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Behavioural activation therapy for depression in adults (Review)

Uphoff E, Ekers D, Robertson L, Dawson S, Sanger E, South E, Samaan Z, Richards D, Meader N, Churchill R

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Behavioural activation therapy for depression in adults (Review)

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[Intervention Review]

Behavioural activation therapy for depression in adults

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ABSTRACT

Background

Behavioural activation is a brief psychotherapeutic approach that seeks to change the way a person interacts with their environment. Behavioural activation is increasingly receiving attention as a potentially cost-effective intervention for depression, which may require less resources and may be easier to deliver and implement than other types of psychotherapy.

Objectives

To examine the effects of behavioural activation compared with other psychological therapies for depression in adults.

To examine the effects of behavioural activation compared with medication for depression in adults.

To examine the effects of behavioural activation compared with treatment as usual/waiting list/placebo no treatment for depression in adults.

Search methods

We searched CCMD-CTR (all available years), CENTRAL (current issue), Ovid MEDLINE (1946 onwards), Ovid EMBASE (1980 onwards), and Ovid PsycINFO (1806 onwards) on the 17 January 2020 to identify randomised controlled trials (RCTs) of 'behavioural activation', or the main elements of behavioural activation for depression in participants with clinically diagnosed depression or subthreshold depression. We did not apply any restrictions on date, language or publication status to the searches. We searched international trials registries via the World Health Organization's trials portal (ICTRP) and [ClinicalTrials.gov](https://clinicaltrials.gov) to identify unpublished or ongoing trials.

Selection criteria

We included randomised controlled trials (RCTs) of behavioural activation for the treatment of depression or symptoms of depression in adults aged 18 or over. We excluded RCTs conducted in inpatient settings and with trial participants selected because of a physical comorbidity. Studies were included regardless of reported outcomes.

Data collection and analysis

Two review authors independently screened all titles/abstracts and full-text manuscripts for inclusion. Data extraction and 'Risk of bias' assessments were also performed by two review authors in duplicate. Where necessary, we contacted study authors for more information.

Behavioural activation therapy for depression in adults (Review)

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Main results

Fifty-three studies with 5495 participants were included; 51 parallel group RCTs and two cluster-RCTs.

We found moderate-certainty evidence that behavioural activation had greater short-term efficacy than treatment as usual (risk ratio (RR) 1.40, 95% confidence interval (CI) 1.10 to 1.78; 7 RCTs, 1533 participants), although this difference was no longer evident in sensitivity analyses using a worst-case or intention-to-treat scenario. Compared with waiting list, behavioural activation may be more effective, but there were fewer data in this comparison and evidence was of low certainty (RR 2.14, 95% CI 0.90 to 5.09; 1 RCT, 26 participants). No evidence on treatment efficacy was available for behavioural activation versus placebo and behavioural activation versus no treatment.

We found moderate-certainty evidence suggesting no evidence of a difference in short-term treatment efficacy between behavioural activation and CBT (RR 0.99, 95% CI 0.92 to 1.07; 5 RCTs, 601 participants). Fewer data were available for other comparators. No evidence of a difference in short-term efficacy was found between behavioural activation and third-wave CBT (RR 1.10, 95% CI 0.91 to 1.33; 2 RCTs, 98 participants; low certainty), and psychodynamic therapy (RR 1.21, 95% CI 0.74 to 1.99; 1 RCT, 60 participants; very low certainty). Behavioural activation was more effective than humanistic therapy (RR 1.84, 95% CI 1.15 to 2.95; 2 RCTs, 46 participants; low certainty) and medication (RR 1.77, 95% CI 1.14 to 2.76; 1 RCT; 141 participants; moderate certainty), but both of these results were based on a small number of trials and participants. No evidence on treatment efficacy was available for comparisons between behavioural activation versus interpersonal, cognitive analytic, and integrative therapies.

There was moderate-certainty evidence that behavioural activation might have lower treatment acceptability (based on dropout rate) than treatment as usual in the short term, although the data did not confirm a difference and results lacked precision (RR 1.64, 95% CI 0.81 to 3.31; 14 RCTs, 2518 participants). Moderate-certainty evidence did not suggest any difference in short-term acceptability between behavioural activation and waiting list (RR 1.17, 95% CI 0.70 to 1.93; 8 RCTs, 359 participants), no treatment (RR 0.97, 95% CI 0.45 to 2.09; 3 RCTs, 187 participants), medication (RR 0.52, 95% CI 0.23 to 1.16; 2 RCTs, 243 participants), or placebo (RR 0.72, 95% CI 0.31 to 1.67; 1 RCT; 96 participants; low-certainty evidence). No evidence on treatment acceptability was available comparing behavioural activation versus psychodynamic therapy.

Low-certainty evidence did not show a difference in short-term treatment acceptability (dropout rate) between behavioural activation and CBT (RR 1.03, 95% CI 0.85 to 1.25; 12 RCTs, 1195 participants), third-wave CBT (RR 0.84, 95% CI 0.33 to 2.10; 3 RCTs, 147 participants); humanistic therapy (RR 1.06, 95% CI 0.20 to 5.55; 2 RCTs, 96 participants) (very low certainty), and interpersonal, cognitive analytic, and integrative therapy (RR 0.84, 95% CI 0.32 to 2.20; 4 RCTs, 123 participants).

Results from medium- and long-term primary outcomes, secondary outcomes, subgroup analyses, and sensitivity analyses are summarised in the text.

Authors' conclusions

This systematic review suggests that behavioural activation may be more effective than humanistic therapy, medication, and treatment as usual, and that it may be no less effective than CBT, psychodynamic therapy, or being placed on a waiting list. However, our confidence in these findings is limited due to concerns about the certainty of the evidence.

We found no evidence of a difference in short-term treatment acceptability (based on dropouts) between behavioural activation and most comparison groups (CBT, humanistic therapy, waiting list, placebo, medication, no treatment or treatment as usual). Again, our confidence in all these findings is limited due to concerns about the certainty of the evidence.

No data were available about the efficacy of behavioural activation compared with placebo, or about treatment acceptability comparing behavioural activation and psychodynamic therapy, interpersonal, cognitive analytic and integrative therapies.

The evidence could be strengthened by better reporting and better quality RCTs of behavioural activation and by assessing working mechanisms of behavioural activation.

PLAIN LANGUAGE SUMMARY

Behavioural activation therapy for depression in adults

Review question

In this Cochrane review, we wanted to find out how well behavioural activation therapy works for depression in adults.

Why this is important

Depression is a common mental health problem that can cause a persistent feeling of sadness and loss of interest in people, activities, and things that were once enjoyable. A person with depression may feel tearful, irritable, or tired most of the time, and may have problems with sleep, concentration, and memory. These and other symptoms can make daily life more difficult than usual.

Treatments for depression include medications (antidepressants) and psychological therapies (talking therapies). Behavioural activation is a type of psychological therapy that encourages a person to develop or get back into activities which are meaningful to them. The therapy involved scheduling activities and monitoring behaviours and looking at specific situations where changing these behaviours and activities may be helpful. A therapist may support people in person, over the phone, or online, usually over multiple sessions.

It is important to know whether behavioural activation could be an effective and acceptable treatment to offer to people with depression.

What we did

In January 2020, we searched for studies of behavioural activation therapy for depression in adults (aged over 18 years). We looked for randomised controlled trials, in which treatments were given to study participants at random; these studies give the most reliable evidence.

We included 53 studies involving 5495 participants. The studies compared behavioural activation with no treatment, standard or usual care, a dummy treatment (placebo), taking medications, being on a waiting list for treatment, or other psychotherapies (cognitive behavioural therapy (CBT), third-wave CBT, humanistic therapy, psychodynamic therapy, and integrative therapy).

The studies were conducted in 14 countries; most were conducted in the USA (27 studies). Most studies lasted from four to 16 weeks.

