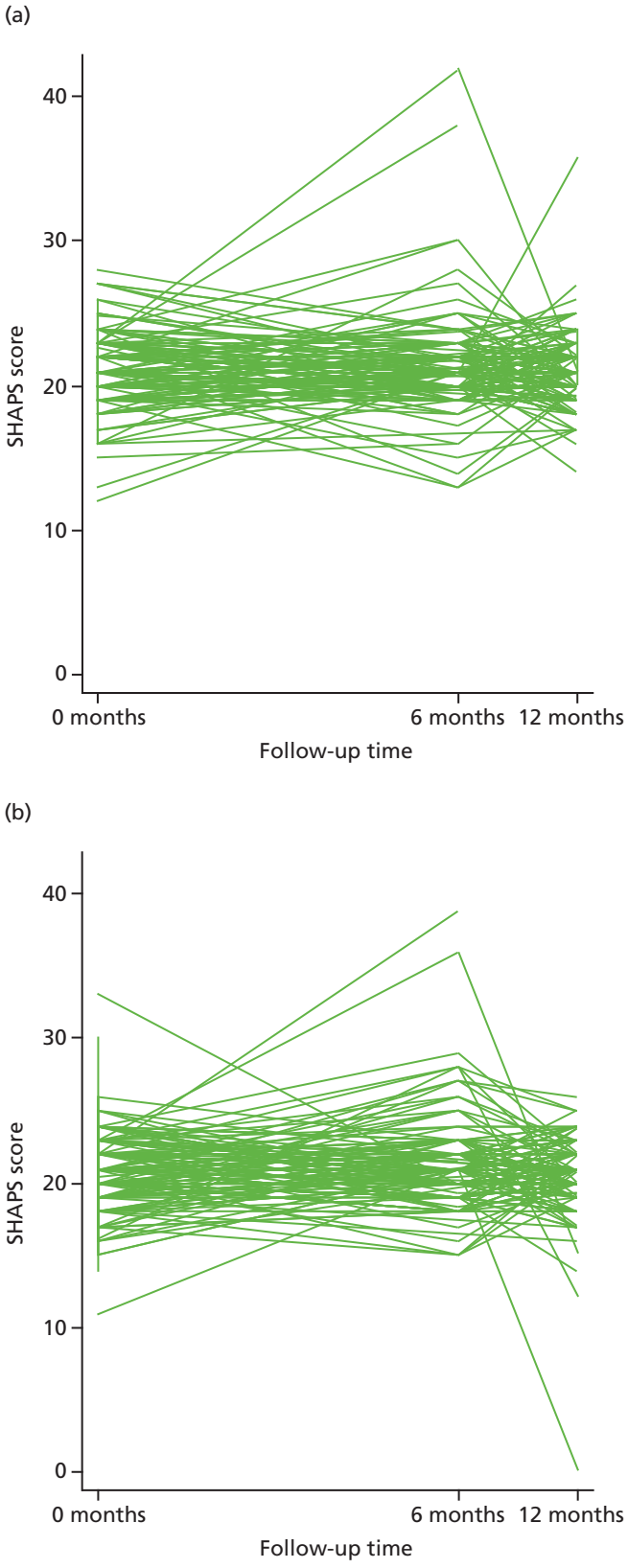


FIGURE 22 Individual participant SHAPS scores at baseline, 6 and 12 months' follow-up for each treatment group for the mediation population. (a) CBT and (b) BA.

Appendix 3 Ethics documents

Dear Patient

COBRA (**C**ost and **O**utcome of **B**ehaviou**R**al **A**ctivation):
A Randomised Controlled Trial of Behavioural Activation versus Cognitive Behavioural Therapy

At this surgery we have decided to take part in a research study being co-ordinated at SITE DETAILS which may be of interest to you. A new trial is taking place for depression comparing two psychological treatments for depression – Behavioural Activation and Cognitive Behavioural Therapy, both explained in the leaflet that comes with this letter. Please take the time to read this and consider if participating in this research would be right for you.

As stated in the information sheet, if you are interested in participating in the study please complete the "Permission for Researcher to Contact" form and send it freepost to the address given. If you have any questions, or are interested in finding out more about the study please ring the research team on the number listed.

In the next week or so you may receive a call from the surgery to check that you have received this letter and to ask if you are interested. To help the surgery please let the practice know if your telephone number has changed.

If you are certain that you do **NOT** want to take part in the research you may return the slip at the bottom of this letter to the surgery and you will not be contacted again.

Thank you for taking the time to read this letter.

Yours sincerely

Surgery GP's name

I DO NOT want to take part in this study and DO NOT want a follow-up call

Name:

Signature:

Please return to GP SURGERY ADMINISTRATOR NAME, at
SURGERY NAME
(COBRA: (**C**ost and **O**utcome of **B**ehaviou**R**al **A**ctivation)

Participant Summary Information Leaflet
COBRA (Cost and Outcome of BehaviouRal Activation):
A Randomised Controlled Trial of Behavioural Activation (BA) versus Cognitive Behaviour Therapy (CBT)

Introduction:
We are carrying out a trial that looks at two types of psychological therapy used in the treatment of depression. We are writing to you because your GP surgery has agreed to help us with this by sending information to you after you visited your GP reporting symptoms that are experienced by many people with depression.

This letter asks you to consider taking part in the research study and for your permission for the researcher to contact you.

What is the treatment that is being tested?
This study is investigating the effects of two psychological therapies for depression. We are interested in whether a relatively simple treatment called 'Behavioural Activation' (BA) is as effective as 'Cognitive Behavioural Therapy' (CBT), which is widely used in the UK. Although both treatments are known to be helpful for people with depression we need to test to see if BA can be used instead of CBT for some people. We will also be comparing how much each treatment costs.

What will happen to me if I take part?
We are asking people from a number of different GP surgeries in this area if they would like to take part. If you decide you would like to do this, a researcher will interview you to see if you are eligible for the study and to explain it in more detail. If you are eligible and agree to take part you will receive one of the treatments. Both treatments involve a maximum of 20 appointments with a trained therapist over a four month period with possibly four more booster sessions later. Once you have been allocated to one of the treatments you will also be seen again for follow-up appointments with a researcher at six months, 12 months and finally at 18 months to complete a number of questionnaires.

This study is a randomised controlled trial which means that once you have been interviewed by a researcher and have decided you would like to take part, the decision about which treatment you receive is made totally by chance. Therefore, half of our participants will be treated by Behavioural Activation and half by Cognitive Behaviour Therapy. What we then do is compare the progress and experiences of patients who received each of the two treatments.

Will my taking part in this study be kept confidential?
All information collected about you during the course of the research will be kept strictly confidential.

How do I find out more?
This is a very short summary about the study, if you would like to find out more you can return the 'Permission for Researcher to Contact' form at the end of this summary, or call the COBRA trial team on local site number. Someone working on the study will then contact you with more information about this study and arrange a time to meet you to answer any questions that you may have.

Thank you for reading this and for considering taking part in this study

'Permission for Researcher to Contact' Form
Study Title: COBRA (Cost and Outcome of BehaviouRal Activation):
A Randomised Controlled Trial of Behavioural Activation versus Cognitive Behaviour Therapy

Patient's GP Surgery name:

I confirm that I have read and understand the summary sheet for the above study and I am happy for a researcher to contact me to discuss whether or not I would like to take part.
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

Name.....
(Please print name)

Address.....

.....

.....

Signature.....

Telephone contact details:

Day.....

Evening.....

Mobile.....

Email address.....

Return in enclosed pre-paid envelope to:

Local Site Details

Telephone No:

Participant Information Sheet

COBRA (Cost and Outcome of BehaviouRal Activation): A Randomised Controlled Trial of Behavioural Activation versus Cognitive Behavioural Therapy

You are being invited to take part in a research study. Before you decide whether you want to take part or not it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Depression causes misery to many people and is a major health problem in the UK. Although drug treatments are effective, talking therapy (psychological) treatments are a very popular alternative. We are interested in whether a treatment called 'Behavioural Activation' (BA) is as effective as 'Cognitive Behavioural Therapy' (CBT), which is widely used in the UK. Although both treatments are known to be helpful for people with depression, we need to compare the progress and experiences of people who receive each of the two treatments; we will also be comparing how much each treatment costs. By comparing the *cost* and the *outcome* of the therapies we hope to find out which one of the treatments will be most useful for the treatment of depression.

Why have I been invited?

Your GP surgery is taking part in this trial and you have recently visited your GP reporting symptoms that are experienced by many people with depression. The letter from your GP asks you to consider taking part in this research study because after your recent visit s/he feels that you may have some of the depression symptoms we are treating in this study. This information sheet is for you to keep, if you decide to take part one of our research team will go through the information sheet with you and answer any questions you have. You will also be asked some questions by the researcher to see if you are eligible to be included for the treatments being tested. However, if you are already receiving one of the treatments then you would not be eligible. Although you would need to be excluded from taking part in this specific study, you will continue with the treatment you are already receiving.

Do I have to take part?

No. It is entirely up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. You will still be still free to withdraw at any time and without giving a reason. A decision to withdraw or not to take part will not affect the care you receive in any way.

What is the treatment that is being tested?

We are testing two treatments - Behavioural Activation (BA) and Cognitive Behavioural Therapy (CBT) which are two different types of treatment, talking therapy (psychological therapy), recommended by the UK National Institute for Health and Clinical Excellence

(NICE) for the treatment of depression. NICE has recommended that further research is needed to directly compare the effects of the treatments and the costs of BA and CBT.

Behavioural Activation (BA) Is based on the idea that behaviours such as inactivity and ruminating (pondering) on certain thoughts can be key factors in maintaining depression. The therapist aims to help you to combat these behaviours. The treatment involves a planned programme of arranging increased contact with positive activities and reducing people's avoidance of important situations, other people and activities.
Cognitive Behavioural Therapy (CBT). Is based on the idea that certain ways of thinking can trigger, or fuel, certain mental health problems such as depression. The therapist helps you to understand your thought patterns. In particular, to identify any harmful or unhelpful ideas or thoughts which you have that can make you depressed. The aim is then to change your ways of thinking to avoid these ideas and to help your thought patterns to be more realistic and helpful, to achieve changes in the way that you think, feel and behave.

What will happen to me if I take part?

If you decide you might like to take part, a researcher will interview you and ask some questions to see if you are eligible to take part in the study and to explain it in more detail, but only after you have agreed to be contacted by us and we have allowed you time to think about whether you want to take part or not. We will arrange to meet with you at (*site details)* over the phone. If you are eligible and agree to take part you will receive one of the treatments. However, if after you have been interviewed by the researcher and answered some questions it is found that you are not eligible to take part, we are really sorry if it causes you disappointment and thank you for your interest and time that you have given. If you are not eligible to take part we would refer you back to your GP to continue treatment in the way s/he feels is appropriate.

If you are eligible to take part we need to explain that this study is a randomised controlled trial which means that once you have been interviewed by a researcher and have decided you would like to take part, the decision about which treatment you receive is made totally by chance. In this trial half of our participants will be treated by Behavioural Activation and half by Cognitive Behaviour Therapy. We will allocate you to either BA or CBT by assigning you a personal identification number, known only to the research team, which will be entered into a secure computer system that picks the numbers at random and allocates them to one of the treatments at random.

Whichever treatment you are allocated to, you will receive a maximum of 20 sessions of one-hour in duration with a therapist, once per week, spread over 16 weeks, with the option of four additional booster sessions. You will receive face-to-face sessions, with the option of the session being conducted up to twice weekly over the first two months and then weekly thereafter.

Once you have been allocated to one of the treatments and received the sessions over the 16-week period, you will be seen again for follow-up appointments with a researcher at six months, 12 months and finally at 18 months to complete a number of questionnaires. Your involvement in the study will only be for eighteen months as described above although the research study will last for four years.

What information do you need from me?

If you agree to take part in the research the first thing we will want to do is to find out about you. We will need to ask about your current and past mental health as well as your life more generally. We will ask you some questions about how you have been feeling recently and there will be a few questionnaires that we would like you to fill out. You will also be able to ask any questions you may have about the study. This meeting will take about 90 minutes.

We expect that the follow-up appointments described above will take no more than 45 minutes. We will collect some questionnaires from you at these follow-ups. We are also interested in finding out what it was like to be part of this study and will be giving a small number of people the opportunity to describe their experiences of the treatment. To do this, we will ask some people selected at random to attend a longer interview of about 60 minutes after they have completed the treatment and we would like to audio or video record this interview. There is a separate part to the consent form to allow for this and you do not have to agree to this part of the interview and recording if you do not want to. It will not affect the standard of care you receive if you choose not to. If you agree, the recordings will be given a code and securely stored for a maximum of 20 years before being destroyed. We will also make typed copies of the recorded conversations. We will ensure all information in these copies is anonymous by removing all named references to you or your family and friends to protect your confidentiality.

We want to make sure that all participants are offered the best service possible, so in a bid to maintain quality we would like to audio or video record some of the sessions with the therapist that delivers your therapy. This is so that we can check the quality of the treatment that is given by the therapist. Recordings will be reviewed by experts in the UK and the US. The recordings will be given a code and securely stored for a maximum of 20 years before being destroyed and the same process will be followed as described above to protect your confidentiality. However, if you would rather the sessions were not recorded, you can refuse. This will not affect your care at all and you can still take part in the study.

Will I have to do anything differently?

No, there are no restrictions in your lifestyle from taking part in this research. You should continue to follow the advice of your GP.

Are there any side effects, disadvantages and risks of taking part?

We are not aware of any side effects, disadvantages or risks to you of taking part in this research.

What are the possible benefits of taking part?

Many people find that BA or CBT are helpful as both have been shown to have a positive effect for some people with depression. We hope that you will find the treatment you are given will help you. However, we cannot guarantee that you will benefit from the treatments. The information we get from this study may help us to treat future patients with depression better.

What happens when the research study stops?

Throughout the study and afterwards, your GP will continue to treat you as s/he feels is best for you and with your agreement.

What if something goes wrong or I have a complaint?

We do not expect any harm coming to you from being in this study. However, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you through the Patient Advice and Liaison Service (PALS) *(insert local contact here).*

Will my taking part in this study be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential. Any information about you that is collected from the questionnaires or interviews will have your name and address removed so that you cannot be recognised from it. As your GP is involved in your treatment, s/he will be informed of your progress as part of the research study, with your permission. Should your condition worsen to a point where it is felt by either a researcher, or the research assistant, that you may be a danger to yourself or others, your GP will be informed of this; with or without your permission. However, this is the only time we would ever break confidentially.

What will happen to the results of the research study?

We will publish the results of this research study widely. As well as producing a research report and writing articles for health professionals to read, you will be given a summary of the findings on request at the end of the trial in 2016. To request the study summary and articles please contact Professor David Richards, whose details are at the end of this information leaflet. The patient organisation Depression Alliance, are collaborating with the research team and will be informed of the results of the trial. You will not be personally identified in any publications from this trial.

Who is organising and funding the research?

The National Institute for Health Research Health Technology Assessment Programme has funded this research study, which is supported by the Department of Health. It is not a commercially funded industry trial; this means that the GP that invited you to express your interest and the research team will not receive any extra money for conducting this study. The study is sponsored by the University of Exeter.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights well-being and dignity. The study has been reviewed and given a favourable opinion by the NRES Committee South West – Exeter.

Further Information – Next Steps

Please look at the 'Participant Flow Chart' that provides the assessment and treatment process in a clear way which we hope you find helpful. An appointment will be arranged and at a time to suit you, for you to come and see (*site details)* and during this meeting you will have the chance to ask any questions you have. If you then want to take part in the study we will ask you to sign a form to say so and then get you to fill out some questionnaires about yourself.

If you need further information to help you decide, please contact Professor David Richards at the address below.

Thank you for reading this and for considering taking part in this study.

Contact for Further Information

If you need further information about this study please contact:

David Richards
Professor of Mental Health Services Research
XXXX

COBRA

COBRA (Cost and Outcome of BehaviouRal Activation) – A Randomised Controlled Trial of Behavioural Activation versus Cognitive Behaviour Therapy

CONSENT FORM

Please see that the consent form is in two parts, you do not have to sign both parts:

Part 1 on Page 1:
This is the main consent for your general participation in the study and if you agree to taking part.

Part 2 on Page 2 is optional; you can choose if you wish to take part.
This is about whether you would agree to being audio/video recorded and being interviewed about your experiences of taking part in the study. It also includes a similar section about data collection.

PART 1: MAIN STUDY CONSENT FORM

Site Details:

	Please initial box
1. I confirm that I have read and understand the information sheet dated 21st May 2012 (Version 4.0) for the above study and have had the opportunity to ask questions.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. I agree to my GP being informed of my participation in this study and updated with information from this study relevant to my medical care.	
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in the research. I give permission for these individuals to have access to my records.	
5. I understand that data already collected as part of the research study can be retained for up to 20 years, even if I decide to withdraw from the study and that it will only be used for this study.	
6. I agree to take part in the above study.	

When you have initialled the boxes above, please complete below including the date yourself.

Name of Participant *(BLOCK CAPITALS)* **Date** **Signature**

I have explained the study to the above patient and he/she has indicated his/her willingness to take part in the study.

Name of Researcher *(BLOCK CAPITALS)* **Date** **Signature**

COBRA (Cost and Outcome of BehaviouRal Activation) – A Randomised Controlled Trial of Behavioural Activation versus Cognitive Behaviour Therapy

PART 2: OPTIONAL CONSENT FORM

Part 2: This section is optional; you can choose if you wish to take part or not and it will not affect your participation in the main part of the study.
This consent form is about whether you would agree to:

- *Being audio/video recorded?*
- *Being interviewed about your experiences of taking part in the study?*
- *The data from one or both of the above in the optional consent being retained?*
- *Non-identifiable data being shared for the purposes of health research only*

Please only initial the boxes that you wish to consent to, thank you.

Site Details

	Please only initial the boxes that apply
1. I am willing to have some of my sessions with the health worker audio or video tape recorded and reviewed by experts in the UK and the US for research purposes only.	
2. I am willing to be interviewed about my experiences of taking part in the study and for this interview to be audio or video recorded for research purposes only.	
3. I agree to the data collected for this additional part of the above study being retained for up to 20 years, even if I decide to withdraw from the study and that it will only be used for this study.	
4. I agree to my data from this study being shared with other health researchers after my personal identifying information has been removed. I understand that it will only be used towards improving health outcomes by assessing the types of treatment that I have agreed to participate in for the main study.	
5. I agree to this additional part of the above study and consent **only** for the sections where I have clearly initialled in the boxes.	

Name of Participant *(BLOCK CAPITALS)* **Date** **Signature**

I have explained the additional part of study to the above patient and he/she has indicated which parts apply.

Name of Researcher *(BLOCK CAPITALS)* **Date** **Signature**

LOCAL SITE ADDRESS

Participant Name
Address1
Address2
Address3
Postcode

Date

PRIVATE & CONFIDENTIAL

Dear Participant Name,

Thank you for your ongoing participation in the COBRA trial, we have learnt a lot from your experiences so far and really value you sharing these with us. When you first consented into the trial you agreed to be contacted about an additional interview to ask you about your experiences of taking part in the trial. We are carrying out these interviews at the moment and would be very keen to speak to you.

The interview is about your general experiences of the treatment and would be carried out over the telephone. Because the interview will include questions about the particular treatment you received, it would be carried out by a researcher from Exeter/Durham/York University so that your usual researchers in Exeter/Durham/York do not find out which therapy you had.

We will be phoning you soon to see if you would like to take part in this extra interview. Please note that because this phone call will be from Exeter/Durham/York University, you may not recognise the number. If you would like to speak to us before then, either to say that you would or would not like to take part, or for further information, you can contact me on PHONE or EMAIL, or you can contact your usual research team in Exeter/Durham/York. If your contact details have changed recently, please also let us know so that we can get in touch.

I look forward to speaking to you soon.

Yours sincerely,

Researcher Name
COBRA Researcher
Exeter/Durham/York University

Local Site Address and contact info

<Insert name and address of GP>

<Insert current Date>

Dear <Name of Doctor>,

Re: <Name of Patient>, <DOB>

As you are aware, <Name of Patient> was invited to take part in the COBRA trial comparing Behavioural Activation with Cognitive Behavioural Therapy for the treatment of depression. As part of the trial a researcher from the COBRA team interviewed <Name of Patient> to assess his/her suitability for the trial.

During this interview <Name of Patient> was found to be eligible for the COBRA trial. He/she will be randomised to receive either Behavioural Activation or Cognitive Behavioural Therapy from a COBRA therapist. However, clinical management of all patients in the COBRA trial remains the responsibility of their GP.

Please find enclosed a copy of the Participant Consent Form for the COBRA trial, signed by <Name of Patient>, for your information.

Yours sincerely,

<Insert Name of Researcher>
COBRA Researcher

Enclosed: Participant Consent Form

Local Site Address and contact info:

<Insert name and address of GP>

<Insert current Date>

Dear <Name of Doctor>,

Re: <Name of Patient>, <DOB>

As you are aware, <Name of Patient> was invited to take part in the COBRA trial comparing Behavioural Activation with Cognitive Behavioural Therapy for the treatment of depression. As part of the trial a researcher from the COBRA team interviewed <Name of Patient> to assess his/her suitability for the trial.

During this interview <Name of Patient> was found to be ineligible for the COBRA trial and will therefore not be receiving treatment from a COBRA therapist.

Yours sincerely,

<Insert Name of Researcher>
COBRA Researcher

Appendix 4 Baseline case report form

Cost and Outcome of BehaviouRal Activation:

A Randomised Controlled Trial of Behavioural Activation versus Cognitive Behaviour Therapy for Depression

BASELINE CASE REPORT FORM

[redacted]

Recruitment Number: ___ ___ ___ ___ ___ ___

Date of Birth: __ __ / __ __ / __ __ __ __ **Gender:** Male ☐ Female ☐

Consent

Has the participant given their consent?	Yes ☐ No ☐
Date of consent:	__ __ / __ __ / __ __ __ __

Exclusion Criteria

1. Is the participant 18 or over?	Yes ☐ No ☐
2. Is the participant currently receiving psychological treatment?	Yes ☐ No ☐

2.i) Has the participant been referred for treatment from any mental health specialist?	Yes ☐ No ☐
If Yes, which service were they referred to? _____	
2.ii) Is the participant currently awaiting treatment from IAPT services?	Yes ☐ No ☐
If 'Yes' to either 2.i) or 2.ii): Ensure participant is aware that they cannot take part in COBRA whilst receiving psychological treatment elsewhere. Does participant wish to take part in COBRA?	Yes ☐ No ☐

Exclusion Criteria: Mini-Cog

Administration

The test is administered as follows:

1. Instruct the participant to listen carefully to and remember the following three words, and then to repeat the words:

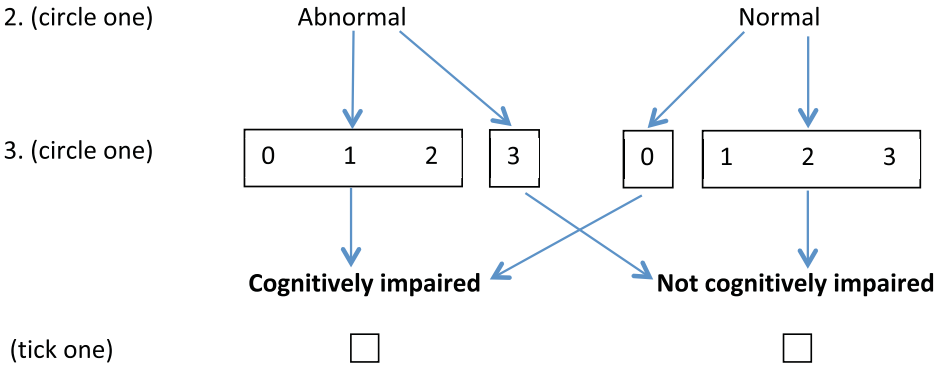
APPLE WATCH PENNY

2. Instruct the participant to draw the face of a clock (on page 4), and then ask them to draw the hands of the clock to represent the time "forty five minutes past ten o'clock".

3. Ask the participant to repeat the three previously stated words.

Scoring

Please circle the scores given for each question below and then tick if the participant is or is not cognitively impaired.



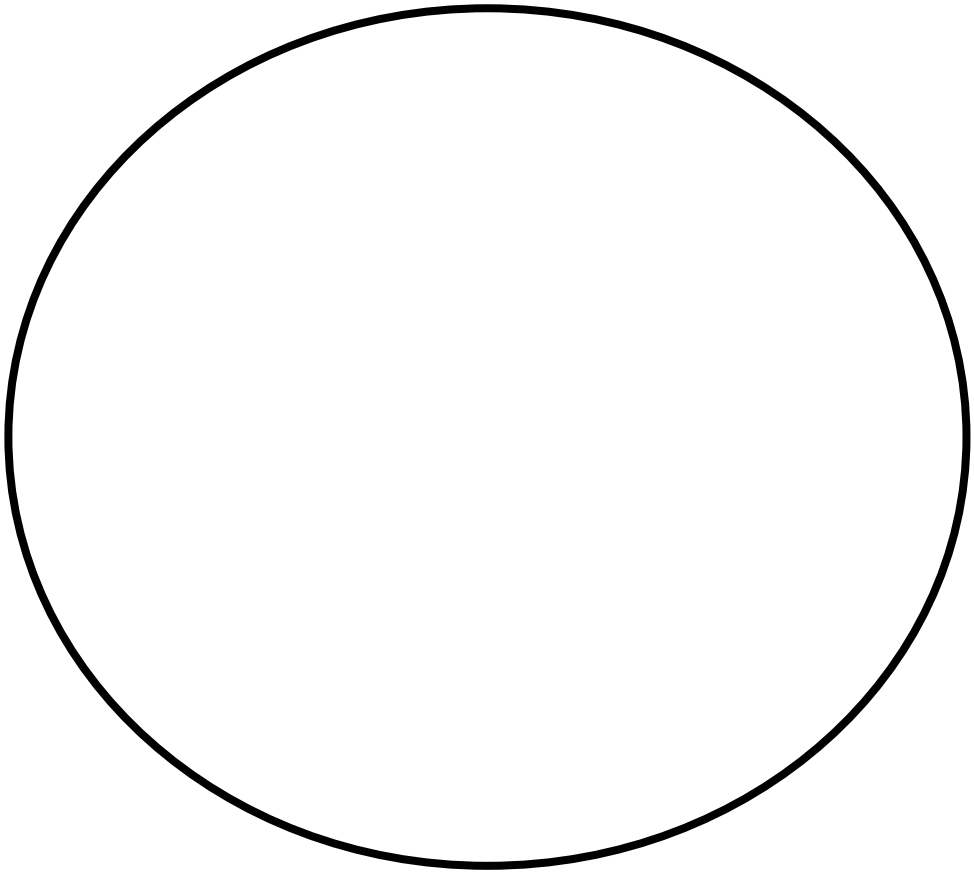
Additional Scoring Information

- Q2 Clock Drawing Test (CDT) – score the CDT 'Normal' or 'Abnormal'. The CDT is considered normal if all numbers are present in the correct sequence and position, and the hands readably display the requested time.
- Q3 Word recall – give 1 point for each recalled word.

Q3 = 0 + any CDT	Cognitively impaired
Q3 = 1 or 2 + CDT Abnormal	Cognitively impaired
Q3 = 1 or 2 + CDT Normal	Not cognitively impaired
Q3 = 3 + any CDT	Not cognitively impaired

Instructions:

Inside the circle please draw the face of a clock. Then place the hands of the clock to represent the time "forty five minutes past ten o'clock".



Exclusion Criteria

Is participant excluded from study? Yes ☐ No ☐

If 'Yes', please specify reason for exclusion:

- Under 18 ☐
- Currently receiving psychological therapy ☐
- Intends to commence therapy ☐
- Cognitively impaired ☐
- Acute risk *(please complete at end of interview)* ☐

SCID
A. MOOD EPISODES

Details of this structured interview can be accessed at www.scid4.org/index.html.

PHQ-9

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use ☑ to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
Little interest or pleasure in doing things	☐ 0	☐ 1	☐ 2	☐ 3
Feeling down, depressed, or hopeless	☐ 0	☐ 1	☐ 2	☐ 3
Trouble falling or staying asleep, or sleeping too much	☐ 0	☐ 1	☐ 2	☐ 3
Feeling tired or having little energy	☐ 0	☐ 1	☐ 2	☐ 3
Poor appetite or overeating	☐ 0	☐ 1	☐ 2	☐ 3
Feeling bad about yourself — or that you are a failure or have let yourself or your family down	☐ 0	☐ 1	☐ 2	☐ 3
Trouble concentrating on things, such as reading the newspaper or watching television	☐ 0	☐ 1	☐ 2	☐ 3
Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	☐ 0	☐ 1	☐ 2	☐ 3
Thoughts that you would be better off dead or of hurting yourself in some way	☐ 0	☐ 1	☐ 2	☐ 3

(*For office coding: Total Score* _____ = Add columns ___ + ___ + ___)

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

From the Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME-MD PHQ). The PHQ was developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

GAD-7

(*For office coding: Total Score* _____ = Add columns ___ + ___ + ___)

Over the last 2 weeks, how often have you been bothered by the following problems? *(Use ☑ to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
Feeling nervous, anxious or on edge	☐ 0	☐ 1	☐ 2	☐ 3
Not being able to stop or control worrying	☐ 0	☐ 1	☐ 2	☐ 3
Worrying too much about different things	☐ 0	☐ 1	☐ 2	☐ 3
Trouble relaxing	☐ 0	☐ 1	☐ 2	☐ 3
Being so restless that it is hard to sit still	☐ 0	☐ 1	☐ 2	☐ 3
Becoming easily annoyed or irritable	☐ 0	☐ 1	☐ 2	☐ 3
Feeling afraid as if something awful might happen	☐ 0	☐ 1	☐ 2	☐ 3

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

EQ-5D

Details of this measure can be accessed at https://euroqol.org.

HEALTH STATUS QUESTIONNAIRE (SF-36v2)

Details of this measure can be accessed at https://campaign.optum.com/content/optum/en/optum-outcomes/what-we-do/health-surveys/sf-36v2-health-survey.html.

Demographics

Marital Status:		**Number of Children:**	
Single	☐	0	☐
Cohabiting (but not married)	☐	1	☐
Civil partnership	☐	2	☐
Married	☐	3	☐
Divorced / Separated	☐	4+	☐
Widowed	☐		
Ethnicity:		**Level of Education:**	
White: British	☐	No qualifications	☐
White: Irish	☐	GCSEs/O-Levels	☐
White: Other White	☐	AS/A-Levels	☐
Mixed: White and Black Caribbean	☐	NVQ or other vocational qualification	☐
Mixed: White and Black African	☐	Undergraduate degree	☐
Mixed: White and Asian	☐	Postgraduate degree	☐
Mixed: Other Mixed	☐	Doctoral degree	☐
Asian: Indian	☐	Professional degree (e.g. MD)	☐
Asian: Pakistani	☐		
Asian: Bangladeshi	☐		
Other Asian	☐		
Black Caribbean	☐		
Black African	☐		
Other Black	☐		
Chinese	☐		
Other	☐		
Prefer not to say	☐		

Previous Treatment and Preferences

Is the participant currently being prescribed anti-depressant medication? Yes ☐ No ☐

Has the participant received psychological therapy in the past? Yes ☐ No ☐

Number of courses of CBT: _____

Number of courses of BA: _____

Number of courses of other therapy: _____

Were the participant to have a choice of treatment, do they have a strong preference for either BA or CBT? Yes ☐ No ☐

Preference? BA ☐ CBT ☐

Cost and Outcome of Behavioural Activation (COBRA)

Adult Service Use Schedule

Instructions

This schedule should be completed in *interview* with the service user.

The schedule covers the respondent's use of all services, *excluding BAT and CBT*:

- At baseline, ask about use of services during the *six months* preceding the interview
  - At 6-month follow-up, ask about use of services *since the baseline interview*
  - At 12-month follow-up, ask about use of services *since the 6-month follow-up interview*
  - At 18-month follow-up, ask about use of services *since the 12-month follow-up interview*

If the respondent missed an earlier follow-up, this schedule can be used to cover the missing period(s) as well as the current interview period. Please note this clearly by ticking all relevant periods below.

Please tell the patient that you want to know about their use of all services *except* the trial interventions – Behavioural Activation or Cognitive Behaviour Therapy.

Use circles to select options from lists.

Numbers, zeros or missing data codes should be placed in every cell.

COBRA Trial ID	

Date of interview:	dd	mm	20 yy

Period(s) covered (tick all that apply)	
Baseline	
6-month	
12-month	
18-month	
If previous interviews missed, this schedule should cover the entire period from previous to current interview date. Please tick all periods that apply.	

Code missing data as follows:

555	*Not applicable*
666	*Research worker unable to evaluate*
999	*Not completed*

Section A: Hospital Services

A1 – Have you had a hospital admission *(if baseline)* **in the last six months /** *(if follow-up)* **since you were last interviewed approximately [X] months ago?**

1	Yes	Go to A2
0	No	Go to A3
666	*Research worker unable to evaluate*	Go to A3
999	*Not completed*	Go to A3

A2 – If yes, record details below

Hospital code	Speciality code	Details if hospital=other and/or speciality=other	Number of nights

A3 – Have you been to hospital for an outpatient/day patient appointment *(if baseline)* **in the last six months /** *(if follow-up)* **since you were last interviewed approximately [X] months ago?**

1	Yes	Go to A4
0	No	Go to A5
666	*Research worker unable to evaluate*	Go to A5
999	*Not completed*	Go to A5

A4 - If yes, record details below

Hospital code	Speciality code	Details if hospital=other and/or speciality=other	Number of appointments

A5 – Have you attended an accident and emergency (A&E) department *(if baseline)* **in the last six months /** *(if follow-up)* **since you were last interviewed approximately [X] months ago?**

1	Yes	Go to A6
0	No	Go to B1
666	*Research worker unable to evaluate*	Go to B1
999	*Not completed*	Go to B1

A6 - If yes, record details below

Hospital code	Details	Admitted	Ambulance	Number of contacts
		Yes/no	Yes/no	
		Yes/no	Yes/no	
		Yes/no	Yes/no	
		Yes/no	Yes/no	

Section B: Community-based health, social and complementary services

B - Which of the following community based professionals or services have you had contact with *(if baseline)* in the last six months / *(if follow-up)* since you were last interviewed approximately [X] months ago?

		Number of contacts	Average duration in minutes per contact
1	General practitioner – surgery		
2	General practitioner – home		
3	General practitioner – telephone		
4	Practice nurse (nurse in GP surgery)		
5	District nurse, health visitor, midwife		
6	Community psychiatric nurse in the community		
7	Psychiatrist in the community		
8	Occupational therapist in the community		
9	Art/drama/music therapy in the community		
10	Social worker		
11	Marriage counselling service e.g. Relate		
12	Advice service e.g. Citizen's Advice Bureau		
13	Helpline e.g. Samaritans, MIND		
14	Day centre/drop-in centre		
15	Chiropractor/osteopath		
16	Homeopathy		
17	Acupuncture		
18	Other – give details		
19	Other – give details		
20	Other – give details		

Section C: Psychotropic medication

C1 – Have you been prescribed any medication for mental health problems *(if baseline)* in the last six months / *(if follow-up)* since you were last interviewed approximately 6 months ago? Include e.g. medications for depression, anxiety, psychosis, and sleep problems.

1	Yes	Go to C2
0	No	Go to C8
666	*Research worker unable to evaluate*	Go to C8
999	*Not completed*	Go to C8

C2 – If yes, record details below

Name of the medication (use code)	Details if code='other'	Date Started	Dose *	Units (use code)	Frequency (use code)	Date Stopped	Continuing at interview?
e.g. 5		*01/04/2007*	*80*	*1*	*2*	*555 - NA*	*Yes*
							Yes/no
							Yes/no
							Yes/no

* For current medication ask for current dose; for medication no longer taken ask for final dose.

Section D: Employment and time off work

D1 – What is your current occupational status?

1	Full-time employment (30+ hours per week)	Go to D3	7	Voluntary worker	Go to D2
2	Part-time employment (<30 hours per week)	Go to D3	8	Unemployed & looking for work	Go to D2
3	Employed & currently unable to work	Go to D3	9	Unemployed & not looking for work (e.g. housewife)	Go to D2
4	Part-time employment & part-time student	Go to D3	10	Unemployed & unable to work for medical reasons	Go to D2
5	Full-time student	Go to D2	11	Medically retired	Go to D2
6	Part-time student	Go to D2	12	Retired	Go to D2
666	*Research worker unable to evaluate*	Go to D2			
999	*Not completed*	Go to D2			

D2 – Have you been in paid employment *(if baseline)* in the last six months / *(if follow-up)* since you were last interviewed approximately [X] months ago?

0	No	END
1	Yes	Go to D3
666	*Research worker unable to evaluate*	
999	*Not completed*	

D3 – What is your approximate gross pay per year (before tax) for your current or most recent employment?

1	Under £5,000	8	£35,001-£40,000
2	£5,001-£10,000	9	£40,001-£45,000
3	£10,001-£15,000	10	£45,001-£50,000
4	£15,001-£20,000	11	£50,001-£75,000
5	£20,001-£25,000	12	£75,001-£100,000
6	£25,001-£30,000	13	£100,001 +
7	£30,001-£35,000		
666	*Research worker unable to evaluate*		
999	*Not completed*		

D4 – How many DAYS have you been absent from work due to illness *(if baseline)* **in the last six months /** *(if follow-up)* **since you were last interviewed approximately [X] months ago?**

1	Days	Number of days
666	*Research worker unable to evaluate*	
999	*Not completed*	

D5 – How many HOURS does/did your employer expect you to work in a typical 7-day week for your current or most recent employment? If it varies, estimate the average. If more than 97, enter 97.

1	Hours	Number of hours
666	*Research worker unable to evaluate*	
999	*Not completed*	

D6 – Have you been in paid employment in the last four weeks?

0	No	END
1	Yes	Go to D7
666	*Research worker unable to evaluate*	
999	*Not completed*	

D7 – Please think about your work experiences over the past 4 weeks (28 days). In the past 4 weeks (28 days), how many days did you…

1	miss an entire work day because of problems with your physical or mental health? Please include only days missed for your own health.	Number of days
2	miss an entire work day for any other reason (including holiday)?	Number of days
3	miss part of a work day because of problems with your physical or mental health? Please include only days missed for your own health.	Number of days
4	miss part of a of a work day for any other reason (including holiday)?	Number of days
666	*Research worker unable to evaluate*	
999	*Not completed*	

D8 – About how many HOURS altogether did you work in the past 4 weeks (28 days)? See examples for calculating hours worked below

1	Hours	Number of hours
666	*Research worker unable to evaluate*	
999	*Not completed*	

D9 – On a scale from 0 to 10 where 0 is the worst job performance anyone could have at your job and 10 is the performance of a top worker, how would you rate the usual performance of most workers in a job similar to yours? Place a ✓ in the circle below the number that best describes this.

Worst performance … *Top performance*

0	1	2	3	4	5	6	7	8	9	10
○	○	○	○	○	○	○	○	○	○	○

D10 – Using the same 0-to-10 scale, how would you rate your usual job performance over the past year or two? Place a ✓ in the circle below the number that best describes this.

Worst performance … *Top performance*

0	1	2	3	4	5	6	7	8	9	10
○	○	○	○	○	○	○	○	○	○	○

D11 – Using the same 0-to-10 scale, how would you rate your overall job performance on the days you worked during the past 4 weeks (28 days)? Place a ✓ in the circle below the number that best describes this.

Worst performance … *Top performance*

0	1	2	3	4	5	6	7	8	9	10
○	○	○	○	○	○	○	○	○	○	○

Examples for Calculating Hours Worked in the Past 4 weeks
40 hours per week for 4 weeks = 160 hours
35 hours per week for 4 weeks = 140 hours
40 hours per week for 4 weeks with 2 8-hour days missed = 144 hours
40 hours per week for 4 weeks with 3 4-hour partial days missed = 148 hours
35 hours per week for 4 weeks with 2 8-hour days missed and 3 4-hour partial days missed = 112 hours
Employment and time off work section taken from the WHO Health Productivity Questionnaire (HPQ), questions B5-B11.

End of interview.

AD-SUS designed by Sarah Byford at the Institute of Psychiatry
For further information please contact:
Centre for the Economics of Mental Health
XXXX

Cost and Outcome of Behavioural Activation (COBRA)

Adult Service Use Schedule CODES

Code missing data as follows:

555	*Not applicable*
666	*Research worker unable to evaluate*
999	*Not completed*

Hospital speciality codes for sections A2 and A4

1	Mental health	22	Infectious Diseases
2	Asthma clinic	23	Maxillo-Facial Surgery
3	Audiological Medicine	24	Nephrology
4	Blood Transfusion	25	Neurology
5	Cardiac Surgery	26	Neurosurgery
6	Cardiology	27	Obstetrics
7	Clinical Haematology	28	Occupational Therapy
8	Colorectal Surgery	29	Oncology
9	Dental Medicine	30	Ophthalmology
10	Dermatology	31	Oral Surgery
11	Diabetic Medicine	32	Orthopaedics
12	Dietetics	33	Pain Management
13	Endocrinology	34	Physiotherapy
14	ENT	35	Plastic Surgery
15	Family Planning Clinic	36	Podiatry
16	Gastroenterology	37	Rheumatology
17	General Medicine	38	Sleep Studies
18	General Surgery	39	Speech therapy
19	Genito-Urinary Medicine	40	Thoracic Medicine/Surgery
20	Gynaecology	41	Urology
21	Hepatology	42	Other – please give details

Hospital codes for sections A2, A4 and A6

Hospital codes for sections A2, A4 and A6 contd.

