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Kitchen, Charlotte Emma Wray orcid.org/0000-0002-9323-0061, Tiffin, Paul Alexander orcid.org/0000-0003-1770-5034, Gega, Lina orcid.org/0000-0003-2902-9256 et al. (1 more author) (2020) Innovations in Practice::A randomised controlled feasibility trial of Behavioural Activation as a treatment for young people with depression. Child and Adolescent Mental Health. ISSN 1475-357X

https://doi.org/10.1111/camh.12415

Child and Adolescent Mental Health

Child and Adolescent Mental Health Volume **, No. *, 2020, pp. **–** doi:10.1111/camh.12415

Innovations in Practice: A randomised controlled feasibility trial of Behavioural Activation as a treatment for young people with depression

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Background: Behavioural Activation (BA) treatment effectively reduces symptoms of depression in adults and is more cost-effective than more complex therapies. Two recent systematic reviews of BA for depression in young people highlighted the need for more studies in this area. **Methods:** In order to evaluate the acceptability of BA treatment for adolescents with depression and the feasibility of conducting a trial of this intervention in Child and Adolescent Mental Health Services (CAMHS), 22 patients from across three sites were randomised to BA or usual CAMHS care. Existing CAMHS staff were trained to deliver the manualised intervention via a brief course. Following treatment, young people and their parents/carers were asked to complete a feedback survey. Symptoms and functioning were assessed at 3- and 6-month follow-up. The trial was registered with the ISRCTN Registry (ref: ISRCTN52147450; https://www.isrctn.com/). **Results:** Recruitment targets were achieved through screening large numbers of CAMHS service users. Intervention adherence by the participating adolescents was high (median number of completed BA sessions was seven out of a total of eight). There were tentative suggestions of improvements following treatment; a large change in a positive direction for the BA group, but not for usual care, was observed by visual comparisons of mean scores on measures of depression, self-esteem and functioning. No adverse events were reported. **Conclusions:** The findings suggest that BA in this setting is acceptable and warrants evaluation via a fully powered randomised controlled trial.

Key Practitioner Message

What is known?

- Behavioural Activation (BA) can be delivered by nonspecialist practitioners to adults with depression in a way that is both clinically and cost-effective.
- There is a lack of evidence relating to the application of BA to an adolescent population, particularly in a UK context.

What is new?

- Self-referral and clinician-led recruitment approaches appear most feasible to recruit to a trial.
- The brief, manualised BA treatment for young people affected by depression in UK CAMHS was acceptable to the participants receiving the intervention.
- The BA intervention could be delivered by a variety of staff in this setting, following a brief training course and with appropriate supervision.

What is significant for clinical practice?

- Psychological therapies, such as BA, have the capacity to enhance clinical practice due to the brief, simple nature of the interventions that can be harnessed by less experienced practitioners.
- Although the results from this study suggest that BA is promising, this treatment approach needs to be evaluated in this population via a fully powered randomised controlled trial in order to answer questions about effectiveness.

Keywords: Behavioural activation; adolescents; depression; feasibility; acceptability

Introduction

Depression in young people is common, long-lasting and disabling; often being associated with educational absenteeism and underachievement, substance use and abuse, violence, poor reproductive and sexual health outcomes, self-harm and/or suicidality (Birmaher et al., 1996; Finning et al., 2019; Thapar, Collishaw, Pine, & Thapar, 2012). Behavioural Activation (BA) is a time-limited, collaborative psychotherapy, informed by behaviour theory. This is based upon the concept that depression results from a loss of positive reinforcement-that is, experiences that result in reward make repetition of the action more likely (Kanter, Busch & Rusch, 2009). In adults, BA is effective for depression and can be delivered more economically than other psychological therapies (Richards et al., 2016). There is a need in clinical services for brief, evidence-based interventions that can be delivered effectively by a variety of multidisciplinary practitioners. However, there is little published research exploring BA as a treatment option for youth depression in the UK (Martin & Oliver, 2019; Tindall et al., 2017). We explored the feasibility and acceptability of conducting a trial of BA for adolescents with depression within Child and Adolescent Mental Health Services (CAMHS).

Methods

This was a multicentre, parallel, randomised controlled feasibility trial.