The outcomes we focussed on were how well the treatments worked and whether they were acceptable to participants. How well treatments worked (efficacy) was measured by the number of people who responded well to treatment or no longer met criteria for depression at the end of treatment. Acceptability was measured by counting how many people dropped out during the study.

What did we find?

Behavioural activation may treat depression better than receiving usual care. We were uncertain whether behavioural activation worked better than medication or being on a waiting list, and we found no evidence for this outcome comparing behavioural activation to no treatment or placebo treatment.

We found no differences between behavioural activation and CBT in treating depression. Although we did not find enough evidence to compare behavioural activation reliably with other psychotherapies, it may work better than humanistic therapy, and we found no differences between behavioural activation and third-wave CBT or psychodynamic therapy. No evidence was available comparing behavioural activation to integrative therapies.

Behavioural activation is probably less acceptable to people than usual care. We found no differences in acceptability of behavioural activation compared with being on a waiting list, no treatment, taking antidepressants, or receiving a placebo treatment. We also found no differences in acceptability between behavioural activation and other psychotherapies studied (CBT, third-wave CBT, humanistic therapy, integrative therapies). For behavioural activation compared with psychodynamic therapy, we found no evidence on treatment acceptability.

Conclusions

Behavioural activation may be an effective and acceptable treatment for depression in adults. Offering this therapy in practice would give people with depression greater treatment choice, and different formats and types of delivery could be explored to meet the demand for mental health support. Our confidence in these findings is limited due to concerns about the certainty of the evidence.

Most findings were short-term, meaning that we cannot be sure behavioural activation would be helpful to people with depression in the longer term.

Certainty of the evidence

Our certainty (confidence) in the evidence is mostly low to moderate. Some findings are based on only a few studies, with poorly reported results, in which the participants knew which treatment they received. Therefore, we are not sure how reliable the results are. Our conclusions may change if more studies are conducted.

SUMMARY OF FINDINGS

Summary of findings 1. Behavioural activation compared with CBT for depression in adults

Behavioural activation compared with CBT for depression in adults

Patient or population: depression in adults

Setting: various including primary care, computer-based at home, and university.

Intervention: behavioural activation

Comparison: CBT

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with CBT	Risk with behavioural activation				
treatment efficacy up to 6 months (5-16 weeks)	Study population		RR 0.99 (0.92 to 1.07)	601 (5 RCTs)	⊕⊕⊕⊖ MODERATE ¹	
	62 per 100	61 per 100 (57 to 66)				
treatment acceptability up to 6 months (4-16 weeks)	Study population		RR 1.03 (0.85 to 1.25)	1195 (12 RCTs)	⊕⊕⊕⊖ LOW ^{2 3}	
	23 per 100	24 per 100 (19 to 29)				
depression symptoms (continuous) up to 6 months (4-16 weeks)	see comment	SMD 0.12 higher (0.08 lower to 0.32 higher)		1205 (16 RCTs)	⊕⊕⊕⊖ MODERATE ⁴	Measured with BDI, HRSD, CES-D, PHQ-9, HSCL-25. SMD 0.12 represents a difference between groups of 1.31 points on the BDI and 0.66 points on the HRSD favouring CBT.
quality of life (continuous) up to 6 months (12-16 weeks)	see comment	SMD 0.04 higher (0.20 lower to 0.28 higher)		268 (2 RCTs)	⊕⊕⊕⊖ MODERATE ⁵	Measured with SF-36 physical component and WHOQOL physical component. SMD 0.04 represents a small effect.
social adjustment and functioning (continuous) up to 6 months (12 weeks)	see comment	SMD 0.13 lower (0.50 lower to 0.24 higher)		111 (2 RCTs)	⊕⊖⊖⊖ VERY LOW ⁶	Measured with Social Adjustment Scale and Sheehan Disability Scale. SMD 0.13 represents a small effect.
anxiety symptoms (continuous) up to 6 months (4-16 weeks)	see comment	SMD 0.03 lower (0.18 lower to 0.13 higher)		646 (4 RCTs)	⊕⊕⊕⊖	Measured with BDI, HSCL-25, PHQ-9. SMD 0.03 represents a small effect.

			MODER- ATE ⁷	
adverse events (16 weeks)	1 study no adverse events, 1 study three serious adverse events in the behavioural activation arm (2 overdose, 1 self-harm) and eight serious adverse events in the CBT arm (7 overdose, 1 self-harm).	398 (2 RCTs)	⊕⊕⊕⊖ MODER- ATE ⁸	Any adverse event summarised narratively.

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

¹ Majority of domains high or unclear risk of bias. High risk for conflict of interest, blinding of participants and personnel, and incomplete outcome data. Downgraded by one level for high risk of bias.

² No blinding of participants. Reporting bias unclear because protocol or trial registration missing in nine studies and high risk of bias in one study. Potential conflict of interest in four studies. High risk of attrition bias in seven studies. Downgraded by one level for high risk of bias (not two levels because trials with higher weight are generally at lower risk of bias).

³ Seven out of 12 studies wide confidence intervals, due to small sample sizes and low rates of dropout in both groups. Downgraded by one level for imprecision.

⁴ No blinding of participants. 6/15 studies no blinding of outcome assessors. 13/15 selective reporting domain unclear. Downgraded by one level for high risk of bias.

⁵ Risk of performance and attrition bias and potential conflict of interest. Downgraded by one level for high risk of bias.

⁶ Two small studies with serious risk of bias across domains (attrition bias, reporting bias, potential conflicts of interest). Downgraded by one level for imprecision and two levels for high risk of bias.

⁷ One study all domains unclear or high; high risk of bias for randomisation, allocation, and blinding of participants and personnel. One study with risk of performance and attrition bias and potential conflict of interest. Downgraded one level for high risk of bias. Two studies with most domains unclear or high have little weight in the analyses.

⁸ Various domains high risk of bias in all studies. Attrition bias high in both studies; dropout may be related to adverse events. Downgraded one level for high risk of bias.

Summary of findings 2. Behavioural activation compared with third-wave CBT for depression in adults

Behavioural activation compared with third-wave CBT for depression in adults

Patient or population: depression in adults

Setting: university and community settings in Sweden, Iran, and the USA

Comparison: third-wave CBT

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N° of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with third-wave CBT	Risk with behavioural activation				
treatment efficacy up to 6 months (4-8 weeks)	Study population		RR 1.10 (0.91 to 1.33)	98 (2 RCTs)	⊕⊕○○ LOW ^{1 2}	
	74 per 100	81 per 100 (67 to 98)				
treatment acceptability up to 6 months (4-8 weeks)	Study population		RR 0.84 (0.33 to 2.10)	147 (3 RCTs)	⊕⊕○○ LOW ^{3 4}	
	12 per 100	10 per 100 (4 to 25)				
depression symptoms (continuous) up to 6 months (4-8 weeks)	see comment	SMD 0.14 lower (0.47 lower to 0.18 higher)		147 (3 RCTs)	⊕⊕○○ LOW ^{3 4}	Measured with BDI and HRSD. SMD 0.14 represents a difference between groups of 1.53 points on the BDI and 0.77 points on the HRSD favouring BA.
quality of life (continuous) up to 6 months (8 weeks)	mean score 1.13	MD 0.02 higher (0.96 lower to 1.00 higher)		81 (1 RCT)	⊕⊕○○ LOW ⁵	Measured with Quality of Life Inventory.
anxiety symptoms (continuous) up to 6 months (4-8 weeks)	see comment	MD 0.69 higher (0.68 lower to 2.06 higher)		147 (3 RCTs)	⊕⊕○○ LOW ^{3 4}	Measured with BAI.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

¹ Evidence of selective reporting and conflict of interest in both trials, in addition to other domains with risk of bias. Downgraded one level for high risk of bias.

² Two small studies with wide confidence intervals. Downgraded one level for imprecision.

³ Ten domains with high risk of bias across three studies, including blinding, allocation concealment, and selective reporting. Treatment acceptability may be affected by lack of blinding and allocation concealment in particular. Downgraded one level for high risk of bias.