	Devon		**Durham**
1	Bovey Tracey Hospital	19	Bensham Hospital
2	Budleigh Salterton Hospital	20	Bishop Auckland Hospital
3	Crediton Hospital	21	BMI Woodlands Hospital
4	Exmouth Hospital	22	Cherry Knowle Hospital
5	Heavitree Hospital	23	Chester Le Street Hospital
6	Honiton Hospital	24	Cobalt NHS Treatment Centre
7	Moretonhampstead Hospital	25	Darlington Memorial Hospital
8	Nuffield Health, Exeter Hospital	26	Dunston Hill Hospital
9	Ottery St Mary Hospital	27	Freeman Hospital
10	Paignton Hospital	28	Great North Children's Hospital
11	Royal Devon and Exeter Hospital	29	Hundens Lane Day Hospital
12	Seaton Hospital	30	North Tyneside General Hospital
13	Sidmouth Hospital	31	Northern centre for cancer
14	Tiverton and District Hospital	32	Nuffield Health, Newcastle-upon-Tyne
15	Torbay Hospital	33	Nuffield Health, Tees Hospital
16	Victoria Hospital	34	Palmer Community Hospital
17	Whipton Hospital	35	Peterlee Community Hospital
18	Other Devon (please specify)	36	Primrose Hill Hospital
		37	Priory Hospital Middleton St George
		38	Prudhoe Hospital Site
		39	Queen Elizabeth Hospital
		40	Ryhope General Hospital
		41	Sedgefield Community Hospital
		42	Shotley Bridge Hospital
		43	Sir G B Hunter Memorial Hospital
		44	South Tyneside District Hospital
		45	Spire Washington Hospital
		46	St Nicholas Hospital (Newcastle Upon Tyne)
		47	Sunderland Royal Hospital
		48	The Royal Victoria Infirmary
		49	Tyneside Surgical Services
		50	University Hospital of Durham
		51	University Hospital Of Hartlepool
		52	University Hospital Of North Durham
		53	University Hospital Of North Tees
		54	Weardale Hospital
		55	West Lane Hospital
		56	West Park Hospital
		57	Other Durham (please specify)

Hospital codes for section A2, A4 and A6 (contd)

	Leeds	77	The Mount Hospital, Leeds
58	Airedale General Hospital	78	Mount Vernon Hospital, Barnsley
59	Barnsley Hospital	79	Nuffield Health, Leeds Hospital
60	BMI The Duchy Hospital	80	Pinderfields Hospital
61	BMI The Huddersfield Hospital	81	Pontefract Hospital
62	Bradford Royal Infirmary	82	Seacroft Hospital
63	Calderdale Royal Hospital	83	Shipley Hospital
64	Castleford and Normanton District Hospital	84	Spire Elland Hospital
65	Chapel Allerton Hospital	85	Spire Leeds Hospital
66	Clayton Hospital	86	Spire Longlands Consulting Rooms
67	Dewsbury and District Hospital	87	Spire Methley Park Hospital
68	Eccleshill Community Hospital	88	St James's Hospital
69	Harrogate District Hospital	89	St Lukes Hospital
70	Huddersfield Medical Services HQ	90	St Mary's Hospital
71	Huddersfield Royal Infirmary	91	The New Selby War Memorial Hospital
72	Keresforth Centre	92	The Yorkshire Clinic
73	Lascelles Younger Disabled Unit	93	Westbourne Green Community Hospital
74	Leeds General Infirmary	94	Westwood Park Diagnostic Treatment Centre
75	Leeds Road Community Hospital	95	Wharfedale Hospital
76	Lynfield Mount Hospital	96	Other Leeds (please specify)
			Other
		97	Other unknown (please specify)

Medication codes for section C

Name

	Antidepressants		**Antipsychotics (cont'd)**
1	Agomelatine/valdoxan	41	Benperidol/Anquil
2	Amitriptyline/Triptafen	42	Chlorpromazine hydrochloride/Largactil
3	Amoxapine/Asendis	43	Clozapine/Clozaril/Denzapine/Zaponex
4	Citalopram/Cipramil	44	Flupentixol/Depixol/Fluanxol
5	Clomipramine	45	Haloperidol/Dozic/Haldol/Serenace
6	Dosulepin/Dothiepin/Prothiaden	46	Levomepromazine/Nozinan
7	Doxepin/Sinequan/Sinepin	47	Olanzapine/Zyprexa
8	Duloxetine/Cymbalta/Yentreve	48	Paliperidone/Invega
9	Escitalopram/Cipralex	49	Pericyazine
10	Fluoxetine/Prozac	50	Perphenazine/Fentazin
11	Flupentixol/Fluanxol/Depixol	51	Pimozide/Orap
12	Fluvoxamine/Faverin	52	Prochlorperazine
13	Imipramine/Tofranil/Triptafen	53	Promazine
14	Isocarboxazid	54	Qeutiapine/Seroquel
15	Lofepramine/Gamanil/Feprapax/Lomont	55	Resperidone/Risperdal
16	Maprotiline/Ludiomil	56	Sulpiride/Dolmatil/Sulpol
17	Mianserin	57	Trifluoperazine/Stelazine
18	Mirtazepine/Zispin	58	Zuclopenthixol acetate/Clopixol acuphase
19	Moclobemide/Manerix	59	Zuclopenthixol/Clopixol
20	Nortriptyline/Allegron/Motival	60	Other antipsychotic (please specify)
21	Paroxetine/Seroxat		**Sleeping tablets/medication for anxiety**
22	Phenelzine/Nardil	61	Alprazolam
23	Reboxetine/Edronax	62	Buspirone/Buspar
24	Sertraline/Lustral	63	Chloral hydrate/welldorm
25	Tranylcypromine	64	Chlorazepate/Tranxene
26	Trazodone/Molipaxin	65	Chlordiazepoxide
27	Trimipramine/Surmontil	66	Clomethiazole/Heminevrin
28	Tryptophan/optimax	67	Diazepam
29	Venlafaxine	68	Flurazepam/Dalmane
30	Venlafaxine XR	69	Loprazolam
31	Other antidepressant (please specify)	70	Lorazepam
	Mood stabilizers	71	Lormetazepam
32	Carbamazepine/Tegretol	72	Meprobamate
33	Lamotrigine/Lamictal	73	Nitrazepam
34	Lithium carbonate/Comcolit, Liskonum	74	Oxazepam
35	Lithium citrate/Li-Liquid, Priadel	75	Temazepam
36	Valproate/Depakote, Convulex	76	Triclofos sodium
37	*Other mood stabilizer (please specify)*	77	Zaleplon/Sonata
	Antipsychotics	78	Zolpidem/Stilnoct
38	Aripiprazole/Abilify	79	Zopiclone/Zimovane
39	Amisulpride/Solian	80	Other sleeping tablet/medication for anxiety (please specify)

Units

1	Milligrams (mg)	6	Inhalers
2	Microgram (mcg)	7	Bottles
3	Grams (g)	8	Packs
4	Millilitres (ml)	9	Other – give details
5	Tubs/tubes		

Frequency

1	Once daily	7	As needed, about three times a week
2	Twice daily	8	As needed, about twice a week
3	Three times daily	9	As needed, about once a week
4	Four times daily	10	As needed, about once a fortnight
5	Once weekly	11	As needed, about once a month
6	Once per fortnight	12	Other – give details

Behavioral Activation Scale

Please read each statement carefully and then circle the number which best describes how much the statement was true for you DURING THE PAST WEEK, INCLUDING TODAY.

0 = Not at all 1 2 = A little 3 4 = A lot 5 6 = Completely	0	1	2	3	4	5	6	For Scoring Purposes only				
								AC	AR	WS	SI	T
1. I stayed in bed for too long even though I had things to do.	O	O	O	O	O	O	O			_		R
2. There were certain things I needed to do that I didn't do.	O	O	O	O	O	O	O			_		R
3. I am content with the amount and types of things I did.	O	O	O	O	O	O	O	_				_
4. I engaged in a wide and diverse array of activities.	O	O	O	O	O	O	O	_				_
5. I made good decisions about what type of activities and/or situations I put myself in.	O	O	O	O	O	O	O	_				_
6. I was active, but did not accomplish any of my goals for the day.	O	O	O	O	O	O	O			_		R
7. I was an active person and accomplished the goals I set out to do.	O	O	O	O	O	O	O	_				_
8. Most of what I did was to escape from or avoid something unpleasant.	O	O	O	O	O	O	O		_			R
9. I did things to avoid feeling sadness or other painful emotions.	O	O	O	O	O	O	O		_			R
10. I tried not to think about certain things.	O	O	O	O	O	O	O		_			R
11. I did things even though they were hard because they fit in with my long-term goals for myself.	O	O	O	O	O	O	O	_				_
12. I did something that was hard to do but it was worth it.	O	O	O	O	O	O	O	_				_
13. I spent a long time thinking over and over about my problems.	O	O	O	O	O	O	O		_			R

0 = Not at all 1 = 2 = little 3 = 4 = A lot 5 = 6 = Completely	0	1	2	3	4	5	6	For Scoring Purposes only				
								AC	AR	WS	SI	T
14. I kept trying to think of ways to solve a problem but never tried any of the solutions.	○	○	○	○	○	○	○		_			R
15. I frequently spent time thinking about my past, people who have hurt me, mistakes I've made, and other bad things in my history.	○	○	○	○	○	○	○		_			R
16. I did not see any of my friends.	○	○	○	○	○	○	○				_	R
17. I was withdrawn and quiet, even around people I know well.	○	○	○	○	○	○	○				_	R
18. I was not social, even though I had opportunities to be.	○	○	○	○	○	○	○				_	R
19. I pushed people away with my negativity.	○	○	○	○	○	○	○				_	R
20. I did things to cut myself off from other people.	○	○	○	○	○	○	○				_	R
21. I took time off of work/school/chores/responsibilities simply because I was too tired or didn't feel like going in.	○	○	○	○	○	○	○			_		R
22. My work/schoolwork/chores/ responsibilities suffered because I was not as active as I needed to be.	○	○	○	○	○	○	○			_		R
23. I structured my day's activities.	○	○	○	○	○	○	○	_				_
24. I only engaged in activities that would distract me from feeling bad.	○	○	○	○	○	○	○		_			R
25. I began to feel badly when others around me expressed negative feelings or experiences.	○	○	○	○	○	○	○		_			R

Subscale Totals: __ __ __ __
BAS Total: __

DAS - A

Details of this measure can be accessed at http://repository.upenn.edu/cgi/viewcontent.cgi?article=2994&context=edissertations.

Responses to Depression (RRS)

People think and do many different things when they feel down, sad or depressed. Please read each of the items below and indicate whether you never, sometimes, often, or always think or do each one when you feel down, sad or depressed. Please indicate what you *generally* do, not what you think you should do.

Almost Never	Sometimes	Often	Almost Always	
☐	☐	☐	☐	1. Think about how alone you feel.
☐	☐	☐	☐	2. Think "I won't be able to do my job/work because I feel so bad"
☐	☐	☐	☐	3. Think about your feelings of fatigue and achiness
☐	☐	☐	☐	4. Think about how hard it is to concentrate
☐	☐	☐	☐	5. Think about how passive and unmotivated you feel
☐	☐	☐	☐	6. Analyse recent events to try and understand why you are depressed.
☐	☐	☐	☐	7. Think about how you don't seem to feel anything anymore
☐	☐	☐	☐	8. Think "Why can't I get going?"
☐	☐	☐	☐	9. Think "Why do I always react this way?"
☐	☐	☐	☐	10. Go away by yourself and think about why you feel this way
☐	☐	☐	☐	11. Write down what you are thinking about and analyse it
☐	☐	☐	☐	12. Think about a recent situation, wishing it would have gone better
☐	☐	☐	☐	13. Think "Why do I have problems other people don't have?"

Please turn over

Almost Never	Sometimes	Often	Almost Always	
☐	☐	☐	☐	14. Think about how sad you feel
☐	☐	☐	☐	15. Think about all your shortcomings, failings, faults and mistakes
☐	☐	☐	☐	16. Think about how you don't feel up to doing anything
☐	☐	☐	☐	17. Analyse your personality to try and understand why you are depressed
☐	☐	☐	☐	18. Go someplace alone to think about your feelings
☐	☐	☐	☐	19. Think about how angry you are with yourself
☐	☐	☐	☐	20. Listen to sad music
☐	☐	☐	☐	21. Isolate yourself and think about the reasons why you feel sad
☐	☐	☐	☐	22. Try to understand yourself by focusing on your depressed mood

SHAPS

This questionnaire is designed to measure your ability to experience pleasure *in the last few days.* It is important to read each statement very carefully. Tick *one* of the boxes to indicate how much you agree or disagree with each statement.

1. I would enjoy my favourite television or radio programme:

- Strongly disagree ☐
- Disagree ☐
- Agree ☐
- Strongly agree ☐

2. I would enjoy being with my family or close friends:

- Definitely agree ☐
- Agree ☐
- Disagree ☐
- Strongly disagree ☐

3. I would find pleasure in my hobbies and past-times:

- Strongly disagree ☐
- Disagree ☐
- Agree ☐
- Strongly agree ☐

4. I would be able to enjoy my favourite meal:

- Definitely agree ☐
- Agree ☐
- Disagree ☐
- Strongly disagree ☐

5. I would enjoy a warm bath or refreshing shower:

- Definitely agree ☐
- Agree ☐
- Disagree ☐
- Strongly disagree ☐

6. I would find pleasure in the scent of fresh flowers or the smell of a fresh sea breeze or freshly baked bread:

- Strongly disagree ☐
- Disagree ☐
- Agree ☐
- Strongly agree ☐

7. I would enjoy seeing other people's smiling faces:

- Definitely agree ☐
- Agree ☐
- Disagree ☐
- Strongly disagree ☐

8. I would enjoy looking smart when I have made an effort with my appearance:

- ☐ Strongly disagree
- ☐ Disagree
- ☐ Agree
- ☐ Strongly agree

9. I would enjoy reading a book, magazine or newspaper:

- ☐ Definitely agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

10. I would enjoy a cup of tea or coffee or my favourite drink:

- ☐ Strongly disagree
- ☐ Disagree
- ☐ Agree
- ☐ Strongly agree

11. I would find pleasure in small things, e.g. bright sunny day, a telephone call from a friend:

- ☐ Strongly disagree
- ☐ Disagree
- ☐ Agree
- ☐ Strongly agree

12. I would be able to enjoy a beautiful landscape or view:

- ☐ Definitely agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

13. I would get pleasure from helping others:

- ☐ Strongly disagree
- ☐ Disagree
- ☐ Agree
- ☐ Strongly agree

14. I would feel pleasure when I receive praise from other people:

- ☐ Definitely agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly disagree

FOR RESEARCHERS ONLY	
Researcher Name:	
Researcher Signature:	
Date:	

Appendix 5 Risk and adverse event documents

PROTOCOL FOR ASSESSING, REPORTING AND MONITORING RISK

1. Policy Statement

GPs are responsible for the ongoing clinical care of COBRA trial participants. Therefore, all trial staff directly involved with research participants have a duty of care to ensure that participants' GPs are aware of any risk to participants or from participants to others, including suicidal thoughts expressed by participants.

Researchers must initiate the risk protocol each time a participant expresses suicidal thoughts, thoughts of self-harm or thoughts of harm to others. This may be as a result of responses to questionnaire items or the participant may disclose information during an interview that leads the researcher to believe that there are thoughts of suicide or harm to self or others. In both instances, the researcher should initiate the risk protocol and notify the site PI (or nominated deputy).

2. Principles

The following principles and procedures govern risk assessment, reporting and monitoring for the COBRA Trial.

The COBRA trial excludes participants at baseline interview who demonstrate any risk to self or others that would require management by specialist mental health or other services. However, included participants might develop such risk during the trial and must be assisted accordingly.

The Chief Investigator has overall responsibility for risk assessment and management for the COBRA trial. The Chief Investigator must ensure that any research personnel involved with the COBRA trial are adequately qualified and trained on risk assessment prior to any patient contact in which risk could be disclosed, and that these personnel receive support and supervision around risk issues during their involvement with the trial.

All cases where significant risk is identified by researchers will be managed according to the COBRA risk protocol and discussed with the Chief Investigator, another designated member of the trial's investigator team and the trial manager. All assessment reports and correspondence relating to risk sent by research staff will be checked by the Chief Investigator or a person from the COBRA team with the designated authority to do so (see delegation of Duties log) before they are sent.

3. Procedures for research personnel

Background training materials are available from the COBRA Trial Team in Exeter. All researchers should attend training in the use of this protocol at least biennially. All researchers will be made familiar with the protocol and new staff who will be involved in assessing/treating patients will be familiarised as part of their induction/training. Risk assessment should therefore be conducted following appropriate training and with appropriate supervision.

The Chief Investigator and Site PIs are responsible for ensuring that appropriate cover is arranged for any risk issues that might arise in their absence when away from research sites. This will entail a person being named as responsible for overseeing risk assessments in their absence and contact details being shared with COBRA trial staff and the trial manager.

Whenever any significant risk is identified (during an interview or through reviewing patient reported outcome measures) a **risk assessment form (appendix A) should be completed and (counter-) signed by the responsible member of staff and site PI or Chief Investigator**. If at all possible this should be done at the time of the assessment, or as soon afterwards as possible. Research staff should seek supervision the same working day that they receive any information regarding risk and ensure management of the information has been handed over to the designated person within the COBRA team.

All contact with patients/GPs and any other professionals around risk should be documented in writing in the participant's Contact and Risk File. Contact with the patient's GP, duty GP or other emergency service should be instigated according to the level of risk identified having followed the COBRA risk policy. As specified in the policy, contact may be by telephone, or if by fax a phone call to the GP Surgery made to ensure receipt of the fax.
Many of the COBRA standardised interviews (e.g., Structured Clinical Interview for DSM-IV – SCID) and questionnaires (e.g. PHQ-9) include questions about suicide risk. COBRA trial staff should always respond to any identified risk (as specified below) via these measures, and a risk assessment in line with this protocol should be completed.

In a SCID interview, reports of suicidal ideation, intent, plans or urges, and any risk of neglect of self or others, or harm to self or others requires further assessment.

A score of more than 0 on the PHQ-9 item 9 requires further assessment.

All personnel working on the COBRA trial should also ensure they ascertain whether participants represent a risk to themselves or others through neglect or active harm and whether participants are themselves at risk of being harmed by others. The same process is to be followed in any instance of risk and **supervision from the designated supervisor should be obtained immediately in the case of significant risk and within the same day for less immediate concerns.**

4. Questions To Ask & Protocol If Risk Has Been Identified For COBRA trial Patients

THOUGHTS

"I see that you've said / you mentioned that…….. These are thoughts / feelings that people suffering from depression often have, but it's important to make sure you are receiving the right kind of support. So if it's OK, I would now like to ask you some more questions that will explore these feelings in a little more depth."

PLANS

1 Do you know how you would kill yourself? Yes / No

If **yes –** details

2 Have you made any actual plans to end your life? Yes / No

If **yes –** details

ACTIONS

3 Have you made any actual preparations to kill yourself? Yes / No

If **yes –** details

4 Have you ever attempted suicide in the past? Yes / No

If **yes –** details

PREVENTION

5 Is there anything stopping you killing or harming yourself at the moment? Yes / No

If **yes –** details

6 Do you feel that there is any immediate danger that you will harm or kill yourself? Yes / No

If **yes -** details:

FOLLOW-UP FROM PREVIOUS CONTACT

7 **If Action B was enacted at previous assessment and level B risk is identified at current assessment**: Last time we met I suggested that you spoke to your GP about these thoughts, and I also wrote to your GP about this. Have you been able to speak with your GP about these thoughts since we last met? Yes / No

To be used following any indication of risk from questionnaire items, responses to interview questions or any other sources. Look at answers from the sheet to determine level of risk, A B or C:

Actions by COBRA trial Staff Member	***Tell Participant***
All answers 'no' apart from Q5 'yes': → **A**	*I can see that things have been very difficult for you, but it seems to me these thoughts about death are not ones you would act on – would this be how you see things? (if they say yes) I would advise you to make an appointment to see your GP to talk about these feelings.*
'Yes' for any **one** of Qs 1-4; plus 'yes' for Q5 and 'no' for Q6 → **B1**	*Things seem to be very hard for you right now and I think it would help if you were to speak to your GP about these feelings. I will be writing to your GP to tell them that you have been here today and have been having some troubling thoughts. I would also advise you to make an appointment to see your GP to talk about these feelings.*
'Yes' for any **one** of Qs 1-4; plus 'yes' for Q5 and 'no' for Q6 **and** 'no' to Q7 → **B2**	*I think it's important that your GP knows how difficult things are for you right now. I will be telephoning your GP to speak with him/her and suggest that you meet with one another. I also advise that you make an appointment to see your GP to talk about these feelings. N.B: telephone call to GP to be followed up by letter. The letter should include the statement "*the clinical management of this patient remains your responsibility, but it is part of our protocol to inform you of any risks disclosed to ourselves so that you can take account of them in your care plan.*"*
Scoring 'no' to Q5 or 'yes' to Q6 → **C** Actively Suicidal	*I am very concerned about your safety at this moment, I am going to make some telephone calls to your GP/ Care Co-ordinator / Crisis Management team/the emergency services to let them know how you are feeling and to arrange for you to receive immediate help.*

Action to take in the case of immediate risk:
Participant needs immediate help – **do not leave them alone, or if on telephone, do not hang up**. Follow your chain of supervisory contact in order to involve supervisory clinician right away. Then (with supervisor if possible) follow the chain of contact below:

1. **GP/out-of-hours GP**; if not
2. **Crisis team;** if not
3. **Clinician accompanies to A&E**; if not (or interview is over telephone)
4. **Call ambulance.**

Date risk protocol enacted: Participant ID:		
Time Point: Telephone screen / Baseline / 6 month / 12 month / 18 month / other, please specify:		
Risk protocol has identified level of risk as: A B1 B2 C		
Suicide Risk Information: Report which questionnaire and the score that gave cause for concern and attach copy of risk assessment. Include whether the participant has reported any of the following: • Current suicidal ideation • Suicide plans • Active preparations to commit suicide • Protective factors or lack of them • Regular contact with GP?		
Clinical supervisor contacted: Y / N Date: Name of supervisor:		
Actions taken:		
Additional relevant information:		
Researcher Name:	Date:	Signature:
Clinical Supervisor Name:	Date:	Signature:

Supervisory Clinicians and Emergency Contact Numbers - Exeter Site

When contacting staff by mobile if you are unable to reach them please text "URGENT please contact regarding COBRA risk protocol"

Supervisory Clinicians

The MDC Operational Manager holds diaries for most University of Exeter staff and can help locate them.

1. Chief Investigator (Exeter): Prof Dave Richards –

2. Co-Investigators (Exeter):
Prof Willem Kuyken –
Prof Ed Watkins –
Dr Paul Farrand –
Dr Kimberly Wright –
Dr Heather O'Mahen –
3. Principle Investigators:
Dr Dean McMillan (York) –
Dr Dave Ekers (Durham) –

4. Trial Manager (Exeter): Shelley Rhodes –

Emergency Contact Numbers

1. The **Mental Wellbeing & Access Networks** are the first points of contact for crisis intervention during normal working hours**:**

- Exeter: Exeter team; 8am – 6pm; Newton Abbot: Teignbridge team; 8am-6pm;
- Barnstaple: Tawside team; 8am-6pm;

2. Out of hours or in an emergency where you cannot get hold of the MWb&A team contact the **Crisis Resolution Home Treatment Team:**

- Exeter: Exeter, East & Mid Devon team;
- Newton Abbot: Teignbridge team;
- Barnstaple: North Devon team;

Please note that these numbers are to make an urgent referral to the Crisis Team and should not be given out to participant /members of the public under any circumstances. The participant's GP can also make an urgent referral to the Crisis Team and should be the first port of call.

1. **Accident and Emergency Department**

- Exeter: Royal Devon & Exeter Hospital, Barrack Road, Exeter, EX2 5DW
- Newton Abbot: Torbay Hospital, Newton Road, Torquay, Devon, TQ2 7AA
- Barnstaple: North Devon District Hospital, Raleigh Park, Barnstaple, Devon, EX31 4JB

Supervisory Clinicians and Emergency Contact Numbers - York Site

When contacting staff by mobile if you are unable to reach them please text "URGENT please contact regarding COBRA risk protocol"

Supervisory Clinicians

1. Principle Investigator (York): Dr Dean McMillan –

    Faye Plummer), Kerry Cipriano (– work days Monday, Tuesday, Wednesday and Friday) and Alice North (– work days 09:30am to 2pm Monday to Thursday) have access to Dean's diary and can be contacted if he is unavailable.

2. Chief Investigator (Exeter): Prof Dave Richards –

3. Co-Investigators (Exeter):
Prof Willem Kuyken –
Prof Ed Watkins –
Dr Paul Farrand –
Dr Kimberly Wright –
Dr Heather O'Mahen –

4. Principle Investigators:
Dr Dean McMillan (York) –
Dr Dave Ekers (Durham) –

5. Trial Manager (Exeter): Shelley Rhodes –

Emergency Contact Numbers

- Out of Hours GP
    a. Contact West Yorkshire Urgent Care Service: 0345 605 99 99

- Crisis team
    a. Working hours
        Crisis resolution team (referrals line) -
        OR Single Point of Access phoneline for psychiatric and secondary care mental health services -

    b. Out of hours
        Crisis resolution team (referrals line) -
        OR Connect Helpline (Leeds survivor led crisis service); 6pm – 10:30pm;

- Accident and Emergency Departments
    a. Leeds General Infirmary, Great George Street, Leeds, West Yorkshire, LS1 3EX
    b. St James's Hospital, Beckett Street, Beckett Street, Leeds, West Yorkshire, LS9 7TF

Supervisory Clinicians and Emergency Contact Numbers – Durham Site

When contacting staff by mobile if you are unable to reach them please text "URGENT please contact regarding COBRA risk protocol"

Supervisory Clinicians

1. Principle Investigator (Durham): Dr Dave Ekers –
BA supervisor Mark Dawson –

2. Principle Investigator (York): Dr Dean McMillan -

3. Chief Investigator (Exeter): Prof Dave Richards –

4. Co-Investigators (Exeter):
Prof Willem Kuyken –
Prof Ed Watkins –
Dr Paul Farrand –
Dr Kimberly Wright –
Dr Heather O'Mahen –

5. Principle Investigators:
Dr Dean McMillan (York) –
Dr Dave Ekers (Durham) –

6. Trial Manager (Exeter): Shelley Rhodes –

Emergency Contact Numbers
Out of hours GP on 111 NHS Direct 0845 46 47

Helplines;
Mental Health Matters 0800 085 7027 SANEline 0845 767 8000
Samaritans 08457 90 90 90 National Domestic Violence Freephone Helpline 0808 2000 247

Crisis Team- 24 hours
- North Durham
- South Durham and Darlington

Accident and Emergency Department / Urgent Care Centre

North Durham
- Durham: University Hospital Of North Durham, North Road, Durham, County Durham, DH1 5TW. Tel: Urgent Care Centre (Peterlee), Peterlee Hospital, O'Neill Drive, Peterlee, County Durham, SR8 5UQ
- Sunderland Royal Hospital, Kayll Road, Sunderland, SR4 7TP

South Durham
- Darlington Memorial Hospital, Hollyhurst Road, Darlington, County Durham, DL3 6HX.
- Darlington Walk-In Centre, Dr Piper House, King Street, Darlington, County Durham, DL3 6JL,

Teesside A&E Departments (some in south may find this is closer than Darlington)
- University Hospital Of North Tees, Hardwick Road, Stockton-on-Tees, Cleveland TS19 8PE.
- The James Cook University Hospital. Marton Road, Middlesbrough, Cleveland, TS4 3BW.

Durham Police 0345 60 60 365 Emergency & Non-Emergency (**In emergencies, if no answer call 999)**

Adverse Event Reporting

Adverse Event

An **Adverse Event (AE)** is any untoward or unintended medical occurrence or response, whether it is causally related to the trial treatments or not.

Serious Adverse Event

An adverse event can be further classified as a **Serious Adverse Event (SAE)** if the event is:

- Fatal
- Life threatening
- Requires hospitalisation or prolongs existing hospitalisation
- Results in significant or persistent disability or incapacity
- Results in congenital abnormality or birth defect
- Leads to any other condition, judged significant by a clinician.

Immediate Action for Reporting an SAE

If you are alerted to an **SAE** please contact your site PI. An immediate report (within 24 hours of a **SAE** coming to light) must be made orally or in writing to the research sponsor (University of Exeter) Therefore, telephone the Chief Investigator (or the Trial Manager (at the Exeter site immediately. If you are unable to speak to either the CI or the TM and have left answer phone messages, it is important that you also text the Chief Investigator.

Please complete an **Adverse & Serious Adverse Event Recording Form** and fax a copy to the Exeter site immediately ().The immediate report must be followed by a detailed written report of the event. This report must also be sent to the main Research Ethics Committee (South West REC) and the COBRA DMC within 15 days of the CI becoming aware of the event. This will be handled by the lead site (Exeter).

At 6, 12 and 18 month follow-up assessments AE & SAE that might have occurred since the previous visit should be elicited from the participant. If a participant (or their GP or next of kin) discloses an AE or SAE please document it using the Adverse & Serious Adverse Event Recording Form. As COBRA is a non-CTIMP we are not required to log all non-serious AE's, however the Adverse Event & Serious Adverse Event Recording Form allows researchers to record AE's when it is not immediately clear if it falls into the SAE category.

General completion guidelines

Ask the participant the start and end date/time of the event. If they cannot remember then enter as accurate an estimate as possible. Document the outcome of the event and any actions taken. Confirm it with your site PI and ask them to countersign it.

Please note that ALL instances where the risk protocol is enacted must be recorded in the usual manner on the Risk Form and countersigned by the site lead or a nominated deputy.

Adverse & Serious Adverse Event Recording Form

Date of incident:	Participant ID:		
Details of incident: Outcome:			
Please indicate type (tick all that apply): Fatality: ☐ Persistent or significant disability or incapacity: ☐ Life-threatening: ☐ Congenital anomaly or birth defect: ☐ Hospitalisation or prolongation of hospitalisation: ☐ Other: ☐			
Additional relevant information:			
Action taken by research team (if any):			
Name of Researcher (BLOCK CAPITALS):	Date:	Signature:	
Name of site PI (BLOCK CAPITALS):	Date:	Signature:	

Serious Adverse Event (SAE) Report Form

The Chief Investigator should report any SAE to the sponsor within 24 hours, orally or in writing. The immediate report must be followed by a detailed written report on the event, using the form below. A copy of this form must also be sent to the main Research Ethics Committee and DMC within 15 days of the CI becoming aware of the event.

1. Details of Chief Investigator

Name:	Prof David A Richards
Address:	XXXX
Telephone:	
Email:	XXXX
Fax:	

2. Details of Study

Full title of study:	COBRA (Cost and Outcome of BehaviouRal Activation): A randomised controlled trial of behavioural activation versus cognitive behavioural therapy for depression
Name of main REC:	South West Research Ethics Committee
REC reference:	12/SW/0029
Research sponsor:	University of Exeter
Sponsor's reference for this report (if applicable):	

3. Type of Event

Please categorise this event, ticking all appropriate options:

Fatality: ☐	Life threatening: ☐	Hospitalisation or prolongation of hospitalisation: ☐
Persistent or significant disability or incapacity: ☐	Congenital anomaly or birth defect: ☐	Other: ☐

4. Circumstances of the Event

Date of event:	
Location of event:	
Describe the circumstances of the event (attach further details if required):	
What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?	

5. Declaration

Name of Chief Investigator: (BLOCK CAPITALS)	
Date of submission:	
Signature:	

6. Acknowledgement of Receipt by REC

The South West Research Ethics Committee acknowledges receipt of the above.

Name: (BLOCK CAPITALS)	
Position on REC:	
Date:	
Signature:	

Signed original to be sent back to the Chief Investigator; copy to be kept for information by main REC.

Appendix 6 Participant results newsletter

[redacted]

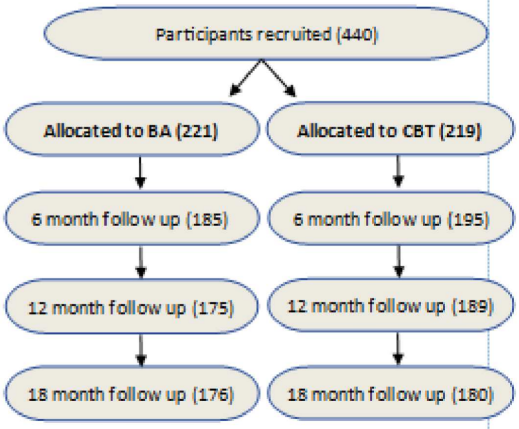
COBRA
Behavioural Activation Trial

The COBRA Trial

COBRA was a clinical trial comparing the effectiveness and costs of Behavioural Activation (BA) versus Cognitive Behavioural Therapy (CBT) for depression. We found that BA was as effective as CBT at reducing symptoms of depression, and was more cost-effective.

Background

- Depression is a common and debilitating condition that is set to become the second biggest cause of global disability.
- CBT is recommended as a treatment for depression by the UK National Institute for Health and Care Excellence (NICE). However, it is a complex treatment delivered by highly trained professionals who are expensive to employ, and this limits access to CBT.
- BA is also an effective treatment for depression and is relatively simple, meaning it can be delivered by junior staff with less training, making it a cost-effective option.
- NICE recommended research to directly compare the outcomes and costs of BA with CBT. COBRA was a randomised controlled trial designed to do this.



What is Behavioural Activation?

BA is based on the idea that certain behaviours such as inactivity are key factors in depression. The therapist encourages patients to focus on meaningful activities driven by their own personal values as a way of overcoming depression.

What is Cognitive Behavioural Therapy?

CBT is based on the idea that certain ways of thinking can maintain depression. The therapist helps patients to identify any unhelpful thoughts that may make them feel depressed. CBT aims to change those ways of thinking and help people think in more realistic and helpful ways.

The Research Questions

1. What is the clinical effectiveness of BA compared to CBT for depressed adults in terms of depression treatment response at 12 and 18 months?
2. What is the cost-effectiveness of BA compared to CBT at 18 months?

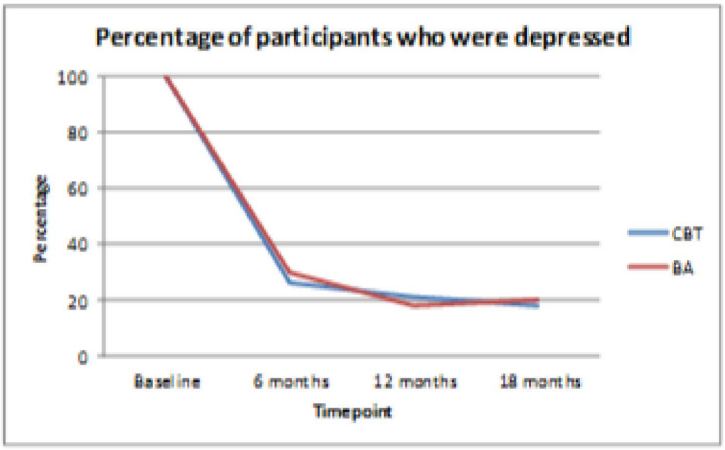
[redacted]

COBRA
Behavioural Activation Trial

Results

Clinical outcomes: We used a structured clinical interview called the SCID to assess whether participants met criteria for depression at each of their research interviews. All participants who were accepted into the trial were depressed at their baseline interview. At 12 months, 79% of participants who received CBT and 82% of participants who received BA were no longer depressed. This finding shows that BA is as effective as CBT for the treatment of depression.

Costs: To work out the costs of each treatment we calculated direct costs such as the therapists' salary, as well as indirect costs such as participants' use of other healthcare services, medication use and work productivity. BA was around 20 per cent cheaper than CBT, making it cost-effective and more realistic for a wider range of countries worldwide.



What does this mean?

Junior mental health workers with no professional training in psychological therapies can deliver BA, a simple psychological treatment, with no lesser effect than CBT and at less cost.

Effective psychological therapy for depression can be delivered without the need for costly and highly trained professionals.

THANK YOU!

We would like to thank everyone involved in the study, especially the patients and therapists who gave up their time to help us.

If you would like to read the published paper it is available free of charge online at:
http://www.thelancet.com/
Richards et al., to be published 22/07/2016

If you would like to contact us our address is:
COBRA trial, Complex Interventions Team, South Cloisters, University of Exeter St Luke's Campus, College Road, Exeter, EX1 1TE

Appendix 7 Behavioural activation clinical practice manual

Cost and Outcome of BehaviouRal Activation:

A Randomised Controlled Trial of Behavioural Activation versus Cognitive Behaviour Therapy for Depression

BEHAVIOURAL ACTIVATION CLINICAL PRACTICE MANUAL

Manual Structure

This manual contains all the necessary information you will need in order to initiate and undertake Behavioural Activation (BA) treatment programmes with patients in the COBRA trial.

Section 1 has some information about the COBRA trial itself. Section 2 outlines some general principles of session timing, duration, frequency and safety. Sections 3 and 4 describe the two treatments being tested in the COBRA trial – BA and Cognitive Behavioural Therapy (CBT) in very broad terms.

Sections 5 and 6 will give you a very good summary of what a course of BA treatment in the COBRA will look like, describing the phasic nature of the COBRA protocol and a summary of the content of each phase. Section 6, in particular, gives a schematic overview of a COBRA BA treatment programme.

Section 7 then goes on to describe the core BA techniques – self-monitoring, functional analysis and activity scheduling. It also briefly describes some of the Phase II modular specific techniques you will be using.

Section 8 then goes on to detail the structure of clinical sessions at all stages of a BA treatment programme. You should follow these structures very closely as your adherence to the overall structure, sessional structure and specific therapeutic content will be critical in ensuring fidelity to the clinical protocol COBRA is testing.

Section 9 consists of a series of helpful 'therapist notes' on each of the principle techniques you will be asked to employ. Think of these as aide memoires. They will help you refresh your memory when it comes to employing these techniques.

Section 10 lists some of the key scientific references underpinning the COBRA trial. This is followed by Appendices A-L, consisting of the therapeutic tools such as diaries you will need to use throughout any treatment programme.

Please consult this manual frequently. Bring it with you to supervision and use it to help you become confident and competent at delivering the COBRA BA clinical protocol. If you would like to personalise it, please do, and if you have any suggestions for additional materials, the trial team will be happy to listen.

Introductory Pages

1. Introduction to the COBRA trial

Clinical depression is one of the most common and debilitating of the psychiatric disorders. It accounts for the greatest burden of disease among all mental health problems, and is expected to become the second-highest amongst all general health problems by 2020.

COBRA is a Randomised Controlled Clinical Trial of two psychological interventions – Behavioural Activation (BA) and Cognitive Behaviour Therapy (CBT) – to establish if there are important clinical and cost differences between them. In detail, the COBRA programme of research seeks to answer two interlinked questions:

1. What is the clinical effectiveness of BA compared to CBT for depressed adults in terms of depression treatment response measured by the PHQ9 at 12 and 18 months?
2. What is the cost-effectiveness of BA compared to CBT at 18 months?

In addition, we will undertake a secondary process evaluation to investigate the moderating, mediating and procedural factors in BA and CBT which influence outcome.

BA and CBT are both active psychological treatments which have previously demonstrated positive effects for people with depression, and are recommended by NICE guidelines for the treatment of depression. Half the participants in the COBRA trial will receive BA and half CBT, allocated on a random basis.

Participants will be assessed for eligibility by a COBRA researcher using a structured clinical interview. If eligible, they will be asked to complete a number of questionnaires with the researcher. They will then be randomly allocated to one of the treatments by the Peninsula Clinical Trials Unit in Plymouth using a process concealed from the research team ensure the team are blind to allocation. Participants will also be seen again for follow-up appointments with a researcher at six months, 12 months and finally at 18 months to complete a number of questionnaires. The research study will last for four years, but each participant's involvement in the study will be for eighteen months.

The study will be taking place in three sites; Devon Durham and Leeds with the lead centre being the University of Exeter's Mood Disorders Centre. COBRA will begin in March 2012, the first participant will start treatment in September 2012 and the study will end in April 2016. Participants will be recruited from August 2012 until April 2014.

The trial is funded by a UK National Institute for Health Research (NIHR) Health Technology Assessment Programme Clinical Evaluation and Trials grant.

2. General clinical procedures

a. Frequency and duration of appointments

Participants will receive a maximum of 20 sessions over 16 weeks with the option of four additional booster sessions.

Sessions will be face to face, of one-hour duration maximum.

Therapists and participants have the option of having sessions up to twice weekly over the first two months of the trial and weekly thereafter.

The final few sessions may be spaced out further if clinically appropriate.

b. Risk assessment and management

Risk will be assessed at every appointment. At the first appointment a full risk assessment will include enquiry on suicide, self-harm, neglect of self, neglect of others, harm to others and harm from others. Risk will be assessed in terms of thoughts, plans, actions taken in support of any plans, and preventative factors. At subsequent appointments risk will be reviewed against the assessment conducted in the first appointment to assess any change in the patient's risk status.

Where any factors are detected which leads the therapist or mental health worker to believe that there is a danger that the patient will harm themselves or others through action or neglect, a risk management plan will be initiated. This plan will follow the principles of the Mood Disorders Centre's policy on risk and any specific actions taken will be determined by the specific policies in place at the NHS clinical provider site. All risks identified and any actions taken will be documented and discussed in supervision and with the COBRA trial manager, site lead and chief investigator.

c. Collecting routine outcome measures

Over recent years, it has become standard practice for therapists and mental health workers to ask patients to complete short clinical outcome scales at every clinical encounter. Measures are used to assist both parties track progress, identify setbacks and provide data for individual patient progress and overall service evaluation. In COBRA, we use the same procedure at every session. Measures are collected from the patient during the early part of the appointment and discussed briefly before moving onto the main session content. Occasionally measures may lead to a change in the session agenda. Measures are always discussed in supervision.

3. What is Behavioural Activation?

Behavioural Activation (BA) is a psychological treatment alleviating depression by focusing directly on changing behaviour based on behavioural theory. This theory states that depression is maintained by avoidance of normal activities. As people withdraw and disrupt their basic routines, they become isolated from positive reinforcement opportunities in their environment. They then end up stuck in a cycle of depressed mood, decreased activity and avoidance. BA systematically disrupts this cycle, initiating action in the presence of negative mood, when people's natural tendency is to withdraw or avoid. BA targets avoidance from a contextual, functional approach not found in CBT – i.e., BA focuses on understanding the function of behaviour and replacing it accordingly. BA also explicitly prioritises the treatment of negatively reinforced avoidance and rumination.

The overall goal of BA is to re-engage participants with stable and diverse sources of positive reinforcement from their environment and to develop depression management strategies for future use. BA sessions consist of a structured programme increasing contact with potentially antidepressant environmental reinforcers through scheduling and reducing the frequency of negatively reinforced avoidant behaviours. Treatment is based on a shared formulation drawn from the behavioural model in the early stages of treatment, thereafter developed with the patient throughout their sessions. Specific BA techniques include the use of a functional analytical approach to develop a shared understanding with patients of behaviours that interfere with meaningful, goal-oriented behaviours and include self-monitoring, identifying 'depressed behaviours', developing alternative goal orientated behaviours and scheduling. In addition the role of avoidance and rumination will be addressed through functional analysis and alternative response development.

4. What is Cognitive Behavioural Therapy?

The overall goal of CBT is to alter the symptomatic expression of depression and reduce risk for subsequent episodes by correcting the negative beliefs, maladaptive information processing and behavioural patterns presumed to underlie the depression Sessions consist of a structured, partially didactic programme. Treatment begins with patients learning the model, behavioural change techniques, and moves on to to identifying and modidfying negative automatic thoughts, maladaptive beliefs and underlying core beliefs. In later sessions, learning is translated to anticipating and practicing the management of stressors that could provoke relapse in the future. Specific CBT techniques include scheduling activity and mastery behaviours, the use of thought records and modifying maladaptive beliefs. The behavioural elements in CBT focus on increasing activity together with practical behavioural experiments to test specific cognitive beliefs. CBT does not take the contextual, functional approach of BA, nor does CBT explicitly prioritise the targeting of avoidance and rumination.