Existing CAMHS staff (NHS band 4–7), from three community CAMHS teams in the north-east of England, were trained to deliver the manualised intervention via a three-day training course. Staff within these teams were aligned to one of three providers (Tier 2 [targeted], Tier 3 [specialist] or Learning Disability Services [LD]), all centrally commissioned and based within the same sites. We recruited staff from Tier 2 and 3 but not LD due to the reading age required for the manual materials. The BA treatment was administered using a treatment manual adapted during a previous study (Arnott, Kitchen, Ekers, Gega, & Tiffin, 2020). Staff were required to pass a half-day competency assessment prior to treating patients in the study. Staff were subsequently able to access monthly group supervision and individual weekly telephone supervision with a BA specialist from the NHS Trust.

Participants were identified via a case note review or through self/clinician referral from across the three CAMHS teams over a period of seventeen months (March 2015–July 2016). Young people (aged 12–17 years old) displaying symptoms of depression (who had not yet received psychotherapy and did not require urgent care) were offered a structured diagnostic interview to confirm depression status (the Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime version [K-SADS-PL]; Kaufman et al., 1997). The K-SADS-PL also includes a researcher-rated measure of functioning (Children's Global Assessment Scale [CGAS]). Additional self-report measures of mood (Mood and Feelings Questionnaire- Child/Parent versions [MFQ-C/P]; Costello & Angold, 1988) and self-esteem (Rosenberg Self-Esteem Measure [RSE]; Rosenberg, 1965) were completed. Potential participants were excluded if there was evidence of active substance abuse/dependence.

Patients meeting the criteria for Major Depressive Disorder [MDD] on the K-SADS-PL were offered the opportunity to participate in the study. Informed consent (from young people aged 16–17 and parents/carers of those aged 12–15) or assent (from young people aged 12–15) was obtained from all participants. Participants were then assigned, individually, to treatment conditions (BA or usual care) using a remote, blocked, telephone randomisation process by an otherwise uninvolved member of NHS staff. Randomisation was performed by an independent statistician in blocks of eight and stratified according to depression severity (mild/moderate or severe) and setting (Tier 2 or 3). The allocation sequence for the participating patients was concealed from the researcher responsible for enrolling/assessing the participants and was only revealed once allocation was complete.

The comparison condition 'usual care' represents standard care in CAMHS; participants received treatments deemed appropriate by their CAMHS professional, and there were no restrictions, protocol or extra training given. Clinicians in the BA arm used the manual to implement BA for eight sessions; other psychotherapies were restricted during this time but any additional psychotherapy as deemed necessary was provided following delivery of BA. Sessions of BA were designed to be delivered face-to-face, spaced one week apart and lasting for one hour. Parent/carer involvement in treatment was at the discretion of the participating young person. Where young people invited their parents/carers to be involved, there was separate intervention content for them to cover.

At 3-month postbaseline, the diagnostic interview was re-administered and the additional outcome measures repeated along with a bespoke treatment satisfaction survey. At 6-month postbaseline, a telephone interview repeated selected outcome measures (MFQ-C/P and RSE).

This study was approved by the Durham University School of Medicine, Pharmacy and Health Research Ethics Sub-Committee (ref: ESC2/2014/14), the National Research Ethics Committee North East – Newcastle and North Tyneside 1 (ref: 15/NE/0002) and the NHS Trust Research and Development Office (ref: 0360/15). The trial was registered with the ISRCTN Registry (ref: ISRCTN52147450; https://www.isrctn.com/).

Results

All study sites and the majority of staff (7/10) trained in the BA intervention were retained throughout the trial (one did not pass the competency assessment, one left the service and another withdrew due to additional management responsibilities).

Participant recruitment required the screening of relatively large numbers of young people (see Figure 1); 66% of patients (53/80) identified by their clinicians and 75% (3/4) of self-referrals met the study eligibility criteria, compared with 3% (8/267) identified via the case note review. Thirty-eight potential participants, provisionally deemed eligible, were excluded prior to the initial diagnostic interview. One no longer met provisional inclusion criteria, 15 had been discharged from CAMHS care, three were transferred to a different part of the service, 10 declined after receiving study materials (one did not like the weekly format, one did not wish to be randomised, one did not like talking therapies, five declined without providing a reason and two did not attend without providing a reason). Nine were excluded by their clinician; one clinician did not want researchers to approach the patient, three felt the patient was too complex or the BA treatment was too simple, one wanted to use the patient as a case study for a training programme, one felt another comorbidity (rather than MDD) should be prioritised, one reported their patient required urgent care and two clinicians felt group therapy was required. Therefore, 26 progressed to K-SADS-PL assessment with 22 offered study entry (see Table 1 for baseline characteristics).