⁴ Three small studies with wide confidence intervals. Downgraded one level for imprecision.

⁵ One small study with three domains at high risk of bias. Downgraded one level for imprecision and one level for high risk of bias. Because only one study was included, this outcome could not be assessed for consistency of results.

Summary of findings 3. Behavioural activation compared with humanistic therapy for depression in adults

Behavioural activation compared with humanistic therapy for depression in adults

Patient or population: depression in adults
Setting: university and community-based in the USA
Intervention: behavioural activation
Comparison: humanistic therapy

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with humanistic therapy	Risk with behavioural activation				
treatment efficacy up to 6 months (8-10 weeks)	Study population		RR 1.84 (1.15 to 2.95)	46 (2 RCTs)	⊕⊕⊕⊕ LOW ¹	Number needed to treat to achieve one beneficial outcome is 2.5.
	48 per 100	88 per 100 (55 to 100)				
treatment acceptability up to 6 months (2-10 weeks)	Study population		RR 1.06 (0.20 to 5.55)	96 (2 RCTs)	⊕⊕⊕⊕ VERY LOW ² 3	
	25 per 100	26 per 100 (5 to 100)				
depression symptoms (continuous) up to 6 months (2-10 weeks)	mean score between 10 and 15	MD 3.75 lower (6.72 lower to 0.78 lower)		93 (3 RCTs)	⊕⊕⊕⊕ MODERATE 4	Measured with BDI.
quality of life (continuous) up to 6 months (2 weeks)	mean score 1.2	MD 0.80 higher (0.12 lower to 1.72 higher)		50 (1 RCT)	⊕⊕⊕⊕ LOW ⁵	Measured with Quality of Life Inventory.
anxiety symptoms (continuous) up to 6 months (2 weeks)	mean score 9.7	MD 1.30 lower (6.10 lower to 3.50 higher)		50 (1 RCT)	⊕⊕⊕⊕ LOW ⁵	Measured with BAI.

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

- 1 Both small studies with several domains high risk of bias or unclear. Risk of attrition bias in both studies and reporting bias in one study may affect treatment efficacy outcome. Downgraded one level for high risk of bias and one level for imprecision.
- 2 Many risk of bias domains unclear in one of the studies. Risk of attrition and reporting bias in the other study. Downgraded one level for high risk of bias and one level for imprecision.
- 3 One study is religious behavioural activation rather than the conventional behavioural activation intervention. Downgraded one level for indirectness.
- 4 Two out of three studies mostly high and unclear risk of bias domains. Downgraded one level for high risk of bias.
- 5 One small study with most domains of the risk of bias tool unclear due to lack of information. Downgraded one level for high risk of bias and one level for imprecision. Because only one study was included, this outcome could not be assessed for consistency of results.

Summary of findings 4. Behavioural activation compared with psychodynamic for depression in adults

Behavioural activation compared with psychodynamic for depression in adults

Patient or population: depression in adults

Setting: Research centre

Intervention: behavioural activation

Comparison: psychodynamic

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with psychodynamic	Risk with behavioural activation				
treatment efficacy up to 6 months (12 weeks)	Study population		RR 1.21 (0.74 to 1.99)	60 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{1 2}	
	47 per 100	56 per 100 (35 to 93)				
depression symptoms (continuous) up to 6 months (12 weeks)	mean score 10	MD 1.10 lower (4.35 lower to 2.15 higher)	-	60 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{1 2}	Measured with HRSD
social adjustment and functioning (continuous) up to 6 months (12 weeks)	mean score 69	MD 2.10 higher (4.92 lower to 9.12 higher)	-	60 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{1 2}	Measured with Global Assessment Scale and Social Adjustment

Scale (measures combined)

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

¹ Four 'Risk of bias' domains unclear due to lack of information. Patients excluded from study for lack of adherence and because of dissatisfaction with treatment. This may influence outcomes treatment efficacy, depression symptoms, and social adjustment and functioning. All other 'Risk of bias' domains high or unclear risk. Downgraded two levels for high risk of bias.

² Only one study with small sample size. Downgraded one level for imprecision. Because only one study was included, this outcome could not be assessed for consistency of results.

Summary of findings 5. Behavioural activation compared with interpersonal, cognitive analytic, integrative for depression in adults

Behavioural activation compared with interpersonal, cognitive analytic, integrative for depression in adults

Patient or population: depression in adults

Setting: university and community-based in the USA

Intervention: behavioural activation

Comparison: interpersonal, cognitive analytic, integrative

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N° of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with interpersonal, cognitive analytic, integrative	Risk with behavioural activation				
treatment acceptability up to 6 months (4-12 weeks)	Study population		RR 0.84 (0.32 to 2.20)	123 (4 RCTs)	⊕○○○ VERY LOW 1	
	16 per 100	14 per 100 (5 to 36)				
depression symptoms (continuous) up to 6 months (4-12 weeks)	see comment	SMD 0.16 lower (0.59 lower to 0.28 higher)		103 (4 RCTs)	⊕○○○ VERY LOW 1	Measured with BDI, Zung rating scale, and HRSD. SMD 0.16 represents a difference between

					groups of 1.75 points on the BDI and 0.88 points on the HRSD favouring BA.
social adjustment and functioning (continuous) up to 6 months (12 weeks)	mean score 79	MD 3.92 lower (16.78 lower to 8.93 higher)	39 (1 RCT)	⊕⊕⊕⊕ VERY LOW 2	Measured with Global Assessment Scale.
anxiety symptoms (continuous) up to 6 months (4 weeks)	mean score 48	MD 0.39 lower (11.78 lower to 11.00 higher)	15 (1 RCT)	⊕⊕⊕⊕ VERY LOW 2	Measured with the anxiety scale of the Multiple Affect Adjective Check List.
adverse events (12 weeks)	2 suicide attempts and 1 case of suicidal thoughts in comparator arm; no adverse events in behavioural activation arm.		24 (1 RCT)	⊕⊕⊕⊕ LOW ³	Any adverse event summarised narratively.

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

¹ Only 2 low risk of bias domains across four studies. High risk of bias for randomisation and allocation concealment in 2/4 studies. Downgraded two levels for high risk of bias. Downgraded one level for imprecision because of wide confidence intervals.

² One small study with high risk of bias across multiple domains. Downgraded two levels for high risk of bias and one level for imprecision. Because only one study was included, this outcome could not be assessed for consistency of results.

³ One very small study, so adverse events reported may not apply to a wider population receiving treatment. High risk of bias included lack of blinding and potential attrition bias and selective reporting may influence reporting of adverse events. Downgraded one level for imprecision and one level for high risk of bias.

Summary of findings 6. Behavioural activation compared with waiting list for depression in adults

Behavioural activation compared with waiting list for depression in adults

Patient or population: depression in adults

Setting: range of settings at home (online), in university, community, and healthcare in a range of countries

Intervention: behavioural activation

Comparison: waiting list

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N° of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with waiting list	Risk with behavioural activation				
treatment efficacy up to 6 months (4 weeks)	Study population		RR 2.14 (0.90 to 5.09)	26 (1 RCT)	⊕⊕⊕⊕ LOW ¹	
	33 per 100	71 per 100 (30 to 100)				
treatment acceptability up to 6 months (1 to 10 weeks)	Study population		RR 1.17 (0.70 to 1.93)	359 (8 RCTs)	⊕⊕⊕⊕ MODER- ATE ²	Three studies could not be included in meta-analyses; no dropouts.
	12 per 100	14 per 100 (8 to 23)				
depression symptoms (continuous) up to 6 months (1 to 10 weeks)	see comment	SMD 1.04 lower (1.44 lower to 0.63 lower)		619 (12 RCTs)	⊕⊕⊕⊕ LOW ^{3 4}	Measured with BDI, HRSD, MADRS, PHQ-9, HS-CL-25. SMD 1.04 represents a difference between groups of 11.37 points on the BDI and 5.75 points on the HRSD favouring BA.
quality of life (continuous) up to 6 months (8 weeks)	mean score 0.75	MD 0.03 higher (0.70 lower to 0.76 higher)		80 (1 RCT)	⊕⊕⊕⊕ LOW ⁵	Measured with quality of life inventory.
anxiety symptoms (continuous) up to 6 months (4-12 weeks)	see comment	SMD 0.91 lower (1.59 lower to 0.23 lower)		424 (5 RCTs)	⊕⊕⊕⊕ LOW ^{6 7}	Measured with BAI, Trait Anxiety Scale, and GAD-7. SMD 0.91 represents a large effect.
adverse events (6 weeks)	see comment			0 (1 RCT)	see comment	Any adverse event summarised narratively. No adverse events.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

¹ One very small study with high risk of bias for five domains including allocation concealment and selective reporting. Downgraded one level for imprecision and one level for high risk of bias.