5. General clinical principles of the protocol

a. Phase I

Phase I represents the introduction and application of the core BA methods. The first session is an assessment where the worker gathers information on the patient's presenting problem and describes the BA model. Phase I then moves on to undertake the core activities associated with successful BA – establishing the link between mood and behaviour, developing functional analysis, linking this to the patient-specific BA formulation, and setting and reviewing activity scheduling exercises. The phase ends with several sessions using the TRAP/TRAC method for introducing alternative behaviours.

b. Phase II

Phase II consists of a series of mandatory and optional therapeutic 'modules' which are undertaken as a tailored response to the patent's presenting problems. The TRAP/TRAC method is used to anchor modular activities throughout, but specific activities are also undertaken dependent on the module being applied. Mandatory modules are on rumination and problem solving. Optional modules include sessions on functional equivalence incorporating values, anxiety, punishment, communication and alcohol/substance use.

c. Phase III

Phase III is focussed on planning to maintain progress and reduce relapse potential. In this phase worker and patient acknowledge the necessity to manage the forthcoming ending of therapy and move on to self-planning without clinical assistance, identifying signposts for action (relapse triggers), reviewing progress on goals and valued activities so far, identifying action to meet remaining goals and valued activities, and identifying help-seeking triggers and action to be taken. The TRAP and TRAC method is used to plan further activity using specific modular techniques for increasing access to mood enhancing activities and reducing or replacing avoided behaviours.

d. Booster phase

These appointments are optional with a very flexible content. Worker and patient undertake a review of difficulties experienced and identify specific therapeutic techniques from the core Phase I stage or any modules in Phase II which may need refreshing, practice or further work. Relapse prevention activities may also be undertaken.

e. Transition and review appointments

These sessions are an opportunity for worker and patient to review progress, reflect on activities undertaken so far and move to the next Phase. The formulation is revisited, progress against goals and valued activities is checked, the therapeutic rationale is repeated, remaining activities are identified and a plan is developed for the next phase

6. Behavioural Activation Protocol Overall Session Chart

<table>
<tr><th colspan="6">PHASE I</th><th>TRANSITION</th><th colspan="8">PHASE II</th><th>TRANSITION</th><th colspan="4">PHASE III</th><th colspan="4">BOOSTER</th></tr>
<tr><td>1</td><td colspan="2">2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td><td>11</td><td>12</td><td>13</td><td>14</td><td>15</td><td>16</td><td>17</td><td>18</td><td>19</td><td>20</td><td>21</td><td>22</td><td>23</td><td>24</td></tr>
<tr><td colspan="6">Assessment/rationale
Formulation diagram</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td colspan="5">Goal setting and introduction of valued activities</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="20">Self-monitoring leading to activity scheduling</td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td colspan="5"></td><td colspan="14">Avoidance-Functional analysis/TRAP and TRAC; developing formulation-diagram</td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td colspan="5"></td><td>Review A
What have learnt/target and hierarchy for next phase of valued activities</td><td></td><td></td><td></td><td>Mini progress review by now</td><td></td><td></td><td></td><td>Review B
What have learnt/target and hierarchy for next phase of valued activities</td><td></td><td></td><td></td><td>Review
What have learnt/target and hierarchy for next phase of valued activities</td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td colspan="5"></td><td colspan="15">Carry on Activating (up your hierarchy….) including grading and stress testing</td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td colspan="5"></td><td colspan="15"><u>Additional module choices guided by functional analysis (mandatory/optional)</u>
Rumination;
Problem solving;
Functional equivalence (including values);
Anxiety;
Punishment;
Communication;
Alcohol and Substance Use</td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td colspan="5"></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td colspan="4">Relapse Prevention/
Maintaining Progress</td><td></td><td></td><td></td><td></td></tr>
</table>

Summary of Core Behavioural Activation Techniques

7. Summary of core behavioural activation techniques

a. Self-monitoring

Self-monitoring is the recording of activities and emotions by patients. It is used to inform the content and direction of almost all other clinical techniques in BA. Self-monitoring is one of the core building blocks upon which the whole BA treatment approach stands.

Self-monitoring records provide an initial baseline against which change can be monitored during the course of treatment. The records then allow patient and therapist to monitor the progress of treatment and identify specific treatment targets. Records include details of activities engaged in and emotions experienced. Patients complete records frequently, at least daily and often hourly, mostly as 'homework'. However, some patients can complete self-monitoring records during one-to-one treatment sessions, particularly in the early stages of treatment or when specific details are missing from homework records.

Patients and therapists should always pay close attention to records. They can identify connections between behaviours and feelings, the overall pattern of feelings and activities, disruptions to routine, and patterns of avoidance. Gathering this information helps patients and therapists identify areas for change including the potential to increase positively reinforced activities and reduce negatively reinforced avoidance behaviours.

Self-monitoring leads on to the other core techniques of activity scheduling and functional analysis covered in the next sections.

b. Functional analysis

Functional analysis is the study of an individual patient's pattern of behaviour and its variability. It is used to determine the contexts under which desired and undesired behaviours occur. The results of functional analysis guide interventions to systematically and therapeutically increase or reduce target behaviours.

Functional analysis is a core behavioural approach to understand why certain behaviours occur more frequently and why others less so. A functional analysis will include information on 'antecedents', 'behaviours' and 'consequences'. Antecedents are often known as 'triggers'. In depression many environmental, personal or social triggers can act as cues for behaviours such as avoidance with the consequence that a person disengages with the world leading to increased depression. Therapists use functional analysis in BA to unpick this general pattern and understand its personal manifestation for individual patients.

We use two acronyms in BA to illustrate the process of functional analysis:

- ABC: Antecedents ⇒ Behaviour ⇒ Consequences
- TRAP: Triggers, Response, *Avoidance Pattern* – where 'Response' refers to the emotional feelings experienced when the trigger occurs.

Therapists and patients use functional analysis to find out detail about the conditions under which the trigger, target behaviour and consequence occur and under what conditions do they do not occur by asking questions about when, where and with who. Therapists also help patients understand the function of behaviour, particularly how patients respond to triggers and how their response might be maintaining negative feelings.

Another acronym – TRAC: Triggers, Response, *Alternative Coping* – is used to help patients plan alternative behavioural responses to the trigger and emotional response. These might include recognising TRAPs, exerting environmental control by disrupting the trigger cues, and developing alternative responses through planning a TRAC. The method BA therapists use to help patients do this is to develop a formal a 'contingency plan'. This is a strategy for the patient to use when the trigger, or the threat of the trigger, occurs. This is often known as an: 'if-then' plan. These contingency plans are developed in response to triggers that act as warning signs, together with the personalised functional analysis.

c. Activity scheduling

Activity scheduling is the final core component of the three-legged stool that makes up BA. Self-monitoring provides knowledge of the patient's individual behavioural context. Functional analysis provides information on the triggers and reinforcers for these behaviours. Activity scheduling is the reshaping of the patient's behaviour towards behaviours that are less depressogenic.

Activity scheduling is all about planning. We encourage the patient to plan activities in a purposeful way. Activities are selected that have a clear focus and are drawn from the insights of the functional analysis. Planned activities may include new 'functionally equivalent' behaviours to replace activities that are no longer possible in a person's changed life. Activities may be a return to old behaviours that have been dropped or avoided. Activity schedules may be explicitly about reducing current behaviours that are actually depressogenic. Some scheduled activities may be used to disrupt depressed thinking or behaviours in the face of known danger signs and triggers.

The main message to give about activity scheduling is that it runs throughout the whole course of a BA programme. We do not rely on new, positively reinforcing behaviours appearing by chance. We plan them into a person's life. Planned behaviours all have a clear rationale, are best if they represent the implementation of a person's value set, and are often designed in an experimental way. Patient's act as scientists in their own personal laboratory, investigating the impact of reducing negatively reinforced avoidance and increasing positively reinforced behaviour. What we expect is that if we understand the triggers and contingencies, once we schedule in the behaviours the reinforcement effects will take over and help shape the person's behaviours in a more positive direction.

Alongside self-monitoring record forms, activity scheduling records will be the most frequently used and discussed tools in the behavioural activationists armoury.

d. Introduction to Phase II modular techniques

Rumination
This module describes how the BA approach, and in particular, functional analysis, is used to treat rumination. Rumination is a covert mental process common in depression that can be approached therapeutically as behaviour, using antecedent, behaviour and consequence ideas to understand the function of rumination and identify alternative responses. Techniques for helping reduce rumination include disrupting cues, finding alternative responses when cues appear, and developing concrete thinking.

Problem solving
Although BA is underpinned by an overall problem-solving stance throughout treatment, therapists can also use problem solving as a discrete clinical technique. Problem solving is a step-wise programme of problem definition in concrete, behavioural terms, identification of potential solutions, implementation of at least one solution and evaluation of the results. Problems may be primary or secondary and avoidant coping or skills deficits may prevent the resolution of problems.

Functional equivalence
A functionally equivalent behaviour is one that 'does the job' of the original behaviour. Therapists help patients identify and substitute functionally equivalent behaviours throughout BA work, particularly when a patient is engaging in a behaviour that works well for them in some ways, but has some significant negative consequences, and when a patient would like to do more positively reinforced activities but cannot undertake some of the behaviours that s/he engaged in previously. This module describes the technique of functional equivalence in more detail and the selection of alternative, value-based, activities that patients find appealing, particularly in situations where they cannot undertake behaviours they previously engaged in.

Anxiety
Most patients with depression also experience significant symptoms of anxiety. As patients engage with their environment, anxiety is likely to be a problem that will require attention at some point. Although the goal of BA is to treat depression, using the same functional analytical approach can help with anxiety also. Therapists undertake functional analysis using TRAP and TRAC sheets to do this. We gather information about anxiety and apply the TRAP technique to consider its maintenance and the short and long-term consequence of associated avoidance. From here therapists and patients use TRAC to explore alternative behaviours that will help the patient undertake more activity. This in turn gives the patient positive reinforcement and encourages future 'outside in' behaviour to overcome anxiety.

Punishment
BA typically involves reintroducing behaviours that used to be reinforced when the person was not depressed or finding alternative behaviours that may serve the same function for a person. One difficulty that occurs in treatment is that sometimes when a person tries to reintroduce a behaviour that s/he once found easy or enjoyable, now the same activity is experienced as very difficult and unrewarding. These types of clinical situation can be understood in behavioural terms in that a behaviour that in

one context was rewarded is now in another context punished. As with any behaviour that is punished, the activity will reduce in frequency. This module provides some guidance on how to deal with this type of situation.

Communication

Interpersonal concerns, specifically communication difficulties, underlie many behavioural activation problems. Sometimes they are a TRAP/TRAC in their own right, at other times communication difficulties can be a barrier to achieving behavioural TRACs. This module focuses on finding communication strategies that work for individual patients in their own contexts, rather than teach overall interpersonal behaviours such as assertiveness. Communication TRACs are patient led –therapist work with patients so that they generate their own communication strategies and solutions.

Alcohol & substance use

Session Guides

8. Session guides

The following pages detail the structures of individual sessions to be conducted as part of the COBRA trial. There are separate pages for: assessment early, mid and late Phase 1 appointments; the transition and review appointment between phase 1 and II; phase II appointments; the transition and review appointment between phase II and the relapse prevention phase; the relapse prevention phase appointments; and the booster sessions.

These session guides should be followed closely. They are the essential structure to the COBRA BA protocol. Individual sessions have different session specific content, the details of which are described in the 'therapist notes' section of this handbook. Please use the technique specific instructions to tailor sessions but start and finish sessions according to the session guides in the following pages.

Assessment Session Guide

1. Introductions and orientation

2. Information gathering
   a. Main problem identification
   b. Autonomic, Behavioural and Cognitive symptoms
   c. Functional analysis including Triggers and Impact
   d. Risk assessment
   e. Sessional measures and feedback
   f. Past history, previous treatments and response, other current treatments, alcohol and drug use, co-morbidities

3. Information giving
   a. BA rationale
   b. Treatment session, duration and content details, role of worker

4. Shared decision making
   a. Diary introduction
   b. First steps

5. Summarise and check out collaborative understanding of session

6. Agree new activities

7. Appointment planning

8. Ending

Clinical tools associated with this session:
BA Assessment Worksheet (Appendix A)
Self-Monitoring Record Form (Appendix D)

Phase I Session Guide: Sessions 2 and/or 3

1. Setting the session agenda
2. Sessional measures
3. Risk review
4. Review of self-monitoring record forms

5. Session specific therapeutic content
    a. Review BA rationale
        i. Introduce simple functional analysis: mood/behaviour link
        ii. Link to formulation diagram
    b. In session functional analysis ABC exercise
    c. Instruction on use of functional analysis ABC sheet between sessions remembering recency and recollection principle of completing sheets based on self-monitoring record
    d. Discuss and record goals

6. Summarise and check out collaborative understanding of session
7. Agree new activities
8. Manage any other business from agenda
9. End by agreeing next appointment time and place

Clinical tools associated with these sessions:
Formulation Diagram (Appendix B)
Functional Analysis ABC Sheet (Appendix C)
Self-Monitoring Record Form (Appendix D)
Goals Sheet (Appendix E)
Valued Activities Worksheet (Appendix F)

Phase I Session Guide: Sessions 3 and/or 4

1. Setting the session agenda
2. Sessional measures
3. Risk review
4. Review of self-monitoring record form

5. Session specific therapeutic content
    a. Review use of functional analysis ABC sheets on self-monitoring record
    b. Introduce principle of activity scheduling for increasing access to mood enhancing activities
    c. Introduce and complete an example activity planning tool
    d. Discuss goals in relation to activity scheduling

6. Summarise and check out collaborative understanding of session
7. Agree new activities
8. Manage any other business from agenda
9. End by agreeing next appointment time and place

Clinical tools associated with these sessions:
Functional Analysis ABC Sheet (Appendix C)
Self-Monitoring Record Form (Appendix D)
Goals Sheet (Appendix E)
Activity Planning Tool (Appendix G)

Phase I Session Guide: Sessions 4-6

1. Setting the session agenda
2. Sessional measures
3. Risk review
4. Review of self-monitoring record forms

5. Session specific therapeutic content
    a. Review use of functional analysis ABC sheets on self-monitoring record
    b. Review use of activity planning tool
    c. Introduce TRAP/TRAC using example of negatively reinforced avoidance from self-monitoring record form
    d. Undertake further activity planning for increasing access to mood enhancing activities and TRAP to TRAC for avoided behaviours

6. Summarise and check out collaborative understanding of session
7. Agree new activities
8. Manage any other business from agenda
9. End by agreeing next appointment time and place

Clinical tools associated with these sessions:
Functional Analysis ABC Sheet (Appendix C)
Self-Monitoring Record Form (Appendix D)
Activity Planning Tool (Appendix G)
TRAP & TRAC Worksheet (Appendix H)

Transition and Review Session A (session 7)

1. Setting the session agenda
2. Sessional measures
3. Risk review
4. Review of self-monitoring record forms

5. Session specific therapeutic content
    a. Revisit formulation
    b. Check progress against goals and valued activities
    c. Repeat rationales
    d. Identify remaining activities
    e. Develop overall plan for next phase

6. Summarise and check out collaborative understanding of session
7. Agree new activities
8. Manage any other business from agenda
9. End by agreeing next appointment time and place

Clinical tools associated with this session:
Formulation Diagram (Appendix B)
Self-Monitoring Record Form (Appendix D)
Goals Sheet (Appendix E)
Valued Activities Worksheet (Appendix F)
Activity Planning Tool (Appendix G)

Phase II Session Guide: Sessions 8-16

1. Setting the session agenda
2. Sessional measures
3. Risk review
4. Review of self-monitoring record forms

5. Session specific therapeutic content
    a. Review use of TRAP/TRAC and activity planning tools
    b. Introduce rationale for additional module
        i. Identification of specific issue to be addressed
        ii. Identification of personal examples of specific issue
        iii. Information giving about specific issue and module techniques
    c. Apply functional analysis
    d. Undertake specific modular exercises in session
    e. Plan further activity using specific modular techniques within functional analysis and TRAP to TRAC frameworks alongside continued activity planning for increasing access to mood enhancing activities and TRAP to TRAC for avoided behaviours

6. Summarise and check out collaborative understanding of session
7. Agree new activities
8. Manage any other business from agenda
9. End by agreeing next appointment time and place

Clinical tools associated with these sessions:
Functional Analysis ABC Sheet (Appendix C)
Self-Monitoring Record Form (Appendix D)
Activity Planning Tool (Appendix G)
TRAP & TRAC Worksheet (Appendix H)
And any additional clinical tools associated with chosen modules, e.g. Rumination Monitoring Form (Appendix I), Problem Solving Worksheet (Appendix J) or Anxiety Cycle Template (Appendix K).

Transition and Review Session B (session 17)

1. Setting the session agenda
2. Sessional measures
3. Risk review
4. Review of self-monitoring record forms

5. Session specific therapeutic content
    a. Revisit formulation
    b. Check progress against goals and valued activities
    c. Repeat rationales
    d. Identify remaining activities
    e. Develop overall plan for next phase

6. Summarise and check out collaborative understanding of session
7. Agree new activities
8. Manage any other business from agenda
9. End by agreeing next appointment time and place

Clinical tools associated with this session:
Self-Monitoring Record Form (Appendix D)
Goals Sheet (Appendix E)
Valued Activities Worksheet (Appendix F)

Phase III Relapse Prevention Session Guide: Session nos. <= 18-20

1. Setting the session agenda
2. Sessional measures
3. Risk review
4. Review of self-monitoring record forms

5. Session specific therapeutic content
    a. Introduce concept of maintaining progress and/or reducing relapse potential
    b. Acknowledge necessity to manage forthcoming therapeutic ending
    c. Consider following topics:
        i. Moving to self-planning without clinical assistance
        ii. Identifying signpost for action (relapse triggers)
        iii. Review goal and valued activities progress so far
        iv. Identify action to meet remaining goals and valued activities
        v. Identify help-seeking triggers and action to be taken
    d. Plan further activity using specific modular techniques within functional analysis and TRAP to TRAC frameworks alongside continued activity planning for increasing access to mood enhancing activities and TRAP to TRAC for avoided behaviours

6. Summarise and check out collaborative understanding of session
7. Agree new activities
8. Manage any other business from agenda
9. End by agreeing next appointment time and place

Clinical tools associated with these sessions:
Functional Analysis ABC Sheet (Appendix C)
Self-Monitoring Record Form (Appendix D)
Goals Sheet (Appendix E)
Valued Activities Worksheet (Appendix F)
Activity Planning Tool (Appendix G)
TRAP & TRAC Worksheet (Appendix H)
Relapse Prevention Worksheet (Appendix L)

Booster Session Guide

1. Setting the session agenda
2. Sessional measures
3. Risk review
4. Review of self-monitoring record forms

5. Session specific therapeutic content
    a. review of difficulties experienced
    b. identification of specific core or modular therapeutic techniques to revisit
    c. relapse prevention activities

6. Summarise and check out collaborative understanding of session
7. Agree new activities
8. Manage any other business from agenda
9. End by agreeing next appointment time and place

Clinical tools associated with these sessions:
Self-Monitoring Record Form (Appendix D)
Relapse Prevention Worksheet (Appendix L)
And any additional clinical tools associated with revisited modules.

9. Therapist notes detailing core and Phase II modular techniques

Core Technique:

a. Self-Monitoring

a. Self-Monitoring

Introduction and general description of the module/technique

Self-monitoring is the recording of activities and emotions by patients during the hours, days and weeks of treatment. Recording is usually done repeatedly during the day, using a specifically designed record sheet.

Self-monitoring is so core to BA, it is initiated early on in the course of therapy and provides information throughout. Martell and colleagues (2001) identify the following eight key functions of self-monitoring, although this list is not exclusive:

- Assess the patient's overall level of activity
- Provide information on the connections between mood and activity
- Assess the range of emotions the patient experiences
- Give information as to which activities are associated with feelings of mastery or pleasure
- Assess the range of activities engaged in by the patient
- Guide the selection of activities to increase, based upon their effects upon mood
- Identify and monitor avoidance behaviours
- Evaluate progress towards valued goals

The module/technique in detail

Step 1: The rationale for self-monitoring

Self-monitoring begins with the careful provision of a rationale. Here is an example:

"*In this therapy we are going to be looking at how changing what you do can change the way you feel. But in order to know which changes might be helpful ones, it is important that we know how the different things you do are linked to how you feel. I could just ask you, but it can be difficult to remember all of the different things we do every hour of every day, and exactly how we felt when we did them. So this might not give us the information we are looking for. Therefore, I am going to invite you to keep a record of what you do each day, and how you feel.*"

It can be helpful to compare changing patterns of behaviour to breaking a habit. For example,

"*Doing BA can be a bit like trying to break a set of habits: you are trying to learn to do certain things differently to get a better outcome. The first step in changing a habit*

is noticing that you are doing it. Keeping a record of your activities and how you feel will help you with this."

Patients can be invited to think about times they have tried to break a habit, in particular the need to be aware of what the negative consequences of the habit were, and the need to be aware of when the habitual behaviour was happening.

Step 2: Introducing self-monitoring in detail

Self-monitoring involves the use of a record form (see Appendix D) in which patients write down activity, mood and intensity, even on an hourly basis. In terms of the approach that patients should be encouraged to take, Martell and colleagues (2010, p.70) suggest that patients should be encouraged to "*act like scientists, examining their lives in detail, and to closely examine and record even the small things that they might otherwise think are unimportant*".

Recording Activity

Therapists should encourage patients to be relatively detailed when recording activity. The prompt questions "Who? What? Where?" can be used to facilitate this. For example rather than writing "*TV*" it can be more helpful to write "*watching TV in my room alone*". Therapists should include the idea that rumination is an activity to be recorded, and encourage patients to note down periods of rumination as part of their self-monitoring.

Recording Mood

Patients should identify and label the emotions they experience in connection with each activity, and rate these according to how intense they are, for example on a scale of 0-10. Initially it can feel more manageable for some patients to begin by rating merely how positive or negative they felt (from -10 = very negative to +10 = very positive), rather than identifying discrete emotions.

Frequency

Patients should complete the self-monitoring records as frequently as possible, ideally on an hourly basis. If this is not acceptable to patient or manageable, the frequency of rating can be broken down in several ways:

- Records can be physically filled in at less frequent points throughout the day. For example a patient might fill in their record at lunchtime for the hours of 8am to 1pm, at teatime for the hours from 1pm to 5pm, and just before bed for the hours from 5pm to 10pm.

- Patients can complete records for set periods of the week only, for example hourly Monday 9-12, Tuesday 12-3, Wednesday 5-10, and so on. These periods should span different times of day and likely patterns of activity.

- The patient can be invited to record less frequently throughout the week but to have a couple of set days when s/he records hourly.

It is important that the added value of frequent recording is emphasised. This can be demonstrated when the patient completes a practice record in session (see below). S/he can be asked to contrast the ease of completion and richness of information when the previous hour is recorded, compared to the previous day.

When planning frequency of record completion it is important to establish a specific plan for putting self-monitoring into action. Therapists need to agree with patients exactly records will be completed, how the patient will remember to do so, what practical steps does s/he will take to make self-monitoring happen, for example by putting a copy of the record in a bag taken to work.

In-Session Practice

Completing a self-monitoring record in session can be an extremely valuable exercise to identify potential misunderstandings or challenges in completion. It provides the patient with an initial positive experience of this new challenge, and helps them to understand exactly what is involved in the task. In-session exercises can include recording the day so far or the previous couple of days.

Homework

Self-monitoring is principally a between-session homework task. In addition to negotiating goals around frequency of completion, therapists should ask patients to identify any possible barriers to completion and these can be problem solved. Below we identify potential solutions to record completion challenges faced by patients.

Step 3: Reviewing self-monitoring records

Therapists and patients should review all self-monitoring records from the previous week together. In general the therapist is interested in what was learned from completing the record. There are some specific exercises that can be undertaken when reviewing the record. Martell and colleagues (2010) identify five questions that can guide therapists in exploring the record with the patient:

1. What connections are there between activity and mood?

From the patient's record it may be possible to identify both activities that are associated with better mood, and activities associated with worse mood. In some cases, the same activity will be associated with different mood states, reflecting differences in the context or in supplemental behaviours engaged in by the patient on each occasion. Particular exercises might involve: i) asking the patient to spot any changes in mood state, and then to explore the activities that occurred before, during and after this change; ii) asking the patient about whether they notice any patterns in the relationship between what they did and how they felt; iii) asking the patient whether there are any activities they notice that are missing from their records which in the past would have had a strong effect on mood, particularly positive '*anti-depressant*' activities.

2. What is the overall pattern of mood and emotion over the week?

Some patients will report a wide range of feelings, and intensities of feeling, across the week whilst others will report having limited emotional variation. In the latter case, therapists can explore this further with patients. This may lead to exploration of the range of potential – but absent – emotions and their features, as described in the previous section.

3. What is the patient's routine like and have there been any disruptions to this?

Often when people are depressed their routine can be affected. Conversely, disruptions to routine can often promote depression. Variations in daily routines can contribute to some physical symptoms of depression such as tiredness and appetite disturbance whereas regular routines can feel containing and comforting (Martell, 2010). Self-monitoring records provide therapists with an opportunity to explore the patient's routine in terms of features such as: sleep-wake times, meal times, and patterns of work and social contact. Therapists can ask patients to consider relationships between these aspects of routine and their mood states.

4. Can any avoidance patterns be identified?

Self-monitoring records can be used to highlight patterns of avoidance. For example, some activities that might be expected in the record might be entirely absent, such as social contact outside of work. In such cases it is important to explore with the patient whether s/he is turning down opportunities for such contact, and whether they are avoiding these opportunities to manage negative emotions that arise when social opportunities are on the horizon. Indeed, instances of increased negative emotions can sometimes indicate the presence of avoidance patterns. Therapists can ask patients to describe what triggered the emotion, what they did in response to the negative feeling and what the consequences of this were. Conversely, an absence of strong negative feelings in someone who reports severe emotional difficulties in their present life may reflect the use of avoidant coping strategies. These may include the drugs or alcohol to numb emotions.

5. Where should the therapist and patient look to initiate change?

Gathering information in the areas outlined above will help the patient and therapist identify areas for change to both increase positively reinforced activities and reduce negatively reinforced avoidance behaviours. This leads on to the other core techniques of functional analysis and activity scheduling covered in subsequent sections.

Often the review will also highlight difficulties encountered by the patient in completing the record. If the patient was not able to meet his / her completion goals with respect to recording the therapist should be alert to the patient having attempted the task, and reinforce the value of this. All information gained is useful, even information as to why the record was not completed.

Issues that can arise when reviewing self-monitoring records:

- *Blocks of time with little detail or variation in terms of mood and activity.* When this happens we explore it further with the patient. It may be that the patient did not use hourly ratings, in which case we can compare this block of time with a period in which hourly ratings were used. We can then encourage more frequent rating. We can also use visualisation to help the patient 'recreate' the block of time, and provide greater details about moods and activities. Finally, we can explore the potential presence of particular mental activities over this period, such as rumination.

- *Difficulty in identifying emotions*. It can be helpful to talk with the patient about the range of possible emotions that can be experienced, including positive or neutral feelings. We can then list these and if necessary we can assist the patient to determine how s/he would know which feeling was present by asking them to identify associated physical sensations, thoughts, behaviours etc.

- *Not completing the record*. Incomplete or absent record keeping is very common, particularly at the beginning of a BA programme. There are three common reasons for incomplete records:

    1. Practical issues, for example, difficulty writing, difficulty remembering to complete the record. We can use problem-solving to overcome these practical barriers, for example by suggesting the use of alternative methods of recording such as an audio recorder or computer.

    2. The patient feels that the benefits of recording do not outweigh the costs. Here, we can explore the patient's beliefs about the costs and benefits of recording and revisit the BA rationale. Patients may identify potential costs such as a fear of making depression worse, fear of 'realising' how little s/he does and how much 'worse' s/he is since becoming depressed. In order to address these ideas, we can try and help the patient with the idea that a first step towards changing depression is to know where you stand with it, using the 'habit metaphor. Next we can encourage the patient to complete a record of the previous day in the session itself. We can also advise the patient to break the recording task down into smaller chunks, for example recording every other day, and then observing the effects of doing so.

       Finally, we can introduce the TRAP pattern by showing how the triggering effect of remembering it is time to complete the record produces an emotional response such as feeling anxious or hopeless, followed by an avoidance pattern of putting the record away without completing. We can explain the consequences of not completing the record, for example it does not solve the problem, it leads to feelings of guilt, and in response we can explore alternative behaviours such as taking a small step towards completion.

    3. The patient believes that s/he has to be in the right frame of mind to complete the record.

       This is an opportunity for us to revisit the 'outside in principle of acting first to change how we feel, even if we do not feel like it. We can reinforce this by inviting the patient to recall times when s/he did something to help themselves despite not feeling like it with the consequent positive effects.

List of therapy materials used in this module and/or with this technique

Self-Monitoring Record Form (Appendix D)

Useful references:

Addis , M.E. & Martell, C.R. (2004). Overcoming depression one step at a time (pp. 23-44).Oakland, CA: New Harbinger Publications.

Martell, C.R., Addis, M.E. & Jacobson, N.S. (2001). *Depression in context: strategies for guided action* (pp.70-88). New York: W.W. Norton.

Martell, C.R., Dimidjian, S. & Herman-Dunn, R. (2010). *Behavioural Activation for depression: A clinician's guide* (pp. 71-75). New York: The Guilford Press.

Moore, R.G. & Garland, A. (2003). Cognitive therapy for chronic and persistent depression (pp. 172-197). Chichester, U.K.: John Wiley & Sons Ltd.

Core Technique:

b. Functional Analysis

b. Functional Analysis

Introduction and general description of the module/technique

Functional analysis is the study of an individual patient's pattern of behaviour and its variability. It is used to determine the contexts under which desired and undesired behaviours occur. The results of functional analysis guide interventions to systematically and therapeutically increase or reduce target behaviours. A functional analysis will include information on 'antecedents', 'behaviours' and 'consequences'.

The module/technique in detail

Step 1: Conduct a functional analysis

We use patients' self-monitoring charts to discuss their patterns of behaviour that are helpful or unhelpful. We do this in order to understand the individual links between behaviours and outcomes, and the *circumstances* under which specific behaviours result in negative or positive outcomes.

We use two acronyms to help the process of functional analysis:

- ABC
- TRAP/TRAC

Although these acronyms are helpful tools, they are not an end in themselves. We merely use the ABC and TRAP/TRAC strategies to help patients understand when behaviour results in specific desired or undesired outcomes.

ABC analysis - Antecedents ⇒ Behaviour ⇒ Consequences

1. examine the patient's self-monitoring record form/discuss recent events
2. look for instances where low mood and behaviour, or a lack of behaviour, are associated
3. alternatively look for when improved mood or performance and a target behaviour are associated
4. examine the record for antecedents or triggers for these instances
5. discuss the consequences of the behaviour or lack of it

TRAP – Triggers, Response, Avoidance Pattern

1. **Triggers** are identical to 'antecedents' and are factors that precipitated a specific kind of response
2. **Response** is an emotional or physical response
3. **Avoidance Pattern** is the behaviour that the individual engaged in

Critical features to consider in the functional analysis

- *What is the context in which the behaviour occurs?* We should consider when, where, how, and with whom behaviours do or do not occur. This will give us clues as to behavioural antecedents and functions, as well as ways to leverage change. For example, if unwanted target behaviours tend to occur in certain places or with certain people, these contextual factors can be examined as triggers. Once we have used the functional analysis to determine what specific element of that place or person is problematic, we then have scope for controlling the environment to reduce the behaviour. For example, if a patient is prone to become bored when sitting at home, plans might be made to make the environment more stimulating. Another example is if being in a hurry or trying to do too much is associated with a stressed response and avoidance, making plans to be more focused and less in a rush may reduce the target behaviour.

- *What is the function of the behaviour?* People engage in most behaviours for good reason. This is quite a normalizing message to give to patients. One way we can look at this with the ABC and TRAP models is to discuss the short and long-term consequences of behaviours. For example, people often engage in avoidance behaviours because they are negatively reinforcing. The more we avoid uncomfortable activities such as talking to someone else about an uncomfortable topic, the more short-term relief we feel and the more likely we will avoid the same activity again. However, there are usually negative long-term consequences of such avoidance in that the problem does not go away and may hang like a black cloud over our head. In a functional analysis it is important to understand the short-term advantages of avoidance as well as the long-term disadvantages.

  Look for patterns of behavioural responses to understand how a patient might habitually respond to particular antecedents. Understanding patterns can help us to design activities that whilst specific to certain contexts are also be generalisable. We can use the antecedents or triggers to help patients identify warning signs for particular habitual patterns of behavioural responses. Identifying such cues to habits enables the patient to consciously act to “nip the habit in the bud”.

- *Obvious and subtle avoidance.* Avoidance can happen in both obvious and subtle ways. Clear-cut examples of avoidance behaviours include lying in bed, calling in sick to work and avoiding paperwork. However, people often avoid in less obvious ways. For example, they can over-engage in behaviours in one domain of their life to the detriment of other important areas, for example staying on at the office late to avoid dealing with difficult situations at home, or spending a lot of time out socialising to avoid having to look for work. Avoidance can also be more subtle or covert such as avoiding eye contact in social situations or ruminating about difficulties. Because avoidance behaviours can become a habit, people may have difficulty identifying their behaviour as avoidance, particularly when it is subtle.

Look for what isn't being done, as much as what is being done. We can discuss 'important', 'routine', 'necessary' and 'pleasurable' activities and the balance between them. If there is considerable imbalance then that may be a clue about specific activity areas that are being avoided.

This series of questions will reveal the triggers and consequences of behaviours and the environments under which they are more or less likely to occur. We can then formulate the potential function of the behaviour and begin to choose interventions for the target behaviour. Critically, with functional analysis, all behaviours are fair game: "everything is grist to the mill". For example, if a patient was to return and report that they did not complete homework, we can perform a functional analysis on times when homework has been done or not to understand what influences completion and then take this into account in future planning.

Step 2: Identify alternative behaviours

Once we have undertaken a functional analysis we can start to identify alternative behaviours in response to the triggers. These alternative behaviours are varied and can include exerting environmental control to disrupt the triggers, or developing alternative responses such as increased approach behaviours. It is here that the TRAP/TRAC acronym really helps. We can help patients to recognise TRAPS and to shift to TRAC – Trigger Response, Alternative Coping – using questions like "*What is the TRAP here?*"; "*So what could get you back on TRAC?*"

Questions for identifying alternative behaviours

1. "*Let's think of all the possible alternative approaches to this, no matter how wild or simple they might seem.*" We can ask the patient to write all of the ideas down, no matter how unlikely a response it seems at first. Later, patients can choose which behaviours might work well and pick the most likely one.

2. "*Have you had similar situations in the past, perhaps when you weren't depressed, when you dealt with this kind of a situation in a way that you felt was more helpful for you? What did you do?*" By obtaining explicit and detailed comparisons of contrasting situations, such as a time when a similar behaviour such as trying to problem solve was helpful, can help us understand alternative behaviours and contextual influences.

3. "*If you knew someone else with a problem like this, what would you recommend they do?*"

Interventions emerging from the functional analysis

1. Altering environmental triggers directly when the functional analysis reveals aspects of the environment that increase the likelihood of unwanted target behaviours including approach, avoidance, and rumination.

2. Replacing behaviours with ones that break the trigger/avoidance pattern or lead to more positive and valued activities. These latter behaviours are covered in more detail in the functional equivalence section of this handbook.

Simple homework exercises set up as behavioural experiments can be tried from as early as session 1 or 2 to influence behaviours by disrupting the antecedent triggers.

Examples might include changing a routine, creating a tidier work-space, focussing on one thing at a time. When designing such alterations of the environment, it is important to determine which aspect of a situation is central to behaviours such as avoidance or rumination. For example, if being by oneself is a trigger for lower mood, this might reflect being alone, feeling lonely, experiencing a lack of encouragement, a sense that activities feel pointless done on their own, and/or a general lack of structure. Further questioning ("thought experiments") can find out what aspect of being alone patients find most difficult and what they really value about being with someone else. We then use this information to inform the environmental change that is likely to be most useful. For example, if a lack of encouragement is the main reason for why being on one's own is problematic, then the contingency plan may examine ways to increase self-encouragement.

We can actually test these ideas 'experimentally' to examine the consequences of changing the patient's environment. For example, we can structure a test where the patient listens to the radio in the morning to move their focus away from feelings of tiredness. If being alone is a trigger, we can test the effect of increased social contact. If sad music in the car triggers negative ruminations, we can test the effect of replacing it with alternative music when the trigger occurs. There are many such examples, all of which will flow from our detailed functional analysis.

Finally, we can address avoidance directly by increasing the patient's daily structure, their activities, and their routines. This is not necessarily an example of the functional equivalence principle, but a more basic introduction of activities which most people use to structure their lives. It is still important to identify activities which make sense to patients and those which they find desirable or useful. These activities will not necessarily be pleasurable. However, routines do anchor many people to a sense of emotional safety. Simple things such as a regular walk, doing some tidying, and clearing up the dishes may not be the most pleasurable of activities but they can begin the process of activation.

Step 3: Develop a contingency plan

Once alternative behaviours are identified, we should draw up a contingency plan with the patient. This is known as the 'if-then' or TRAC plan. The patient uses this plan in response to triggers identified in the functional analysis.

The "if" component describes the warning signs and context that triggers the problematic behaviour. The "then" component describes the alternative behaviour to enact in response to the trigger. For example, for a patient who tends to avoid confrontation, the contingency plan might be: "*if I notice that I disagree with someone, then I will practise expressing my point of view*". Patients should write down such plans explicitly as part of their homework plans. Because avoidant

behaviour is often habitual, repeated practice at utilising the alternative response is required before it becomes more automatic and well-established.

Contingency plans usually consist of two types of strategy:

- Strategies to break up avoidance and rumination patterns often focused around activity scheduling and problem-solving. These are covered in more detail in the respective sections of this manual.

- Strategies to replace avoidance and rumination patterns. Usually, these should be activities that are valued by patients. These are covered in more depth in the Rumination and Functional Equivalence section of this manual.

The core principle of a contingency plan is to identify the triggers for unhelpful avoidant behaviour as early as possible and to replace the avoidant behaviour with approach behaviour, thereby "nipping in the bud" the avoidant behaviour.

We can suggest any strategy or technique within the BA repertoire as an alternative response to interrupt or replace any identified avoidance behaviour. We select a alternative behaviour that is consistent with the antecedents preceding the target behaviour identified in step 1. The alternative behaviour must fit the original behaviour's hypothesised function. The exact contingency plan made will need to depend upon the specific patient-centred details shaped by the functional analysis. Any contingency plan is initiated in real life when the specific trigger for the target behaviour occurs. We select alternatives based on the functional analysis described earlier utilising if-then, TRAP, and TRAC plans. A number of possible alternative behaviours are described below.

Exerting environmental control on target behaviour

- If avoidance tends to occur at a regular point in the day, then planning a more active schedule at that time may be helpful. For example, for the patient who tends to sit down and do nothing in a lounge chair on return from work, preventing this sitting down and scheduling in other activities may disrupt the reduction in mood.

- If a patient tends to lie in bed, getting out of bed and doing something else would be an important part of the contingency plan.

Alternative behaviour

- Breaking tasks down into smaller steps

  If an activity seems too big for patients to do, it can feel like it is overwhelming and impossible to do, causing the patient to become avoidant or feel hopeless. It can help to break the task down into the smallest steps possible, choose the first smallest step necessary to start moving forwards, and to start on that.

- Opposite action

If an unwanted target behaviour is linked to a particular negative emotion or feeling (i.e. the Response in TRAP), we need to instigate a plan that generates an alternative emotion. For example, if the danger trigger is feeling low and lacking in energy, the solution could be to undertake a behaviour that is positive and energising.

Patients can sometimes get stuck because they are waiting to "feel right", "be in the right frame of mind" or "feel good enough" to act on one of their plans. We should encourage patients to practice acting towards a goal and acting "as if" the desired state or outcome was present. For example, patients can practice acting as if self-esteem was high and they felt really good about what they did.

Shifting the focus to "acting as if" and following through a plan despite how s/he feels can be an important lesson. It can establish the idea that feelings can follow actions, rather than actions follow feelings.

- *Activity scheduling and building up approach behaviours*

  Where the target behaviour-to-be-reduced acts as a form of direct avoidance (e.g., not seeking work; not talking to family about a problem), it is particularly helpful to examine the pros and cons of this behaviour and to encourage patients to try the actual avoided activities in the real world. We can set up a behavioural experiment where the patient attempts to approach and address difficulties directly. There is an important idea about learning to try things out in the real world, learning from experience, and providing the opportunity for success. In terms of short versus long-term outcomes, it is helpful to review how whilst avoidance can avoid the risk for short-term failure, it also avoids long-term opportunities for positive events and experiences. When selecting approach behaviours, it is important to bear in mind the functional analysis and chose events that are likely to be meaningful, relevant, and valued by the patient. The likelihood of completing planned activities can be increased by setting up situational contingencies for the behaviour such as putting it in a schedule, the patient telling other people what they are going to do and engaging their support, and setting up physical surroundings that are conducive to facilitate the activity. For example, if the plan is to increase exercise, it is helpful to make plans to ensure the relevant sporting kit is easily to hand, that the sporting facilities are nearby and open, and the time for exercise is unlikely to be encroached upon, e.g. Packing up swimming trunks, goggles and towel in a bag and taking it to work, so that the patient can go straight to the swimming pool from work. It can also be helpful to collaboratively order potential approach activities in terms of difficulty and then plan to gradually move through this hierarchy starting with the easiest actions. For further details see the later section on activity scheduling.

- *Progressive muscle relaxation*

  This is useful when there are clear physical stress response and anxiety triggers for the avoidance behaviour and where the patient is using the avoidance to reduce anxiety and/or anger. In this situation, relaxation may provide a more functional alternative.

- *Communication (for further details see Communication Module)*

  When the identified avoidant behaviour is focused on interpersonal situations and involves not addressing issues with other people, work on improving communication might be helpful.

- *Rehearsal and role-playing in the session*

  When planning new approach behaviours that patients are less confident about and feel more hesitant about, especially those involving a social interaction, it may be helpful to explicitly rehearse the behaviour and role-play performing the action in the therapy session.

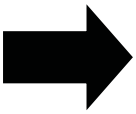
- *Problem-Solving*

  Avoidance can reflect a failed attempt at problem-solving and planning. Therefore, teaching the patient to practice a systematic problem-solving system, using a recognised and logical set of steps, can thus be a useful alternative. For further details, see later module.

The Rumination module also provides detailed examples of functional analysis and the development of contingency plans.