Behavioural Activation was delivered by six clinicians (mean caseload of 1.8 randomised patients); one clinician was not allocated any patients during the study. Most participants completed a high number of the

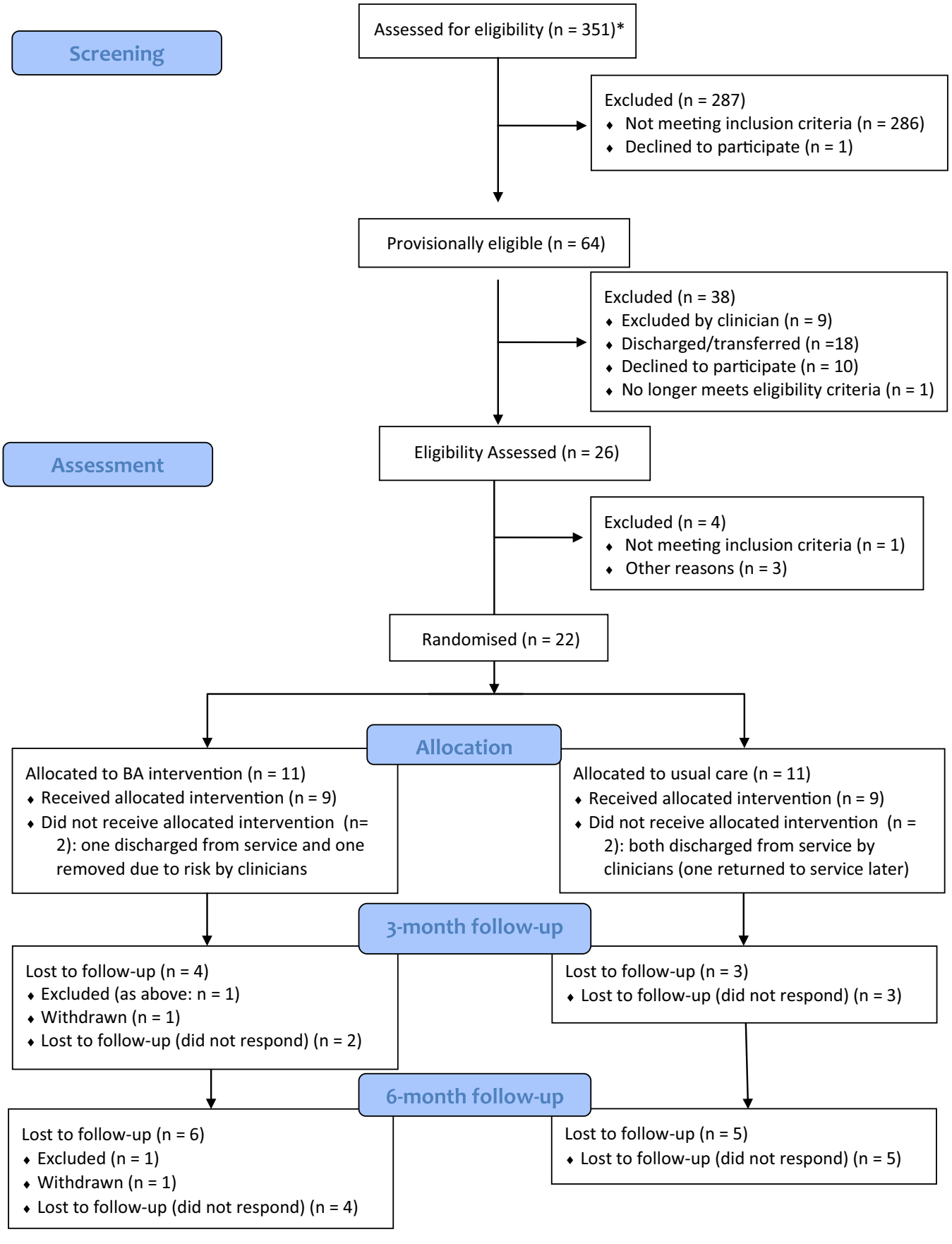

Figure 1. CONSORT Diagram. *Identified by case note review (n = 267), study poster (n = 4) or clinician (n = 80)

prescribed BA sessions (mean 5.7; median 7). Although not powered to demonstrate statistically or clinically significant intergroup differences, descriptive study data provided some tentative suggestions that BA may result in improved outcomes compared with usual care (see Table 2 for baseline, 3- and 6-month follow-up data,