- 2 Most studies high or unclear risk of bias with regard to blinding of participants and outcome assessors, selective reporting, and various other risks of bias: no baseline characteristics reported, potential conflicts of interest. Downgraded one level for high risk of bias.
- 3 Only domain mostly scoring low risk of bias across studies (7/12) is random sequence generation. Blinding of outcome assessors unclear or high risk of bias in all but two studies. Downgraded one level for high risk of bias.
- 4 Larger effects reported by smaller studies; smaller studies favouring waiting list are absent. Downgraded one level for risk of publication bias.
- 5 One study with high risk of bias for three domains including potential conflict of interest. Downgraded one level for high risk of bias and one level for imprecision. Because only one study was included, this outcome could not be assessed for consistency of results.
- 6 All studies majority of domains unclear or high risk of bias. Some problems with randomisation and allocation concealment. Downgraded one level for high risk of bias.
- 7 Two studies reporting large effect in favour of behavioural activation while three find no difference between study arms. Downgraded one level for inconsistency.

Summary of findings 7. Behavioural activation compared with placebo for depression in adults

Behavioural activation compared with placebo for depression in adults

Patient or population: depression in adults
Setting: university and community-based in the USA
Intervention: behavioural activation
Comparison: placebo

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N° of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with placebo	Risk with behavioural activation				
treatment acceptability up to 6 months (16 weeks)	Study population		RR 0.72 (0.31, 1.67)	96 (1 RCT)	⊕⊕⊕⊕ LOW ¹	
	23 per 100	16 per 100 (7 to 38)				
depression symptoms (continuous) up to 6 months (2 weeks)	see comment	SMD 0.18 lower (0.57 lower to 0.20 higher)		108 (2 RCTs)	⊕⊕⊕⊕ LOW ^{2 3}	Measured with HRSD and Depression Adjective Checklist. SMD 0.18 represents a difference between groups of 1.97 points on the BDI and 1.00 point on the HRSD favouring BA.
adverse events (16 weeks)	Various physical side effects from placebo.			96 (1 RCT)	⊕⊕⊕⊕ LOW ⁴	Any adverse event summarised narratively.

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

1 Incomplete outcome data influences reporting of dropouts; downgraded one level for high risk of bias. Downgraded one level for imprecision due to large confidence intervals resulting from relatively few dropouts. Because only one study was included, this outcome could not be assessed for consistency of results.

2 One study with poor reporting, which may indicate high risk of bias. Downgraded one level for high risk of bias.

3 Two small studies; one with large confidence intervals. Downgraded one level for imprecision.

4 Incomplete outcome data and potential conflict of interest may have influenced reporting of adverse events. Downgraded one level for high risk of bias. Downgraded one level for imprecision as 96 participants would not be sufficient to measure less frequently occurring side effects.

Summary of findings 8. Behavioural activation compared with medication for depression in adults

Behavioural activation compared with medication for depression in adults

Patient or population: depression in adults

Setting: recruitment in community and through referral in the USA and Iran.

Intervention: behavioural activation

Comparison: medication

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with medication	Risk with behavioural activation				
	Study population		RR 1.77 (1.14 to 2.76)	141 (1 RCT)	⊕⊕⊕⊖ MODERATE ¹	
treatment efficacy up to 6 months (16 weeks)	28 per 100	49 per 100 (31 to 76)				
treatment acceptability up to 6 months (12-16 weeks)	34 per 100	18 per 100 (9 to 39)	RR 0.52 (0.23 to 1.16)	243 (2 RCTs)	⊕⊕⊕⊖ MODERATE ²	
depression symptoms (continuous) up to 6 months (12-16 weeks)	mean change in score between -8 and -14	mean difference 1.42 lower (4.80 lower to 1.96 higher)		180 (2 RCTs)	⊕⊕⊕⊖ LOW ^{2,3}	Measured with HRSD.
adverse events (16 weeks)	Various physical side effects from antidepressant medication. One suicide in antidepressant arm.			143 (1 RCT)	⊕⊕⊕⊖ MODERATE ⁴	Any adverse event summarised

narrative-ly.

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

- 1 The most concerning issue relating to risk of bias was the large number of dropouts from the medication study arm in particular. Downgraded one level for high risk of bias. Because only one study was included, this outcome could not be assessed for consistency of results.
- 2 Incomplete outcome data for both studies. No blinding of participants. Potential conflict of interest for one study. Downgraded one level for high risk of bias.
- 3 Downgraded one level for imprecision; large variation in confidence interval, crossing zero.
- 4 Incomplete outcome data and potential conflict of interest may have influenced reporting of adverse events. Downgraded one level for high risk of bias.

Summary of findings 9. Behavioural activation compared with no treatment for depression in adults

Behavioural activation compared with no treatment for depression in adults

Patient or population: depression in adults

Setting: universities in the USA and Japan

Intervention: behavioural activation

Comparison: no treatment

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with no treatment	Risk with behavioural activation				
treatment acceptability up to 6 months (2-5 weeks)	Study population		RR 0.97 (0.45 to 2.09)	187 (3 RCTs)	⊕⊕⊕⊖ MODERATE ¹	
	9 per 100	9 per 100 (4 to 19)				
depression symptoms (continuous) up to 6 months (2-5 weeks)	see comment	MD 6.10 lower (7.87 lower to 4.33 lower)		187 (3 RCTs)	⊕⊕⊕⊖ MODERATE ²	Measured with BDI

quality of life (continuous) up to 6 months (5 weeks)	mean score 0.9	MD 0.07 higher (0.03 higher to 0.11 higher)	118 (1 RCT)	⊕⊕⊕⊕ HIGH ³	Measured with EQ-5D
anxiety symptoms (continuous) up to 6 months (2 weeks)	mean score 11	MD 5.50 lower (10.01 lower to 0.99 lower)	30 (1 RCT)	⊕⊕⊕⊖ LOW ⁴	Measured with BAI

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

¹ High risk of bias for blinding of participants (3/3), conflict of interest (1/3), and no baseline characteristics reported (1/3). Downgraded one level for high risk of bias.

² One study mostly low risk of bias, one study mostly unclear risk of bias. Downgraded one level for high risk of bias.

³ Because only one study was included, this outcome could not be assessed for consistency of results.

⁴ One small study with four domains of bias unclear and two high risk of bias; performance bias and potential conflict of interest. Downgraded one level for high risk of bias and one level for imprecision. Because only one study was included, this outcome could not be assessed for consistency of results.

Summary of findings 10. Behavioural activation compared with treatment as usual for depression in adults

Behavioural activation compared with treatment as usual for depression in adults

Patient or population: depression in adults

Setting: primary care, local health centres, online, and nursing homes, in England, the USA, China, India, Indonesia, and Spain.