Example TRAP → TRAC

Trigger (perceived criticism)
Response (increased anxiety)
Avoidance -
Pattern (rumination)



Trigger (perceived criticism
Response (increased anxiety)
Alternative
Coping (problem-solving)

List of therapy materials used in this module and/or with this technique

Functional Analysis ABC Sheet (Appendix C)
TRAP & TRAC Worksheet (Appendix H)

Useful references:

Addis , M.E. & Martell, C.R. (2004). Overcoming depression one step at a time (pp. 23-44).Oakland, CA: New Harbinger Publications.

Martell, C.R., Addis, M.E. & Jacobson, N.S. (2001). *Depression in context: strategies for guided action* (pp.70-88). New York: W.W. Norton.

Martell, C.R., Dimidjian, S. & Herman-Dunn, R. (2010). *Behavioural Activation for depression: A clinician's guide* (pp. 71-75). New York: The Guilford Press.

Core Technique:

c. Activity Scheduling

c. Activity Scheduling

Introduction and general description of the module/technique

As noted in the page summary earlier, activity scheduling is the final core component of BA. Self-monitoring helps us understand the patient's individual behavioural context. Functional analysis gives us information on the triggers and reinforcers for these behaviours. Activity scheduling is the planned reshaping of the patient's behaviour towards those that are less depressogenic.

The module/technique in detail

Because activity scheduling runs throughout BA, schedules may look quite different at different stages of treatment. However, throughout therapy, activities are always selected with a clear and specific purpose in mind. There should always be a reason why certain activities are scheduled into a person's plan.

The most likely reason is that scheduled behaviours have been selected will be because they represent an alternative to either avoidance or short-term but ultimately self-defeating behaviours. We cannot rely on new, positively reinforcing behaviours appearing by chance. We plan them into a person's life.

It is helpful to think about activity scheduling in seven steps, summarised below.

1. Identify situations and behaviours from the self-monitoring record forms that are associated with the patient's low mood

2. Ask the patient to consider alternative behaviours. These may be anything at all, not necessarily 'anti-depressant' activities. They may be even more likely to lead to depressed mood. It is, however, important to consider the full range of alternatives at this stage.

3. Ask the patient to select one or more of these alternative behaviours and schedule them into a weekly plan (see Appendix G), often as small steps, not giant leaps.

4. As noted in the section on functional analysis, we should encourage patients to adopt an 'experimental' attitude to their activity scheduling. What we mean by this is for them to be curious about the **outcome** of the new scheduled behaviour(s). Rather than a test of perseverance, instigating new behaviours is a test of the effect of these behaviours on patients' mood.

5. Once patients have decided what new behaviours to try and have planned them into their weekly schedule, they should implement them. It is better if this plan includes trying the behaviours more than once if possible. It is better that one new behaviour is tried a number of times than many different behaviours implemented only occasionally.

6. We should encourage patients to evaluate the results of implementing these new behaviours in terms of the impact it has on their mood. Records kept in the activity schedule self-monitoring log should, therefore, include a rating of activity **AND** mood.

7. We now have to ensure patients continue with the experimental attitude. They should not expect 'quick fixes'. New activities should be tried repeatedly, scheduled in regularly and examined in terms of the outcomes. We should encourage patients to think about a two-three week schedule of activities where similar new behaviours are planned carefully on a regular basis.

The seven activity scheduling steps in more detail

1. Identifying situations associated with low mood

We use the self-monitoring record forms to identify when a patient is feeling low. Taking this situation, time of the day etc., we then investigate what was happening during this time. Matching behaviours to mood is the first essential step. The most useful mood-behaviour pairings are those that happen more than once, often as a regular pattern. We are trying to help patients find predictable times, situations and if possible, regular behaviours that are all linked to low mood.

2. Generating ideas for alternative behaviours

Once we have helped the patient to identify the time-situation-behaviour-mood examples in step 1, we can help them to think of new 'alternative' behaviours. It does not matter whether these behaviours are realistic or fanciful, likely to be helpful or make the situation worse. The main objective in step 2 is to think of as many different alternatives to the current behaviour as possible, since the current behaviour is linked to low mood. Even this process itself can be helpful, since it highlights to patients that they may have choices, something many depressed people feel that they lack.

3. Selecting new behaviours and scheduling them into a weekly plan

By now, one or more situations associated with low mood should be accompanied by a list of alternative behaviours. The next stage is to help the patient select one or more activities that you and they believe might improve mood in these situations. During the early stages of therapy, we have to walk a tightrope between over stretching and doing too little. It is far better to choose activities that the patient feels they have a reasonable change of completing. However, many patients can easily get into a 'boom and bust' cycle where they attempt too much too soon. Once the activities are *selected* they should be *scheduled.* Using an activity scheduling record sheet is absolutely essential so that patients have a clear plan of what they will do and when they will do it.

4. Experimenting

This is not so much a step as an overarching attitude. We must encourage patients to think curiously about what effect the new behaviour has on their mood. It may make them feel better; it may make them feel worse. This is where we can reiterate the 'outside-in' principle. We should make sure that patients are not waiting to feel better before they implement an alternative behaviour. The main thing is to see what the **outcomes** of the new scheduled behaviour(s) are. If you really instigate this manner of thinking then you guard against disappointment, since any result is going to be useful for discussions at the next appointment. There is no success or failure, just interesting information to review and reflect on.

5. Implementing alternative behaviours

Quite simply, this step is when the patient leaves the appointment with a plan and they complete the activities specified in that plan. Very importantly, they should record these activities *and* their mood during them, using the self-monitoring record forms used earlier. You should advise the patients to make sure they are fully involved in implementing the planned behaviours, focused on them and not distracted or thinking about something else. Secondly, you should advise patients to wait until the behaviour is finished before evaluating it. Finally, all experiments need replication. Implementing alternative behaviours is no different. Remind patients to try the new activities several times.

6. Evaluating the effect of the alternative behaviours

The great beauty of record keeping is that we can use them to compare progress. Self-monitoring record forms with new activities scheduled on them can be compared with old sheets. The important piece of information to compare is how the mood ratings have shifted or not in response to the new behaviours. This is the 'raw data' from which we can evaluate the success or failure of the alternative behaviours. This data tells us much about the impact of behaviours on mood. We use these ratings as major discussion points in our next session or sessions. We should always focus on what we can learn, and what the ratings tell the patient about mood and behaviour links. It is not a success or failure conversation. It is a learning conversation.

7. Continuing to experiment

As stated above, regular and repeated practice is the way to embed new, more helpful behaviours into someone's life. There are no really quick fixes. We need to help people make the new more helpful behaviour a very regular part of their lives. Each week's activity records should be scheduled to this effect.

Of course, this is only desirable if the new behaviour has had a positive effect. If not, more experiments are needed, trying out new behaviours in new situations. Recording this carefully, including ratings of mood will help patients understand the connection between mood and behaviour and make the 'outside-in' link. If the experiment has not been successful the first step is to check to see if the patient was fully involved in what they were doing. Secondly, if this was true, we can help them select another behaviour, reflecting on what it was about the previous one that did not do the trick. Avoid giving in too easily, however. Often it might be a good idea to try an alternative behaviour a few times before giving up. Finally, make sure patients record their mood soon after undertaking the alternative behaviour. When people are depressed they often find it difficult to remember exactly how they felt at the time of doing something, particularly if their mood is very low. What we want are accurate ratings, not inaccurate retrospective accounts.

Other points

Activity scheduling in the early stages of treatment can take one of two forms. Either, the self-monitoring will have identified very clearly that some basic activities are just not happening, or a patient will want to replace obviously negative behaviours with alternatives. The latter is an example of how problem solving as a state of mind runs right through BA. Initially, selection of behaviours may not flow from a TRAP/TRAC

analysis. It may be absolutely obvious that a person needs to do something immediately to stabilise their situation. It is important that patients do not wait to feel ready to do these things, but do them to help feel better over time.

Generally, however, we encourage patients to plan activities in a purposeful way. Activities are selected that have a clear focus and are drawn from the insights of the functional analysis. Planned activities may include new 'functionally equivalent' behaviours to replace activities that are no longer possible in a person's changed life. Activities may be a return to old behaviours that have been dropped or avoided. Activity schedules may be explicitly about reducing current behaviours that are actually depressogenic. Some scheduled activities may be used to disrupt depressed thinking or behaviours in the face of known danger signs and triggers.

The main message to give about activity scheduling is that it runs throughout the whole course of a BA programme. Planned behaviours all have a clear rationale, are best if they represent the implementation of a person's value set, and are often designed in an experimental way. Patients act as scientists in their own personal laboratory, investigating the impact of reducing negatively reinforced avoidance and increasing positively reinforced behaviour. What we expect is that if we understand the triggers and contingencies, once we schedule in the behaviours the reinforcement effects will take over and help shape the person's behaviours in a more positive direction.

Alongside self-monitoring record forms, activity scheduling records will be the most frequently used and discussed tools in the behavioural activationists armoury.

Activity scheduling is not a particularly difficult behavioural activation technique, but it can be done badly, nonetheless. Once a patient has got familiar with the idea of self-monitoring situations, behaviours and mood, we can use functional analysis to help identify a way out of the TRAPs people find themselves in. Selecting alternative behaviours to address these TRAPS and get on TRAC is the trick to activity scheduling. Activity scheduling may seem like only the planning of things to do. It is much more than that, however. It is the pathway out of depression. Our job as therapists is to provide patients with a map of that path.

List of therapy materials used in this module and/or with this technique

Self-Monitoring Record Form (Appendix D)

Activity Planning Tool (Appendix G)

d. Phase II Modular Techniques

i) Rumination Module

d.i) Rumination Module

Introduction and general description of the module/technique

This module is based on the development and evaluation of treatments for rumination (BA for rumination; concreteness training) conducted by Watkins over the last 15 years. It includes material directly adapted from existing manuals (copyright retained, © Watkins, 2004, 2008, 2009, 2011). For further details please see Watkins et al., 2007; Watkins, 2007, 2009; Watkins et al., 2009; Watkins et al., 2011; Watkins et al., 2012.

Rumination is repetitive negative thought, a covert mental process common in depression. It tends to focus on self, negative mood, problems and difficulties. Rumination is characterised by judgemental, evaluative thinking and often includes negative comparisons, focused on the meanings and implications of events, for example, "*Why me?*" "*Why can't I feel better?*"

From a BA perspective, rumination is a form of avoidance that has been negatively reinforced in the past through the removal of aversive experiences. The reinforcement of rumination may involve:

1. Superstitious reinforcement, i.e., a false association between rumination and a positive outcome as a result of the person interpreting ruminating and the positive outcome occurring close together, as connected

2. Partial reinforcement, i.e. there have been times when rumination was useful and intermittently functional. This 'intermittent reinforcement schedule' means that it is hard for the behaviour to reduce when no longer of value

3. Poor discrimination between repetitive thinking which is helpful, such as helpful thinking about problems in a problem-solving manner, and unhelpful brooding.

The potential avoidant functions of rumination are numerous but may include: avoiding job challenges or the tedium of the daily grind; avoidance of the risk of failure or humiliation by putting off doing something by thinking about it instead; cognitive avoidance or worry through mental preparation, planning and attempted cognitive problem-solving; pre-empting other's criticism and anticipating potential negative responses through second guessing or mind-reading to avoid actual criticism; controlling one' feelings; making excuses.

The view taken by contextual-functional approaches to depression such as BA (Martell, Addis & Jacobson, 2001; Watkins et al., 2007) is that rumination may be more frequent and extensive if it has been learned in the course of someone's life in response to particular environments with perceived positive consequences. This module describes how the BA approach, and in particular functional analysis, is used to treat rumination (see Watkins et al., 2007, 2011). To do so, we have to think about rumination as a behaviour and undertake rumination-focussed BA exercises just like we do for physical behaviours themselves.

The key elements of this rumination module are:

- A patient-centred assessment with a clear rationale for the focus on rumination, building on the idea that rumination is learnt behaviour. We incorporate the patients' developmental history into our rationale.
- Practice at spotting rumination, avoidance, and early warning signs, using formal homework such as monitoring records that also include reports of rumination.
- Functional analysis to examine the context and functions of rumination, when rumination occurred what preceded it and what its consequences were.
- The development of contingency plans, involving different and more helpful responses to rumination triggers.
- The use of experiments to examine whether rumination is adaptive or not and to try out alternative strategies.
- Increased activity and reduced avoidance, building up routines, and increasing non-ruminative activities, explicitly targeting behavioural changes**.**
- Exercises to provide experience of using attention as a counter to rumination to establish alternative thinking styles, such as problem-solving or a focus on being engaged and absorbed in the world rather than in one's head.
- A focus on the patient's values to minimise rumination about non-valued areas and to encourage activity in line with values.

The module/technique in detail

Step 1: Rationale and explanation of rumination

It is usually helpful to provide patients with information on rumination and to check that it matches their personal experience. We can acknowledge rumination as a common, understandable, but unhelpful process. This strengthens our rationale and helps to develop the therapeutic alliance. The rationale builds on the established functional-contextual approach used throughout BA. The history and development of rumination can be identified and made sense of with the patient. Most patients find that the explicit recognition of rumination and worry is very helpful as it may not have been discussed with them before.

Summary of the treatment rationale:

Recurrent negative thinking and avoidance are the central engines maintaining depression. Both avoidance and rumination are quite normal and functional in limited amounts under the right circumstances. However, when used excessively or when they are out of balance, they can become a problem. Excessive use occurs because of past learning that rumination was at least temporarily beneficial. Because it was learnt, it can be replaced with a new more helpful strategy. Therapy teaches patients to learn a new personalised and more adaptive approach. This leads onto the functional analysis. The joint development of this rationale can be used to explicitly normalize rumination, e.g., discussing how we all ruminate some of the time, and how it makes sense to ruminate under the patient's particular circumstances.

After this general rationale, we can review the patient's own experience, talking through the overall effects of rumination including recent examples. We can get a sense of how it may have developed as a learnt behaviour, and generate evidence of how it is unhelpful. By reviewing the development of rumination as a learned behaviour we can see how the development of rumination makes sense in the

context of the individual's life. For example, ruminating about how someone else thinks about you could act as a means to second guess a difficult parent and avoid criticism and abuse. The problem arises where rumination has become overgeneralized to other situations.

This initial rationale phase therefore includes assessment of rumination generally and specifically. The purpose is to understand where rumination is a major problem involving extensive unproductive dwelling on negative material, examine the consequences of rumination, identify rumination as the target of therapy and explain what rumination is, using examples from the patient's own experience. The focus is on identifying rumination as recurrent, repetitive thinking about self, mood, problems and difficulties that is unhelpful and in which patients get stuck. We can use terms such as 'rumination', 'brooding', 'worry', 'getting stuck in my head', 'going round and round in my head', etc. It is good practice to use the term that makes most sense for the patient and reflects their own use of language.

It is noteworthy that rumination has been implicated in both anxiety and depression, so targeting of rumination may be particularly beneficial for addressing such co-morbidity.

An important part of this rationale is the identification of rumination as a learnt habit, i.e. as an automatic TRAP response triggered by particular circumstances. This idea is straightforward, plausible to patients, and naturally leads into a discussion of how it might change. The discussion on change can begin through the identification of triggers for rumination, and then considering either removing those environmental or internal triggers and/or learning of new habits through repeated practice of an alternative response to the same trigger. It can be useful to reflect on any lessons learnt from a patient's prior experience of changing habits, for example study habits, exercise habits, eating habits and smoking habits.

Step 2: Functional analysis

In addressing rumination, we use exactly the same functional analytic principles as used more generally in BA. We apply this to understanding the particular functions of rumination including understanding, self-motivation, planning, avoiding, etc.

The functional analysis is then used to help patients:

- Recognise warning signs for rumination as cues for the 'rumination habit'
- Develop alternative strategies and contingency plans which are incompatible responses to that of rumination and which either interrupt the bout of rumination or replace the function of rumination with a more constructive alternative such as approach behaviour, problem-solving, compassion, absorption, connecting with experience, assertiveness or relaxation.
- Alter the environmental and behavioural contingencies maintaining rumination, towards more self-fulfilling activities.
- Shift towards more helpful thinking.

This plan can incorporate the TRAP and TRAC plans typically used in BA with a focus on rumination.

Antecedents: common triggers for rumination include:

- Stressful situations, for example, when there is too much to do, when being judged, when bored, when being criticised, when reminded of a particular event.
- Certain places, for example, at home, private space, in bed, at school or college or work. Many people report that they ruminate in particular places such as when lying in bed, when sitting down for a coffee. Individuals may have got into routines where they tend to ruminate at particular places and times. Identifying the routine and then shifting away from it can be a useful approach to break out of the rumination.
- Certain times of the day. The most common times reported for ruminating are first thing in the morning just after waking up and in the evening, at the end of the day, often lying in bed, not able to sleep. Frequent rumination at these times makes sense because these are times when someone may anticipate or reflect on the day, and also tend to occur when less physically active and when there is less external distraction.
- A number of physical and bodily responses are common warning signs for rumination, including tension in the shoulders, neck or back, feeling wound up, anxious, irritated and frustrated. Other warning signs include a person's tone and volume of voice becoming louder and more critical, becoming hot/ flushed, increased heart rate, butterflies in stomach, sinking feeling, heavy feeling, upset stomach.
- Certain behaviours can be a risk factor for rumination, for example, becoming inactive, lying around and not doing much, putting things off, rushing around, avoiding people, confronting people, withdrawing, thinking rather than doing.
- Particular aspects of thinking are also common warning signs and triggers for rumination, for example attention narrowing onto a single concern or problem and becoming closed and rigid into a kind of 'tunnel vision', finding it hard to concentrate on other things, thinking becoming chaotic, muddled, messy and woolly, a mind that is 'whirring' and jumping from one thing to another, self-doubt, thinking that is moving away from the particular situation to consider other situations, self-criticism, focusing on how the way things are going is different from how one expects or wants them to be. Much of this way of thinking can be seen as "*Why?*" thinking.

Identifying these warning signs can be used to try to help patients 'nip rumination in the bud' by engaging in counter-ruminative activities before the bout of rumination gains momentum. For example, for physical triggers, activities such as relaxation to reduce stress and arousal may be helpful in preventing thinking escalating into a bout of rumination. For external environmental triggers, leaving the situation or changing the environment can prevent the rumination. If a mental sign such as narrowing attention is a warning sign for rumination, a useful alternative may be a deliberate attempt to expand attention outwards to the world rather than inward on the self. This strategy is described by Martell and colleagues as connecting with the environment, in which the patient pays close attention to the world by going for a walk for example, and being as aware as possible of the sights and sounds of the countryside.

Behaviour: the function of rumination. During the functional analysis we provide some explanation of how rumination as a habit makes sense, usually because

patients' past experiences have taught them that rumination provided an initially helpful function. Habits tend to develop through repeated practice of an action and when the action gets some pay-off it is reinforced. It is therefore useful to find an alternative response that has the advantages and not the disadvantages of ruminating, an alternative behaviour that has some of the same pay-offs but without the downsides making it more likely that the new helpful response will persist.

Consequences: examining the consequences of rumination provides further information about the function of the ruminative behaviour.

Here is a list of common functions for worry and rumination that we can use to check with the patient to see if they are consist with their behaviours:

- To help predict what could go wrong and prevent bad things from happening
- To try and understand and problem solve a problem or difficulty
- To motivate and stop letting things slip
- To try and be certain about the best way to do something before acting
- Because it is safer to "*do it in my head*" than to take a risk in the real world
- To put off doing something
- To punish
- To try and mind-read and second guess others
- To change emotions
- To avoid becoming the kind of person a patient does not want to be
- To avoid the risk of failure or embarrassment
- To justify the way a patient is feeling
- To stop letting go of something important

For example, for a patient who ruminates in response to feeling angry, and for whom the consequence of rumination is to reduce anger but maintain depressed feelings, we would formulate the rumination as serving the function of controlling anger. Further exploration of the patient's history might then reveal that he had a very violent and aggressive parent and that he is afraid of becoming like him and losing control of his temper – such that for him being angry is very aversive. Thus, rumination for him is focused on putting himself down and minimising his own importance and acts as a form of avoidance that is negatively reinforced because it serves to reduce this aversive anger. This is despite rumination being a trigger for his depressed feelings.

Step 3: Contingency plans for disrupting rumination

We can suggest any strategy or technique within the BA repertoire as an alternative response to interrupt or replace rumination. We select the alternative behaviour that is consistent with the antecedents to the rumination and fits the hypothesised function. The exact contingency plan made will need to depend upon the specific patient-centred details shaped by the functional analysis. Like any contingency plan, it is initiated when a specific trigger for rumination occurs. We select alternatives to rumination based on the functional analysis described earlier utilising TRAP and TRAC plans (or formulated as if-then plans, as described in the functional analysis section).

Exerting environmental control on rumination.

- If rumination tends to occur at the point that a patient is sitting down at the end of the day and beginning to reflect on the day, then planning a more active schedule at that time may be helpful

- If a patient ruminates when listening to sad music, a simple environmental change would be to play different music

- If a patient tends to ruminate when lying in bed, getting out of bed and doing something else might break the rumination.

In each of these cases, the change in behaviour could be investigated as an experiment to determine its effect on rumination and other symptoms.

Interrupting rumination.

- Slowing things down

  We can use this when patients describe situations where they have too much to do. In these cases they might feel anxious, experience physical reactions such as a pounding heart, try to do everything at once, and have thoughts which jump from one to another. If rumination occurs when patients are trying to do too many things at once, it might help to slow things down and to focus on only doing one thing at a time, to pace themselves, and to prioritize what they are doing.

- Becoming more active

  Here the opposite situation is the case, where patients are bored and don't have anything to do, are inactive, and experience ruminative negative thoughts. In this case we can encourage patients to plan to be more active and do something interesting, enjoyable, or merely useful at those times. It might also be useful if the patient clarifies their schedule and sequence of activities over the week to identify particular times that tend to have more 'dead time' so they can plan to be more active at those times.

- Breaking tasks down into smaller steps

  If a looming deadline or other activity seems too big for patients to do, it can feel like it is overwhelming and impossible to do, causing the patient to become stressed and start ruminating. It can help to break the task down into the smallest steps possible, choose the first smallest step necessary to start moving forwards, and to start on that.

- Opposite action

  If rumination is linked to a particular emotion or feeling, it can be helpful to have a plan that generates an alternative emotion. For example, if patients ruminate when feeling tense or irritable, they can plan to do something calming or relaxing

to head off the tendency to ruminate. Even simple examples like looking down at the ground when feeling sad can be changed to standing straight and looking up. Changing activity is another example, when patients would rather stay at home they can use this as a trigger to go outside and do something active. Opposite action means acting in a way that is different than the emotion felt so that patients actually act themselves into feeling differently. This doesn't mean patients pretending not to feel their emotion since it may be perfectly appropriate to do so. Opposite action just means that patients decide it is not helpful to act on the emotion they are feeling in the moment.

Other behavioural techniques to counter rumination.

- *Activity scheduling and building up approach behaviours*

  Where rumination acts as a form of direct avoidance it can be helpful to examine the pros and cons of this behaviour and to encourage patients to try the actual avoided activities in the real world. We can set up a behavioural experiment where the patient attempts to approach and address difficulties directly. Even when patients do try out something in real life and it doesn't end up the way they wanted, they can learn something by it, namely that many things in life can only be addressed through trial and error, learning how to do it through experience rather than by ruminative analysis. It is important to explore and experiment with patients whether some skills and abilities are best developed through experience rather than conceptual analysis, e.g., "Can you become good at interacting with others just by thinking about it?" Rumination is often more frequent when individuals are busy with activities that they feel they are obligated to do ("responsibilities", "chores") but do not enjoy. Building in activities that individuals are excited and enthusiastic about can be important to reduce such rumination.

- *Progressive muscle relaxation*

  This is useful when there are clear physical stress response triggers for rumination and where the patient is using rumination to control their feelings and reduce arousal such as anxiety or anger.

- *Communication*

  When rumination is focused on interpersonal situations and the avoidance of addressing issues with other people, some work on improving assertiveness and communication might be helpful.

- *Rehearsal and role-playing in the session*

  Rumination often involves thinking over and over again about possible future events and the outcomes of trying a new thing. Patients typically get caught up in thinking through the implications of such action in terms of "*What will happen?*" This function of rumination concerns trying to be certain about will happen or to avoid bad things happening. In these situations, the strategy is to teach the patient to replace repeated thinking about the possible outcomes with 'concrete rehearsal' of what the patient will say and do. This move from abstract to

concrete thinking, as preparation for going and doing the activity can be enhanced through rehearsal and role-playing in the session.

- *Problem-Solving*

  Rumination can be a failed attempt at problem-solving and planning. Therefore, teaching the patient to practice a systematic problem-solving system, using a recognised and logical set of steps, can thus be a useful alternative (see section on Concrete thinking later and module on Problem Solving).

- *Increasing absorption and connection with experience*

  One of the common effects of rumination is that it can interfere with the ability to connect directly with the reinforcing experience of a rewarding activity. For example, even though a patient may be doing an activity such as going for a run that they previously experienced as rewarding and pleasurable, if s/he is ruminating this may block any rewarding effect. This may be because: the focus of the patient's attention is internal and self-focused rather than on the activity itself; their rumination is abstract or evaluative and may involve negative comparisons such as "*I used to be much better at this*" or "*This is harder than I expected.*" Ruminations in this type of situation often occur in the form of an internal 'running commentary' on the activity that interferes with the potential benefit of the increased activity. Finding ways to become more absorbed and connected with experience is therefore a useful means to interrupt rumination and to optimise the impact of activity scheduling.

  Absorbed "flow" states tend to involve: a deep and effortless involvement in activity with a merging of action & awareness. In order to optimise absorption, activities should be challenging but manageable and patients should focus directly on the task in hand in the here and now. It is better if the patient focuses outwards towards the external environment with an activity that provides immediate feedback, for example, when playing a musical instrument one can hear immediately whether the right note is played. Activities that have a delay between activity and outcome (such as waiting for a response from others) should be discouraged. Activities where patients can feel a sense of control and which are rewarding – valued as an end in itself – are particularly helpful for absorption.

Helpful versus unhelpful repetitive thought

An important element within any functional analysis of rumination is to recognise that sometimes dwelling on a problem can be helpful, for example, when problem-solving, or when coming to terms with an upset or loss. This is a reason why people learn to ruminate – because there have been times when thinking through a difficulty has paid off. We need to help an individual recognise when repetitive thinking is helpful or unhelpful, and to tell the difference between rumination and problem-solving.

Identifying at least two episodes of repetitive thinking that have different outcomes (one helpful versus one unhelpful; one relatively short vs. one relatively long) will help the patient unpack these differences. We should painstakingly investigate the sequence of each bout in specific detail, including the environment in which it occurred (external context and internal state) and the moment-by-moment sequence of thought, feeling, behaviour, consequence. This involves detailed questioning to recreate the scene of the event and a moment-by-moment fine-grained analysis of how it occurred. Asking about When, Where, Who, What, How will help the patient to describe the actual behaviours that occurred, including internal behaviours such as what the patient is saying to her/himself, his/her attitude to the situation, what s/he is attending to; the way they are approaching the situation etc. Once we have two detailed descriptions of the bouts, we can compare the details to identify differences between them that provide clues as to factors that determined whether the bout was helpful or unhelpful. We can help the patient test these factors in behavioural experiments and incorporate them into future contingency plans.

Concrete versus Abstract Thinking

Rumination is often characterised by abstract thinking focused on the meanings and implications of events. Patients will often ask, “why did this happen? Why me? What does this mean about me?, Why can’t I get better? Why is this so difficult? Why do other people treat me like this?” Patients thinking in an abstract way focus on evaluating the reasons, meanings, consequences, and implications of behaviours and events rather than the specifics of a situation. Abstract thinking leads to patients overgeneralising beyond the details of the situation, losing perspective, and finding it difficult to solve problems because thinking ends up being remote from the immediate situation. When talking over examples of bouts of rumination with patients, it is useful to note down the full list of “Why” type questions that someone asks himself or herself.

In contrast to abstract thinking, people can also think in a more concrete way characterised by the what, when, where and how questions that provide a detailed grounding in the situation, for example, “How did this happen? What did I do? What did he do? How did this problem start? How can I move forward from here?” Being concrete and specific tends to be helpful because it gives someone more cues as to how to solve a problem. There is greater detail about the situation and what was done, events are kept in proportion, and a more active approach is likely because people are focussing on behaviours that can change rather than on personal characteristics that are harder to change.

We use functional analysis of rumination to determine whether patients are thinking in abstract or concrete ways. This distinction is often an important factor determining whether thinking about a problem becomes unhelpful rumination or useful problem solving. We can then teach patients to practice asking themselves the more helpful “How?” questions in response to rumination warning signs.

A useful within session behavioural experiment is the ‘*How vs. Why’ experiment*, in which we prompt patients to think about a recent rumination situation. We first ask the patient to imagine that situation as vividly as possible and whilst imagining him/herself in that situation, prompt him/her to ask themselves ‘Why’ type questions.

Ideally, we prompt the patient with the "Why" type questions identified in previous functional analysis of rumination. We then ask the patient to reimagine the same situation accompanied by prompting with 'How' questions as noted above. We rate mood, confidence, energy etc. before and after each type of practice using 0-10 scales to give patient's first–hand experience of the impact on mood of thinking in these two different ways. Typically, patients will report better mood, confidence, energy or generation of solutions in the *How* condition than the *Why* condition. This can provide a dramatic demonstration of how their approach to a problem can influence outcome. This experiment can then be followed by building the use of How questions into contingency plans in response to triggers for rumination. This can be facilitated by audio-taping the session and giving the patient the tape to remind them of the exercise.

One helpful technique is to give patients a cue-card as a reminder to ask themselves the following questions when faced with warning signs of rumination. These questions may also be useful prompts for the *How-Why experiment*.

1. Focus on sensory experience and notice what is specific and distinctive
    - Ask yourself: "What is happening? How? Where? When? With whom? How is it different and unique from other events?"
2. Notice the process by which events and behaviours unfold
    - Be aware of the sequence of events, what comes before, and what follows after each action and event. Notice the series of steps, of actions and events that lead up to an event.
    - Look out for clues or warning signs.
    - Look out for turning points. Notice any points or steps where a different decision, action or circumstance might change the outcome.
    - Ask yourself "How did this come about? What are warning signs? What might change the outcome?"
3. Focus on *how* you can move forwards
    - Plan. Ask yourself how you can break things down into discrete, manageable steps which you can take to move forward into helpful action.
    - Act. Take the first step in the chain of actions (whether mental or physical) that you can do to deal with a given difficulty and then follow the sequence, step by step, dealing with new difficulties as they arise and acknowledging your own progress when things go well
    - Ask "How can I move forwards? How can I break this down into smaller steps? What is the first step I can take?"

As noted earlier, the use of such alternative behaviours is best practised in the session and then repeated over several weeks to enable the behaviour to become well-established.

A good guideline that a patient has shifted into more concrete thinking is that their description of events is focused on explicit behaviours rather than interpretations, and that it produces a clear visual image of what happened in the therapist's mind. For example, a patient may describe an event as "He insulted me". This is still somewhat abstract as it describes an interpretation of the behaviour rather than an actual physical behaviour. Asking concrete questions (as above) to help the patient describe the behaviour in terms of observable physical acts ("He turned away from

me when I asked him a question") can be very helpful in clarifying the situation. (See Modules on Problem-Solving and Communication for further examples of encouraging concreteness).

There are also a number of rules-of-thumb that can help patients discriminate between helpful and unhelpful thinking.

First rule of thumb: Is this an unanswerable question?
Is the focus of your thinking the kind of question to which most people would find it hard to have a definitive answer? Is it the kind of question where the possible answer keeps changing or is too open-ended? If it is, then it may not be helpful to keep thinking about it. This is particularly the case when it comes to understanding people, emotions, and when asking existential and philosophical questions, for example, "Why me?" questions.

Second rule of thumb: Stop worrying if it leads nowhere after a period of time
Keep in mind how long you have been worrying. It is helpful to be aware of how much time you spend going over and over something in your mind before you find a solution, come up with an idea, or make a decision. How long does it normally take to come up with a useful answer or make a decision? People often report that effective thinking mostly leads to an answer in about half an hour of concentrated thinking, whilst unhelpful rumination can go on for hours without leading to a solution. Moreover, people often report that the solutions to problems come to mind when they are not even thinking about the problem but when they go to do something else, freeing up their mind to relax and be more creative, so that the problem can be worked on subconsciously.

Third rule of thumb: Ask yourself "Are these thoughts leading to a decision or action?" If not, your thoughts are probably too abstract and unhelpful.
If your thoughts about a problem just lead to more thoughts, then you are probably being too abstract and you are likely to end up in a spiral of worrying, overgeneralizing, and inactivity. However, when your thoughts about a problem lead to a response to the problem, whether that it is a plan or a decision, or to some kind of action to deal with the problem, then your thoughts are concrete and it is much more likely to be helpful thinking rather than unhelpful worrying. The plan or decision could include deciding to do nothing or to accept something or to let go of something. This 'concrete thinking' is exactly what you should do when confronted with difficulties or stressful events: – this is where asking "How?" could be helpful, as it makes it more likely that you are 'problem solving'.

Exercises with patients associated with the module/technique

TRAP and TRAC exercises; ABC.

List of therapy materials used in this module and/or with this technique

Functional Analysis ABC Sheet (Appendix C)

TRAP & TRAC Worksheet (Appendix H)

Rumination Monitoring Form (Appendix I)

d. Phase II Modular Technique:

ii) Problem Solving Module

d.ii) Problem Solving Module

Introduction and general description of the module/technique

Patients with depression may experience difficulties with solving problems for a number of reasons.

First, as emphasised by the contextual approach underpinning BA, patients may become depressed because of changes in their circumstances which represent problems they cannot easily solve. These can be thought of as *primary problems*.

Second, the consequences of depression such as low energy and motivation, and increased avoidance can create further problems in the patient's life which may lead to the patient feeling overwhelmed with problems. These can be thought of as secondary problems.

Third, Martell and colleagues (2010) highlight the potential for depression to impair problem-solving abilities. This may be as a result of impaired ability to plan, manage and remember important activities or through an increase in over-general and abstract styles of thinking, leading to rumination.

Finally, some patients with depression may never have had the opportunity to learn effective problem solving skills, for example because attempts to actively problem solve were not modelled or positively reinforced in early life, or because passive means of problem solving such as allowing others to deal with difficulties on one's behalf were reinforced.

The general approach we take as therapists in Behavioural Activation work could be described as a problem-solving one: we support the patient to clearly define in behavioural terms the difficulties they are struggling with, identify, try out, and evaluate means of solving the problem. Thus, therapists and patients are engaged in problem-solving by conducting functional analysis, selecting and implementing alternative behaviours, and evaluating the results of this. In BA problem solving tends to be woven through the fabric of the sessions, and does not necessarily involve the therapist 'teaching' the patient an explicit set of steps to be followed. That said, for some patients it may be appropriate to move from supporting them in solving their problems to explicitly equipping them with a framework to use for this.

The module/technique in detail

This module describes the overall problem solving approach in two ways. Initially, we will consider the general problem solving therapy attitude as a series of steps in a therapeutic conversation. Secondly, we will outline the formal seven step problem solving approach which can be taught to patients.

1. Problem solving as a therapeutic conversation

Step 1: Defining the problem in concrete, behavioural terms

If the patient has stated their problem in abstract terms it is important to elicit a specific behavioural description of it. For example, Clara has the problem "I feel tired all of the time": a specific description might be "When the kids come home from school I notice that I feel tired and overwhelmed at the prospect of spending time with them. Three times this week I made an excuse to my partner that I needed to do some housework instead of spend time with them, even though I did very little of it. I felt guilty the whole time, and then when we ate dinner together I was beating myself up about it in my head so much I didn't join in with the conversation."

Useful questions to help patients define their problem include:

- Can you tell me about a time recently when this problem flared up?
- Can you tell me about a time in the last week when you noticed that this problem got in the way of what you needed or wanted to be doing?
- If I had been with you last week, what would I have seen happening when this problem was going on for you?
- If we could wave a wand and get rid of this problem overnight, what would you be doing differently tomorrow that would tell you the problem had gone away?

Step 2: Identifying alternative behaviours and selecting one to try

Once we have a concrete description of the problem, possible means of addressing it can be discussed. Questions that can help this process include:

- What might you do differently?
- What have you thought about trying?
- Have there been any times when this problem occurred and you were able to deal with it effectively?

We can undertake this step formally by listing (see Appendix J) or less formally as part of the session conversation, in each case making sure that the relative advantages and disadvantages of each option are discussed. In Clara's case, watching a DVD with the children may suit her but not the children's needs. A better plan might be to engage them in a more energetic outdoor game to burn off their energy.

Step 3: Planning to implement the new behaviour

Once a suitable behaviour has been identified, we help the patient identify the steps s/he needs to take to put the solution into action. The plan should be concrete and specific. Some solutions will require preparation in advance. For Clara, setting up the garden for an outdoor game. For many others, explaining the plan to partners. Ideally we are aiming for the patient to schedule in a specific set of behaviours for the coming week, for example "Tonight after the kids are in bed I will tell my husband what I am planning to do. On Tuesday I will go out at 3pm and set up the garden for a game of football. When the kids come home I will invite them to play football for 15 minutes, after which I will return to the housework. During the game of football I will

be in goal – this feels like it will be less tiring for me than running about." In planning to implement a solution further challenges may come to light. It may be necessary to break the solution up into smaller steps, some of which can be completed before the next session.

Once a plan has been formed, we can encourage the patient to visualise putting the solution into action. By asking the patient to 'see' a video in his or her mind's eye of the solution in action, s/he is encouraged to think in concrete terms about the steps involved. As well as visualising the potential benefits of the solution this process can reveal previously unnoticed barriers to its implementing which can be then be addressed. This technique is described in detail in the next section.

Step 4: Reviewing

In the next therapy session the chosen behavioural solution is reviewed. Patients are encouraged to be specific about what happened, what behaviours were enacted and what the consequences were. When solutions are difficult or painful patients often report affective consequences "it made me feel anxious". We should specifically ask them to what extent enacting the solution solved the problem they were addressing. Lessons learned from this can then be used to determine the next step.

Issues to be aware of whilst solving problems with patients

- Whilst primary problems can be the 'big' issues that patients have difficulty with, and that may have contributed to the onset of depression, these can often be very challenging to address. Therefore it can be more motivating for patients to begin solving secondary problems, in other words, difficulties that have arisen as a consequence of the affect evoked by the primary problem. For example, a patient may have difficulties in his relationship with his wife (primary problem). This situation leads him to feel sad and anxious (secondary problem). Unable to resolve the situation he turns to 'solving' the problem of his negative mood by drinking alcohol and spending his spare time surfing the internet (avoidant coping). Therapy might involve first working with him to find other ways of responding to negative mood that are more adaptive in terms of serving his valued goals, before moving on –if appropriate – to exploring ways of responding to the difficulties in his relationship.

- It can be useful to identify whether the problem is contributed to by an avoidance pattern, a skills deficit, or a combination of the two. For example, the patient may be engaging in a particular behaviour because it functions as a means of avoiding negative emotion (in other words, they are caught in a TRAP). In such situations, the patient is trying to solve the problem of feeling bad, but his or her attempts at 'solving' the negative feeling are not effective in the long term, and do not improve the situation that has triggered the bad feelings. In Clara's case, she may be responding to feelings of being tired and overwhelmed by the prospect of spending time with her children by avoiding doing so, resulting in temporary relief, but intense feelings of guilt in the longer term. Alternatively, or in addition, she may not know how to spend time with her children in a way that is rewarding for all involved and does not place excessive demands on her energy levels, i.e. she does not currently have the skills to do this. These possibilities have different

implications for solving the problem: if avoidance is a key factor, the skills around TRAP/TRAC are highly relevant; if the patient is prevented from solving the problem because s/he does not possess the necessary skills to do so, patient and therapist may need to look at how these skills can be acquired or practiced (for example planning for and role playing an anticipated conversation in which particular communication skills are needed).

- Various factors can make it difficult for patients to solve problems, and resort to avoidant means of coping with the surrounding emotions. However these responses are understandable in the context of patient's' learning histories. The therapist's stance should be one of validating the patient's natural desire to avoid, whilst at the same cheerleading him or her through the process of making changes.

Exercises with patients associated with the module/technique

Visualising enacting the solution

Once a potential solution has been identified, visualisation can be used to solidify the plan, anticipate challenges and anticipate positively reinforcing aspects of engaging in the behaviour.

The patient is asked to close his or her eyes if comfortable to do so, and to recreate in their mind's eye the situation s/he will be in right before enacting the solution. The therapist asks the patient to see the situation as if through his or her own eyes (rather than seeing themselves from a detached perspective), and to talk the therapist through what s/he is doing in the present tense, for example "I am walking through the back door towards the shed. I am opening the shed door and looking for the football..". At the start of the exercise the therapist can ask the patient to describe sensory details such as sounds, smells, temperatures, etc. to help themselves recreate the situation and feel immersed in it. If the patient becomes overgeneral about the steps s/he is enacting, for example "the kids come home and we play football", s/he can be invited to go back and talk through the physical steps s/he is taking as this part of the video unfolds.

After the exercise is complete the patient can be asked about the extent to which s/he was immersed in the visualisation, and then about what they learned from it, and what changes s/he would make to the plan as a consequence.

2. Teaching problem–solving as a formal technique

In addition to the less formal means of helping patients to solve problems outlined above, therapists may formally 'teach' problem solving to patients. This involves several steps:

1. Introducing the idea of problem solving and giving a rationale. This might involve explaining to patients that depression can be associated with difficulties in problem solving for the reasons outlined in the introductory section, and then looking together at the potential benefits of learning, or reconnecting with,

problem-solving skills. The patient can be introduced to the idea that there is a series of steps that can be followed when faced with a problem to solve.

2. Setting out the steps to be followed, namely:

   1) identifying the problem and determine the costs and benefits of attempting to solve it versus not doing so

   "Identify the problem as clearly and precisely as possible. Each problem should be broken down into its smaller parts, for example, a financial problem can be broken down into the components of debt, income and expenditure. Ask yourself: What?, When?, Where?, With whom? and How often? questions to help you describe the problem in detail. Then ask yourself: What is the result of this problem?"

   2) generating solutions

   "Identify as many potential solutions as you can. At this stage, reject nothing, no matter how apparently ridiculous solutions may seem. If the problem has been broken down, write solutions for each stage."

   3) analysing strengths and weaknesses of all the potential solutions

   "List each solution's strengths and weaknesses to assess the main advantages and disadvantages of each solution. Advantages and disadvantages can refer to likelihood of success, ease or difficulty of carrying out, resources needed for example money, etc."

   4) selecting a solution to try

   "Choose a solution based on step 3. Remember to choose a solution which has a realistic chance of being successfully carried out for example choosing a solution with no funding when money is required will lead to automatic failure."