Table 1. Participant Baseline Characteristics as randomised

Characteristics	BA (n = 11)	Usual care (n = 11)
Sex, No. (%)		
Female	9 (81.8)	9 (81.8)
Male	2 (18.2)	2 (18.2)
Age at consent, y:m		
Mean (*SD*)	15:8 (1:5)	15:5 (1:0)
Median (range)	15:10 (13:11-17:7)	15:7 (13:8-16:10)
K-SADS-PL, No. (%)		
No. (%) with data	11 (100)	11 (100)
Diagnosis*		
MDD	11 (100)	11 (100)
Melancholic	4 (36.4)	4 (36.4)
Atypical	2 (18.2)	2 (18.2)
Severity		
Mild	4 (36.4)	6 (54.5)
Moderate	3 (27.3)	2 (18.2)
Severe	4 (36.4)	3 (27.3)
Comorbidities*		
No. (%)	11 (100)	11 (100)
Mean (*SD*)	4.55 (1.21)	3.64 (1.75)
Median (range)	5 (2-6)	4 (1-6)
Mania	1 (9.1)	1 (9.1)
Panic Disorder	4 (36.4)	4 (36.4)
Separation Anxiety Disorder	6 (54.5)	3 (27.3)
Avoidant Disorder/Social Phobia	6 (54.5)	5 (4.5)
Agoraphobia & Specific Phobias	3 (27.3)	2 (18.2)
Overanxious/Generalised Anxiety Disorder	11 (100)	11 (100)
Anorexia Nervosa	1 (9.1)	1 (9.1)
Bulimia Nervosa	1 (9.1)	0 (0)
Attention Deficit Hyperactivity Disorder	4 (36.4)	1 (9.1)
Oppositional Defiant Disorder	4 (36.4)	1 (9.1)
Conduct Disorder	4 (36.4)	4 (36.4)
Tic Disorders	1 (9.1)	1 (9.1)
Post-Traumatic Stress Disorder	4 (36.4)	6 (54.5)
MFQ-C score[a]		
No. (%) with data	11 (100)	11 (100)
Mean (*SD*)	33.91 (11.8)	35.55 (11.09)
Median (range)	34 (17-58)	35 (18-50)
MFQ-P score[b]		
No. (%) with data	6 (100**)	7 (100**)
Mean (*SD*)	29.83 (7.36)	29 (8.58)
Median (range)	28 (23-42)	32 (16-38)
RSE score[c]		
No. (%) with data	11 (100)	11 (100)
Mean (*SD*)	11.09 (4.37)	12.45 (4.84)
Median (range)	11 (5-20)	13 (6-21)
CGAS score[d]		
No. (%) with data	11 (100)	11 (100)
Mean (*SD*)	54.55 (9.47)	59.64 (6.8)
Median (range)	58 (30-65)	59 (50-68)

[a]Mood and Feelings Questionnaire: Long Version Child Self-Report (MFQ-C) score range, 0–66; higher scores indicate worse mood.

[b]Mood and Feelings Questionnaire: Long Version Parent Self-Report (MFQ-P) score range, 0–68; higher scores indicate worse mood.

[c]Rosenberg Self-Esteem Measure (RSE) score range, 0–30; scores between 15 and 25 are in the normal range, scores below 15 suggest low self-esteem.

[d]Children's Global Assessment Scale (CGAS) score range, 1–100; scores between 1–10 extremely impaired, 11–20 very severely impaired, 21–30 severe problems, 31–40 serious problems, 41–50 obvious problems, 51–60 some noticeable problems, 61–70 some problems, 71–80 doing alright, 81–90 doing well and 91–100 doing very well.