Intervention: behavioural activation

Comparison: treatment as usual

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with treatment as usual	Risk with behavioural activation				
treatment efficacy up to 6 months (5-12 weeks)	Study population		RR 1.40 (1.10 to 1.79)	1533 (7 RCTs)	⊕⊕⊕⊖ MODER- ATE ¹	Number needed to treat to achieve one beneficial outcome is 4.5

	53 per 100	75 per 100 (59 to 96)				
treatment acceptability up to 6 months (5-12 weeks)	Study population		RR 1.64 (0.81 to 3.31)	2518 (14 RCTs)	⊕⊕⊕⊕ MODER- ATE ²	
	6 per 100	11 per 100 (5 to 24)				
depression symptoms (continuous) up to 6 months (5-12 weeks)	see comment	SMD 0.78 lower (1.05 lower to 0.51 lower)		2208 (15 RCTs)	⊕⊕⊕⊕ LOW ^{2 3}	Measured with PHQ-9, CES-D, BDI, HRSD, and GDS. SMD 0.78 represents a difference between groups of 8.53 points on the BDI and 4.31 points on the HRSD.
quality of life (continuous) up to 6 months (8-12 weeks)	see comment	SMD 0.97 higher (0.38 higher to 1.57 higher)		1299 (6 RCTs)	⊕⊕⊕⊕ VERY LOW ^{2 4}	Measured with SF-12 physical component and WHOQOL. SMD 0.97 represents a large effect.
social adjustment and functioning (continuous) up to 6 months (12 weeks)	see comment	SMD 1.27 lower (1.74 lower to 0.84 lower)		88 (2 RCTs)	⊕⊕⊕⊕ LOW ⁵	Measured with Work and Social Adjustment Scale (WSAS) and Sheehan Disability Scale. SMD 1.27 represents a large effect.
anxiety symptoms (continuous) up to 6 months (8-12 weeks)	see comment	SMD 0.33 lower (0.45 lower to 0.21 lower)		1063 (4 RCTs)	⊕⊕⊕⊕ MODER- ATE ⁶	Measured with GAD-7 and BAI. SMD 0.33 represents a small effect.
adverse events (8-10 weeks)	behavioural activation arm: 103 events. treatment as usual arm: 107 events.			1471 (3 RCTs)	⊕⊕⊕⊕ MODER- ATE ⁷	Any adverse event summarised narratively

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

¹ Mostly low risk of bias for sequence generation, allocation concealment, and selective reporting. Mostly high risk of bias only for blinding of participants and personnel. Some evidence of incomplete outcome data. Downgraded one level for high risk of bias.

- 2 Several studies with incomplete outcome data and potential conflict of interest. Randomisation and allocation concealment largely low risk of bias. Downgraded one level for high risk of bias.
- 3 Pooled estimate is influenced by large effect in one small study. Downgraded one level for inconsistency.
- 4 Pooled estimate is driven by one study with large effect favouring behavioural activation. Wide confidence interval. Downgraded one level for inconsistency and one level for imprecision.
- 5 One small study with three high risk of bias domains including incomplete outcome data. Other study unclear risk of selection bias, and high risk for attrition bias, reporting bias, and conflict of interest. Downgraded two levels for high risk of bias. Although studies are small, estimates are consistent.
- 6 No blinding of participants/personnel and outcome assessors in 3/4 studies. Evidence of attrition bias (2/4), performance bias (3/4) and potential conflict of interest (3/4). No evidence of selection bias in 2/4 studies, other two studies some information missing (unclear). Downgraded one level for high risk of bias.
- 7 One out of three studies with selective reporting, attrition bias, and potential conflict of interest. One study potential conflict of interest. Downgraded one level for high risk of bias.

BACKGROUND

Description of the condition

Depression, when diagnosed in a clinical setting, most often refers to a major depressive disorder. It is characterised by a period of at least two weeks of depressed mood, or a persistent loss of interest or pleasure in activities which were previously considered enjoyable, or both (APA 2013). A range of symptoms may accompany these key features of depression, including weight loss or weight gain, insomnia or hypersomnia (excessive sleeping and/or sleepiness), psychomotor agitation (mental and physical restlessness) or retardation (mental and physical slowness), fatigue, loss of energy, feelings of excessive guilt and worthlessness, diminished concentration, and recurrent thoughts of death (APA 2013).

Depression is the fifth global cause of disease burden in terms of years lived with a disability (YLD), and was ranked in the top 10 of YLD in 191 out of 195 countries worldwide (Vos 2017). In 2014, 7.1% of the population living in the 28 countries of the European Union was estimated to report depression, with higher rates reported by women and by Europeans living in cities. Prevalence rates of self-reported depression varied from 4% in 15- to 24-year-olds to 10% in those aged 75 and over (Eurostat 2014).

Depression has a long-lasting impact on patients, their families, and wider society. It is associated with marked personal and societal economic losses due to healthcare costs for mental and comorbid physical healthcare, reduced productivity in the workplace, and years of life lost (Greenberg 2015). A meta-analysis of data from 35 countries found a 52% increased risk of mortality, after adjusting for publication bias (Cuijpers 2014).

Description of the intervention

Clinical guidelines recommend pharmacological and psychological interventions, alone or in combination, in the treatment of mild to moderate depression in adults (NICE 2009).

The prescribing of antidepressants has increased dramatically in many Western countries over the past 20 years, mainly with the advent of selective serotonin reuptake inhibitors (SSRIs) and other agents such as serotonin–noradrenaline reuptake inhibitors (SNRIs) and noradrenalinergic and specific serotonergic antidepressants (NaSSAs) (Ilyas 2012). Antidepressants remain the mainstay of treatment for moderate to severe depression in healthcare settings, whereas for subthreshold depressive symptoms (not meeting the threshold for clinical diagnosis) or mild depression, low-intensity psychosocial therapy and psychological therapies are recommended (NICE 2009).

Whilst antidepressants are proven to be effective for the acute treatment of depression for some people (Arroll 2009; Magni 2013; Cipriani 2009a; Cipriani 2009b; Cipriani 2010; Guaiana 2007), adherence rates remain very low (Hunot 2007; van Geffen 2009), in part because of patients' concerns about side effects and dependency (Hunot 2007; Fawzi 2012). Not adhering to antidepressant medication is related to relapse and/or recurrence, hospital visits and hospitalisation, worsening of depression symptoms, and a lower likelihood of recovery (Ho 2016). Furthermore, surveys consistently demonstrate patients' preference for psychological therapies over antidepressant treatment (Churchill 2000; McHugh 2013; Riedel-Heller 2005).

Therefore, psychological therapies can be an important alternative intervention or an additional treatment for depressive disorders.

A diverse range of psychological therapies is available for the treatment of depression. Psychological therapies may be broadly categorised into four separate philosophical and theoretical schools, comprising psychoanalytic/dynamic (Freud 1949; Jung 1963; Klein 1960), behavioural (Skinner 1953; Watson 1924; Wolpe 1958), humanistic (Maslow 1943; May 1961; Rogers 1951), and cognitive approaches (Beck 1979; Lazarus 1971). Each of these four schools incorporates several different and overlapping psychotherapeutic approaches. Some psychotherapeutic approaches, such as cognitive-analytic therapy (CAT) (Ryle 1990), explicitly integrate components from several theoretical schools. Other approaches, such as interpersonal therapy (IPT) for depression (Klerman 1984), have been developed to address characteristics considered specific to the disorder of interest.

Behavioural therapy is a term that has been used to describe a broad range of therapies using principles of operant conditioning, in which behaviours are modified through learning. It became a dominant force in the 1950s, drawing on the work of Skinner 1953, Wolpe 1958, and Eysenck 1960. Behavioural therapy emphasises the role of environmental cues in influencing the adoption and maintenance of behaviours (Nelson-Jones 1990) and, in contrast with psychoanalysis, was developed though experimentally- rather than theoretically-derived principles (Rachman 1997).