   5) planning implementation of the chosen solution

   "Many solutions require careful planning. Write down the steps required to apply your chosen solution and list resources. The steps should be specific, linked and realistic. Use the 'Four Ws' – What, When, Where, With whom - again to help plan the implementation"

   6) implementing of the chosen solution

   "Carry out the plan identified in stage 5. Record your progress in a simple diary."

   7) reviewing implementation and making further plans.

   "Regularly review how well your chosen solution is sorting out the original problem. The advantage of problem solving is that alternative options always exist. If the solution has worked, continue carrying it out. If not, go back and

choose another solution."

3. Practicing working through the steps in session.

4. Helping the patient to generalise the skill of problem solving across areas of difficulty, and outside of the therapy room.

Whilst this is a similar process to the less formal one outlined earlier, the following may be different:

- The costs and benefits of attempting to solve versus not attempting to solve the problem can be explored
- Generating solutions can be done as a 'brainstorming' process whereby the patient is invited to generate as many possible solutions as s/he can, without censoring them. Helpful questions include:
    - What have you thought about doing but dismissed?
    - What have other people suggested?
    - What would you suggest to a friend in your situation?
    - What have you tried in the past?
- When solutions are evaluated, this can be done using an explicit rating process, such as scoring each out of 5 for manageability and for helpfulness.
- Once the patient has started to use problem-solving, the therapist can help the patient to consolidate and generalise the skill by:
    - Putting together prompts or reminders of the steps to follow as a flashcard
    - Involving the patient's network in supporting problem solving by, for example, inviting them to a session in which the purpose of and steps in problem solving are shared
    - Handing over more and more responsibility to the patient for i) identifying when problem solving is needed; ii) initiating the process; iii) directing the process

List of therapy materials used in this module and/or with this technique

Problem Solving Worksheet (Appendix J)

Useful references:

D'Zurilla, T.J. & Nezu, A.M. (1982). *Problem solving therapy: A social competence approach to clinical intervention (2nd ed.)*. New York: Springer.

Martell, C.R., Addis, M.E. & Jacobson, N.S. (2001). *Depression in context: strategies for guided action* (pp.126-135). New York: W.W. Norton.

Martell, C.R., Dimidjian, S. & Herman-Dunn, R. (2010). *Behavioural Activation for depression: A clinician's guide* (pp. 109-127). New York: The Guilford Press.

d. Phase II Modular Technique:

iii) Functional Equivalence (including values) Module

d.iii) Functional Equivalence (including values) Module

Introduction and general description of the module/technique

Sometimes patients may engage in behaviours that have a clear pay-off which they value, but at the same time result in undesirable consequences. For example, Joe sometimes shouts at his partner in order to win an argument: the desirable consequence is that his partner gives in to his point of view, however an undesirable consequence is that his behaviour is ultimately damaging to their relationship. In such situations the therapist and Joe may look to find alternative behaviours that fulfil the same key function, for example a behaviour that helps Joe to put forward his point of view effectively, but that has fewer disadvantages. Such behaviours may be termed 'functionally equivalent' in that they do the same job as the original behaviour, but are substituted because they have fewer adverse costs.

Another circumstance in which therapist and patient may look to institute functionally equivalent behaviours is when the patient used to engage in particular "antidepressant" activities that were positively reinforced, but is no longer able to engage in these behaviours. For example, Clive derived great enjoyment and satisfaction from his hobby of sailing. However his current financial circumstances mean that he is no longer able to take part in this activity. Using the notion of functional equivalence, his therapist may help him to identify activities that are currently available to him that might bring about some of the same benefits as sailing did.

The module/technique in detail

When to look for functionally equivalent behaviours

Therapists and patients use the concept of functional equivalence very frequently throughout BA work, whether or not this is acknowledged. For example, during activity scheduling therapist and patient will be involved in conversations about which 'antidepressant' activities can be scheduled in, based upon what is known about what works for that patient. When some of the original activities are not possible, the search for alternatives that fulfil the same role is a search for functionally equivalent behaviours.

When patients have identified TRAPs and have started to explore alternatives to avoidant behaviour, therapist and patient often look for new behaviours that will have some of the benefits of the old behaviour, but with fewer medium to long term costs. Thus helping patients to identify and institute functionally equivalent behaviours is not limited to this particular module: it can occur at any point throughout BA.

However, this module may be particularly relevant if your patient is struggling with either of the issues outlined in the previous section, namely if he or she:

- Is 'stuck' in repeating an ultimately unhelpful behaviour because of the benefits it brings.
- Is finding it difficult to increase levels of antidepressant behaviours because circumstances prevent him or her engaging in those that worked in the past.

Using the idea of Functional Equivalence when working with 'unhelpful' behaviours

The first step is to conduct a functional analysis of times when the behaviour in question appears. This will bring to light potential triggers of the behaviour, and importantly the short and long term consequences. These consequences may be in terms of the effect on mood, physical state, cognition, or changes in the external world, for example, changes in other people's behaviour. When exploring potential consequences the following questions may be helpful:

- What are the benefits of doing X in this situation?
- You have told me that doing X causes you problems, but that you find you keep doing it. That suggests that there is probably some sort of pay-off from doing it, even if it doesn't seem like it now. What do you think it might be?
- When you start doing X, where are you hoping or expecting it will get you?
- If you didn't do X anymore, what problems would this cause?
- What are the costs of doing X in this situation?
- You have told me that doing X can be really helpful for you, but are there any downsides?
- If you didn't do X anymore, would there be any positive consequences?

If the patient wishes to change the behaviour, the process is then essentially one of problem solving. The next step is to explore potential alternatives that will bring the same or similar benefits but with fewer costs. For example, in Joe's situation he might generate ideas about different ways to get his point across to his partner, other than shouting. The problem solving module gives tips on supporting patients in generating alternative behaviours, for example asking him what has worked in the past, what he has thought about trying, and so on. The rumination module gives suggestions about possible functions and alternatives for rumination.

The patient then chooses a preferred option, following discussion about the feasibility and likely consequences of ideas raised. This option is implemented as part of homework, and the consequences reviewed.

Using the idea of Functional Equivalence when increasing positively reinforced behaviours

Very often, people with depression are in contexts where previously positively reinforced behaviours are no longer possible, for example because of the loss of a job or a relationship, or changes in financial circumstances or physical health and mobility. In such instances, the task of the therapist is to help the patient find out what it was about his or her past activities that worked. Understanding this is the key to helping the patient discover alternative activities that are most likely to be rewarding. Replacing past activities with new ones that merely look the same is less likely to be successful.

For example, to say to Clive, who used to enjoy sailing, "what about going on a boat trip?" without knowing what it was about sailing that he particularly liked may ignore some important alternative possibilities. On further discussion Clive may reveal that it was the contact with nature that he particularly liked, or the fact he was absorbed in a difficult physical task, or the exercise sailing provides, or the status of being someone who is seen to own a boat. Each of these suggests a different set of alternative activities.

Some useful questions:

- What was it about X that you particularly liked?
- When you stopped doing X, what did you miss most about it?
- People might enjoy doing X for different reasons. For you, what were the reasons you did X?

At this point it may be helpful to have an explicit conversation about what the patient values. Coming up with an abstract set of values can be used as a way of searching out new activities that are in line with these values. This process is described in the section below.

Similarly to the process outlined in the previous section, the next step is to explore alternative behaviours. Useful questions might include:

- We have spoken about some of the things you liked about X. Are there any other things you have done that have brought you any of these benefits?
- We've spoken about how it's not possible for you to do X anymore in the same way you used to. Is there some way you can do some version of X that brings you some of the benefits it did?
- What are you already doing that brings you some of the things you used to get from X?

Once alternative behaviours are identified, we then encourage the patient to schedule in one or more of these, and we review the impact of doing them at the next session. Importantly, as well as the general impact of doing these and what was learned about the activity, the therapist should ask about the extent to which engaging in the new behaviour brought about some of the sort of positive consequences associated with the old behaviour.

Exercises with patients associated with the module/technique

Identifying Values

Step 1: What are values?
When trying to schedule in positively reinforced behaviours the therapist might introduce the idea of values by looking for themes in the patient's past and present 'rewarding' activities, for example: "you have mentioned a few things that felt important and meaningful for you to do, such as sailing, teaching art, and playing the guitar in a band. What do those things say about what really matters to you? About what you value most in life?" Alternatively or additionally the therapist might explicitly introduce the concept of values, for example "Often we find that the activities that are the most rewarding are those that are in line with our values."

Therapist and patient might then go on to agree what a value is. In terms of how these are seen in the current approach, values are what give meaning to our lives and to our actions: they are what we consider to be important to us. Examples of values are honesty, responsibility, curiosity, closeness, and many more. Values are different from goals: a goal is something you aim towards, whilst a value is a

direction that you travel in. Whilst you can succeed or fail in attaining a goal, for example going to the gym twice a week all year, saving £500 by Christmas, you cannot fully achieve or fail at a value, because acting in accordance with a value such as honesty is an ongoing process which is sometimes easier and sometimes harder. All you can say is that you are moving in the direction of the value, or not. A useful metaphor here is that of traveling east – you can always head in that direction, even if you get diverted, yet you never actually get to 'East'.

It can also be helpful to note the relationship between values and depression. From a BA perspective, this would be viewed as follows. Often people feel most fulfilled when they act in ways that are in line with their values. One view of depression is that we become more vulnerable to it when we end up acting in ways that are removed from what we really value. There are lots of reasons why this might happen, for example, other people's expectations, fear of failing or of feeling bad. However, the end result is that much of what we spend our time doing doesn't feel meaningful to us. Extending the metaphor above of travelling east, depression is like a big mountain range that appears in front of us – suddenly travelling east becomes much harder. It is still possible, but it will need small steps, and it might be necessary to keep checking we are going in the right direction.

Step 2: what are your values?
This may have emerged from the previous conversation. If not, the patient could be asked directly to think of some examples of values a person might hold, saying whether or not they would apply to them. It can be important with some patients to determine whether the values mentioned feel valuable to them, or whether they represent only values imposed upon them by others.

Step 3: What are you already doing that is in line with your values?
Sometimes a discussion about values can be disheartening for someone with depression as it can be a reminder about what has been lost or 'failed' at, or it may imply that some huge change of behaviour is required. Therefore, it can be valuable to look at how the patient is already living according to his or her values every day. These acts may not be large, for example a patient who values being adventurous might have suggested a new café to meet a friend in. A patient who values being close to family might have spent an extra five minutes reading a story to his son in the morning.

Step 4: how can you include more 'valued' activities in your life?
Having identified some key values, the patient can then use this 'direction of travel' to work out some activities that fit in with it. These can be considered as potential anti-depressant behaviours and scheduled in. We can then review the effect on mood and other outcomes of attempting the behaviour. It is important to remember that because values are abstract and not limited to a particular activity, even if one activity fails or is not possible it is still possible to find other ways of living in accordance with a value.

Further applications of values work:

1. The notion of valued activity can be used to help find alternatives to avoidance behaviours, in other words to build TRAC from TRAP. For

example, Jenny might have a TRAP in which, after breakfast, she finds herself alone at home with nothing to do, knowing everyone else is going to work (trigger). She feels sad and ashamed (emotional response) and in response she watches daytime TV (avoidance behaviour), which distracts her temporarily but does not 'solve' the problem. This leads her to feel more ashamed in the longer term when she reflects on what she has done with her day. In this instance it is difficult for Jenny to solve the primary problem in that she wants to work but has had no success in finding a job despite trying hard. She continues to work towards this goal but cannot do it every hour of every day. What should she do as an alternative? One possibility is for her to consider activities that are in line with her values. These may be things that have been positively reinforced in the past, or may be new activities.

2. Responding to setbacks and "failures"

   Even when we end up acting out of line with our values, we can still respond to this situation in a way that fits them. For example, Raj values being close to his family. Therefore he sets himself the goal of being home from work once a week in time to have dinner with his children and put them to bed. One day he finds he cannot make it because of work commitments. Whilst he has not met his goal for that week, he can still act in line with his value. He does this by calling up his family in advance, apologising and arranging to be home early another night, an agreement he sticks to. Therefore, when a patient reports that they have 'failed' in living according to their values it can be helpful to ask: "how might you respond to this situation in a way that fits with the value of X?"; "Can you resolve this situation in a way that shows you value of: being close to your family; honesty; looking after the environment?"

List of therapy materials used in this module and/or with this technique

Functional Analysis ABC Sheet (Appendix C)

TRAP & TRAC Worksheet (Appendix H)

Useful references:
ACT text

d. Phase II Modular Technique:

iv) Anxiety Module

d.iv) Anxiety Module

Introduction and general description of the module/technique

Mixed anxiety and depression is much more common than depression alone. Anxiety is likely to be a problem that will require attention at some point, particularly when the patient engages with the environment. This issue should have been identified through assessment and during phase 1 of BA treatment. If a problem has been identified it is appropriate to reach an agreement at review session 7 to work on the problem during phase 2.

The rationale for attending to anxiety in BA is a process that will be familiar to both the therapist and the patient by this point, as it will have been used previously to deal with depressive avoidance. We use the familiar functional analysis via TRAP and TRAC sheets. We use the information gathered about anxiety and apply the TRAP system to consider the short and long term consequence of associated avoidance which maintains anxiety. From here TRAC can be used to explore changes in behaviour that will help the person activate. This in turn should facilitate positive reinforcement, encouraging future 'outside in' behaviour to overcome the anxiety. This is an ongoing and gradual process. The goal of BA in this study is to treat depression but using the same approach can also help with anxiety. This shared understanding is used to instil hope that change is possible using the BA model where anxiety blocks changing depressed behaviour.

Key elements that underpin the BA approach to anxiety are:

- Anxiety can occur to a person for a number of reasons and build up slowly
- The way we try to cope with feelings by trying to escape or avoid them can often result in ongoing problems with anxiety in exactly the same way as depression. This is by a process of negative reinforcement which maintains avoidance.
- Using the same gradual step by step approach to changing the coping behaviours that we have learnt for depression, we can also break the cycle of anxiety
- The BA approach aims to make such changes collaboratively, learn from what we see and gradually emerge from a depressed cycle. Sometimes we also need to break this cycle for anxiety

The module/technique in detail

Step 1.

The first step to engaging the person in the BA approach to anxiety is to complete a functional analysis of the problem. At this point you should identify an example of a situation, preferably from scheduling records, over the past week where it seems anxiety has blocked an 'outside in' behaviour. You as a therapist will have been thinking about how this fits with the TRAP/TRAC structure and the BA cycle. This is important as we aim to keep BA simple and provide the patient the same structure to understand their problems and how to plan to address them. Firstly, we provide an overall description of how you plan to address anxiety in BA such as:

> "*As we have discussed this treatment is behavioural in nature, which means that we will work toward changing your behaviour as a method for improving your thoughts, mood, and overall quality of life. This can work just as well for anxiety if we apply the same principles. We have developed some understanding of the current situation you are in and you have been able to start to make changes in order to move forward. We call this working from* ***'the outside in'*** *rather than the '****inside out****'. We have used the TRAP and TRAC sheets and seen how the short term relief you get by avoiding can result in longer term difficulties which in turn keep you stuck in depression. The same principle applies with anxiety, when faced with a situation the discomfort you feel such as* [recap the symptoms the patient has disclosed] *is relieved when you escape. This relief feels better than the anxiety, hence you will escape more and also then begin to avoid the situation. This can be a problem if the situation is one that you need to overcome to break your cycle of depression. How does that sound? Can we use a TRAP form now to understand in more detail a specific situation."*

The aim of this manual is not to put words in your mouth but to guide you. You can see from the above example the aim is to give a general explanation.

Step 2

The next step is to tailor this to the person using the TRAP form and information gathered therein. The role of therapy is to develop a shared understanding using this approach and then work out the most productive way to make changes. The process should be a collaborative discussion.

An example of a TRAP sheet regarding anxiety is outlined below

Trigger: What situation, activity, or thinking occurred?

Going to the library to get some books to read, I opened the door and it was very busy

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Response: What was my response to the trigger? (What did I do or feel?)

I felt overwhelmed, my heart started beating fast, I was scared to look at anyone and just wanted to get out

---

Avoidance-
Pattern: What did I do to stop my discomfort?

I left the situation without my books and went home and had a cup of tea.

What are the activities that seemed difficult or painful to do?

Stay in the library choose my books and speak to the librarian at the desk

---

In what way was by behaviour immediately effective in stopping my discomfort?

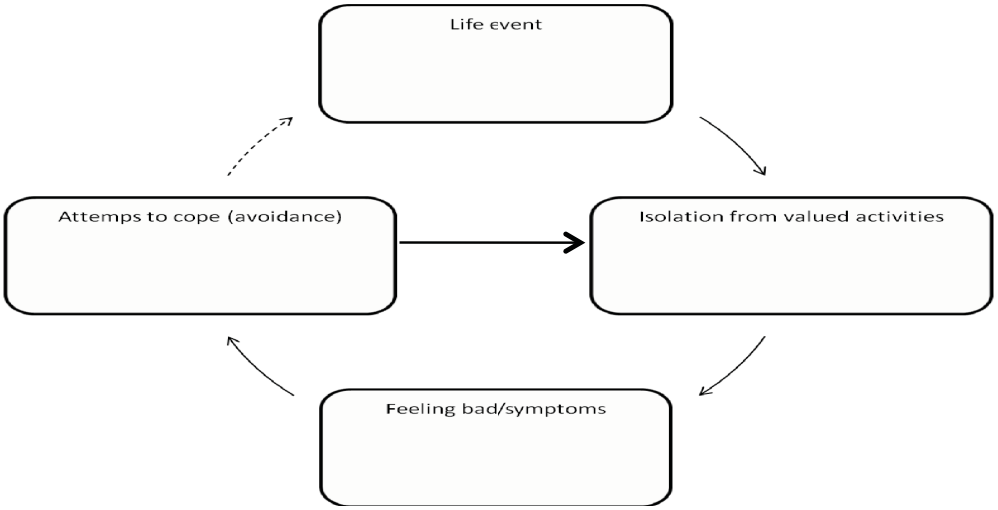
As I left my heart slowed down and I stopped worrying about what people might say to me or what I might say to them. I felt relief

What are possible long-term consequences of my behaviour?

I like reading but cannot afford to buy books, the library is a place I might be able to meet like minded people

After doing the above activity (or inactivity) am I **MORE** or **LESS** depressed? *(circle which)*

Later in the day I felt worse, I thought I will never get past this and went to bed, lying thinking about my problems



Then go on to review your shared rationale and how this TRAP fits in the attempts to cope box, maintaining the isolation from valued activities.

Step 3

The next step, as used previously in changing depressed avoidance is to use the TRAC form to plan to make changes. When dealing with anxiety remember these golden rules in planning behaviour change. Any changes should be:

- Graded: start with easier behaviours that the person feels they can manage.
- Sustained: the aim is to get used to the situation so the person has to be able to stay long enough for this to happen.
- Repeated: once is rarely enough, as per the above point the aim is to get used to the situation.
- Focussed: it may feel right to try to distract from the situation that a person is in but this will impact negatively on their ability to get used to the situation.

Check out again the person's understanding of this rationale and complete a TRAP form derived from the TRAP you have identified (see example below). Build this into scheduling and agree to review at the next session. Check the patient has understood the content and how the same approach is used for anxiety and depression in BA.

Step 4

Review the changed behaviour and what happened. Consider this in the BA cycle and if it could be built up, what would the potential benefits be.

Trigger: What situation, activity or thinking occurred?

Going to the library to get some books to read opened the door and was very busy

---

Response: What was my normal response?

I felt overwhelmed, my heart started beating fast, I was scared to look at anyone and just wanted to get out

Alternative:

Coping: What new activity can I try?
Plan to go at a quiet time and sit and read for 30 mins before leaving to get used to being there before going back on a Saturday

When will I do it?
At 11 am on Tuesday, Wednesday and Friday as these are quiet times.

How will I do it?
(break into small steps)
I will go in at 11 and pick a book to read,
I will make sure I sit facing the room and look around regularly.
I will say goodbye to the librarian before I leave

In what way may this help me over time?

It will help me get used to going in there and build up my confidence the librarians will get to recognise me.,

How does it help me break out of TRAP?

I want to be a member of the library and join the book club. I have wanted to do this for a while but not had the energy or confidence to do so. This will help build my social circles and confidence and I enjoyed reading in the past.

Trouble shooting

- *The patient cannot identify a specific anxiety situation.*
  Look in the diary at times where they have avoided situations and use this as a discussion. Ask what led them to raise anxiety as a problem and to specify when it is worse or better, in those times what are the fears they have?

- *The patient cannot break down into small steps.*
  Help out and think about if the large anxiety can be split into smaller sections. If it is not possible with the situation think of another easier one to practice on first.

- *The patient does not feel this approach will work.*
  Explore if what they are doing now is working, from a collaborative standpoint. It probably is in short term for the anxiety, but explore the longer term impact on anxiety and the focus of this treatment, depression. Have an open discussion about the pros and cons of working on anxiety and what is there to lose.

Exercises with patients associated with the module/technique

TRAP and TRAC exercises; ABC.

List of therapy materials used in this module and/or with this technique

TRAP & TRAC Worksheet (Appendix H)
Anxiety Cycle Template (Appendix K)

d. Phase II Modular Technique:

v) Punishment Module

d.v) Punishment Module

Introduction and general description of the module/technique

Behavioural activation involves reintroducing behaviours that used to be reinforced when the person was not depressed or finding alternative behaviours that may serve the same function for a person. One difficulty that occurs in treatment is that a person may try to reintroduce a behaviour that s/he once found easy or enjoyable, but that now the activity is experienced as very difficult and unrewarding.

An example would be a person who used to enjoy meeting up once a week with friends for coffee, but who has not done this for some months because of her low mood. As a between-session task she tries to go out for coffee with her friends as she used to. However, she reports in the next session that she felt uncomfortable all the time she was there, that she ended up saying very little, and she thought her friends would all have enjoyed it more if she had not come along. She mentioned that she ended up making an excuse to leave early, and afterwards she spent some time ruminating about how bad her situation was because she couldn't even do something as simple as meet up with her friends. She has cancelled her next meeting with her friends.

What happened here and more generally in these types of situation can be understood in behavioural terms. A behaviour that in one context was rewarded is in another context punished. As with any behaviour that is punished, behaviour theory predicts that the activity will reduce in frequency.

This section provides some guidance on how to deal with this type of situation. The suggested strategies that can be used also draw on behavioural principles. One important principle that features several times here is that short-term rewards tend to control behaviour more than long-term rewards. In other words, an immediate consequence of a behaviour is likely to have much more influence on whether that behaviour occurs again, than a consequence that occurs a long time after the behaviour.

This basic behavioural principle can be used to help understand lots of behaviours, such as why a person who is trying to diet may, when hungry, eat a very fatty and sugary snack. The instant reward of the unhealthy but pleasurable treat exerts more control over the behaviour of eating the snack than the longer-term consequence of dieting which is losing weight. Another example is why people continue to overindulge in drinking alcohol despite the experience of hangovers the next morning. Here, the short-term effect of feeling relaxed and happy outweighs the long-term result of the hangover in the morning. This basic behavioural principle, of the controlling effect of short-term rewards, known as contingencies, can be used to understand the clinical situation that is the focus of this section. We can use this principle to structure the intervention so that the therapist and patient can work together to deal with this scheduling difficulty.

As with other phase II modular techniques, there is no expectation that the strategies described in this section will be used with every participant. They should be used if the difficulty described above occurs during activity scheduling.

The strategies will be used predominantly as 'session specific therapeutic content' in phase II sessions. However, if this emerges as a significant difficulty earlier in treatment it may be necessary to introduce at least some of the techniques earlier. If this additional module is covered in detail during phase II it will also be necessary to review this work during the later stages of therapy. Clinical judgement will be required in determining when to introduce the strategies outlined here and how long to spend on them.

The module/technique in detail

If a person reports that previously enjoyed behaviours are now punishing we should use this module. However, the therapist should carry out a number of therapeutic behaviours themselves before introducing the rationale for the additional module.

- Empathise: demonstrate empathy and understanding for the difficulty the patient found with the activity scheduling (for example, 'It sounds like that was really difficult for you.')
- Reinforce the behaviour: provide reinforcement for the attempt to try out the activity (for example, 'Although it was really difficult for you, it's really good to see that you had a shot at doing it.')
- Normalise: make it clear to the patient that this difficulty often occurs in this type of treatment (for example, 'This type of thing quite often happens at some point during this type of treatment.')
- Expectancy of change: emphasise that although the patient found it difficult, there are specific things you and the patient can work on together to help deal with this difficulty; the difficulty is surmountable (for example, 'Shall we have a think about how we might be able to deal with this?)

The therapist must make a clinical judgement about how much time needs to be devoted to these preliminary therapeutic tasks before moving on to introduce the rationale for this module, but often they can all be achieved in a few sentences seamlessly interwoven into the review of the between-session tasks.

Introducing the rationale for this module
Discuss with the patient how it looks like s/he found some of the activity scheduling difficult this week. Use a collaborative approach to find out whether the patient thinks it would be useful to spend some time working on this in the session.

T: 'It looks like you had a really good go at meeting up with your friends, but it turned out to be difficult.'
C: 'The thing is that I used to find it really enjoyable, but I didn't enjoy any of it. It was awful.'
T: 'Would it help if we spent sometime during this session trying to get our head around what was going on, and what we might be able to do about it to help?'

Identification of specific issue to be addressed

The specific issue that is addressed in this module is that an activity was experienced as aversive, difficult and so on even though in the past the same activity was something that was enjoyable, straightforward or rewarding in some way.

Identification of personal examples of the specific issue
This difficulty may have occurred over several weeks and several activities. Use an open-ended questioning style to encourage the patient to identify several examples. Ask if s/he can think of other examples unrelated to the formal scheduling in which an activity that is easy or enjoyable when not depressed has come to feel very difficult or aversive when depressed.

Information giving about specific issues and module techniques
Re-emphasise that this is a very common difficulty in depression. Discuss how there are several strategies that may be able to help here.

Apply functional analysis
Use standard functional analysis techniques described elsewhere in this manual as your basic approach here. Conduct a functional analysis of one or more of the difficult situations.

One aim of the functional analysis is to gain an understanding of how the behaviour is now being punished. It is possible, even likely, that the behaviour is being punished in more than one way. Try to identify the different punishing consequences of the behaviour. It may also help to discuss how this contrasts with how the behaviour is reinforced when the person is not feeling low.

An additional aim is to help the patient understand the consequences of the punishment, i.e. that the behaviour is likely to decrease, and how this can then be understood in TRAP-TRAC terms, just like many other examples you may already have discussed. If the behaviour is punished it is likely to reduce. This may lead to avoidance coping in which a short-term gain, for example, reduction of unpleasant feelings, is at the expense of a longer-term gain, for example engaging in activities that are needed to help improve mood.

If the functional analysis identifies that one of the reasons the person is not finding the behaviour rewarding is the presence of rumination or not fully engaging with the experience, it may be necessary to consider using strategies from the rumination module.

Exercises with patients associated with the module technique

Once a connection is made that this situation may well be understood as a specific example of a more general phenomenon of avoidance coping, the patient may be able to generate strategies that could be applied here that s/he has used with other avoidance behaviours.

These may include:

- Remembering the basic BA principle of experimenting with a behaviour long enough to see what its impact is over the longer term rather than abandoning a behaviour too soon
- Breaking the activity up into smaller, more manageable sections

Additional strategies that it may be useful to try:

Detailed planning of the activity in the session
One strategy is to plan in great detail the particular activity that the participant will try out. This will include planning in detail exactly when, where, with whom etc. the person will try out the activity. If these are not clearly specified well in advance, the decision to disengage in a difficult behaviour may be made as a result of the short-term consequence occurring. If this is the case, then the potential short-term reward of not performing the behaviour, for example, feelings of relief, removal of anxiety, may exert more control over the behaviour than the longer-term benefit of doing the activity such as feeling less depressed in the long-run. However, if a decision to engage in a particular behaviour is made well in advance, the advantage of the short-term avoidance in controlling the behaviour is reduced.

If it is difficult to achieve this level of specification in the session, other strategies may be to encourage the person to write down the night before very specific plans for the next day, particularly if there is diurnal mood variation where the person feels very low in the morning, but less low in the evening. Again, this may help overcome the controlling effect of short-term rewards controlling behaviour the next day.

Pair an immediate reward with the currently punishing consequence
As discussed above, if a particular activity is being punished in the short-term it may reduce even if there is a long-term benefit to the behaviour. Another strategy to overcome the controlling effect of the short-term punishing contingency is to pair an immediate reward with the activity to compete with the punishing consequence. For example, the person who found it difficult to meet up with friends could reward herself immediately after completing the activity by doing something in town that she finds easy and enjoyable, such as meeting up with her partner to go to the cinema. Selecting the reward may require some discussion with the patient. The principles here are to ensure that the reward can be delivered feasibly and immediately and will be experienced as sufficiently rewarding to counteract the immediate punishment that may have occurred.

Identify a functionally equivalent but easier to achieve behaviour as a stepping stone
If the patient finds the idea of trying a particular activity again very difficult, because of how punishing it was in previous activity scheduling, it may be worth trying to identify a 'functionally equivalent' behaviour. A functionally equivalent behaviour is one that would have the same intended reinforcement as the behaviour that is found to be very difficult at the moment. For example, the person who found going along to the coffee shop very distressing may not want to repeat the behaviour next week. If the intended consequence is to gain pleasure from social interaction, then it may be worth working with the patient to find other behaviours that would have the equivalent function of obtaining social interaction, but that s/he would be more willing to try. For example, while the patient may not want to go to the coffee shop in the next week she may be willing to phone one of the friends to meet up. If this is

achievable, the therapist and patient can work on moving towards the goal of going to the coffee shop in subsequent sessions.

This should not necessarily be a first line strategy, because it can feed into avoidance. However, if the patient is unwilling to try a behaviour again, then thinking in terms of functionally equivalent behaviours and seeing these as a stepping stone to the more difficult behaviours may be a useful option. There is more detail on this type of strategy in the functional equivalence module.

Planning further activities
Use the strategies discussed in the session to generate specific activities for the following week.

List of therapy materials used in this module and/or with this technique

Activity Planning Tool (Appendix G)

d. Phase II Modular Technique:

vi) Communication Module

d.vi) Communication Module

Introduction and general description of the module/technique

Interpersonal concerns, and specifically, communication difficulties underlie many behavioural activation problems. Sometimes they are a TRAP/TRAC in their own right, at other times they are a barrier to achieving behavioural TRACs. For example, a patient may have a self-care goal/TRAC but is struggling to achieve it because s/he needs their partner to help watch the children during the times s/he wants to implement the self-care activity.

This module is premised on the principle that improving communication helps improve support, a key factor associated with mental well-being. It focuses on keeping strategies idiographic – that is, finding communication strategies that work for the patient in the context(s) they are in. This module does not adopt ideas that there is a right or wrong way to behave interpersonally, for example, in an 'assertive' way. Communication TRACs are patient led – the therapist should work with the patient so that s/he generates their own solutions.

It is important to understand interpersonal behaviours in the context of core BA principles. We all do behaviours for a reason. At one point they may have worked, but they may not be working in this context. Also, we must work to be concrete. It is easy to get abstract very quickly with interpersonal concerns. Stick with understanding specific, concrete behaviours.

Look for conversational patterns – for example, patterns of avoiding communication, particular types of conflict or misunderstanding. Although most of the 'work' will be done on specific conversations, if you pick those that are representative of a pattern of behaving, then you will have a bigger impact.

The module/technique in detail

Step 1: Help participant to gain an understanding of support needs, both instrumental and emotional, and the way that communication contributes to difficulties in support

Modify the monitoring sheet to focus on interpersonal situations and links with mood. This can be done in several ways:

- Prospectively – each day ask patients to record interpersonal events alongside their mood. For patients who identify interpersonal concerns as significant and want to work on this module, another way to accomplish this task is to have the participant record their best or worst moment each day. These will often be interpersonal in nature.
- Prospectively – ask patients to identify interpersonal goals, for example areas they want to improve on interpersonally, then ask them to record instances related to goals and related mood during the week.
- Retrospectively – review monitoring logs for instances that are interpersonal in nature. Examine what interpersonal behaviours were engaged in or not.

Hints:

- It's important to look as much for what is not there as what is there. Do not just look for conflict. Look for a failure to do behaviours that might otherwise be expected, for example, partner comes home, patient is exhausted after a day with the children. Partner says, "where's dinner?" and then sits down. The patient continues to get on with caring for their children and making dinner. The main problem recorded on monitoring sheet is an argument with one of the children over bath time. In fact the real problem is lack of support from partner.
    - Look for situations where the two individuals in the problem situation may have different expectations or desired outcomes for the situation. They may not speak about it, thus there may not be overt conflict, but there may be covert conflict. It can be useful to ask, "what did you want from the situation? What did the other person, to the best of your knowledge, want from the situation."
- Do not necessarily take assertions such as "*my partner/family member/friend is great. We have a fabulous relationship. S/he is a really wonderful partner*" at face value. Look for unbalanced descriptions. 'All great' may be a sign that things are in fact not so. Often there are two things that may underlie a "s/he is great" description – (1) concerns about admitting to self that things are not great and what the implications this may have for the relationship, (2) social prescriptions about how to speak about one's partner/family (this may take some trust/rapport building).

Step 2: Use an interpersonal monitoring chart to identify interpersonal or communication TRAPS

The idea in this step is to narrow the interpersonal problem down to difficulties with communication and to identify specific communication problems.

TRAP – Triggers, Response, Avoidance Pattern
Triggers: I needed to ask my husband whether he could do the bedtime routine on his own once a week so I could go swimming.
Response Worried, Frustrated, Isolated, Low. Worried about what he might say
Avoidance Pattern Silence! I could not bring myself to ask him
Consequences short term: I felt relieved I did not have to have the conversation at first. Then I just felt really frustrated with myself. Long term: Feels like I am never going to be able to make changes and get some life back for me. This makes me feel very isolated and low.

Step 3: Communication analysis
Primary concept: breaking down communication. It is important to be concrete and understand the specific factors contributing to poor communication. Hint: ask the patient to describe the situation as if you were a fly on the wall, or as if it was a movie transcript. For example, a mother who would like her ex-partner help her with childcare.
"*I phoned him up and said that I needed him to take Daniel one night this week. He said that he couldn't as he's busy all week and taking him this weekend. I couldn't believe how selfish he was being and told him so.*"
What this conversation looks like after breaking it down more:

- Marie: *Hi. I need you to take Daniel this Wednesday evening*.

- Ex-husband: *I can't this week as I have a late work meeting and won't be home until gone eight.*
- Marie: *Look, I really need some support and a break here*
- Ex-husband: *I really can't this Wednesday. I am having him at the weekend so you can get a break then*
- Marie: *I do really need some time here – you are being really unhelpful*
- Ex-husband: *Marie, I really can't. Also, this is a really bad time. I am just about to go into a meeting. Plus I am taking him at the weekend.*
- Marie: *You really are selfish. Every time I talk to you I am reminded about just how selfish you are*.
  Slams down phone.

Hint: this often takes a considerable amount of time. Plan for 20 minutes.

Step 4: Getting on communication TRAC

Conversation planner: help patient get back on TRAC with communication.

- Building communication confidence: starting with manageable communication changes. Questions to ask: Can you get it done? - Is the conversation manageable? - Do you need to break down the conversation further? Hint, if the situation is quite tricky, it may be a good idea to try out new conversational patterns with a 'safer' person and then working up to the target individual. If someone else was in my situation, what would they request? How would I feel if someone asked this from me?
- Ask the person to examine their TRAP and ask, "*what did you want from the situation?"* The aim is help the individual achieve their goals in a way that works for both them and the other person. This is quite important as many depressed individuals worry that if they ask for something for themselves they will be over riding the needs of the other individual.

THE FOLLOWING SECTION WILL BE AMENDED

- Often question B can get quite abstract. Use the goal pyramid (see below) to assist you and the patient in breaking down the goal to something that is concrete and achievable.
- Use conversation planner to generate specific goals for the conversation and to plan the context in which the conversation might occur.
- Use TRAC model to plan out moving the TRAP to TRAC.
- Role play new behaviour, allowing for at least ten minutes.
- Plan for contingencies.

Exercises with patients associated with the module/technique

List of therapy materials used in this module and/or with this technique

Self-Monitoring Record Form (Appendix D)

TRAP & TRAC Worksheet (Appendix H)

d. Phase II Modular Technique:

vii) Alcohol and Substance Use Module

d.vii) Alcohol and Substance Use Module

Introduction and general description of the module/technique

This section is designed to give a brief introduction into the management of alcohol or substance use in the COBRA trial. It is not designed to cover in detail the issues associated with the use of such substances. Those deemed to have dependency should have been screened out of the study at baseline assessment. It is of note however that people with depression may often use alcohol or non-prescribed drugs for a number of reasons, both positive and negative, in a way that is consistent with our behavioural understanding. All actions will have a consequence; if we understand the relationship between the action and the consequence, short and long term we will be able to intervene as necessary. We must note that BA is a collaborative treatment; there must be a shared understanding that the alcohol/substance constitutes a problem that the person wished to alter. This is consistent with the motivational interviewing approach that describes states of change as pre-contemplation, contemplation, action and relapse. Further details of MI are not included in this section but can be accessed and discussed in supervision. Our focus in this treatment is to use the stages of BA of self-monitoring, functional assessment goal setting and scheduling to help the person move through these MI stages to action that places them in touch with positive reinforcement in their environment. These issues should be discussed in supervision.

The module/technique in detail

Step 1: Draw links between alcohol and substance use and problems in activation/mood.

Primarily this is an extension of the use of the self-monitoring diary. If there is a suspicion that these problems are present this should be discussed in an open way and linked back to the BA rationale. This allows the person to consider the relationship between mood states/movement towards goals and their use of alcohol/drugs.

"It seems that on occasions you have reported that you were drinking alcohol, I wonder how much you are drinking on an average week. Are we able to look at this on your self monitoring forms?"

This is used collaboratively to allow the person to consider the issue and contemplate to what degree it is a problem and if they wish to address it.

Step 2: Use functional analysis to consider the relationship between the alcohol/substance use and consequence

When a situation has been identified it is important to consider it with the person in an open way to explore the consequence it has. At this point it is important not to appear judgemental or prescriptive.
"OK last week we discussed the degree to which you use alcohol and how helpful/unhelpful this was for us as we try to help you manage your depression. You were going to keep a record of when you drank over the past week, how have you

found that? When you look at the form do you notice any relationships with your mood?"

Followed up by:

"Perhaps we can look at this in more detail now, I would like to consider your drinking like the other behaviours we have looked at in treatment, that is to be open and consider the consequences, both good and bad, and how they relate to your overall goal. We can use the same structure we have used before"

At this point an ABC form can be used, this is preferable to a TRAP (although it may be possible to move on to use a TRAP/TRAC approach) as the consequence cannot always be seen as avoidance.

Antecedent: Cue to the drinking behaviour

Behaviour: Drink

Consequence: Escape from painful feelings (negative reinforcement of drinking)
Get a buzz; engage with social circles (positive reinforcement)

If negatively reinforced avoidance is the clear consequence of drinking/substance use then it is possible to move forward and use TRAP/TRAC. If the consequence is drinking is positively reinforced it is advised to look at the longer term consequence, such as feeling lethargic and stay in bed the next day. This is the related back to rationale cycle and treatment goals.

This stage again works with the person to contemplate changes to be made.

Step 3: Identify new behaviours to be tried at risk times and schedule these in diary

This moves to an action stage, and the scheduling follows the same stages as outlined earlier in this section. Remember behaviours should be specific and clear and collaboratively set.

It is of note that we see new behaviours that are useful as those that move the person towards their goals and provide positive reinforcement. This is experimental and it is important we are open and evaluate the consequences of any new behaviours in subsequent sessions.

Exercises with patients associated with the module/technique

As we are viewing these problems as the same as other problematic behaviours discussed throughout this manual there are no new exercises to be added. The flexible use of self-monitoring, functional assessment and scheduling are exercises that will have already been repeatedly used in clinical sessions. It is important we use the same approach applied consistently using the same exercises to allow the participant to view their drinking/substance use behaviour in this way and not add undue complication to the BA treatment.

List of therapy materials used in this module and/or with this technique

Self-Monitoring Record Form (Appendix D)

Functional Analysis ABC Sheet (Appendix C)

TRAP & TRAC Worksheet (Appendix H)

Activity Planning Tool (Appendix G)

10. References

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11. Appendices: Clinical Tools

Appendix A: BA Assessment Worksheet

What is main problem (can you describe to me the main problem that brings you to see me)?

When will this problem occur (are there any particular patterns to this, day/month particular triggers to worsening, any times you note when you feel a little better)?

Where will it occur/feels worse (are there any particular places home, outside, *get specific;* any times you note you feel a little better)?

With whom (does anyone, or type of people have an impact on the problem, anyone make you feel better, explain how)?

What are the worries that go through your mind when you are feeling this way?