*Diagnostic categories/comorbidities are not mutually exclusive (i.e. one participant may meet the criteria for multiple depression-types/comorbidities)

**100% of those asked; only those young people aged 15 and under required parental consent to participate so only those parents were asked to complete the MFQ-P.

presented by treatment group). Fifteen participants (68%) were able to be followed up at three months (BA [7/11; 64%]; usual care [8/11; 73%]); in the usual care arm 1/8 (13%) no longer met the criteria for MDD compared with 4/7 (57%) in the BA arm. Improvements in functioning were observed at 3-month follow-up (CGAS scores improved by 10.74 points in the BA arm and decreased by 3.5 in the usual care arm). Mean scores on the MFC-C reduced in both study arms but more so for those in the BA arm at 6-month follow-up (−18.11 compared with –8.88 MFQ-C points in the usual care arm [−18.83 on the MFQ-P in the BA arm and −2 in the usual care arm]). Similarly, self-esteem scores improved in both arms but by a greater degree in the BA arm at 6-month follow-up (RSE scores improved in the BA arm by 4.71 points and by 2.05 in the usual care arm). No adverse events were recorded.

Following treatment, young people who received BA were asked if they found it helpful; five (5/7) reported BA was helpful to some degree whilst one did not find it helpful (one did not receive treatment). Three (3/4) of their parents found BA to be helpful to some degree, and one did not. Free-text responses indicated one young person who received BA treatment valued that their feelings were acknowledged and that they were listened to whilst also being given practical advice. One young person liked that BA was based upon them helping themselves rather than having to rely upon other people. Their parent found it helpful that BA focused upon things their child used to enjoy and guided them in reviving those interests. Treatment was felt to be nonblaming; helping their young person to realise it was not their fault that they felt the way they did. Another young participant reported that their BA practitioner was 'lovely and really helpful' and that BA helped them a lot. This young person's parent liked the weekly format of the BA sessions. Another parent found the BA treatment easy to follow and understand. In response to the survey, six young people reported they were happy to some degree with the BA treatment received whilst one was 'very unhappy'. All four parents asked, were happy to some degree with the BA treatment. In contrast, one parent commented they 'didn't do much' during BA. Another parent felt they already knew most of what was taught during the BA sessions.

Participants, parents and the assessor responsible for conducting the diagnostic interviews were not blinded to treatment allocation. The number and content of usual care appointments were recorded inconsistently in patient electronic records. Although fidelity checks involving recording and independently assessing therapy sessions were not completed in the study, we had in place quality controls to minimise variance due to the therapists delivering BA; we achieved this by ensuring consistent intervention delivery through standardised training and treatment materials, and ongoing supervision.

Discussion

This study demonstrates that it is possible to recruit young people to a trial of BA in this complex service setting. However, despite screening large numbers of case notes, this recruitment method resulted in few potentially eligible participants; the recruitment rate could

Table 2. Comparison of groups for Outcome Measure means (Standard Deviation)

	Baseline		Three-month follow-up		Six-month follow-up	
	BA	TAU	BA	TAU	BA	TAU
No. participants	11	11	7	8	5	6
MFQ-C	33.91 (11.80)	35.55 (11.09)	23.43 (9.59)	30.5 (8.67)	15.8 (6.22)	26.67 (12.6)
MFQ-P	29.83 (7.36)	29 (8.58)	29.33 (8.62)	26.6 (15.79)	11 (1.41)	27 (4.76)
RSE	11.09 (4.37)	12.45 (4.84)	14.57 (4.79)	13.5 (4.38)	15.8 (5.22)	14.5 (5.09)
CGAS	54.55 (9.47)	59.64 (6.80)	65.29 (14.03)	56.14 (7.82)	.	.

therefore be improved by focusing on clinician-led and self-referral recruitment methods.