With the advent of cognitive therapy in the 1970s, behavioural therapy approaches based purely on operant (learning from the consequences of behaviours) and respondent (responsive behaviour as a result of a stimulus) principles became regarded as insufficient. However, the interest in the feasibility of behavioural treatments for depression has since been renewed (Dimidjian 2011; Ekers 2014; Hopko 2003a). The term behavioural activation appears to have been used for the first time in 1990, as a description of the behavioural components in cognitive therapy (Hollon 1990). Jacobson showed that the behavioural component of cognitive-behavioural therapy (CBT) was as effective as the full package of CBT, and developed a new and more comprehensive model of behavioural activation that would be amenable to dissemination (Jacobson 1996; Jacobson 2001). It would appear that 'behavioural activation' has now become the commonly adopted description, and we will use this term in the rest of this review to refer to the intervention (Martell 2010).

How the intervention might work

Skinner proposed that depression was associated with an interruption in established sequences of healthy behaviour that were previously positively reinforced by the social environment and were based on operant conditioning principles (in which behaviour patterns are learnt, rather than instinctive) (Skinner 1953). In subsequent expansions of this model, reduction of positively reinforced healthy behaviours has also been attributed to a decrease in the number and range of reinforcing stimuli available to the individual, lack of skill in obtaining positive reinforcement (Lewinsohn 1974), increased frequency of punishment, or a combination of two, or all of these (Lewinsohn 1984).

Behavioural activation can be defined as a brief psychotherapeutic approach that seeks to change the way a person interacts with their environment, aiming to:

1. increase access to positive reinforcers of healthy behaviours;
2. reduce avoidance behaviours that limit access to positive reinforcement;
3. understand and address barriers to activation.

Treatments are collaborative and focused on the present. Many differing techniques are incorporated into treatment; however all use self-monitoring of a mood-environment link and scheduling of new or adaptive behaviours to meet targets (Kanter 2010). In doing so, the therapy helps people to make contact with potentially reinforcing experiences (Jacobson 2001).

The original model of behavioural activation, developed by Jacobson, was defined primarily by the elimination of cognitive intervention elements (Dimidjian 2006). On the basis of its original design, behavioural activation model components commonly include developing a shared treatment rationale; promoting access to meaningful events, activities, and consequences; activity scheduling; developing social skills; and self-monitoring links between behaviour and mood. In some cases the use of some form of problem-solving or functional analysis are added to understand, consider and overcome any potential barriers to the scheduling of activities. In contrast to CBT, no attempt is made to directly change cognitions. However, behavioural activation commonly involves an exploration of how cognitive processes, such as rumination, can limit access to behaviours and events which give positive reinforcement, for example in stopping people with depression from meeting up with friends or participating in physical exercise.

Why it is important to do this review

According to the clinical guidelines produced by the National Institute for Health and Clinical Excellence (NICE), behavioural activation is one of the recommended treatment options for subthreshold depressive symptoms, mild to moderate depression, and severe depression, along with CBT and IPT. However, the guidelines acknowledge that evidence for behavioural activation is currently less robust than for the other recommended therapies (NICE 2009).

The effects of behavioural therapies for depression versus other psychological therapies were previously examined in a Cochrane Review, which reported that low- to moderate-certainty evidence from 25 trials suggested that behavioural therapies and other psychological therapies were equally effective (Shinohara 2013). This Cochrane Review did not cover trials comparing behavioural therapy to treatment as usual, nor did it include the emerging literature on new treatment models of behavioural activation.

Two Cochrane Reviews of 'third-wave' cognitive and behavioural therapies, one comparing the intervention to treatment as usual and one comparing to other therapies, identified three trials of behavioural activation for depression (Churchill 2013; Hunot 2013). The small number of trials together with the low certainty of the evidence limited the ability to draw any conclusions on effectiveness. Another systematic review of behavioural activation found evidence from 26 trials, most of them low quality, indicating that behavioural activation is more effective than a wide range of control treatments, including medication (Ekers 2014).

There is no Cochrane Review that includes all behavioural activation therapies currently used for the treatment of depression. Behavioural activation is increasingly receiving attention as a potentially cost-effective intervention for depression, which may be delivered and implemented in settings with low-resources or where the demand is greater than the availability of mental health practitioners to deliver more complex treatments (Richards 2016). Given this resurgence of interest, a comprehensive review of the comparative effectiveness and acceptability of behavioural activation interventions for depression is timely to inform and update clinical practice and future clinical guideline development.

OBJECTIVES

1. To examine the effects of behavioural activation compared with all other psychological therapies for depression in adults.
2. To examine the effects of behavioural activation compared with all medication for depression in adults.
3. To examine the effects of behavioural activation compared with treatment as usual/ waiting list/placebo/no treatment control conditions for depression in adults.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) were eligible for inclusion in this review. We included trials employing a cross-over design (whilst we acknowledge that this design is rarely used in psychological therapy trials), but we only used data from the first active treatment phase. Cluster-RCTs and pilot RCTs were also eligible for inclusion.

Quasi-randomised controlled trials, in which treatment assignment is decided through methods such as alternate days of the week, were not eligible for inclusion. We included trials that replaced dropouts without randomisation only when the proportion of replaced participants was less than 20%.

Types of participants

Participant characteristics

Randomised controlled trials of adults aged 18 years and over of any sex or gender were eligible for inclusion. We excluded trials that involved participants under 18 years of age.

Setting

Trials could be conducted in a primary, secondary or community setting. Trials conducted in a hospital clinic were included, but we excluded trials involving inpatients. We included trials that focused on specific populations - nurses, care givers, depressed participants at a specific workplace - if all participants met criteria for depression. Nursing homes in this review were considered outpatient settings, as they are places of residence.

Diagnosis

We included all trials that focused on acute phase treatment of clinically diagnosed depression or subthreshold depression.

1. We included trials adopting any standardised diagnostic criteria to define participants suffering from an acute phase

unipolar depressive disorder. Accepted diagnostic criteria include Feighner criteria, Research Diagnostic Criteria and criteria of the *Diagnostic and Statistical Manual of Mental Disorders, Third Edition* ((DSM-III); [APA 1980](#)), *DSM-III-Revised* ((R); [APA 1987](#)), *DSM-Fourth Edition* ((IV); [APA 1994](#)), *DSM-IV-Text Revision* ((TR); [APA 2000](#)), *DSM-5* ([APA 2013](#)), and *International Classification of Diseases, Tenth Edition* ((ICD-10); [WHO 1992](#)).

2. To fully represent the broad spectrum of severity of depressive symptoms encountered by healthcare professionals in primary care, we included trials that used non-operationalised diagnostic criteria (*ICD-Ninth Edition* ((ICD-9); [WHO 1978](#)) or a validated clinician or self-report depression symptom questionnaire, such as the Hamilton Rating Scale for Depression (HRSD) ([Hamilton 1960](#)), or the Beck Depression Inventory (BDI) ([Beck 1961](#)), to identify depression cases as based on a recognised threshold.
3. Subthreshold depression, also called subsyndromal, subclinical, or minor depression, in which people experience symptoms of depression but do not meet the threshold for diagnosis. We accepted any trials that established subthreshold depression based on the above diagnostic criteria or validated depression symptom questionnaires.

When possible, we used accepted strategies for classifying mild, moderate and severe depression on the basis of criteria used in the evidence syntheses underpinning the [NICE 2009](#) guidelines for depression. [NICE 2009](#) defines severity of depression in accordance with DSM-IV ([APA 1994](#)) as follows: mild depression: few, if any, symptoms in excess of the five required to make the diagnosis, with symptoms resulting in only minor functional impairment. Moderate depression: symptoms of functional impairment between 'mild' and 'severe'. Severe depression: most symptoms, and marked interference of the symptoms with functioning. Can occur with or without psychotic symptoms.

We excluded trials focusing on chronic depression or treatment-resistant depression (i.e. trials that list these conditions as inclusion criteria). We also excluded trials in which participants were receiving treatment to prevent relapse after a depressive episode (i.e. where participants did not have symptoms of depression at trial entry). Postnatal depression is considered a separate condition with contributing factors distinct from major depressive disorder, and we therefore excluded it.