Frequency of fluctuations

Range of intensity of feelings linked to above (use a scale)

Duration (of symptoms, how long would fluctuations last)

Excesses (behaviours the sufferer has increased to cope with the problem, e.g. taking phone of hook, shopping at quiet times, using alcohol, sleeping more etc)

Avoidance (what is now avoided in order to cope such as work, socialising etc)

Functional Analysis of problem (use recent situation to get a detailed picture, you are looking for the behavioural responses to a surge in depressive symptoms, and the consequence of that)

	Autonomic symptoms	Behavioural symptoms	Cognitive symptoms
Antecedent			
Behaviour			
Consequence			

Impact of problem (look for impact on the way the person is able to interact with their world, social, family, daily activities, etc and previous positive reinforcing activities)

Onset (Any key event that occurred around the time of onset that may be linked in a change to engaging with world)

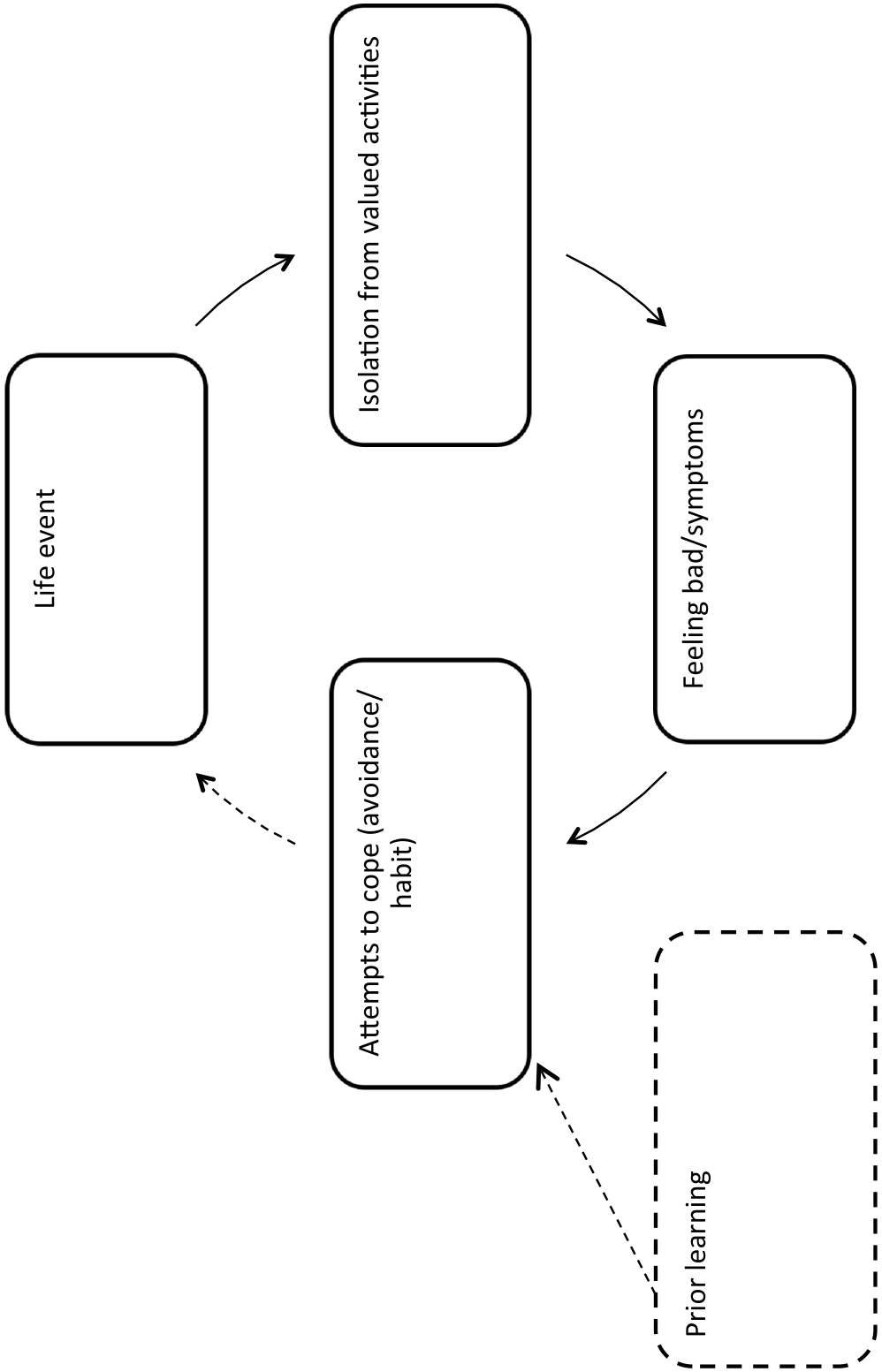
Fluctuations

Previous treatment for this problem/other psychological difficulties

Check use of alcohol or drugs

Risk assessment (ask about suicide, thoughts, any intent, plans, previous attempts etc)

Appendix B: Formulation Diagram



Appendix C: Functional Analysis ABC Sheet

Antecedent	
Behaviour	
Consequence	

Appendix D: Self-Monitoring Record Form

In each box write the activities you engaged in during the hour, and how you felt. Rate your feeling on a scale of 1 to 10, with 1 being the least intensity of feeling and 10 being the most.	
Time:	**Day and Date:**
Midnight	
Mood	
1:00 A.M.	
Mood	
2:00 A.M.	
Mood	
3:00 A.M.	
Mood	
4:00 A.M.	
Mood	
5:00 A.M.	
Mood	
6:00 A.M.	
Mood	
7:00 A.M.	
Mood	
8:00 A.M.	
Mood	
9:00 A.M.	
Mood	
10:00 A.M.	

Mood	
11:00 A.M.	
Mood	
Noon	
Mood	
1:00 P.M.	
Mood	
2:00 P.M.	
Mood	
3:00 P.M.	
Mood	
4:00 P.M.	
Mood	
5:00 P.M.	
Mood	
6:00 P.M.	
Mood	
7:00 P.M.	
Mood	
8:00 P.M.	
Mood	
9:00 P.M.	
Mood	
10:00 P.M.	

Mood	
11:00 P.M.	
Mood	

Appendix E: Goals Sheet

Please write down some of the things you would like to be doing that are currently hard to achieve. These goals will help you plan your treatment with your therapist. They will be most useful if they are specific, realistic activities and if they are things that are important to you, reflecting your life values.

Goals

Goal 1

Goal 2

Goal 3

Goal 4

On the scale below please rate the current percentage success you have in attempting to achieve your goals **regularly without difficulty**:

0 ---------- 1 ---------- 2 ---------- 3 ---------- 4 ---------- 5 ---------- 6 ---------- 7 ---------- 8

No success 25% success 50% success 75% success complete success

Appendix F: Valued Activities Worksheet

Write down your routine activities here:
e.g. cleaning, cooking, shopping etc.

Write down your pleasurable activities here:
e.g. going out/visiting friends or family

Write down your necessary activities here:
e.g. paying bills etc.

Appendix G: Activity Planning Tool

Time	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
AM 6-7							
7-8							
8-9							
9-10							
10-11							
11-12							
PM 12-1							
1-2							

2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10	10-11	11-12

Appendix H: TRAP & TRAC Worksheet

Trigger: What situation, activity, or thinking occurred?

Response: What was my response to the trigger? (What did I do or feel?)

Avoidance-**P**attern: What did I do to stop my discomfort?

What are the activities that seemed difficult or that I was unable to do?

In what way was by behaviour immediately effective in stopping my discomfort?

What are possible long-term consequences of my behaviour?

After doing the above activity (or inactivity) am I **MORE** or **LESS** depressed? *(circle which)*

What change in my behaviour can I try in order to break out of the **"TRAP"**?

When will I try this behaviour?

Outcome (after trying new behaviour):

Trigger: What situation, activity or thinking occurred?

Response: What was my normal response?

Alternative:
Coping: What new activity can I try?

When will I do it?

How will I do it?
(break into small steps)

In what way may this help me over time?

How does it help me break out of TRAP?

Appendix I: Rumination Monitoring Form

During the week identify situations where you find yourself turning over thoughts in your mind. Use the spaces below to see where this occurs, what the content is and how this makes you feel/what you do as a result. In the next session your therapist will look at this with you and together you can discuss how this may be impacting on your depression.

Situation	Rumination	Consequence

Appendix J: Problem Solving Worksheet

Problem:

Goal(s):

Solutions:

a)	**a) Pros (+)**	**a) Cons (-)**
b)	**b) Pros (+)**	**b) Cons (-)**
c)	**c) Pros (+)**	**c) Cons (-)**
d)	**d) Pros (+)**	**d) Cons (-)**

Choice of solution:

Steps to achieve solution (homework):

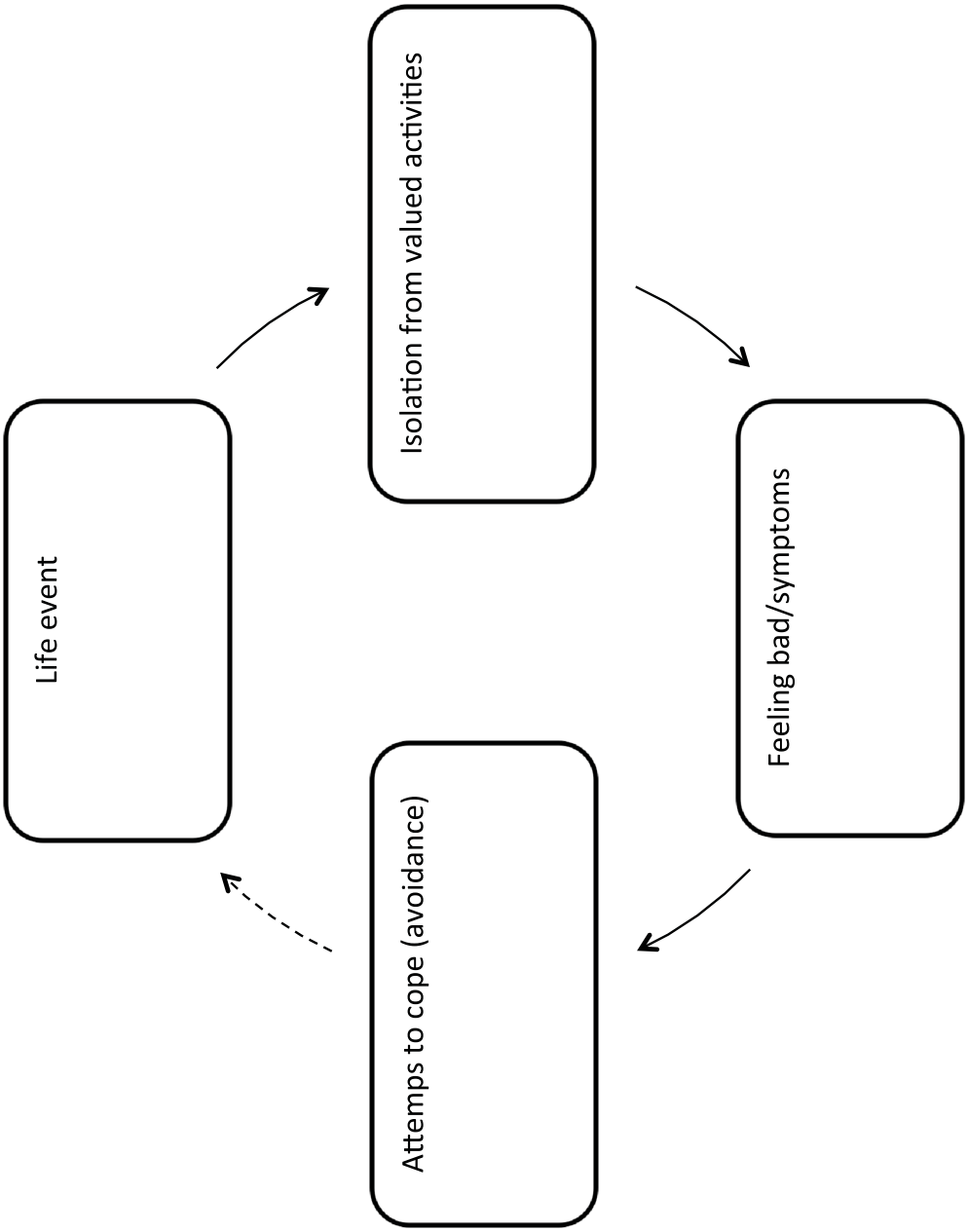
a)

b)

c)

d)

Appendix K: Anxiety Cycle Template



Appendix L: Relapse Prevention Worksheet

What are 5 signs my depression is getting worse? *Be specific, e.g. I have avoided social engagements more than twice in a week; I have woke early getting stuck with ruminations 3 times in past week.*
What are 5 steps you can take to help yourself when you notice the above?

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Clinical Practice Manual

COBRA Trial Behavioural Activation Protocol Clinical Practice Manual

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Professor David A Richards
University of Exeter Medical School
XXXX

Appendix 8 Cognitive–behavioural therapy clinical practice manual

COBRA Trial CBT Protocol

Clinical Practice Manual

Cost and Outcome of BehaviouRal Activation:

A Randomised Controlled Trial of Behavioural Activation versus Cognitive Behaviour Therapy for Depression

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COGNITIVE BEHAVIOURAL THERAPY CLINICAL PRACTICE MANUAL

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Manual Structure

This manual contains the necessary information you will need in order to initiate and undertake cognitive-behavioural therapy (CBT) with patients in the COBRA trial.

Section 1 has some information about the COBRA trial itself. Section 2 outlines some general principles of session timing, duration, frequency and safety. Sections 3 and 4 describe the two treatments being tested in the COBRA trial – BA and Cognitive Behavioural Therapy (CBT) in very broad terms.

Sections 5 and 6 will give you a very good summary of what a course of CBT treatment in the COBRA trial will look like, describing the phasic nature of the COBRA protocol and a summary of the content of each phase. Section 6, in particular, gives a schematic overview of a COBRA CBT treatment programme.

Section 7 then goes on to describe the core CBT techniques – assessment/orientation, activity scheduling, cognitive restructuring and relapse prevention. It also briefly describes some of the modular specific techniques you will be using for co-morbid presentations.

Section 8 then goes on to detail the structure of clinical sessions at all stages of a CBT treatment programme. You should follow these structures very closely as your adherence to the overall structure, sessional structure and specific therapeutic content will be critical in ensuring fidelity to the clinical protocol COBRA is testing. As part of assuring treatment integrity tapes from all therapists will be formally assessed by independent assessors from the Oxford Cognitive Therapy Centre, initially with formative feedback and across treatment as a whole summatively to describe the trial CBT.

Section 9 consists of a series of helpful ‘therapist notes’ on each of the principle techniques you will be asked to employ. Think of these as aide memoires. They will help you refresh your memory when it comes to employing these techniques.

Section 10 lists some of the key scientific references underpinning the COBRA trial. This is followed by Section 11 (Appendices), consisting of the therapeutic tools such as diaries that you will need to use throughout any treatment programme.

Please consult this manual frequently. Bring it with you to supervision and use it to help you become confident and competent at delivering the COBRA CBT clinical protocol. If you would like to personalise it, please do, and if you have any suggestions for additional materials, the trial team will be happy to listen.

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Introductory Pages

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Introduction to the COBRA trial

Clinical depression is one of the most common and debilitating of the psychiatric disorders. It accounts for the greatest burden of disease among all mental health problems, and is expected to become the second-highest amongst all general health problems by 2020.

COBRA is a Randomised Controlled Clinical Trial of two psychological interventions – Behavioural Activation (BA) and Cognitive Behaviour Therapy (CBT) – to establish if there are important clinical and cost differences between them. In detail, the COBRA programme of research seeks to answer two interlinked questions:

3. What is the clinical effectiveness of BA compared to CBT for depressed adults in terms of depression treatment response measured by the PHQ9 at 12 and 18 months?
4. What is the cost-effectiveness of BA compared to CBT at 18 months?

In addition, we will undertake a secondary process evaluation to investigate the moderating, mediating and procedural factors in BA and CBT that influence outcome.

BA and CBT are both active psychological treatments which have previously demonstrated positive effects for people with depression, and are recommended by NICE guidelines for the treatment of depression. Half the participants in the COBRA trial will receive BA and half CBT, allocated on a random basis.

Participants will be assessed for eligibility by a COBRA researcher using a structured clinical interview. If eligible, they will be asked to complete a number of questionnaires with the researcher. They will then be randomly allocated to one of the treatments by the Peninsula Clinical Trials Unit in Plymouth using a process concealed from the research team to ensure the team are blind to allocation. Participants will also be seen again for follow-up appointments with a researcher at six months, 12 months and finally at 18 months to complete a number of questionnaires. The research study will last for four years, but each participant's involvement in the study will be for eighteen months.

The study will be taking place in three sites; Devon Durham and Leeds with the lead centre being the University of Exeter's Mood Disorders Centre. COBRA will begin in March 2012, the first participant will start treatment in September 2012 and the study will end in April 2016. Participants will be recruited from August 2012 until April 2014.

The trial is funded by a UK National Institute for Health Research (NIHR) Health Technology Assessment Programme Clinical Evaluation and Trials grant.

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General clinical procedures

d. Frequency and duration of appointments

Participants will receive a maximum of 20 sessions over 16 weeks with the option of four additional booster sessions.

Sessions will be face to face, of one-hour duration maximum.

Therapists and participants have the option of having sessions up to twice weekly over the first two months of the trial and weekly thereafter where this is clinically indicated (e.g., with a severely depressed client and twice weekly sessions would support initial behavioural work).

The final few sessions may be spaced out further if clincially appropriate to support relapse prevention.

e. Risk assessment and management

Risk will be assessed at every appointment. At the first appointment a full risk assessment will include enquiry on suicide, self-harm, neglect of self, neglect of others, harm to others and harm from others. Risk will be assessed in terms of thoughts, plans, actions taken in support of any plans, and preventative factors. At subsequent appointments risk will be reviewed against the assessment conducted in the first appointment to assess any change in the patient's risk status.

Where any factors are detected which leads the therapist or mental health worker to believe that there is a danger that the patient will harm themselves or others through action or neglect, a risk management plan will be initiated. This plan will follow the principles of the Mood Disorders Centre's policy on risk and any actions taken will be determined by the specific policies in place at the NHS clinical provider site. All risks identified and any actions taken will be documented and discussed in supervision and with the COBRA trial manager, site lead and chief investigator.

f. Collecting routine outcome measures

Over recent years, it has become standard practice for therapists and mental health workers to ask patients to complete short clinical outcome scales at every clinical encounter. Measures are used to assist both parties to track progress, identify setbacks and provide data for individual patient progress and overall service evaluation. In COBRA we use the same procedure at every session. In the CBT arm this will be the Beck Depression Inventory (BDI). Measures are collected from the patient during the early part of the appointment and discussed briefly before moving onto the main session content. Occasionally measures may lead to a change in the session agenda. A summary of all therapists' outcomes on the BDI is always discussed in supervision.

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What is Behavioural Activation?

Behavioural Activation (BA) is a psychological treatment alleviating depression by focusing directly on changing behaviour based on behavioural theory. This theory states that depression is maintained by avoidance of normal activities. As people withdraw and disrupt their basic routines, they become isolated from positive reinforcement opportunities in their environment. They then end up stuck in a cycle of depressed mood, decreased activity and avoidance. BA systematically disrupts this cycle, initiating action in the presence of negative mood, when people's natural tendency is to withdraw or avoid. BA targets avoidance from a contextual, functional approach not found in CBT – i.e., BA focuses on understanding the function of behaviour and replacing it accordingly. BA also explicitly prioritises the treatment of negatively reinforced avoidance and rumination.

The overall goal of BA is to re-engage participants with stable and diverse sources of positive reinforcement from their environment and to develop depression management strategies for future use. BA sessions consist of a structured programme increasing contact with potentially antidepressant environmental reinforcers through scheduling and reducing the frequency of negatively reinforced avoidant behaviours. Treatment is based on a shared formulation drawn from the behavioural model in the early stages of treatment, thereafter developed with the patient throughout their sessions. Specific BA techniques include the use of a functional analytical approach to develop a shared understanding with patients of behaviours that interfere with meaningful, goal-oriented behaviours and include self-monitoring, identifying 'depressed behaviours', developing alternative goal oriented behaviours and scheduling. In addition the role of avoidance and rumination will be addressed through functional analysis and alternative response development.

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What is Cognitive Behavioural Therapy?

The overall goal of CBT is to alter the symptomatic expression of depression and reduce risk for subsequent episodes by correcting the negative beliefs, maladaptive information processing and behavioural patterns presumed to underlie the depression. Sessions consist of a structured, partially didactic programme. Treatment begins with patients learning the model and behavioural change techniques, then moves on to identifying and modifying negative automatic thoughts, maladaptive beliefs and underlying core beliefs. In later sessions, learning is translated to anticipating and practicing the management of stressors that could provoke relapse in the future. Specific CBT techniques include scheduling activity and mastery behaviours, the use of thought records and modifying maladaptive beliefs. The behavioural elements in CBT focus on increasing activity together with practical behavioural experiments to test specific cognitive beliefs. CBT does not take the contextual, functional approach of BA, nor does CBT explicitly prioritise the targeting of avoidance and rumination.

COBRA Trial CBT Protocol

Clinical Practice Manual

General clinical principles of the protocol

CBT for depression (Beck et al., 1979) is a manualised approach that has been demonstrated to have proven efficacy and effectiveness in numerous treatment trials. In this trial, therapists will use two seminal treatment manuals in this area (A.T. Beck et al., 1979; J.S. Beck, 2011). Several innovations in CBT since the publication of the original manual have emphasised approaches that help to individualise treatment (Kuyken, Padesky & Dudley, 2009) and overcome cognitive and behavioural avoidance (Moore & Garland, 2003). Moreover, there has been much clinical innovation in CBT that has been about ensuring core behavioural and cognitive strategies are as acceptable and potent as possible (e.g., J.S. Beck, 2011; Westbrook, Kennerly & Kirk, 2011; Padeksy & Mooney, 1990). Therapists will make use of cognitive and behavioural tools or approaches that have become part of the mainstream tool kit of well-trained CBT therapists.

In addition, we anticipate that a significant proportion of patients will present with psychiatric co-morbidities. Based on our previous trials and the epidemiological data these are most likely to be generalised anxiety disorder, social phobia, panic disorder and simple phobia. As with real world CBT, therapists will need to address patients' presenting problems including any co-morbid presentations. Therapists will use CBT case conceptualisation to understand how beliefs and strategies link patients' presenting issues and use evidence-based CBT models and protocols appropriate to the individual patient's presentation. In line with recommended standard CBT practice, therapists will record patients' depressive symptoms at each session using the BDI to monitor treatment progress and amend their conceptualisation and treatment plan if patients do not progress as anticipated.

Primary CBT protocols and evidence summaries used by therapists in the trial:

- Depression (unipolar):
  - Beck, A. T., Rush, A. J., Shaw, B. F., & Emery, G. (1979). *Cognitive therapy of depression*. New York: Guilford Press.
  - Moore, R. G., & Garland, A. (2003). *Cognitive therapy for chronic and persistent depression*. Chichester: Wiley.

- Social Phobia:
  - Clark, D.M. (1997). Panic disorder and social phobia. In Clark, D.M. & Fairburn, C.G. (Ed.) *Science and Practice of Cognitive Behaviour Therapy (pp.119-154).* Oxford: Oxford University Press.

- Panic:
  - Clark, D. M. (1986). A cognitive approach to panic. *Behaviour Research and Therapy, 24*, 461-470.

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- GAD:
  - Dugas, M.J. & Robichaud, M. (2006). *Cognitive-behavioral treatment for generalized anxiety disorder: From science to practice.* New York: Routledge.

- Post-traumatic Stress Disorder:
  - Ehlers, A., Clark, D. M., Hackmann, A., McManus, F., & Fennell, M. (2005). Cognitive therapy for post-traumatic stress disorder: development and evaluation. *Behaviour Research and Therapy, 43*(4), 413-431.
  - Harvey, A. G., Bryant, R. A., & Tarrier, N. (2003). Cognitive behaviour therapy for posttraumatic stress disorder. *Clinical Psychology Review, 23*(3), 501-522.

- Personality disorders:
  - Beck, A. T., Freeman, A., Davis, D., & Associates. (2003). *Cognitive therapy of personality disorders* (Vol. Second Edition). New York: Guilford.

- Eating disorders:
  - Fairburn, C. G., Cooper, Z., & Shafran, R. (2003). Cognitive behaviour therapy for eating disorders: a "transdiagnostic" theory and treatment. *Behaviour Research and Therapy, 41*(5), 509-528.
  - No summary to date, but see Roth, A., & Fonagy, P. (2005). *What works for whom: A critical review of psychotherapy research* (Vol. Second Edition). New York: Guilford.

When addressing co-morbidities therapists may wish to use disorder specific measures to assess severity and to monitor progress. The manuals may suggest such measures or alternatively therapists may use bespoke tools for assessment / evaluation.

CBT normally progresses through several phases (A.T. Beck, 1979; J.S. Beck, 2011):

a. Phase I

Phase I represents the introduction of the core CBT methods. The first session is an assessment where the worker gathers information on the patient's presenting issues and illustrates the CBT model with respect to the presenting issues. A list of collaboratively agreed presenting issues and SMART treatment goals is generated. Phase I then moves on to socialise the client to CBT and start to introduce some of the core therapeutic activities with the intention to achieve some early symptom gains. This typically includes linking mood, thinking and behaviour through a descriptive case formulation and setting up some behavioural monitoring/activation.

b. Phase II

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Phase II moves into cognitive interventions focused first on automatic thoughts and then moving on to working with conditional assumptions, using thought records and other in-session and homework tools. Typically a theory driven cross-sectional case formulation would be used here. Behavioural experiments are central to testing and reframing conditional assumptions.

c. Phase III

Phase III is focused on planning to maintain progress and reduce relapse potential by working on beliefs and behaviours that will confer resilience in the face of future stress. If appropriate, a longitudinal case formulation is used to anticipate and plan for set-backs.

d. Booster phase

These appointments are optional with a very flexible content. Therapist and patient undertake a review of the difficulties experienced and identify specific therapeutic techniques from the core Phase I stage or any modules in Phase II which may need refreshing, practice or further work. Relapse prevention activities may also be undertaken.

e. Transition and review appointments

These sessions are an opportunity for therapist and patient to review progress, reflect on activities undertaken so far and move to the next Phase. The list of presenting issues and goals is reviewed and the formulation is revisited. A revised set of presenting issues and goals is developed for the next phase.

CBT Protocol Overall Session Chart

PHASE I						TRANSITION	PHASE II								TRANSITION	PHASE III				BOOSTER			
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Assessment/rationale/ agreed presenting issues/shaping towards goals. Descriptive case formulation diagram																							
	Goal setting and first interventions					Progress to goals reviewed									Progress to goals reviewed								
Homework																							
Behavioural experiments																							
	Behavioural interventions: Activity and mastery and scheduling pleasurable /rewarding activities																						
		Identifying and responding to automatic thoughts																					
						Identifying conditional assumptions and using cognitive and behavioural strategies to reframe conditional assumptions and articulate and test out more adaptive beliefs. Cross-sectional case formulation.																	
															Longitudinal case formulation, only if necessary, identifying and working with core beliefs, again only if necessary.								
																Relapse Prevention/ Maintaining Progress							

Dark blue = core activities for these sessions; Light blue = non-core, but optional activities for these sessions

Summary of Core CBT Techniques

7. Summary of core CBT techniques

a. Socialisation to the CBT model

Socialising the client to the CBT model includes the development of a shared sense of the treatment rationale. This includes the understanding of depression in relation to the 5 areas approach (Padesky & Mooney, 1990; Kuyken et al., 2009), and that change is possible though working on this model. Doubts and concerns are openly discussed and can be tested as part of treatment. Formulation of a presenting issue can help to apply this directly to the client's situation and add a sense of face validity, cautious optimism, and begin to indicate treatment. This also helps to socialise the client to the style of CBT as one that is collaborative, Socratic and involves two experts in the room (the client as expert in their difficulties and the therapist as an expert in CBT).

Structural aspects of the treatment are also outlined including agenda setting, homework between sessions, the empirical nature of treatment, use of measures, confidentiality agreements, the treatment contract, and frequency and duration of appointments.

b. Goal setting

Goal setting involves the shared development and agreement with the client on the specific goals for treatment in each of the problem areas identified. This is a further aid to the collaborative nature of the work to ensure that both therapist and client have the same aims in mind for treatment. Goals are important in making the expectation of treatment explicit and appropriate (as opposed to the unrealistic goal of never feeling anxious or placing expectations on the behaviour of others). Setting goals is important in identifying explicitly the possibility of change, and can help focus the client upon this possibility. Goals also help to underline the active focused nature of CBT treatment and that progress can be evaluated and reviewed. Goals also serve an important motivational function in providing a point of focus against which current patterns of activities, changes and future patterns can be judged as helpful and/or worthwhile.

Goals developed should be consistent with the 'SMART' notion of goals in being; Specific, Measurable, Achievable, Realistic and Time limited. Goals may be developed further through being prioritised, graded and expressed in positive terms.

c. Activity scheduling

Physical and social inactivity is a key feature for many people with depression. Periods of inactivity may be seen to lead to reduced experience of mastery and pleasure and increased negative thinking, typically rumination and self-criticism. Activities or tasks which the depressed person may previously have completed with ease or with enjoyment become challenging and may be avoided. Cognitions related to performance (I will fail, I will not enjoy it) may reduce further the motivation and likelihood of engaging in tasks. Activity scheduling is a strategy aimed at addressing low levels of motivation, inactivity and rumination and increasing activity that is associated with mastery and pleasure.

By recording a person's activity on an hour by hour basis and tracking mood over this time a picture can be built up to see the impact of the level and range of activity (or inactivity) upon the person's level of depression. This is discussed with the client to identify those behaviours that impact negatively upon mood and those which help to improve mood. Where there is an absence of activity that improves mood this can be built into the person's day to maintain momentum.

This will allow the development of links between behaviour and emotion and subsequently cognition. Activities can be developed on the basis of increasing helpful activity, planning these at difficult times of the day and expanding the repertoire of behaviour. Prior activities that the person has enjoyed or selection of events from a pleasant events schedule (see J.S Beck, 2011) can be planned into the activity schedule.

Barriers to engaging in activities can be helped though a range of strategies including problem solving, challenging negative automatic thoughts, planning and grading activities and cognitive rehearsal.

Progress may be reviewed through a mood rating, scores for enjoyment (pleasure) and scores for achievement (mastery). The initial focus is upon changing the behaviour in advance of shifts in emotion. Small single point shifts in mood (up or down one point out of 10) are seen as significant and indicate future change. Changes in behaviour may need to be emphasised as having to reach a 'therapeutic dose' before improvements are noticed.

As changes in mood (however small) are noted, these provide evidence to challenge any negative automatic thoughts associated with the task (e.g. 'I can't do anything', 'nothing will make a difference,' 'these trivial events prove how pathetic I am').
It is important to keep this work focused on the collaboratively agreed presenting issues and goals.

d. Introduction to automatic thoughts – cognitive strategies

Depression is characterised by a number of cognitive features. This includes Beck et al's 'cognitive triad' that outlines depressive thinking in relation to the self, current experience and the future. Negative views of the self are often characterised by thoughts that one is defective, useless, or inadequate. In this way difficult experiences are attributed to the self. This can also then lead to strong self-criticism. The second component leads the person to interpret their current experience negatively, with insurmountable problems or difficulties leading to a sense of defeat. The final element is about the future as difficult, expectation of failure and hopelessness.

Automatic thoughts are an expression of this triad and occur habitually, automatically and involuntarily. A number of different categorisations of styles of automatic thinking have been developed, but all serve to fit perception with the negative triad. This then subsequently impacts upon the person's emotions, behaviour and physical experiences and vice versa. These will often be raised in relation to the effectiveness of therapy and out of session tasks proposed.

By practicing the identification and self-monitoring of these the client can become more aware of their presence and impact and begin to work to challenge these. Typically this may lead to the use of diary thought records and review of evidence to work towards a more balanced interpretation of events. This may well lead to planned behavioural experiments and the identification of patterns of thinking and behaviour that are more consistent with the client's smart goals. Other cognitive strategies may include the use of survey methods to check for accuracy of cognitions and may be collected by the client, therapist or both. It is important to keep this work focused on the collaboratively agreed presenting issues and goals.

e. Cognitive-Behavioural strategies – behavioural experiments

'The best way to increase the believability of your alternative or balanced thoughts is to try them out in your day to day life.' *(Greenberger & Padesky, 1995).*
Verbal challenging of thoughts is often followed by or developed through the use of behavioural experiments. This is often an important step in moving from an 'in the head' understanding through to a more felt sense of change by putting new or alternative understandings into practice; namely 'walking the talk.' Behavioural experiments are planned experiential activities based on experimentation or observation which the client does within or between therapy sessions.

The primary purpose is to obtain new information which may help to test the validity of the patients' existing beliefs, construct and test new more adaptive beliefs and contribute to the development and verification of the formulation. This will most often follow a process of identifying the cognition, developing an alternative and testing

these out on the basis of a clear prediction on how things will go according to these different perspectives. For an excellent overview of using behavioural experiments see Bennett-Levy et al. (2004). It is important to keep this work focused on the collaboratively agreed presenting issues and goals.

f. Underlying assumptions/rules

Underlying assumptions and rules represent the conditional level of belief and are typically captured in a cross-sectional case conceptualisation of the client's presenting issues. These are the highly individualised conditional and generalised rules or terms of reference a person may hold, are usually functional and which dictate behaviour. Padesky (1994) has proposed that these are often best expressed in an If _____ then _____ format. For example, in depression this may be, '**If** I make a mistake at work, **then** I am worthless' or '**If** my partner and I argue, **then** it means s/he will leave me.' A collaborative articulation of conditional assumptions is a pre-requisite for testing beliefs using behavioural experiments.

The same rule can be expressed negatively (If I don't do something) or positively (If I do something). **If** I don't make a single mistake and everyone says how well I am doing **then** I am okay; versus **If** I make a single mistake **then** I am worthless. Distress may be alleviated on a temporary basis by being able to meet the conditions for coping (the 'if' part of the rule). This however is seldom possible and does not normally support long-term change. The emphasis of intervention at this stage is therefore on the development of alternative more adaptive beliefs that provide a better fit with the person's goals for treatment (e.g. **If** I make a mistake at work, **then** I am just like everyone else, and I can learn from it and develop).

A possible example of an underlying assumption expressed as a rule is: 'I must do things perfectly.' This reflects the rigid, overgeneralised, absolute and extreme nature of problematic rules. Themes present within rules tend to be ones of achievement, acceptance, love or control. Violation of rules tends to be associated with extreme/excessive emotional reactions (anger, sadness, fear). Rules are likely to be activated in situations relating to individuals' specific vulnerability. However they are often not conscious and are uncovered through the development of cross sectional formulations and themes occurring across time and events, or through specific techniques, such as the downward arrow technique; e.g. 'if I can't provide for my family, then my wife will be cross'.

Socratic methods are used to review evidence for and against the belief, tracking the impact of the belief upon the person's goals, and the generation of an alternative belief. Further experimentation is then used to strengthen conviction in this alternative and support its use over and above the original rule. This will very likely require patients do a lot of practice within sessions and as homework. It is important to keep this work focused on the collaboratively agreed presenting issues and goals.

g. Relapse prevention

Relapse prevention is activity undertaken with the client to make explicit the learning and skills development that has taken place across the course of treatment. By helping the client to become aware of the specific skills used in self-formulation and which techniques are helpful, the chance of the client engaging with these skills and maintaining coping after treatment is enhanced. Explicit awareness of skills is typically identified alongside anticipated future difficulties and rehearsal of skills that would be helpful in this context. Relapse prevention can include further short, medium and long-term goals that the client will continue to work towards following the end of treatment, and a plan for how self-therapy will be continued.

The emphasis upon coping may also be enhanced with the use of resilience formulation. This is the application of the same Beckian formulation model, but populated with the thoughts, feelings, behaviours and physical sensations associated with progress, alleviation of distress and meeting the goals for therapy. This may well include alternative underlying assumptions or rules for living developed over the course of treatment (See Kuyken et al., 2009).

Session Guides

8. Session guides

The following pages detail the structure of individual sessions to be conducted as part of the COBRA trial. There are separate pages for: assessment, Phase I early, mid and late sessions, the Phase I to Phase II transition, Phase II sessions, the Phase II to III transition, the relapse prevention sessions and the booster sessions.

These session guides are the essential structure to the COBRA CBT protocol. Individual sessions have different session specific content, the details of which are described in the 'therapist notes' section of this handbook. Please use the technique specific instructions to tailor sessions but start and finish the sessions according to the session guides in the following pages.

Assessment Session Guide: Sessions 1-2

9. Introductions and orientation

10. Information gathering
    a. Brief description of problems (problem list):
       Development: precipitants, time course, predisposing factors
    b. Description of problem behaviour (typical example)
       Behavioural, cognitive, emotional, physical
    c. Contexts and modulating variables: Situational, behavioural, cognitive, affective, interpersonal, physiological
    d. Maintaining factors: Situational, behavioural, cognitive, affective, interpersonal, physiological
    e. Avoidance
    f. Coping resources
    g. Sessional measures and feedback
    h. Psychosocial situation: Family, relationships, accommodation, occupation, social relationships, hobbies/interests
    i. Past history, previous treatments and response, other current treatments, alcohol and drug use, co-morbidities
    j. Risk assessment

11. Information giving
    a. CBT rationale
    b. Treatment session, duration and content details, role of worker
    c. Descriptive formulation of a typical presenting issue

12. Homework setting
    a. Setting appropriate task: Further measures, complete activity record

13. Summarise and check out collaborative understanding of session

14. Appointment planning

15. Ending

Phase I Session Guide: Sessions 2 and/or 3

10. Setting the session agenda
11. Sessional measures – review of measure completed on arrival in waiting area
12. Risk review
13. Review goals – develop SMART elements

14. Session specific therapeutic content
    e. Review typical example of presenting problem
    f. Descriptive formulation of typical presenting issue
    g. Illustrate bi-directional nature of 5 areas approach
    h. Consider role of behaviour
    i. Talk through activity schedule and scoring (Mood overall, option of additional rating for achievement and enjoyment), and practice by completion of current day
    j. Set homework as activity recording for the week – problem solve any barriers to this

15. Manage any other business from agenda
16. Summarise (ideally client summarises), major feedback from client about therapy/therapist
17. End by agreeing next appointment time and place

Phase I Session Guide: Sessions 3 and/or 4

10. Setting the session agenda
11. Sessional measures
12. Risk review
13. Review of activity schedule

14. Session specific therapeutic content
    a. Review use of activity schedule
    b. Check for omissions and distortions
    c. Begin to demonstrate relationship between activity and affect
    d. Linking this to descriptive formulation of difficulty- beginning to note NATs linked to this
    e. Addressing NATs that have interfered with the homework
    f. Identification of behaviours that nurture and those that deplete
    g. Planning increase in nurturing behaviours
    h. Setting behaviour change as homework and problem solving barriers

15. Manage any other business from agenda
16. Major summary and feedback
17. End by agreeing next appointment time and place

Phase I Session Guide: Sessions 4-6

10. Setting the session agenda
11. Sessional measures
12. Risk review
13. Review of activity recording sheets

14. Session specific therapeutic content
    a. Development of role of NATs in activity and developing links between the 5 areas
    b. Identifying and recording NATs
    c. Considering thinking bias
    d. Developing diary thought record (DTR)
    e. Generating alternatives – linking DTR to Behavioural experiments (BE)
    f. Linking different responses to goals
    g. Homework linked to developing use of DTR and BEs

15. Manage any other business from agenda
16. Summarise and major feedback
17. End by agreeing next appointment time and place

Transition and Review Session A (Session 7)

10. Setting the session agenda
11. Sessional measures
12. Risk review
13. Review of DTR and BEs

14. Session specific therapeutic content
    a. Revisit formulation
    b. Check progress against goals
    c. Address remaining treatment interfering processes
    d. Consider cross sectional formulation from descriptive formulations developed
    e. Develop overall plan for next phase

15. Manage any other business from agenda
16. Summarise and major summary
17. End by agreeing next appointment time and place

Phase II Session Guide: Sessions 8-16

10. Setting the session agenda
11. Sessional measures
12. Risk review
13. Review of DTR and BEs

14. Session specific therapeutic content
    a. Introduce role of cross sectional formulation
    b. Develop cross sectional formulation
    c. Link to conditional levels of belief (underlying assumptions)/rules for living
    d. Develop alternative conditional beliefs (underlying assumptions)/rules for living
    e. Linking different rules/assumptions to impact on goals
    f. Undertake specific exercises to challenge problematic conditional beliefs and build strength in alternatives
    g. Delivery of cognitive and behavioural interventions in line with the above

15. Manage any other business from agenda
16. Summarise and major summary
17. End by agreeing next appointment time and place

Transition and Review Session B (session 17)

10. Setting the session agenda
11. Sessional measures
12. Risk review
13. Review of homework/out of session task

14. Session specific therapeutic content
    a. Revisit formulation
    b. Check progress against goals
    c. Repeat rationales
    d. Identify remaining activities
    e. Consider need for longitudinal focus versus relapse prevention for progress to date

15. Manage any other business from agenda
16. Summarise and major summary
17. End by agreeing next appointment time and place

Phase III Relapse Prevention Session Guide: Session nos. <= 18-20

10. Setting the session agenda
11. Sessional measures
12. Risk review
13. Review of homework/out of session task

14. Session specific therapeutic content
    a. Introduce concept of maintaining progress and/or reducing relapse potential
    b. Acknowledge necessity to manage forthcoming therapeutic ending
    c. Develop coping blue print, consider inclusion of:
        i. High risk situations
        ii. Early warning signs
        iii. Formulation developed
        iv. Coping in line with goals
        v. Resilience formulation
        vi. Goals for the future (short, medium and long term)
    d. Plan Longitudinal formulation if appropriate
    e. Intervention strategies at conditional level of belief (continua methods, alternative conditional beliefs, point-counterpoint)

15. Manage any other business from agenda
16. Summarise and major summary
17. End by agreeing next appointment time and place

Booster Session Guide

10. Setting the session agenda
11. Sessional measures
12. Risk review
13. Review of homework/out of session task

14. Session specific therapeutic content
    a. review of difficulties experienced
    b. review of formulation
    c. identification of specific therapeutic techniques to revisit
    d. relapse prevention activities

15. Manage any other business from agenda
16. Summarise and major summary
17. End by agreeing next appointment time and place/end

9. Therapist notes detailing core techniques

Assessment Session Guide

Assessment Session Guide

A number of sources provide information on the structure and focus of a CBT assessment. This information will focus upon the guidance developed from A.T. Beck at al (1979); J.S. Beck (2011); Kirk (1989) and Moore and Garland (2003).

Initial contact with the client can serve a number of purposes, not least of which is to develop an individual formulation of how the cognitive model applies to this client's difficulties. This necessitates an understanding of how problems have developed and how they are maintained. This will help to devise the treatment plan and may help to predict difficulties in treatment. The development of assessment and formulation is also used to develop the collaborative sense of treatment and to convey that the therapist understands the difficulties the client describes. Through this approach the therapist aims to inspire a sense of hope and to start to form a good therapeutic alliance. Formulation of a client's presenting issue from information gathered is also an optimal way of socialising the client to the model and the expectations for treatment.

The main aims of a CBT assessment may therefore be considered as:

- Generating a 'list of presenting issues (problem list)'
- Identifying SMART goals for treatment
- Assessment of factors maintaining the problem(s)/current situation
- Socialising to the model and treatment
- Generating a descriptive formulation (5-part model or hot cross bun)
- Assessment of the development of presenting issues
- Assessment of the client's view of presenting issues and treatment

Setting the boundaries and expectations:

The structural elements and expectations of treatment should be explicit and transparent. This includes discussion of arrangements with regard to:

- Consent to treatment, recording and information collection (measures) and sharing.

- Confidentiality arrangements, with particular respect to storing of materials (notes, recordings), supervision arrangements, information sharing, and when the law requires information to be shared (e.g. risk to self or others) and how this will happen.

- Treatment as an active process with an expectation upon out of session work between meetings, and an active collaborative experimental approach.

- Arrangement for timing, frequency and location of meetings, including the setting of a treatment contact and any limitations in terms of the maximum length of treatment and non-attendance.

Assessment and generating the presenting issues list:

Current symptoms and problems are assessed in order to develop the list of presenting issues (sometimes known as the 'problem list'). This requires the collection of information about what the client feels they are intending to gain help with. Basic information is then collected regarding the onset, duration and course of difficulties.