Participants' session attendance rates were high, and the BA intervention was viewed positively by most participating young people and their families, indicating BA is an acceptable treatment option for depression in this context. To date, BA interventions have mainly been evaluated using uncontrolled before and after comparisons. In the absence of a control group, lower ratings at follow-up may merely reflect regression to the mean effects but be wrongly attributed to the intervention. As such, progression to pilot and future definitive randomised controlled trials (RCTs) would greatly add to knowledge in this area. We found a trend towards greater improvements in mood, self-esteem and functioning in those individuals who received BA compared with usual care. In adults, BA is effective and cost-effective and can be delivered by trained therapists or nonspecialist staff, as evidenced by the findings of RCTs and meta-analyses (Ekers et al., 2011, 2014; Richards et al., 2016). In adolescents, the most recent meta-analysis of four RCTs on BA (Martin & Oliver, 2019) reported a large effect in favour of BA versus controls (one active intervention, one signposting and two no treatment) with a pooled standardised mean difference of −0.70 (95% CI −1.20, −0.20). An earlier meta-analysis (Tindall et al., 2017) combined the results of three RCTs, including an unpublished PhD thesis. The pooled results favoured BA over its comparators, estimating a moderate effect size (pooled mean difference of −4.17), albeit with a wide associated confidence interval (95% CI −8.25, −0.09).

A closer look at the five individual RCTs (one from Japan and four from the US) included in the two meta-analyses of BA for adolescents shows that: Takagaki et al. (2016) included only 18- to 19-year-old university students with subthreshold depression; Chu et al. (2016) and Weering et al. (2017) included a range of diagnoses apart from depression and reported global rather than depression-specific outcomes; Stark (1985) only included children aged 9–12 years; McCauley et al. (2016) included 12–18 year olds and compared BA with a suite of evidence-based interventions (e.g. cognitive behavioural therapy) but it was underpowered to firmly establish 'equivalence' of BA with 'gold standard' alternatives.

To our knowledge, this is the only European RCT of BA for adolescents with a diagnosis of depression measuring not only depression-specific outcomes but also depression recovery against usual care in CAMHS. A previous UK-based RCT (Goodyer et al., 2016) of psychological interventions for adolescents with major depression included a 'brief psychosocial intervention' that had BA elements (action-orientated interpersonal and enjoyable activities), but did not claim to be BA, nor did it follow a BA model. We recruited from a clinically referred help-seeking sample and used limited exclusion criteria, making our results relatively representative of the CAMHS settings. Therapy was delivered by staff from the setting, in the setting. The pragmatic approach to trial design led to a comparison of viable, clinically relevant alternative treatments, providing insight into the realities of delivering this treatment in a UK-based CAMHS service.

Our trial involved three CAMHS teams, all based in the north-east of England. This may limit the generalisability of the results to other geographies. It was not possible to quantify or control for the contribution of medication. We were unable to assess practitioner's fidelity to the BA model. Nevertheless, our findings suggest that this approach warrants robust evaluation via a fully powered randomised clinical trial.

Acknowledgements

C.E.W.K. was in receipt of a NHS Doctoral Studentship (2013-2017). D.E. is a NHS employee and P.A.T. is employed by the NHS in an honorary capacity and is also supported in his research by a National Institute for Health Research (NIHR) Career Development Fellowship. The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the NIHR, NHS, or the Department of Health. The sponsor (the NHS Trust) played no role in the analysis or interpretation of the results, or preparation of the article. This research did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors.

D.E., P.A.T., S.L. and C.E.W.K. were responsible for study conception and design, and C.E.W.K. was responsible for data collection under the supervision of D.E., P.A.T. and S.L. All authors were responsible for data analysis and drafting the manuscript. The authors thank the staff, young people and their families who participated in or supported this research project. The authors are indebted to Elizabeth A. McCauley and her team at the University of Washington for sharing their BA manual upon which the manual used in this study was based. The authors also would like to thank the COBRA team at the University of York for sharing their treatment and practitioner manual, which the authors relied upon to guide the BA intervention and training. The authors are grateful to Jackie Harvey and Rose McNulty from Tees, Esk and Wear Valleys NHS Foundation Trust for their assistance with the telephone randomisation and to Lazaro Mwakesi Mwandigha for conducting the randomisation procedure. The authors have declared that they have no competing or potential conflicts of interest.

Ethical information

This study was approved by the Durham University School of Medicine, Pharmacy and Health Research

Ethics Sub-Committee (ref: ESC2/2014/14), the National Research Ethics Committee North East – Newcastle and North Tyneside 1 (ref: 15/NE/0002) and the NHS Trust Research and Development Office (ref: 0360/15). Written consent procedure detailed in the manuscript.

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Accepted for publication: 3 July 2020