If participants met the criteria for depression or subthreshold depression as stated above, we included trials with people described as 'at risk of suicide' or with dysthymia (persistent depressive disorder), or other affective disorders such as panic disorder, but otherwise we excluded these trials.

We did not include subgroup analyses of people with depression selected from people with mixed diagnoses because such trials would be susceptible to publication bias (the trial authors reported such subgroup trials because the results were 'interesting'). In other words, we included these trials only if the inclusion criteria for the entire trial satisfied our eligibility criteria.

Comorbidity

Trials involving participants with comorbid physical or common mental disorders were eligible for inclusion as long as the comorbidity was not the focus of the trial. For example, we excluded trials that focused on depression among individuals

with Parkinson's disease or after acute myocardial infarction but accepted trials that may have included some participants with Parkinson's disease or with acute myocardial infarction. This decision was made because the intervention and study design may in such cases be adapted for these specific populations. A separate Cochrane Review of behavioural activation for the treatment of depression in people with physical comorbidities is to be published in 2020 ([Uphoff 2019b](#)).

Types of interventions

Experimental interventions

A previously published Cochrane Review for behavioural therapy in depression provided a framework for psychological therapies, including behavioural therapy ([Shinohara 2013](#)). Given recent developments in literature and practice regarding behavioural activation approaches, we consider behavioural activation as part of behavioural therapies, rather than being classified as a 'third-wave' therapy. In line with the behavioural therapy review, we created the comparator categories of psychological therapies on the basis of both treatment approach (e.g. their theoretical background and the manuals they used) and content (what therapeutic techniques they mainly used or what was their area of focus). See also [Appendix 1](#).

Behavioural activation

We included trials evaluating treatment approaches for depression that are either explicitly called 'behavioural activation', or treatments that are described using the main elements of behavioural activation for depression, such as pleasant events and activities, activity scheduling, positive reinforcement from the environment, positive interaction or re-engagement with the environment. This means that we included behavioural therapies in the treatment group as long as they were described using the main elements of behavioural activation. Experimental interventions that contained some elements of behavioural therapy, such as CBT or problem-solving therapy, were not eligible for inclusion.

Format of psychological therapies

Therapies delivered by therapists of all levels were eligible for inclusion. This includes: 1) psychologists or psychotherapists accredited by a professional body for psychology or psychotherapy, who completed formal training to deliver psychological therapies, 2) those who received substantial training (more than a year) but are not yet qualified, and 3) lay counsellors and non-specialist therapists who have been specifically trained to deliver treatment according to a behavioural activation protocol.

We included computerised and self-help interventions if they were facilitated. This means at least some element of interaction with a therapist was required.

Psychological therapies conducted on an individual or group basis were eligible for inclusion.

The number of sessions was not limited, and we accepted psychological therapies delivered in only one session.

Comparators

All comparators were accepted as long as they are not a type of behavioural activation. We categorised psychological therapies as behavioural therapy, social skills training/assertiveness

training, relaxation therapy, CBT, third-wave CBT, psychodynamic, humanistic and integrative approaches.

Behavioural therapy

We planned to include any behavioural therapies that did not contain the main elements of behavioural activation as comparators.

Social skills training/assertiveness training

The social skills training model (SST) proposes that depressed people may have difficulty initiating, maintaining and ending conversations (Jackson 1985). Because of these deficits, the individual is unable to elicit mutually reinforcing behaviour from other people in his or her environment. SST subsumes assertion and conversational skills, together with more specialised subskills such as dating and job interview skills. Different social contexts may be targeted, for example interaction with friends, family members, people at school, or at work, and interventions such as instruction, modelling, rehearsal, feedback and reinforcement are used to enable the development of new responses (Jackson 1985). As assertiveness training represents a key component of SST, we included it in the SST category.

Relaxation therapy

Relaxation training is a behavioural stress management technique that induces a relaxation response, helping to switch off the fight/flight response and causing levels of stress hormones in the bloodstream to fall. A variety of techniques may be used to induce relaxation, the most common of which is Jacobson's progressive muscle relaxation training (Bernstein 1973).

Cognitive-behavioural therapies (CBTs)

In CBT, therapists aim to work together with people receiving treatment to understand the link between thoughts, feelings and behaviours, and to identify and modify unhelpful thinking patterns and underlying assumptions about the self, others and the world (Beck 1979). Cognitive change methods for depression are targeted at the automatic thought level in the first instance and include thought catching, reality testing and task assigning as well as generating alternative strategies (Williams 1997). Behavioural experiments are then used to re-evaluate underlying beliefs and assumptions (Bennett-Levy 2004). We categorised these therapies into six subcategories: cognitive therapy, rational emotive behaviour therapy, problem-solving therapy, self-control therapy, a coping with depression course and other CBTs.

'Third-wave' cognitive and behavioural therapies (third-wave CBTs)

Third-wave CBT approaches have been developed more recently and now exist alongside established therapies such as CBT. Rather than focusing on the contents of thoughts, these therapies tend to focus on the process and functions of thoughts and an individual's relationship with thoughts and emotions. This may include suppressing or avoidance of emotions, thoughts, and bodily sensations (Hofmann 2008). Third-wave approaches use strategies relating to mindfulness, emotions, acceptance, relationships, values, goals, and understanding the thinking process, to bring about changes in thinking (Hayes 2007). Drawing from psychodynamic and humanistic principles, third-wave CBT approaches place great emphasis on use of the therapeutic relationship. We categorised these therapies into subcategories: acceptance and commitment therapy, compassionate mind

training, functional analytic psychotherapy, metacognitive therapy, mindfulness-based cognitive therapy, dialectical behaviour therapy and other third-wave CBTs.

Psychodynamic therapies

Grounded in psychoanalytic theory (Freud 1949), psychodynamic therapy (PD) uses the therapeutic relationship to explore and resolve unconscious conflict through transference (projection of feelings on to the therapist) and interpretation, with development of insight and character change (within certain boundaries) as therapeutic goals, and relief of symptoms as an indirect outcome. Brief therapy models have been devised by Malan 1963, Mann 1973 and Strupp 1984. We categorised these therapies into four subcategories: drive/structural model (Freud), relational model (Strupp, Luborsky), integrative analytic model (Mann) and other psychodynamic therapies.

Humanistic therapies

Contemporary models of humanistic therapies differ from one another somewhat in clinical approach, but all focus attention on the therapeutic relationship (Cain 2002), within which therapist 'core conditions' of empathy, genuineness, and unconditional acceptance and support (positive regard) (Rogers 1951), are regarded as cornerstones for facilitating insight and change. We categorised these therapies into seven subcategories: person-centred therapy (Rogerian), gestalt therapy, experiential therapies, transactional analysis, existential therapy, non-directive/supportive therapies, and other humanistic therapies.

Interpersonal, cognitive analytic and other integrative therapies

Integrative therapies are approaches that combine components of different psychological therapy models. Integrative therapy models include interpersonal therapy (IPT) (Klerman 1984), cognitive analytic therapy (CAT; Ryle 1990), and Hobson's conversational model (Hobson 1985), manualised as psychodynamic interpersonal therapy (Shapiro 1990). With its focus on the interpersonal context, IPT was developed to specify what was thought to be a set of helpful procedures commonly used in psychotherapy for depressed outpatients (Weissman 2007), drawing in part from attachment theory (Bowlby 1980), and cognitive-behavioural therapy within a set timeframe (time-limited). CAT, also devised as a time-limited psychotherapy, integrates components from cognitive and psychodynamic approaches. The conversational model integrates psychodynamic, interpersonal and person-centred model components.

Counselling interventions traditionally draw from a wide range of psychological therapy models, including person-centred, psychodynamic and cognitive-behavioural approaches, applied in combination, according to the theoretical orientation of practitioners (Stiles 2008). Therefore, we usually included trials of counselling with integrative therapies. However, if the counselling intervention consists of a single discrete psychological therapy approach, we categorised it as such, even if the intervention is referred to as 'counselling'. If the intervention was manualised, this would inform our classification.