During this phase it is particularly important to use the client's words, to listen carefully and communicate caring concern to the client, with validation of the difficulty that the client is experiencing. This is placed alongside instilling optimism for the possibility of change. Validating statements such as 'This is obviously very difficult/upsetting for you' and summarising the client's discussion and checking for understanding are important.

To generate the list of presenting issues it is helpful to ask the client what he/she sees as the main problems. These can then be explored subsequently in greater detail once a brief description of each has been elicited. Difficulties may then be prioritised by the client in order of difficulty and focus. The area of greatest concern can then be explored in greater detail by discussion of a typical example.

The presenting issues list can then be added to over the course of the assessment and reviewed as the client discusses each of their presenting issues in turn. These may be added to and revised over the course of treatment.

Development of the problem:

Assessment of developmental factors in CBT is focused upon information that is of direct relevance to the development and maintenance of the presenting issue which is being focused upon.

Onset, duration and course:

Difficulties may have a clear onset, or may be more likely to have developed gradually over a succession of events and time. The course of events may also vary for the individual, perhaps persisting steadily or coming in waves with marked fluctuation. It may be helpful to track long standing fluctuations on an event time chart. Changes in presentation may also be considered in light to any treatment or intervention entered into. It may also be the case that the factors leading to the onset of difficulties may vary from those that are now maintaining it. Any clear predisposing factors that made the client more vulnerable to the difficulties currently presenting may also be noted from the perspective of understanding why difficulties have developed and to aid what that may mean for treatment now.

Description of the problem behaviour: typical example

Once an overview of the presenting issues has been identified, it is helpful to consider a detailed example of the main (highest priority) presenting issue. It is important to check that the example to be discussed is typical of the presenting issue.

Ask the client to then give you detail regarding that example. If this is difficult for the client to explain, it may be helpful for the person to close their eyes and imagine the scene as it was happening.

The therapist can then assess the example from the 5 areas approach by considering:

The context or environment:
Where was the client, when was it, what were they doing, who else was involved, how were you feeling physically, how where you feeling emotionally?

Emotions:
Clients will most often be feeling aware of how they are feeling emotionally in situations. People will often seek to avoid or control their experience of emotions which can play a large part in their maintenance. The emotions the person experiences will therefore need to be assessed. A person with a diagnosis of depression will typically not only be feeling a strong sense of sadness, but may also experience anxiety, anger and shame amongst other emotions. How did that person's emotional state impact upon their thinking, behaviour and physical sensations?

Behaviour:
Within depression as noted above, the behaviours that a person engages with will be aimed at managing or avoiding certain emotion experience (but then becomes maintaining of this). What is it that the client is doing to manage his or her situation?

Common behavioural responses to depression are withdrawal, isolation and rumination. Avoidance is common within depression and can serve to maintain the person's sense of failure or self-criticism.

Within the specific example: How did the person react in that situation? What did they do in order to manage how they are feeling? What was the impact of that behaviour? What did they hope to achieve by that behaviour? How does the person feel about responding in this way; do they see it as a problem or something that is helpful? How does it fit with their hopes for the future?

Thoughts:
What are the NATs or other cognitions that were maintaining of the person's difficulty? What was going through your mind at that point? Is that typical for you? How much do you believe this? How does this thought make you feel? What do you want to do when you have this thought?

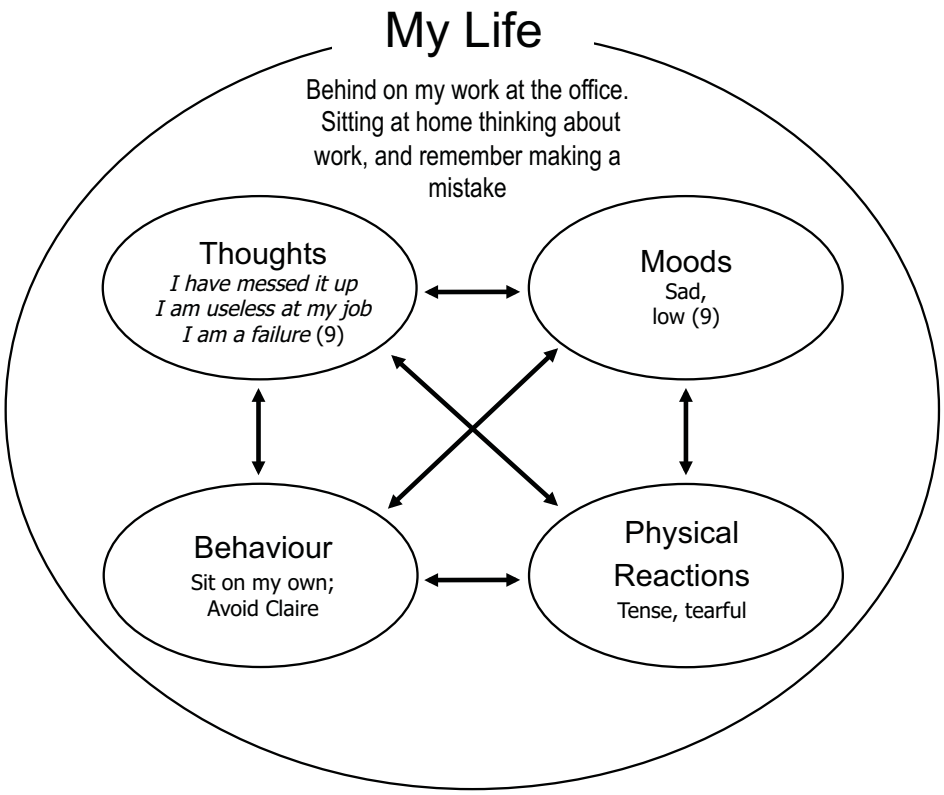
Physical sensations:
How does the person feel physically in this situation? Does this typical pattern of events led to other physical difficulties, such as poor concentration, poor sleep, poor memory, lethargy, shaking, numbness, pain or other physical sensations. Physical embodiment of depression is not uncommon and may even impact upon your client's presentation in the room in terms of their posture, eye contact or level of engagement and energy.

Socialising to the model (CBT rationale) and the bidirectional relationships between areas:

This information can then be collaboratively used to develop a descriptive formulation of this presenting issue to provide some psycho-education regarding the focus of CBT work. Socratic exploration of the impact of each area upon another and that this relationship is bidirectional is important.

- When you were in this situation what was going through your mind?
- When you were thinking this way how did that make you feel?
- The more you had these feelings what happened to these thoughts?
- When you were thinking and feeling this way what did you do in order to manage this?
- What was the impact of this upon these thoughts and these feelings, etc?
- What do you think this might mean about what is important for you to move forward?

Below is an example of descriptive conceptualisation for a man who experienced depression and anxiety that was impacting his work and home life.



Once a typical example had been explored other examples or presenting issues could be explored with exploration around the 5 areas to consider other modulating and maintaining factors.

Modulating variables and maintaining factors:
It may be important to assess for other factors outside of the typical example which impact upon the person's presentation.

Are there contexts when the difficulties are more or less present, or when the client had been able to show increased coping in the past. Are difficulties more prominent in the presence of others? What are the relationships like with key others in the person's life and how do these impact upon the person's presentation? Are there short and long term impacts upon the person's pattern of behaviour?

Moore and Garland (2003) provide some useful questions to elicit further information regarding emotions, cognitions cognitive processes and behaviour.

Coping resources:

It is also important in the assessment of depression to be able to see and build upon the coping resources and resilience that a person has. These may well provide a good platform for further competence and may be the starting point for expansion into alternative coping in line with the persons preferred sense of their future.

These may also be considered from the same five areas approach. Has the person had times when he/she has been able to engage in difficult events and find that he/she was able to cope? What activities, roles or friendships has the person been able to maintain despite the difficulties he/she is experiencing? It is important to keep these explicit and these may even be formulated.

Psychosocial situation:

Consider the broader context within which difficulties are occurring; some of which it may be possible to help access professional support for and other may be facilitated through problem solving. This broader context includes; family, relationships, accommodation, occupation, debt, unemployment, social relationships, and physical health concerns.

Goals:

As part of the assessment and formulation it is important to have a developing sense of the client's goals for treatment. Initially this may be broad and is shaped up further over time. Goals can be helpful to provide a clear shared sense of what the client and therapist are both working towards through treatment and how they will know if this is being achieved. What would the client like to be different by the end of treatment? How would things look if the difficulties were no longer present, and how would others know about or see this change? This beginning will be shaped into SMART goals at this or subsequent sessions.

Phase I Session Guide: Sessions 2-4

Goal Setting and Behavioural Scheduling

Phase I: Sessions 2 - 4

Goal Setting and Behavioural Scheduling

Goal setting:

The collaborative setting of goals for treatment should be developed in SMART terms. SMART stands for:

Specific: what would that look like?

Measurable: how would you know, what would have changed?

Achievable: does this goal involve changing things that are under your control?

Realistic: is this something you can see happening? Would other people say this is a realistic goal?

Time constrained: when would you like this to have changed by?

Goals should also be expressed in positive terms (what will be present) rather than negative terms (things being absent). In other words, rather than 'feeling less depressed' (negative statement of goal) the therapist might enquire, 'So if you were feeling less depressed, how would you be feeling instead', and 'how would you know that this had happened, what would others notice?'

On this last question goals may also be best expressed in concrete operational terms. In other words, how would this impact upon the person's behaviour, what would we see them doing. By expressing goals in these terms they can be easier to measure.

Goals developed may also be prioritised:

- Do you need to tackle any of these goals right away to avoid a crisis?
- Which goal would make the most immediate improvement to your life?
- Is there another goal you need to reach first before you can accomplish this one?
- Which of these goals is most important to you?
- Which of these goals would be the easiest?

Goals may also be broken down into smaller steps to shape performance in approximating towards goals with manageable steps helping to increase the possibility of engagement.

Questions for eliciting goals (Moore & Garland, 2003):

- What goals would you like to work towards in treatment?
- In what ways would you like things to be different?
- What would you like to change most about your current circumstances?
- What things have you stopped doing since you became depressed which you would like to resume?
- Are there things that you have started doing since you became depressed which you would like to change?
- What would you be doing differently if you were not depressed?

On a recent trial with a depressed population (Thomas et al. 2011), difficulties related to goal setting were often cognitive in nature, such as;

'I can't set goals, or things will go wrong'
'If I set goals then I'll only fail and feel worse'
'I can only cope 1 day at a time'.

There are cognitive responses which are amenable to the same interventions as other thoughts. It has been helpful to conduct behavioural experiments on these thoughts, to break goals down further into smaller more manageable steps and to consider the impact of these thoughts on the possibility of change.

Homework setting

Why set homework?

Homework is set in CBT to develop alternative understandings, provide a structure for gathering data and testing hypotheses (used in sessions) and the transfer of in-session skills to a real world setting. Homework is also focused upon maintaining skills use and preventing relapse. It also reflects the stance in CBT of developing skills in order to develop the client's autonomy rather than reliance. Perhaps most importantly, setting and completing homework makes progress in treatment more likely, more rapid and longer lasting (Kazantis et al., 2000).

How do we set homework?

In setting any homework tasks, it is important that the therapist provides a clear rationale for tasks undertaken, and that this rationale is checked and understood. Tasks must be developed through negotiation and collaboration. Tasks which are empowering and jointly developed rather than imposed are more likely to be completed. A clear description of tasks with precise goals should be developed and the content of these should flow naturally from material in the session.

The nature of the rationale should include the idea of this as a no lose or win-win scenario. If an experiment is undertaken and positive changes take place as a result then we win. If homework is undertaken and difficulties emerge, then through

discussing these difficulties, understanding them and developing skills to manage and overcome them we really win.

Homework should be explored with sufficient time in the session to work with the client to explore potential obstacles and how these may be overcome. This includes open discussion to elicit client reactions, and to take feedback on this. Does the task seem useful, meaningful, purposeful, manageable and clear?

What to set as homework?

At the beginning of treatment this may well be set by the therapist to begin to form the expectation of homework as a weekly occurrence. The homework developed should be a continuation of the content of the session. As an intervention and development of understanding, this should be linked to the formulation and help to develop the client's skills.

Initially homework tasks may be more psycho-educational, including reading materials provided, listening to a recording of the session or working up to goals for treatment. These may then develop as the work progresses towards testing new beliefs, exploration of beliefs and alternatives, experiments with new behaviours and the use of strategies to overcome obstacles.

Homework should be adjusted according to the difficulty that the client has in completing the task, and care should be taken not to overload clients. During a more acute phase of depression small and specific tasks are likely to be more appropriate. As symptoms relief is achieved, then more complex tasks may be negotiated.

Within depression the client may often report feeling unsure as to what the homework task was. Tasks should therefore be simple, explicit and concrete. This may also be helpful where the client may have worries regarding not completing the task correctly. For example, asking a client to keep a thought diary of negative automatic thoughts may be aimed at recording 5 examples of this, rather than the client feeling that they needed to capture every experience of this. This should be rehearsed within the session, with the client having a clear understanding of the rationale for this.

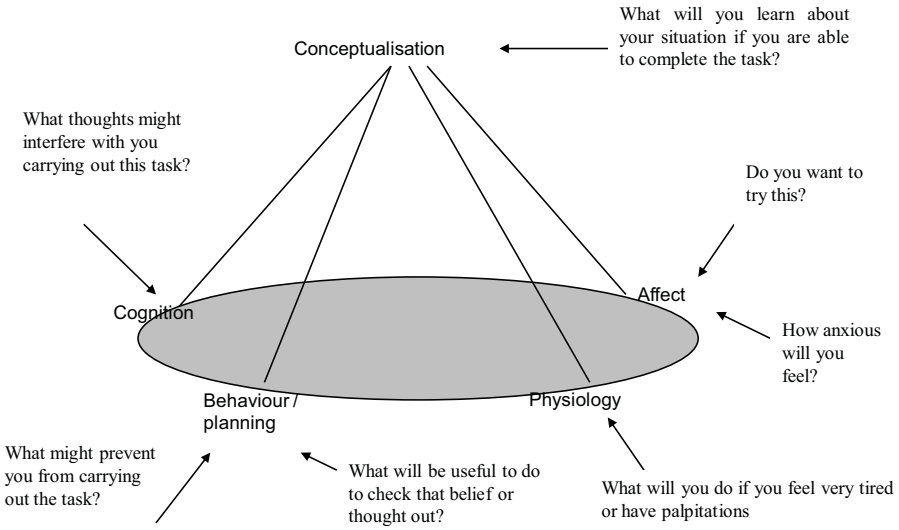
Review of homework should always be a priority for the next session. Failure to do this may result in reduced motivation for work between sessions, a feeling of disinterest or disrespect on the therapist's behalf, or a sense of having done this work or being unworthy of this interest. Learning developed from experiments should ideally be recorded by the client and related to the formulation.

Tips for homework setting:

- Ensure homework is collaboratively set
- Check the client understanding of both the task and the rationale
- Rehearse the task wherever possible
- Elicit client reactions to the task
- Identify together any possible barriers to completion and problem solve these (the win-win approach)

- Formulate barriers to completion
- Don't give up setting homework
- Consider any therapist interfering cognitions in effective homework setting (e.g. 'there's no point', 'I'll just give a task, there isn't time to set one together').
- Relate the task to the formulation (see diagram below)

Consider from CTS-R



Useful questions to ask yourself:

- Did I give a rationale underpinning the assignment?
- Did I check the client was confident in being able to take on the task?
- Did the client see the relevance of the task?
- Was the homework adequately planned within the session?
- Were obstacles to the homework discussed?
- Was the most appropriate task set?
- Was it consistent with the content of the session?
- Will the client learn something useful from engaging in this task?

Obstacles to homework:

Client does not do homework. How could you respond?

- Use this as the focus of the session.
- Assess what led to difficulties in completion
- Were there any practical difficulties (cost, opportunity, other priorities)?

- Beliefs or emotional response to the task?
- Did the client understand the task?
- Did the client understand the rationale?

Partial completion of homework; how do you respond?

- Reinforcement/shaping
- Problem solving

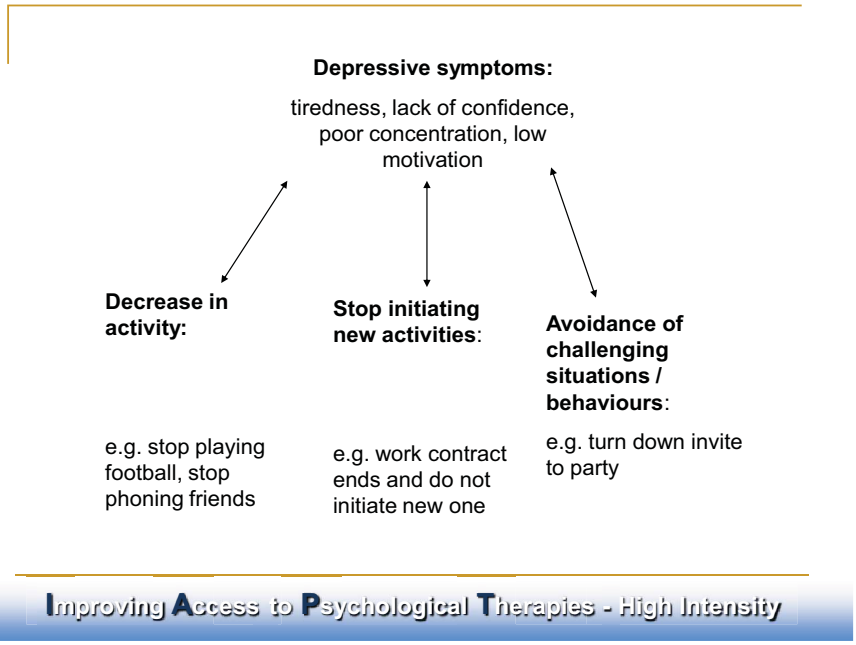
Activity Scheduling

Activity Scheduling

Depression is characterised by long periods of inactivity and rumination. Reduced levels of activity with negative thinking and low mood are conceptualised as forming a vicious cycle for depression. Once the client has been socialised to the model, standard treatment within CBT leads to behavioural activation.

Impact of depression upon behaviour:

- Reduction in activity, increase in withdrawal/avoidance
- Increased engagement with rumination
- Reduction in sense of enjoyment and achievement
- Energy often focused upon maintaining chores and duties
- Loss of contact with support network and protective factors
- Activities maintained may become aversive (I did it poorly, no-one was interested, I'm much worse at it).



Step 1: The first stage of activity scheduling is to monitor the client's level of activity.

This involves asking clients to record their activity on an hour by hour basis and to rate their mood at that time. This may be broken down further into rating of achievement (a sense of mastery) and enjoyment, though for many clients this may remain as a global rating of mood overall. Typically these will be given a rating out of 10 where 0 amounts to none at all and 10 being the highest level. One of the key points to emphasise here is that a client is never doing 'nothing'. When you are sitting in a chair thinking things over and over, this is your activity. In depression it may be important to rate 'mood' overall out of 10 where the client is unable to break this down further, and may experience strong NATs about their ability to complete the task.

The therapist and client then consider this recording to consider the activities that help to improve mood and are more consistent with the client's goals and those which deplete the client further. This can help to emphasise the links between activity and emotion; and may well be helpful in identifying cognitions that are maintaining difficulties (e.g. none of this will do any good') as well as helping to challenge this thought as activation progresses. The capacity to change behaviour and experience a direct impact on mood is also important in developing a sense of agency as being the agent for change.

This will be best rehearsed in the session and the brief nature of description and scoring can help to overcome client concerns about the level of difficulty in completing the task.

	Monday	**Tuesday**	**Wednesday**
8 – 9am	*Get up, shower and dress* *E = 3* *A = 3*	*Lie in and watch TV* *E = 2* *A = 1*	*Get up, shower and dress* *E = 2* *A = 2*
9 – 10am	*Eat breakfast and read paper* *E = 5* *A = 2*	*Get up, shower and dress* *E = 2* *A = 3*	*Answer emails and drink coffee* *E = 4* *A = 5*

Step 2: Monitor and review. Identifying activities that promote positive mood and nurture the client in line with their treatment goals and activities that deplete the client and lead to lower mood ratings.

This means being sensitive to activities that raise or lower mood by a single point and that planning and developing positive activities at key times for vulnerability can increase a sense of agency and the possibility of change.

Once the client has completed the activity record, this data is then used to provide a baseline for the overall level of activity and mood. The therapist and client review those activities completed and consider:

- Which activities increased the rating of mood (and enjoyment and achievement) or maintained improved mood levels?
- Which activities reduced mood or maintained low levels of mood (and enjoyment and achievement)?
- Were there times of the day when mood was most vulnerable?
- Which patterns were most consistent with the person's goals?
- And on the basis of the above, what would be important in the coming week?

In essence, step 2 includes steps to increase frequency and intensity of rewarding behaviour:

- Identify sources of reward
- Increase rewarding behaviour
  - Intensify/increase existing behaviours
  - Enhance skills in behaviours that bring reward
- Decrease avoidance behaviour
- Enhance self-reinforcement

Additional behaviours that may help promote positive mood may be drawn from prior experience/activity, be activities that the person has recently withdrawn from, may be activities that the person has previously considered, may be drawn from lists of suggested possible activities.

Helpful Questions/Considerations

- How is time being used?
- Are activities planned or spontaneous?
- Are activities rewarding? Monotonous? 'Shoulds'? Alone/with others? Ruminative?
- Which activities are associated with most/least E and A? – list
- How do activities relate to life goals?
- What did you learn from this?

Step 3: Scheduling & review: During this stage the therapist is working to engage the client in activities of daily living and tackle biological symptoms of depression (e.g. concentration and memory deficits, lack of energy, procrastination). This stage may also include addressing those cognitions that prevent engagement with the task. A model of looking at TICs (Task Interfering Cognitions) and TOCs (Task Orienting Cognitions) has been developed by Burns (1989).

The concept of TICs and TOCs is aimed at addressing the negative thoughts that clients' may have when planning tasks. This approach helps to identify the process and impact of negative thoughts and in this way awareness and alternative responses can be facilitated. Some thoughts (TICs) are tracked as obstacles to the task in hand (e.g. 'I can't do it') and the consequences of them made explicit. The validity of these thoughts can then be tested through activity and experimentation. TOCs represent the thoughts that are helpful in allowing the person to attempt the task in hand (e.g. 'I can give this a try').

Common problems in activity scheduling:

Moore and Garland (2003) provide guidance on managing challenges in monitoring activity levels in clients with depression. Below is a summary of some of the issues considered.

<u>The client has difficulty in completing an activity schedule:</u>

Don't

- Give up in monitoring of activities
- Conclude that the client is too unmotivated to make progress
- Pressurise or lecture the client that not doing tasks will stop them from getting better (as this is likely to lead to thoughts that trying only leads to failure and therefore future engagement is reduced further)

Do:

- Find out about the reasons for difficulty
- Simplify the monitoring procedure (e.g. rate mood overall rather than enjoyment and achievement, simplify the recording form to am and pm).
- Monitor activity monitoring in the session
- Frame the task as an experiment to find out more about the difficulties

<u>The client gets no sense of mastery or pleasure (or enjoyment) from their activities:</u>

Activities previously performed may have become less satisfying through a number of possibilities including tiredness, applying a high standard of expectation for performance, being duty-focused activities or the sense of anhedonia.

Don't:

- Try to persuade the client that the things that they are doing are in fact satisfying
- Make numerous suggestions of activities that the person may find pleasurable

Do:

- Check that ratings accurately reflect satisfaction gained when performing the activity
- Identify if previously satisfying activities are being overlooked or may have become unsatisfying
- Elicit and highlight thoughts which may deprive the client of potential satisfaction
- Use graded task assignment to simplify tasks
- Test ratings of mood, enjoyment and pleasure on reducing excessive activity levels

Graded task assignment refers to increasing the likelihood of success in setting new behaviours by breaking down tasks into small, manageable steps. Each small step is reinforced in its own right. The moving through steps is aided by identifying and challenging barriers to completion. This may lead to cognitive challenging or strategies to manage anxiety provoking situations such as exposure response prevention. Graded task assignment aims to reduce the client's experience of difficulty (and the chances of taking this as evidence of failure) by encouraging progress towards goals with manageable steps, to increase the frequency of rewards through repeated completion of these steps, and to judge progress in light of the difficulties that they are facing (Fennell, 1989).

<u>The therapist is confronted by a barrage of negative automatic thoughts as to why graded task assignment is not going to work</u>

Clients may often report thoughts in relations to activity scheduling on themes of: 'it won't do any good' or 'it will make me feel worse'. A sense of low expectation for the task may relate to rules applied by the person for them to be effective, i.e. task perfectly completed.

Don't:

- Attempt to modify a barrage of automatic thoughts
- Accept the person's assertion (e.g. this won't do any good)

Do:

- Remain focused upon the task in hand
- Draw the client's attention to the negative thoughts
- Use the TICs/TOCs technique
- Formulate the consequences of the negative thinking

<u>Engaging in the task results in a worsening of depressive symptoms</u>

Whilst in general terms engagement in activity leads to some alleviation of depressive symptoms, it is also possible that clients will report feelings of exhaustion and lowering of mood when engaging with tasks.

Don't:

- Disbelieve the client or dispute that they feel worse
- Press on with assigning activities as though everything was going well
- Give up on assigning activities

Do:

- Take the limitations imposed by depressive symptoms fully into account
- Break down tasks into smaller chunks or less demanding tasks
- Draw attention to the effects of deprecatory thoughts about starting with small activities
- Weigh up the pros and cons of engaging in small activities

The effects of depressive symptoms on energy levels, concentration and pain levels are all too real and have physical effects that could perhaps be measured. It may be important for clients to acknowledge this difficulty. This may highlight the client to see the difficulties in aiming for an immediate non-depressed level of activity and functioning. This is replaced by breaking down tasks into feasible steps forward. The role of the therapist therefore includes helping to strike the balance between what is an appropriate level of demand when goal setting in the context of the constraints imposed by depressive symptoms.

<u>The client's hopelessness and avoidance are so entrenched that suggesting any activity provokes a hostile reaction</u>

The level of difficulty and hopelessness that a client may experience in depression could lead to any suggestions for engagement in activity being experienced by the client as a failure of the therapist to understand their difficulties. Therapist suggestions may be seen as attacking or insulting.

Don't:

- Give up or become quiet and withdrawn
- Insist that the client carry out the suggested task
- Rely solely on questioning
- Retaliate or become angry or critical of the client

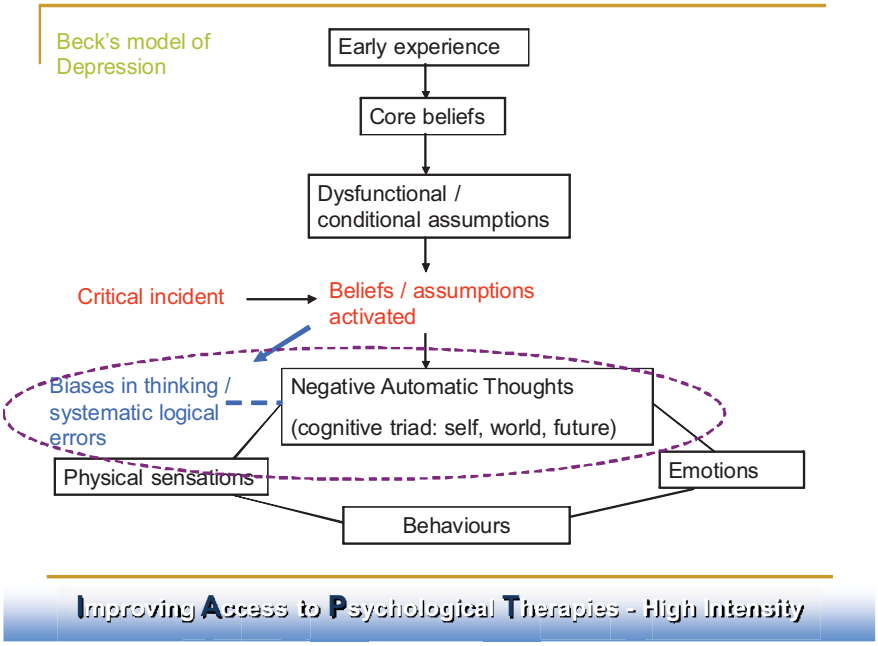
Do:

- Try to maintain activity and structure in the session
- Focus on understanding the client's reaction
- Make educated guesses about this reaction and share them with the client
- Return to formulating and socialising the client to the cognitive model

Phase I Session Guide: Sessions 4-6

Phase I Session Guide: Sessions 4-6

Much of CBT intervention is focused on developing the client's skills to identify, test and challenge negative automatic thoughts (NATs). The focus of techniques designed to develop these skills is on symptomatic relief and the management of difficulties in life. Negative automatic thoughts are the situation-specific thoughts of which patients are often largely unaware. They are automatic, habitual and plausible for the recipient.



The first step in managing NATs is to be able to catch and identify them. This is the first step of cognitive skills developed in treatment. Typically the experience of unpleasant emotions is taken as a trigger to consider the situation in which the emotions occur and then to identify the associated negative automatic thoughts.

Changes in mood are a signal to the presence of NATs. The client can be helped to begin the process by rating (0-10) and becoming aware of changes in emotion. Socialising clients to rating their emotions can also help to increase their sensitivity to changes in strength and nuances of emotions when challenging NATs. Then ask the client to consider in what situation these feelings were occurring. What were they doing, or thinking, who were they with, where were they and what were they doing? Clients should then be asked to consider what was going through their mind when they began to feel this way and to rate how much they believe this thought (0-10). This can lead into further descriptive formulation (hot cross bun) and homework based upon practising this skill. Recording of NATs identified will typically be completed with the use of a thought diary, such as those provided by Greenberger and Padesky (1995).

These skills may be facilitated by the therapist in noticing shifts in emotion as they occur during the session and exploring the above steps with the client through the Socratic Method.

Questions to help elicit NATs:

- What was going through your mind just before you started to feel this way?
- What does this say about you?
- What does this mean about you? Your life? Your future?
- What are you afraid might happen?
- What is the worst thing that could happen if this is true?
- What does this mean about how the other person thinks/feels about you?
- What does this mean about the other person(s) or people in general?
- What images or memories did you have in this situation?
- What images went through your mind?

Beck at al (1979) highlight strategies for the detection of automatic thoughts as:

1. Catching thoughts as they occur and recording them at the time that they occur.
2. Setting aside some time each evening to replay events that led to the thoughts as well as the thoughts themselves.
3. Identifying specific environmental events leading to feelings of depression; are there times or events that often lead to low mood and what is the meaning of these events to the person? This may even lead to deliberate engagement with these environmental events to help to identify cognitions, which are then focused upon in treatment to work to symptomatic relief.

Fennell (1989) identifies some common difficulties in working with clients to identify NATs including:

a) Client avoids recording thoughts:

Strong feeling of depression may make it difficult for the client to diffuse from the emotional experience in order to identify their thoughts. Awareness may at time increase the level of negative affect. Therefore for those who find this difficult the development of behavioural interventions to alleviate low mood may be critical. Additionally, it is important for clients to have a clear sense from socialisation of the rationale for this approach to facilitate engagement. Awareness however, may be particularly helpful for clients to begin to address those distressing thoughts in order to move forward.

b) Therapist and client find it difficult to identify the NATs:

Where clients are unable to identify any NATs it may be helpful to socratically question the personal significance of events (e.g. 'what does this mean to you, what does it say about you/your situation/your future?') Moore and Garland (2003) also identify this difficulty when working with depression and suggest that therapists:

Don't:

- Become abstract and try to describe the definitive features of an automatic thought
- Assume there is necessarily avoidance or resistance at work

Do:

- Consider words, images and meanings
- Persist with standard techniques, including review of upsetting events, mood changes occurring in session and automatic thought records

Among further difficulties and strategies identified by Moore and Garland (2003) is the challenge that:

The client refuses to discuss upsetting situations

Avoidance may take many forms in depression, including intentional cognitive avoidance as a strategy to try to manage distress. It may therefore be particularly challenging for clients using this strategy to be asked to deliberately focus upon and record their thoughts.

Don't:

- Insist that the client discusses the upsetting situation
- Change focus to an unrelated area

Do:

- Identify the client's thoughts about discussing upsets
- Use these thoughts to illustrate the cognitive model
- Discuss the pros and cons of not thinking about upsetting things
- Approach discussion of upsetting situations in a graded fashion
- Point to the possibility that particular underlying beliefs may be magnifying upsets.

By developing awareness of NATs, clients may also be helped to identify patterns in their thinking which can help to increase their awareness, create distance from them and manage them.

Systematic logical errors: Reasoning biases

- Mind reading is making assumptions about what others are thinking.

- Emotional Reasoning is using how you feel to infer what is going on.

- Discounting is ignoring evidence that contradicts your view.

- Labelling is putting a global label on an incident of a certain type without responding to what is specific and different about that incident.

- Arbitrary inference is drawing a specific conclusion in the absence of evidence or when the evidence is contrary to the prediction. Jumping to conclusions.

- Selective abstraction is focusing on a detail out of context whilst ignoring other important features of the situation. Mental filter/tunnel vision.

- Overgeneralisation is drawing a general conclusion on the basis of one or more isolated incidents and applying across the board to related and unrelated situations.

- Magnification/catastrophisation is exaggerating the significance or importance of an event in a negative direction. Fortune telling.

- Personalisation is inappropriately relating external events to oneself.

- Dichotomous thinking is judging events as either good or bad, black and white thinking. All-or-nothing thinking.

- Making 'should' or 'must' statements is having an over-precise idea of how you or others should behave, not taking into account situational factors.

Further examples of thinking errors are available, one example being Moore and Garland (2003, p.389).

Once the client has identified NATs the next step is to question the thoughts and track their impact upon the person's mood, how they fit with the client's SMART goals, and the validity of the thoughts. There are a number of methods to help the client test automatic thoughts.

Methods:

- Reviewing evidence for and against (thought records)

- Behavioural experiments – this will be expanded further in relation to underlying/conditional assumptions

- Responsibility pies - Attribution of blame/responsibility beliefs

- Surveys – ‘everyone thinks/does this don’t they?’

- Looking at the origins of the thought
    - Can you remember when you began to hold this view?
    - Are there times in the past when X happened and you did not think this?
    - What experiences have led you to think this?

- Role playing the thought
    - Client argues FOR the thought, therapist argues AGAINST it.
    - Then swap roles

Thought records

Thought records as identified below are typically worked through with the client to begin to challenge the NATs identified. The example below is based on Greenberger and Padesky (1995) and provides prompting questions that the therapist and client can work through together in the session, prior to use between sessions.

The client is asked to consider current and historical factual evidence that is consistent with both the 'hot thought' (the thought with the most emotion attached) and evidence that is not consistent with the thought. This information may be currently available, or experiments may need to be carried out in order to test the thoughts. The use of thinking bias may be helpful in considering how information that is not consistent with the hot thought is excluded, or processes such as 'emotional reasoning' ('I feel it therefore it must be true') that may treat emotions as if they were facts.

THOUGHT RECORD

1. Situation	2. Emotions	3. Automatic thoughts	4. Evidence that supports the hot thought	5. Evidence that does not support the hot thought	6. Alternative / balanced thoughts	7. Re-rate moods now	8. What should I do now?
Brief description of what was happening, what you were doing at the time?	Describe each emotion in one word. Rate the intensity of the emotion from 0-100%	What was going through your mind? What does this say about you? What is the worst that could happen?	Write factual evidence to support his conclusion. Try to avoid mind reading / emotional reasoning.	Write factual evidence that does not support this conclusion.	Based upon the evidence what would be a balanced alternative thought? Rate how much you believe this thought 0-100%	Copy the emotions from column 2. Re-rate their intensity from 0-100%	What should you now do based upon the balanced thought?

Improving Access to Psychological Therapies - High Intensity

Useful questions:

- What evidence do you have that supports this thought? Are there other times/experiences that have made you think this?
- Is there any evidence that does not support this thought? Before you got anxious/depressed…, when you were younger?
- Are there any experiences that show the thought is not completely true all the time?
- What would I say to a friend?
- What would a friend say to me?
- When I'm not feeling like this do I think about this situation in a different way?
- When I felt this way in the past, what did I think about to help me feel better?
- What have I learnt in my prior experience that might help me now?
- Action plan – does the new thought suggest any action?

In many situations the alternative evidence for thoughts will not be immediately available. In this instance, intervention will be focused on setting up experiments in order to gather information to test thoughts and assumptions. Behavioural experiments may be set up in relation to NATs or underlying/conditional assumptions.

Transition and Review Session (Session 7)

Transition and Review Session (Session 7)

This session is used to review work to date, revisit the presenting issues and goals agreed at assessment and plan the next phase of work. The intention is to support patient learning up until this point, celebrate any positive change, ensure the focus for therapy remains collaboratively agreed and appropriate and map out the work that will take place in Phase II.

Normally at this stage the client will be socialised to the model, comfortable with the therapy format and therapist, able to use behavioural skills and identify and challenge automatic thoughts. The next phase turns to beliefs that underpin automatic thoughts and behavioural repertoires involved in maintaining depression.

However, every client is different and the rate of progress will be different for every client.

Phase II Session Guide: Sessions 8-16

Phase II Session Guide: Sessions 8-16

Once the client can skilfully and effectively challenge NATs the focus of cognitive intervention shifts to the level of underlying/conditional assumptions. In this stage the therapist works to identify the rules or assumptions that the client holds. This level of focus is more consistent with a cross-sectional level of formulation (Kuyken, Padesky & Dudley, 2009). This is focused on identifying the typical themes and patterns that repeatedly occur across different situations.

Underlying assumptions may be explored by the therapist and client by considering the themes in thinking that occur across time and different situations. A further approach is the downward arrow technique where the client is asked specifically about the meaning of NATs or what NATs say about them e.g.:

- What does this mean to you?
- If this was true, what does this say about you as a person?
- What is the worst thing about that?

Underlying assumptions may be best identified in the 'if_____ then _____' format as identified by Mooney and Padesky (2000). These are the rules or assumptions that the person makes in different situations (e.g. if 'I don't do things perfectly or make a mistake then I am worthless'). Underlying/conditional assumptions expressed in this format are more amenable to experimentation. Behavioural experiments are one method for challenging such beliefs.

Underlying assumptions should be integrated into the formulation and considered in terms of their impact upon the client and how they fit with the client's goals for treatment. It is also important to consider with the client the context of the development of these rules and assumptions, which they may have needed in order to survive difficult or toxic situations. However the invitation in treatment is to now consider whether these rules are optimal for the client's goals and current life situation.

The therapist also aims to assist the client in identifying that the underlying/ conditional beliefs are beliefs rather than facts. One approach for this is to consider the prejudice model outlined by Padesky (1990).

Steps involved in working with underlying/conditional assumptions:

- Formulation of the conditional belief - what is the belief held by the client?
- Observation of the belief in action in everyday situations – what is the impact of this belief? Formulate this and consider this in relation to treatment goals.
- Socratic questioning/discussion of evidence for and against belief(s)
- Consequences of beliefs: self-fulfilling?

- Is change seen as advantageous?
    - Advantages and disadvantages of conditional belief
- Identifying alternative rule
- Behavioural experiments

Socratic Qs of conditional beliefs

- Are there times when this rule does/does not work for you?
- What experiences have you had that support this belief?
- What experiences have you had that don't support this belief?
- How does this belief fit with what is realistic or possible for you/for other people?
- How does this belief fit with the rules you expect other people to fit to (are you setting very tough standards for yourself)?

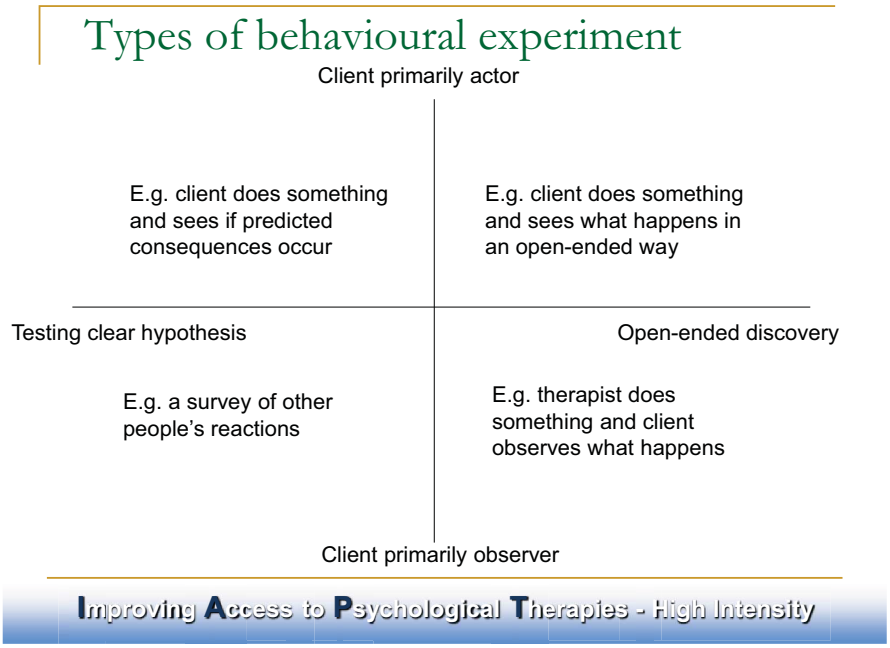
Exploring the consequences of CBs

- What are the consequences of having this rule?
    - Compensatory behaviours
    - Feelings/reactions when the rule is activated

Generating an alternative, balanced conditional belief

- What might be a more helpful rule to have?
- What sort of new rule could you come up with that would better reflect the realities of your situation?
- What sort of alternative rule could you have which would help you have the sort of life/relationships that you want? E.g. my value as a father and a husband depends on more than just the amount I am paid.
- Flashcards for modifying conditional beliefs.

There are different types of behavioural experiments (Figure below). It is important to take in to account when designing behavioural experiments how much the activity is driven by the conditional belief and how often the behavior occurs in the client's normal repertoire of behavior.



Planning and Implementing Behavioural Experiments

- Collaborative, logical, planned, rationalised

Behavioural experiments should be developed in partnership with the client and make sense to the client both in terms of why the experiment is being undertaken and how the client will carry this out.

- Be clear about the belief you are testing (e.g., "So your prediction is that you go to this party you will end up standing by yourself most of the time and you believe this 95%")

The behavioural experiment should be clearly focused on a specific belief.

- Design experiment collaboratively 'how could we test this out?'

As well as developing the experiment collaboratively it is important to consider the opportunity to learn and develop whatever the outcome. In this sense the experiment is a no lose experiment, as whatever the outcome we learn more about how to cope.

- Make clear prediction(s) and rate conviction

In advance of completing the experiment the client should be able to state clearly what the outcome of the experiment will be if the assumption is true and what will illustrate that the rule may not be true. In this way disconfirmatory experience upon completion of the experiment is less like to be discounted.

- Open-minded approach

All parties should consider the experiment in an empirical way, with all outcomes being seen as possible.

- Anticipate negative outcomes and rehearse coping strategies

Consider how the client will cope if there is difficulty in completion of the experiment. Can any barriers be anticipated and problems solved or planned for?

- Experiment can be in-session too!

Reviewing behavioural experiments:

- What actually happened: thoughts, feelings, outcomes? Match to prediction(s) – review the specific outcome of the experiment in light of the prediction made

- Integrating meaning of BE:
    - What new information does this give us?
    - How can we make sense of what happened?
    - What does this mean for similar situations in the future?
    - Attending to 'yes, but…'
    - What is the next step (extend or generalise conclusions? Improve design of current experiment?)
    - Re-rate belief in cognition(s)
    - Consider a new conditional belief (theory A, theory B)
    - Using behavioural experiments to test out conditional beliefs
- Test old versus new conditional beliefs – complete further experiments designed.

(See BE experiment sheet in clinical tools section, potentially include example).

Responsibility pie chart:

Responsibility pie charts are useful when the person attributes a higher than appropriate level of responsibility for a negative outcome or event to him or herself, leading to mood based difficulties. This may well touch on an underlying/conditional assumption that they hold, which predisposes them to hold a high level of responsibility for negative events.

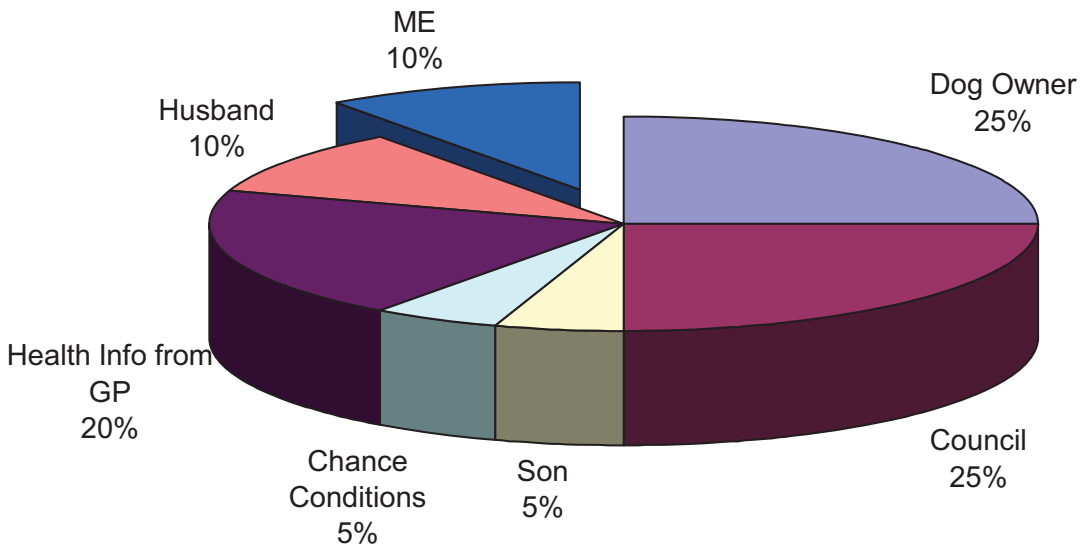
In this instance the level of responsibility for such events or outcomes can be elicited from the client (e.g. I am 100% responsible) which then forms the basis for intervention.

Steps in creating a responsibility pie chart:

I am 100% responsible for . . .

- Gather as much information as possible on who or what else may share this responsibility - list these (theirs first).
- Get the client to rate how much each item on the list is responsible as a percentage, in reverse order (leaving the client as the last item).
- Place these in the responsibility pie chart as you go.
- The slice that is left is their responsibility.

If my son contracts toxoplasmosis it will be my fault.



Surveys

Survey methods can provide a good way to judge whether the 'normal' beliefs or experiences that a client has are also normal and typical for others. This can help to normalise concerns and reduce the strength of belief in metacognition in relation to these beliefs ('the fact that I have this belief means....').

In this method the client and the therapist draw up a list of questions to test whether others have similar experiences/thoughts. The client and therapist then work together to identify the client's expectations on how others will respond to these questions (based on their beliefs, what do they expect people will say?). It is also considered what it would mean about the client's belief if people do not respond in the way that the client predicts. Then either the client or the therapist (or both) ask people they come into contact with to respond to the questions and responses are recorded. These responses are then discussed in the session and considered against the prediction the client made and what this may mean in terms of alternative beliefs.

Identifying and working with core beliefs

For the main part, intervention will be at the level of underlying/conditional assumptions. There may be some occasions, however, when it is necessary to consider working at the level of unconditional belief (schema/core belief).

What are core beliefs?

Core beliefs are unconditional beliefs that a person may hold about themselves. They reflect our understanding of our early experiences and statements about the self that are of an absolute, global and stable nature.

- I am unlovable; I am worthless; I am a failure.

Core beliefs may lie dormant until activated by a situation that matches with them. Once activated they work to filter out all information that is not consistent with them and focus attention on the information that supports and maintains the core belief.

Core beliefs are at times the least accessible thoughts helped by a person and may not be available in a precise verbal form.

Identifying core beliefs

- Core beliefs may be expressed as NATs at times, e.g. 'I am _____' statements made by the client in relation to specific events.
- Downward arrow technique using guided discovery –
    - 'What's the worst that could happen?'
    - 'What does that say/mean about you/other people/the future?'
    - 'As we are talking about this, do you have any images in your mind?' (describe and use downward arrow technique)
    - 'If you play that image forwards, what happens?'
- Working back 'have you felt like this before / found yourself thinking this about yourself before?'
- Can be 'then……' part of conditional beliefs
- Looking out for themes, e.g. in thought record – themes in meaning of different situations and contexts
- Completing three phrases (Padesky, 1994):
    - I am……
    - Others are….

- The world is……

- Following strong and pervasive emotion, especially shame, guilt or feelings of self-hatred.

When Do I Use a Longitudinal Conceptualisation?

Use when:

- Longstanding issues are part of the presenting issues

- The client needs a sense of 'why?' At times clients will express a desire to understand why their difficulties are present. A longitudinal formulation gives the opportunity to develop this understanding of onset, to normalise and validate the ways of understanding the world as necessary in a difficult or toxic situation, and to consider alternative rules or coping that may fit the person's current life situation and goals better.

- There is an inadequate response to well-delivered therapy – where schemas or core beliefs held by the client are treatment-interfering if left unaddressed.

- It strengthens resilience and reduces the chances of relapse – developing understanding, coping and alternative responses through continua methods can help reduce vulnerability and promote resilience.

Identifying positive core beliefs

Identify alternative (positive) core beliefs: creating/re-accessing alternative 'file drawer' for experience

- Look at negative belief and look for exceptions: what alternative belief would fit these exceptions?

- 'How would you like to be?'

- Should be inconsistent with negative belief (but not necessarily the opposite). However, positive alternative schemas should also be expressed in absolute terms. Whilst negative schemas imply total absence (unlovable meaning never being loved) a positive schema contains greater flexibility (some experience show it is possible for me to be lovable).

- Careful attention to wording

Exploring beliefs to weaken negative schemas and build positive alternatives is explored by Padesky (1993) through the use of continua methods.

1. A continua is developed focused upon the positive alternative schema (e.g. I am lovable). This is scaled from 0 to 100%. This focus automatically seeks the focus of attention on to discovery of instances of the positive quality. This also immediately moves the person to a more balanced midpoint between unlovable and lovable. In other words rather than starting from 100% unlovable, the start point is halfway to lovable at 0% lovable.

Endpoints of the scale can be defined in absolute terms to help shift the person's perception of themselves (e.g. 100% unlovable must mean never ever being liked in the slightest by anyone ever in the history of their life). Friends may also be plotted on the scale, followed by disliked people (e.g. a cruel boss, an abusive family member or neighbour, even figures from history). This is also helpful in anchoring the end points of the scale.

2. Behavioural sub-continua of the global scale are then developed. What are the behavioural qualities that show someone is loveable; what are the qualities that embody this? This can be facilitated by considering someone they know that represents the alternative belief (i.e. who is someone you know you would consider lovable) and by identifying what the qualities they possess are that demonstrate this. The attention to wording is important in helping to reframe these beliefs. Also, the therapist needs to explain the rationale for the start point of the continuum scale not being opposite to positive belief as progress may be hampered by thinking errors, e.g., black or white thinking, negative bias etc. Therapists may have covered thinking errors in earlier sessions, but progress in therapy may not be linear and thinking errors are probably likely to still be problematic when tackling core beliefs and this work provides an opportunity to build on earlier work.

3. These qualities are developed in sub-continua, with clearly defined endpoints. The person is then asked to rate themselves on these specific criteria, as people will rate themselves less negative on specific items than global criteria.

4. The differences between specific and global ratings are discussed to shift global ratings.

5. Experiments are based on meeting sub-continua and developing competence in these, or having the opportunity to do so (e.g. contacting other friends).

6. These help to create a positive data log.

Positive data log

- Positive data logs are a form of behavioural experiment.

- Evidence consistent with positive beliefs is clearly recorded. This is then reviewed in order to consider the client's confidence rating (0-100%) in this alternative belief.

- Positive data does not need to fit with the positive belief 100% and the positive belief may not need to reach a 100% rating either.

- One of the main aims of this log is to help the client become increasingly alert for prejudice or negative filtering of information at work.

- The therapist will need to be alert to instances consistent with the alternative belief and help the client to identify these, particularly in the early stages. It can be difficult to identify evidence unprompted. Therefore adding structure to the collection of this evidence as identified below may be important.

What sort of evidence might you look out for?

Category	Example	%
I didn't 'cave in' to an unreasonable request		
I organised myself in advance for activities		
People trusted me with responsibility		

Behavioural change

A clear goal of developing these alternatives is to translate this into behaviour, which will further increase the collection of evidence in support of them.

- Acting/living according to the new belief:
    - Identify occasions in past week when client acted according to new belief.
    - Identify opportunities to act in accordance with new belief in next week 'if you really believe X, how would you approach this situation?'
    - 'What would someone who believed X about themselves do in this situation?'
    - Review outcomes: not just the outcome itself but also how well the client's action fitted with the new belief.

Transition and Review Session B (Session 17)

Transition and Review Session B (Session 17)

This session consolidates all the gains thus far against the previous list of presenting issues and goals and maps out the final phase which is focused on relapse prevention and building long-term resilience.

Phase III Relapse Prevention Session Guide: Sessions 18-20

Phase III Relapse Prevention Session Guide: Session nos. <= 18-20

Relapse prevention

Doing a relapse plan or blueprint for change can make a difference in long-term outcomes (Hollon et al., 2005). This work involves working with the patient using all that has been learned in therapy to devise a relapse signature that will support the patient in:

- Detecting early warning signs for relapse
- Accessing action plans for tackling setbacks

A blueprint for change typically includes:

- What have I learnt in cognitive therapy?
- How do I plan to build on what I have learnt in everyday life?
- What obstacles are there for building on my gains?
- How am I going to overcome these?
- What might lead to a setback for me?
- If I did have a setback what would I do about it?

Typically this phase of therapy involves very explicitly planning further behavioural experiments that will expose the client to situations that will activate old conditional/underlying beliefs and provide an opportunity to challenge these, activate new more functional conditional/underlying beliefs and behave more functionally. They can use their relapse signature and blueprints for change and have the knowledge that ongoing therapy sessions are available to support them in this work.

It is really important in this phase of therapy to support patients become more self-sufficient in using the tools of CBT, including setting time aside for self-therapy and reviewing their therapy folder.

Finally, in this phase of therapy, the focus of formulation moves to a formulation of the client's resilience. That is to say applying the formulations developed so far, but now the explicit focus is on thoughts, feelings, behaviours, physical sensations and underlying assumption that are supportive of progress made in therapy. This is best linked to explicit skills that will help to move the client towards coping resiliently with challenges.

Booster Session Guide

Booster Session Guide

The booster sessions are used very flexibly and have the main aim of supporting clients in maintaining gains, practising skills they learned in therapy and staying well in the long term. A model that works best is offering these sessions to clients on an as-needed basis during the trial follow-up period, so they can phone up and make an appointment when they need it. However, some clients may prefer the security of having a session in the diary and with others the therapist may judge that it would be best for whatever reason to pre-schedule these appointments.

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11. Appendices: Clinical Tools

Appendix A: Introduction to CBT

What is depression?

"My partner doesn't care about me anymore. I'm not good enough for him, but I could never survive without him"

"I'm going bald and losing my looks. No-one will care about me anymore"

"I can't cope with my job. My boss and workmates only put up with me because they feel sorry for me. *Nothing* I do ever turns out right"

"I just can't make myself do the housework. My marriage is falling apart"

These are some thoughts that are typical of people with depression. These sorts of thoughts can happen to anyone, and usually the individual would be able to challenge them and move on. However, when someone has depression, these sorts of thoughts become more common, and they also become harder to deal with.

People who are depressed often think about themselves and the world in a different and more negative way compared with how they thought before their illness. Their thoughts, their feelings, and even their actions have *changed.* Often the change comes on gradually, so it is not always noticed for a while. But it is a big change; people who are depressed often stop enjoying things that used to be fun, they may lose interest in things and people that are important to them. They may even feel hopeless and want to end their life.

Depression affects people in different ways. Often the most obvious sign of depression is a sad mood. Depressed people may often cry, but aren't sure why. They may feel isolated and find it difficult to respond to others as they used to. They could have trouble sleeping and might wake very early in the morning, feeling miserable. They can feel tired and lack energy. They can be irritable with others and find it more difficult than usual to concentrate and make decisions. They may feel scared and lose all their confidence. People with depression often become less active and sometimes avoid work and social activities.

What does the research say?

We know that people with depression often think of themselves as 'worthless', bad or failing - perhaps not even fit to live. Why are these feelings so common?

One of the most important research findings is that people with depression often interpret situations wrongly or unhelpfully. They focus on the bad or upsetting things, for example, things they haven't done and might criticise themselves for not having done anything. How they think of themselves affects how they feel, and they often mistakenly believe that they are inadequate and no one cares about them. Unhelpful thinking of this sort can lead to a

vicious cycle in which negative thoughts reduce confidence, which in turn leads to not doing things and so on.

Cognitive behavioural therapy (CBT) is a way of helping people with depression change the way they think in order to improve how they feel and to change what they do. Learning how to change upsetting negative thinking can help people with depression start to feel better about themselves and improve their mood.

How are thinking and depression related?

People with depression often notice more unpleasant thoughts. With every negative thought, the depressed feeling gets worse and worse, and their mood plummets down. But often these negative thoughts are not based on real facts, and so people with depression feel sadder than the situation warrants. For example, negative thoughts that "I won't enjoy it" may keep an individual with depression from joining in activities with others. They may then criticise themselves and think they are "lazy" or "useless" and this makes them feel even worse.

Consider this example: Suppose you are walking down the street and you see a friend who appears to ignore you completely.

Naturally you feel sad. You may wonder how you have upset your friend. Perhaps he wasn't wearing his contact lenses. Sometimes, if you are depressed you might think that your friend has rejected you. You may not even mention it to him and assume this rejection is true. You may come home and mull over this hurt again and again. In future you may avoid him because you no longer trust that he likes you. However, if you later mention the incident to him he might tell you that he was so preoccupied that he didn't even see you! Jumping to the wrong conclusion might have upset your friend.

Research evidence suggests that people with depression make mistakes like this over and over again. They often do not check their negative interpretations of events and therefore don't discover that many of their concerns are unfounded.

What are typical thinking errors?

Here are some typical errors of thinking that may apply to people with depression:

Exaggeration: everything seems extreme, difficulties turn into disaster. Problems, and the harm they can cause, are exaggerated. The individual underestimates their ability to deal with problems. For example, "Now I have upset her, our friendship is over and I'll end up with no friends".

Bias against themselves*:* the individual makes strong statements that emphasise the negative. For example, if someone criticises them, they may think "I am a failure" and "Nobody likes me".

Ignoring the positive/focusing on the negative: The individual only seems to remember and dwell on negative events. They dismiss good experiences as 'unimportant', "So what if I finished my work? It's what I'm supposed to do".

Black or white/All or nothing thinking: The individual sees things in black and white. If something falls short of perfection it is a failure.

Jumping to the worst conclusions: The individual interprets what happens in a negative way without any facts to support their view. For example, they indulge in *mind reading* (they assume someone feels or thinks badly of them without checking it out). For example, "He thinks I'm a bore" or "She's really laughing at me". Or they may be sure that things will turn out badly without any evidence. "This is never going to work".

Labelling: The individual deals with their mistakes (and other people's) by using general labels. For example, "I'm a bad mother". This is very demoralising when the person keeps doing it.

Taking things to heart: The individual assumes responsibility for things that aren't really under their control. For example, "It's my fault he started drinking again".

Saying should/must/ought thoughts: The individual tells themselves how they ought to act, feel or think. For example, "I should please everyone" or "I shouldn't have to put up with this".

Working with a CBT therapist

The CBT therapist will help the individual to identify and correct their unrealistic and unhelpful negative thoughts and work out ways to deal more effectively with day-to-day problems. A course of CBT usually lasts between 12 and 18 sessions, each lasting just under one hour. It is an educational approach in which the individual will receive suggestions of things to do and they can then try these out for themselves to see what works.

What happens in CBT?

CBT encourages the individual to plan changes in their activity/behaviour to help them get back to enjoyable and meaningful activities.

CBT focuses on helping the individual change their thoughts, beliefs and unhelpful thinking patterns.

It deals with the here and now, although it also looks at the influence of past events. It helps the individual change step by step using a clear plan.

The patient and therapist work together. Therefore, a good relationship is an important part of therapy.

The therapist will suggest new ways of dealing with situations, but the individual will only benefit if they try these out themselves to work out what helps. *This is the key to progress,*

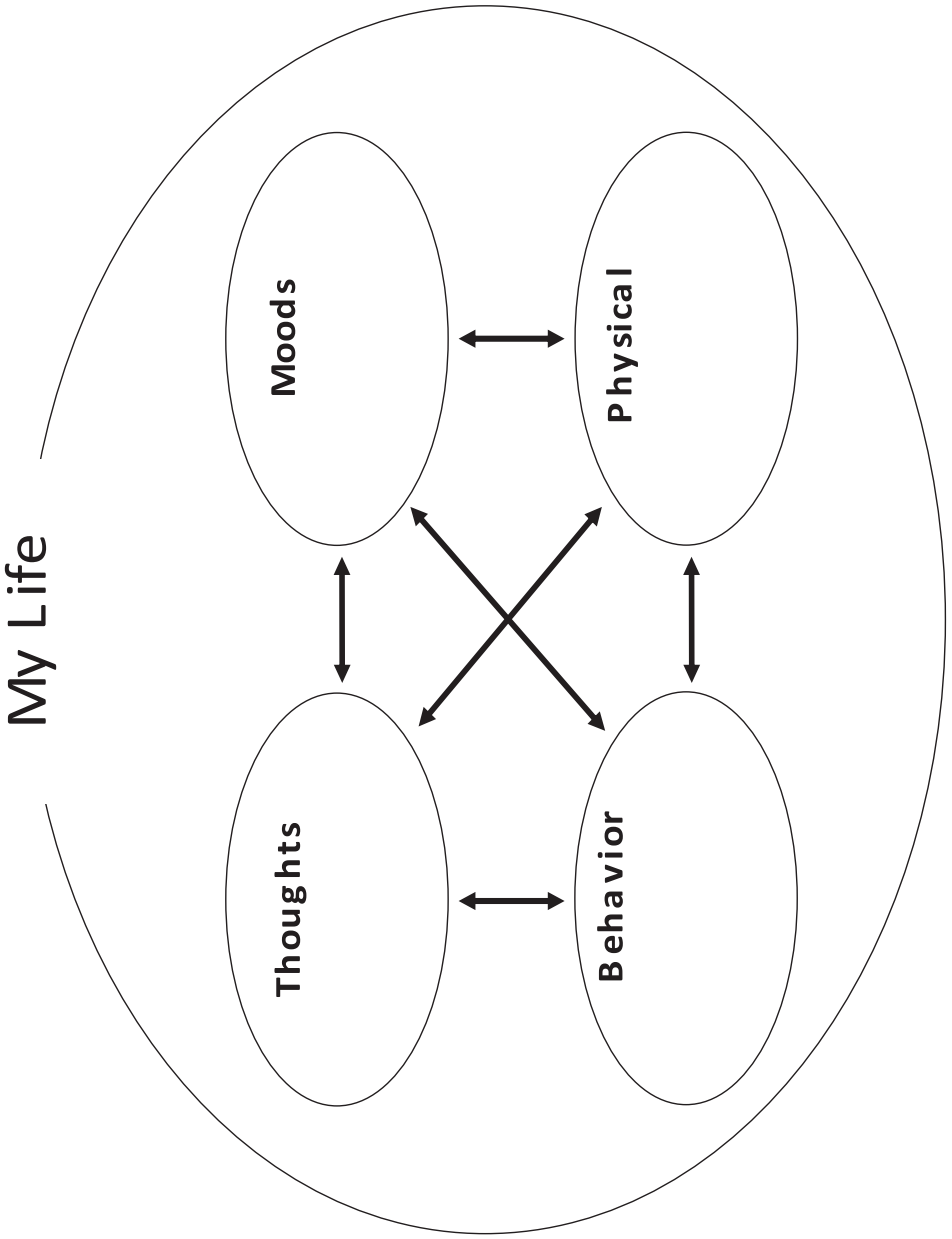
as evidence shows that people who do this and reflect a lot on their thoughts between sessions do the best.

The therapist will use questions to help the person identify their thoughts and problems, and help them come up with solutions.

The therapist is not a "guru" who has special insight into the patient's deepest feelings. He or she will not "interpret" the patient's thoughts or feelings, but will work with the individual to see how their thoughts are affecting their life and show how they can learn to feel differently. For the therapist to know what worries, fears or concerns the individual has, they will need to tell their therapist.

The therapy is educational and the individual will learn skills to deal with their problems, skills that they will be able to use when the therapy is finished.

Appendix B: Descriptive Case Conceptualisation



Descriptive case conceptualization. © Kuyken, Padesky & Dudley, 2009

Appendix C: Weekly Activity Schedule

Time	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
AM 6-7							
7-8							
8-9							
9-10							
10-11							
11-12							
PM 12-1							
1-2							

2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10	10-11	11-12

Appendix D: How to Activate Yourself

The Problem

Depression is a vicious circle. It slows you down, mentally and physically. Everything becomes an effort and you tire easily. You do less and then blame yourself for doing less. You come to believe that you can do nothing and that you will never get over your depression. Then you feel even more depressed. It becomes even more difficult to do anything. And so it goes on.

Overcoming the problem: Activity scheduling

Becoming more active is one way of breaking the vicious circle. It has a number of advantages:

Activity makes you feel better. At the very least, it takes your mind off your painful feelings. It can give you the sense that you are taking control of your life again, and achieving something worthwhile. You may even find that there are things you enjoy, once you try them.

Activity makes you feel less tired. Normally, when you are tired, you need rest. When you are depressed, the opposite is true. You need to do more. Doing nothing will only make you feel more lethargic and exhausted. And doing nothing leaves your mind unoccupied, so you are more likely to brood on your difficulties, and to feel even more depressed.

Activity motivates you to do more. In depression, motivation works backwards. The more you do the more you feel like doing.

Activity improves your ability to think. Once you get started, problems which you thought you could do nothing about come into perspective.

In spite of these advantages, getting going again is not easy. This is because the gloomy, pessimistic thoughts which are typical of depression stand in your way. When you are depressed, you may think that you are doing nothing, achieving nothing, and enjoying nothing. It may be difficult to organise your time productively, or to involve yourself in things you normally enjoy. When you are faced with something you want to do, you may find yourself thinking, "I won't enjoy it", "I'll only make a mess of it" or "It's too difficult". Thoughts like these stop you from taking action and help to keep you in the vicious circle.

Later on in therapy, you will learn how to work directly on depressing thoughts which stop you from getting down to what you want to do. Your goal will be to notice and challenge the thoughts, so that they no longer stand in your way. First of all, though, you need to get a detailed idea of exactly what you are doing, and how much pleasure and satisfaction you get from what you do. What you discover will help you to plan your time so as to get the most out of each day's activities. This is called "activity scheduling" and you will find details of how to do it below. There are two steps involved: self-monitoring and planning ahead.

Step I: Self-Monitoring

'Self-monitoring' simply means observing your pattern of activities. It involves keeping a detailed record of what to do, hour-by-hour. You can do this in a notebook or diary, or your therapist will give you a special record sheet.

Your record will show you in black and white how you are spending your time and will make your aware of how much satisfaction you get from what you do. This will allow you to test thoughts like "I'm not doing anything" or "I don't enjoy anything I do", and to see if they hold water when compared with facts. You may well find that you are more active and competent than you assumed, and that you are enjoying yourself more than you thought. Even if this is not the case, you will have a factual record to help you find out more about what is getting in your way, and to form a basis for changing how you spend your time.

How to do it

For the next few days, in your diary or on your record sheet write down:

1. Your activities. Record exactly what you do, hour by hour.
2. Pleasure and mastery. Give each activity a rating between 0 and 10 for pleasure (P) and for mastery (M). 'P' refers to how much you enjoyed what you did. So 'P10' would mean that you had enjoyed something very much. 'P0' would mean that you had not enjoyed it at all. You could use any number between 0 and 10 to show how much you had enjoyed a particular activity. 'M' refers to how much mastery you experienced in what you did. How much of an achievement was it, given how you felt? 'M10' would mean that what you did was a real achievement. 'M0' would mean that it was not an achievement at all. Again, you could use any number between 0 and 10 to show how much mastery was involved in a particular activity.

Common problems in self-monitoring

- Thinking you are doing nothing. Sitting in a chair in front of the television is an activity. So are going to bed, and staring out of the window brooding. You are never doing 'nothing'. But some activities may be less helpful to you than others. It will help you to identify these if you specify on your record sheet what they are, rather than simply writing 'nothing'.
- Underestimating your achievements. 'M' should be rated for how difficult an activity is for you now, not how difficult it was for you before you got depressed, or how difficult another person might find it. When you are depressed, things which would normally be very easy become difficult. Even getting out of bed, or making a slice of toast, can be a major achievement, given how you feel. Beware of thoughts like 'But I should be able to do this better' or 'So what? Any fool could do this'. They will only keep you trapped in depression's vicious circle. Take a stand against them by making sure that you give yourself credit for what you do.
- Delaying your ratings. It is important to rate your activities for P and M at the same time. If you wait until later, your depression will colour how you see your day and may well cause you to ignore or devalue good things you have done. When people are depressed, bad things that happen are easily noticed and remembered. In contrast, good things are often blotted out or discounted. If you make your ratings at the time this bias in how you see things is less likely. Immediate ratings will also help you to become sensitive to even small degrees of pleasure and mastery, which might otherwise go unnoticed.

Step II: Planning Ahead

Now that you can see how you are spending your time; the next step is to plan each day in advance, making sure that you include activities which will give you a sense of pleasure and mastery.

Planning ahead will allow you to feel that you are taking control of your life, and will give you a sense of purpose. The framework you give yourself will prevent you from sinking into a swamp of minor decisions ('What shall I do next?'), and will help you to keep going even when you feel bad. Once the day's activities are laid out in writing, they will seem less overwhelming. You will have broken the day

down into a series of manageable chunks, rather than a long shapeless stretch of time which you must somehow fill.

How to do it

1. Plan your activities. Every evening, or first thing in the morning, set aside time to plan the day ahead. Find out what time suits you best to do this, remembering that you are likely to be able to plan more realistically and constructively when you are feeling relatively well and clearheaded. If you find it difficult to remember to make time to plan ahead, give yourself reminder cues. Put up signs around the house, for example, or ask someone to remind you that 7.30 is your time for planning tomorrow. As far as possible, try to ensure that your planning time is not interrupted, and that there are no other pressing demands to distract you. Turn off the television and take the phone off the hook.

   Aim for a balance between pleasure and mastery in your day. If you fill your time with duties and chores, and allow no time for enjoyment or relaxation, you may find yourself feeling tired, resentful and depressed at the end of the day. On the other hand, if you completely ignore things you have to do, you may find your pleasure soured by a sense that nothing has been achieved, and your list of necessary tasks will mount up. You may find it helpful to aim for the pattern of activities you found most rewarding in the past. There is a fair chance that, once you get going, you will find this pattern works for you again.

   Encourage yourself by starting the day with an activity which will give you a sense of mastery or pleasure, and which you have a good chance of completing successfully. This is particularly important if you have trouble getting going in the morning. And plan to reward yourself with a pleasurable or relaxing activity when you tackle something difficult. You might, for example, set aside time to have a cup of coffee and listen to your favourite radio programme when you have spent an hour doing housework. Avoid bed. Beds are for sleeping in, not for retreating to during the day. If you need rest or relaxation, plan to achieve it in some other way.

   To begin with, you may find that trying to plan a whole day at a time is too much for you. If so, break the day down into smaller chunks, and deal with them one at a time.

2. Record what you actually do. Put your plan into practice. Write down how you in fact spend your time on your record sheet, just as you did at the self-monitoring stage. Rate each activity out of 10 for mastery and pleasure.

3. Review what you have done. At the end of each day, review what you have done. Take the time to sit down and examine how you spent your day, how much pleasure and mastery you got from what you did, and how far you managed to carry out the activities you had planned. This will help you to see clearly how you are spending your time, what room there is for improvement, and what changes you might like to make in the pattern of your day.

   If you have managed overall to stick to your plan, and have found what you did reasonably satisfying, this gives you something positive to build on. If on the other hand, you did not stick to your plan and you got little satisfaction from what you did, this will give you valuable information about the kind of things that are preventing you from making the most of your time. What exactly was the problem? Did you overestimate what you could do in the time available? Did you feel too tired to carry out everything you had planned? Did you aim too high, forgetting to take into account how you feel at the moment? Did you spend your day doing things that you felt you ought to do, rather than things that would give you pleasure and help you to relax? Were your best efforts

blocked by pessimistic thoughts? If you can find out what went wrong, you can learn from these experiences. Use what you have found out to help you plan in future.

Coping with practical tasks

Depression often leads people to put off practical tasks they need to carry out. The pile mounts, and in the end they feel completely overwhelmed. You can help yourself to get started on things you need to do by following these steps:

1. Make a list of all the things you have been putting off, in whatever order they occur to you.
2. Number the tasks in order of priority. Which needs to be done first? If you cannot decide, or it genuinely does not matter, number them in alphabetical order. The important thing at this stage is to do something.
3. Take the first task and break it down into small steps. What exactly do you have to do in order to complete it?
4. Rehearse the task mentally step by step. Write down any practical difficulties you may encounter, and work out what to do about them.
5. Write down any negative thoughts that come to you about doing the task and answer them if you can (see below). If you cannot find answers, simply note the thoughts down (recognising them for what they are), put them to one side for later discussion with your therapist, and concentrate on what you are doing.
6. Take the task step by step, dealing with difficulties and negative thoughts as they occur, just as you did in your mental rehearsal.
7. Write down what you have done on your activity schedule, and rate it out of 10 for P and M, as soon as you have completed the task.
8. Focus on what you have achieved, not on all the other things you still have to do. Watch out for negative thoughts that will make you devalue or discount what you have done. Write these thoughts down, and answer them if you can. If not, note them and put them to one side for later discussion with your therapist.
9. Take the next task and tackle it in the same way.

Common problems with planning ahead

Not being able to get going

If you have difficulty getting down to a particular activity, tell your body in detail what to do. 'Get on with it' is too vague. 'Legs, walk. Hand, pick up pen. Now write' will give you the impetus to begin. As soon as you have told yourself what to do, do it. Do not allow any pause for doubts to creep in.

Being too rigid

Your plan is a guide, not a god. It is not carved on stone tablets. It is there to help you, not to rule your life. So, for example, something unexpected may happen to throw you off schedule. A friend drops in unexpectedly, or the washing machine breaks down. At this point, you may feel that your efforts to plan your day have been wasted: unless you can stick to what you have planned, you might just as well not bother.

There are a number of things you can do to cope with the unexpected:

- Accept the disruption. Accept that things have not worked out the way you thought they would, and continue with your original plan when you can. Your friend leaves at 4 o'clock. What did you have scheduled for that time?
- Think of alternatives. Some of the activities you have planned may depend on factors beyond your control, such as the weather or other people's health. Supposing, for example, you plan a picnic,

have something up your sleeve in case it rains. Or supposing you had planned to spend the weekend with an old friend and at the last minute she comes down with flu, look for an alternative that you will enjoy, rather than giving up and doing nothing in particular.

- Do not try to make up things you have missed. If for some reason you cannot do what you had planned at a particular time (you wanted to clean the bedroom and ended up talking to your son about his holiday plans), do not go back and try to do it later. Move on to the next activity on your plan, and re-schedule what you missed for the next day. Similarly, if you find that you finish an activity sooner than planned; leave your next activity until the time you had scheduled. Fill the gap with something you enjoy. You may find it useful to have a list of pleasurable activities handy so that you have something to choose from.

Being too specific or too general

You need to write down what you intend to do in nit-picking detail. Listing every piece of furniture and ornament you have to dust is too specific. Equally, do not be so general. 'Housework', for example, is too general for you to feel clear about what it is that you are aiming to do. So you will not know when you have achieved your goal. Schedule your activities roughly by the hour or half hour. Experience will tell you how long each activity is likely to take.

Planning for quality, not quantity

Write down the amount of time you are going to spend on a particular activity, not how much you are going to do in that time. When the time is up, stop. How much you do in a given period may depend on factors outside your control (e.g. interruptions, machines breaking down), or on other problems (e.g. concentration difficulties, fatigue). If you tell yourself you must weed the whole garden this afternoon and you do not do it, you will probably think of yourself as a failure and give yourself no credit for what you *have* done. If on the other hand, you set yourself to weed for an hour, then how much you do is neither here nor there. Reward the effort, not the outcome.

Expecting miracles

Your immediate goal is to carry out what you have planned as best you can, not to get over your depression. You will probably feel less depressed when you are doing some things than when you are doing others. And if you work steadily at becoming more active, you will eventually feel better. But no single thing you do is likely to produce a miracle cure. Don't expect to be over your depression after an hour's television, or cleaning out the cupboard under the stairs. If you do, you will only disappoint yourself.

Stopping when the going gets tough

Quit an activity when you are winning, not when you have exhausted yourself, or when things are going badly. This will leave you feeling good about what you have achieved, and ready to carry on.

Thoughts that stop you activating yourself

We have already discussed how pessimistic, gloomy thinking can get in the way of your attempts to activate yourself, and trap you in the vicious circle of depression. The most powerful way to overcome your depression is to identify your depressing thoughts when they occur, and to challenge them. You will learn how to do this later in therapy. In the meantime, monitoring what you do and planning ahead will give you a good opportunity to start becoming more aware of depressing thoughts that block progress and get in your way.

In the last section of this handout, you will find some examples of the kind of thoughts that may be preventing you from becoming more active, together with some possible answers to them. These are not the right answers, nor the only answers. They are just some suggestions. The answers which work for you personally might be quite different. With practice you will learn to find effective answers, which change how you feel and help you to tackle your difficulties constructively, for yourself.

Automatic thoughts

I can't do anything – there are too many practical difficulties.

I can't keep a schedule – I've never been a record keeper.

There's too much to do – I won't be able to cope.

It's too difficult.

I won't know how to go about it.

I don't want to.

I'm not up to it just now; I'll wait till I'm feeling better.

It's too late; I should never have done it before.

anyone who could give me advice with things I don't know how to handle?

Keeping written records is a skill that I may not have done before, but that doesn't mean to say I can't do it. After all, I've used lists before, for shopping and to remember what to take on holiday. I could start by listing all the things I have to do.

Believing that is all part of depression. It may not be true. If I write down what I need to do, it won't seem so overwhelming. I don't have to do it all at once. I can take things on at a time.

It only seems difficult because I'm depressed. I've done more difficult things than this in the past.

The idea is to have a go, not to produce a perfect performance. It's better to try and find out how I do, than not do anything at all.

That's true. But whether I want to or not, what is in my best interests? Which will make me feel better and more in control of things? Doing it? Or not doing it?

I won't know if I'm to it until I try. If I wait till I'm feeling better, I'll never do it. Doing it will make me feel better.

Maybe it would have been better if I'd done it before. But the fact is I didn't. Feeling guilty is not going to help me. Better later than never – do it now instead of wasting time in regrets.

I can't decide what to do first.

There's no point in trying. I'll only make a mess of it and feel worse.

Possible answers

There are many practical difficulties involved in doing anything – it's a part of life. What would I do about them if I wasn't depressed? Is there

I won't enjoy it.	I don't know that till I try. Nobody's asking for a five-star performance. Even if I do make a mess of it, it's not the end of the world – I can learn from my mistakes if I don't take them too seriously.
I won't be able to do everything I've planned.	How do I know? I'm not a fortune-teller. I might enjoy it more than I think, once I get involved in what I'm doing. That has happened before.
I'm not doing anything.	No one does everything they've planned all the time, so there's no need to feel badly about it. Before I got depressed, if I didn't get everything done, I just put it forward to next day. Do what you can, and forget what you can't. The world won't end because I don't clean out the attic today.
I don't do anything worthwhile.	Am I sure of that? Or is it that I'm not giving myself credit for what I do? Why not keep a record for a few days, and see. Maybe I just *think* I'm not doing anything.
I don't deserve to enjoy myself. I should get on with all the things I've got to do.	I didn't see it that way before I got depressed. I was doing much the same then as I am now, but I could see that it was worthwhile, even though none of it was very dramatic or exciting. If I discount everything I do I will only get discouraged.
So I cleaned the car. So what?	Doing things I enjoy will help me feel better. That's what I want. Also, if I'm more relaxed and feeling better, I'm likely to do what I've got to do more efficiently, instead of getting in a muddle and dashing from one thing to another. I know that from experience; I get more done when I give myself breaks than when I plough on non-stop.
It really doesn't matter. The important thing at this stage is to do *something.* Take the thing that comes first in the alphabet. Once you get going, it will probably be clearer what to do next. If not, just go on down the alphabet.	Normally, cleaning the car would be nothing very special. But given the way I feel, it is in fact very difficult. So doing it is an achievement. I deserve to give myself credit for that.

Appendix E: How to Become Aware of Your Automatic Thoughts

The aim in cognitive therapy is to reduce the effect of your negative thoughts on how you feel. The first step is to recognise these thoughts.

What are negative automatic thoughts (NATs)? Negative automatic thoughts are:

1. *Negative:* they make you feel even worse about yourself (e.g. I'm useless) and your life (e.g. it's all hopeless). They also stop you from helping yourself (e.g. there's no point).
2. *Automatic:* they just pop up into your mind, you don't decide to think them. In fact, you may find it hard not to think them, as they are like a habit.
3. *Believable:* they seem to be right; they seem to be facts and you will tend to accept them.
4. *Biased:* although they seem right, they are likely to be distorted or inaccurate. They may have some support from how you feel or things that may have happened but ignore many other facts which do not fit such a negative view.

How to catch NATs. This will be quite hard at first. They may have become a habit or you may think that they are not thoughts but reality. To learn to catch these thoughts:
1. *Use your feelings as a cue.* Whenever you notice feeling upset or your mood takes a downturn, as yourself "What was going through my mind just then?"
2. Look out for *pictures* as well as words. Sometimes the NATs take the form of pictures or images in your mind's eye. It is important to watch out for these images.
3. If you seem to be upset by an event rather than a thought, ask "How did I view this situation?" or "What did this mean to me?"

Counting NATs. With breaking any habit, catching yourself at it is the first hurdle. Counting the thoughts is one way of doing this. At first, "tuning in" to the negative things you are saying to yourself can make you feel bad. However, you will soon find that you are more able to stand back from them. Try to catch and observe them as they come to mind. You might try putting ticks on a piece of paper or card, or counting them using a golf or knitting counter. Then you can see easily how many you had that day. At first, the daily tally will go up as you get better at catching them.

Writing down your NATs. The best way to become aware of your NATs is to write them down. It is best to do this as soon as you notice your mood going down. However, sometimes it may be necessary just to make a mental note and jot it down later. You may find that some thoughts come to mind over and over again. Sometimes, just catching them and jotting them down can take out some of the sting or help you see things differently. At other times, you will need to use the ways of answering back these thoughts that you will learn during therapy.

Beware: There are a number of reasons or excuses for not catching or writing down your thoughts. It may seem like a lot of effort when you are already finding it hard to cope. You may worry that writing the thoughts will only make you feel worse. You may think that it is stupid having such thoughts. Although identifying NATs may involve effort and upset at first, remember that *it will get easier with practice.* On the other hand, not tackling these thoughts leaves them free to bother you just as much in the future. There is no pain free way of overcoming depression, but as your skills improve, your efforts will help you to feel better.

Appendix F: Thought Record

1. Situation	2. Moods	3. Automatic thoughts	4. Evidence that supports the thought	5. Evidence that does not support the thought	6. Alternative / balanced thoughts	7. Rate moods now	8. What should I do now?
Brief description of what was happening; what you were doing at the time.	Describe each emotion in one word. Rate the intensity of the emotion from 0-100%	What was going through your mind? What does this say about you? What is the worst that could happen?	Write factual evidence to support this conclusion. Try to avoid mind reading/interpretation of facts.	Write factual evidence that does not support your conclusion.	Based on the evidence what would be a balanced alternative thought? Rate how much you believe this thought 0-100%	Copy the emotions from column 2. Re-rate their intensity from 0-100%	What should you now do based on the balanced thought?

Appendix G: Record Sheet for Behavioural Experiments

DATE	SITUATION	PREDICTION (What exactly did you think would happen? How would you know? Rate belief 0-100%)	EXPERIMENT (What did you do to test the prediction?)	OUTCOME (What actually happened? Was the prediction correct?)	WHAT I LEARNED 1. Balanced view? (Rate belief 0-100%) 2. How likely is what you predicted to happen in future? (Rate 0-100%)

Appendix H: Coping Worksheet

What have you learned?

What has been useful to you?

How can you build on why you have learned?

What will make it difficult to do so?

How will you overcome the difficulties?

What might lead to a setback for you?

What would you do about a setback?

What gains have I made in therapy?

What is different now from before therapy?

What have I done to make this happen?

What skills do I want to take with me after finishing?

How can I continue to use the therapy in my everyday life?

What are the early warning signs that I need to be aware of?

What do I need to do if I experience this?

What are the possible high-risk situations for me in terms of slip backs?

What do I need to do if I encounter these situations?

What is my emergency plan in the event of a lapse / slip back?

What will be the most adaptive way to think about a lapse?

What are my specific goals for the next month / 3 months?

What could sabotage my plans?

What could I do to prevent this?

Any other potential setbacks that can be anticipated?

What are the warning signs to becoming unwell?
Thoughts:

Feelings:

Behaviours:

What are your thoughts about how it is now?

How do you identify 'feeling better'?
Thoughts:

Feelings:

Behaviours:

EME
HS&DR
HTA
PGfAR
PHR

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