Motivational interviewing and other forms of integrative therapy approaches are also included in this category.

Waiting list

Participants are randomly assigned to the active intervention group or control group, and they will either receive the intervention first or be assigned to a waiting list until all participants in the intervention group have received the intervention. During the course of the trial, people on the waiting list can receive any appropriate medical care.

Attention placebo

We define this as a control condition that is regarded as inactive by both researchers and participants in a trial.

Psychological placebo

We define this as a control condition in a trial that is regarded by researchers as inactive but is regarded by participants as active (also called placebo therapy or sham treatment).

Medication

All medication prescribed with the goal to treat depression, most commonly antidepressants; any dose, route of administration, duration, and frequency.

Medical placebo

All types of medical placebos or 'sugar pills'.

No treatment

Trial participants not receiving any treatment for depression during the course of the trial.

Treatment as usual

Treatment as usual, standard care, or usual care would be any appropriate medical care during the course of the study. This may for example involve monitoring of the person receiving treatment, regular check-ups, no treatment, or any type of treatment. What constitutes treatment as usual will depend on the setting and healthcare system in which the study was conducted. If a study arm fitted clearly in any of the above categories, for example 'no treatment' or a type of psychological therapy, we categorised it as such.

Excluded interventions

We excluded from the review trials of long-term, continuation, or maintenance therapy interventions designed to prevent relapse of depression or to treat chronic depressive disorders. Similarly, we excluded trials of interventions designed to prevent a future episode of depression.

We excluded psychological therapy models based on social constructionist principles (that focus on the ways in which individuals and groups participate in the construction of their perceived social reality), including couples therapy, family therapy, solution-focused therapy (de Shazer 1988), narrative therapy, personal construct therapy, neuro-linguistic programming and brief problem-solving (Watzlavick 1974). These therapies work with patterns and dynamics of relating within and between family, social and cultural systems to create a socially constructed framework of ideas (O'Connell 2007), rather than focusing on an individual's reality. A previously published Cochrane Review on couples therapy for depression has recently been updated (Barbato 2018), and a review of family therapy for depression is to be updated (Henken 2007).

Types of outcome measures

Primary outcomes

1. Treatment efficacy: the number of participants who responded to treatment, as determined by changes in scores for Beck Depression Inventory (BDI; Beck 1961), Hamilton Rating Scale for Depression (HRSD; Hamilton 1960), or Montgomery-Asberg Depression Rating Scale (MADRS; Montgomery 1979), or in scores from any other validated depression scale. Many trials define response as 50% or greater reduction on BDI, HRSD, etc., with some trials defining response using Jacobson's Reliable Change Index; we accepted the trial authors' original definition. If trials reported multiple measures of treatment efficacy, we prioritised remission over clinically significant improvement, and recovery or remission over response.
2. Treatment acceptability: the number of participants who dropped out of the study for any reason after being randomised and allocated to a study arm.

Secondary outcomes

1. Improvement in depression symptoms, based on a continuous outcome of group mean scores at the end of treatment using BDI, HAM-D, MADRS or any other validated depression scale
2. Quality of life, as assessed with the use of validated measures such as Short Form (SF)-36 (Ware 1993), Health of the Nation Outcome Scales (HoNOS; Wing 1994), EuroQol (Brooks 1995), and World Health Organization Quality of Life (WHOQOL; WHOQL 1998).
3. Social adjustment and social functioning, including Global Assessment of Function (GAF) (Luborsky 1962) scores.
4. Improvement in anxiety symptoms, as measured using a validated continuous scale, either assessor-rated, such as the Hamilton Anxiety Scale (HAM-A) (Hamilton 1959), or self-report, including the Trait subscale of the Spielberger State-Trait Anxiety Inventory (STAI-T) (Spielberger 1983), and the Beck Anxiety Inventory (BAI) (Beck 1988).
5. Adverse effects, such as counts of completed suicides, attempted suicides, or worsening of symptoms were summarised in narrative form.

Management of time points

We summarised and categorised post-treatment outcomes and outcomes at each reported follow-up point as follows: short term (up to six months post-treatment), medium term (seven to 12 months post-treatment) and long term (longer than 12 months). If data at multiple time points were available within one of our categories, we used the latest time point.

Search methods for identification of studies

Electronic searches

The Cochrane Common Mental Disorders' Information Specialist conducted searches on 17 January 2020 (and a previous search on 17 January 2019) in the following bibliographic databases using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource. The search strategies were designed to identify RCTs of 'behavioural activation', or the main elements of behavioural activation for depression in participants with clinically diagnosed depression or subthreshold depression.

- Cochrane Common Mental Disorders Trials Register (CCMD-CTR); all available years ([Appendix 2](#)).
- Cochrane Central Register of Controlled Trials (CENTRAL; current issue).
- Ovid MEDLINE (1946 onwards; [Appendix 3](#)).
- Ovid Embase (1980 onwards).
- Ovid PsycINFO (1806 onwards).

We did not apply any restrictions on date, language or publication status to the searches.

We searched international trials registries via the World Health Organization's trials portal ([ICTRP](#)) and [ClinicalTrials.gov](#) to identify unpublished or ongoing trials.

We also searched for any relevant retraction statements and errata in January 2020.

Searching other resources

Grey literature

We searched the following sources of grey literature (primarily for dissertations and theses) on 17 January 2020:

- Open Grey (www.opengrey.eu/);
- ProQuest Dissertations & Theses Global (www.proquest.com/products-services/pqdtglobal.html);
- DART-Europe E-theses Portal (www.dart-europe.eu/);
- ETHOS - the British Libraries e-theses online service (ethos.bl.uk/);
- Open Acces Theses and Dissertations (oatd.org).

Reference lists

We checked the reference lists of all included trials and relevant systematic reviews to identify additional trials missed from the original electronic searches (e.g. unpublished or in-press citations).

Personal communication

We contacted trial authors and subject experts for information on unpublished or ongoing trials, or to request additional trial data.

Data collection and analysis

Selection of studies

Two review authors independently examined each title and abstract obtained through the search strategy (EU, LR, SD, ESo). We then obtained full articles of all trials identified by any one of the review authors and two review authors independently assessed full-texts according to the criteria relating to characteristics of the studies, participants, and interventions (EU, LR, SD, ESo). We discussed reasons for disagreement with a third reviewer (DE, DR, RC), and contacted external experts or trial authors if necessary in order to reach agreement. We recorded reasons for excluding records at this stage. For all included studies, we linked multiple reports from the same study. We presented a PRISMA flow diagram to show the process of study selection ([Moher 2009](#)).

Data extraction and management

Two review authors independently extracted data from each trial (EU, LR, ESa, ESo). These review authors discussed any

disagreement with an additional review author (DE, RC), and, when necessary, contacted the authors of the trials for further information.

We extracted and entered information for the following categories into Covidence data extraction forms: trial design, source of funding, study population, interventions and comparators, outcomes and sample size.

Assessment of risk of bias in included studies

We assessed risk of bias for each included trial using the Cochrane Collaboration's 'Risk of bias' tool ([Higgins 2016](#)), which considers the following domains.

1. Risk of bias arising from the randomisation process, including allocation and randomisation
2. Risk of bias due to deviations from the intended interventions, including blinding of participants and people delivering the interventions
3. Incomplete outcome data
4. Risk of bias in measurement of the outcome, including blinding of outcome assessors
5. Selective outcome reporting
6. Other bias

In the assessment of risk of attrition bias (domain 5), we considered the amount of missing outcome data in each study arm and judged whether these data were likely to be missing at random.

In the 'other bias' domain we considered any other problems with a study that may lead to bias, including the following items specific to psychological therapy trials.

1. Treatment fidelity: was the therapy monitored against a manual or a scale through audiotapes or videotapes?
2. Researcher allegiance/conflict of interest: did the researcher have a vested interest for or against the therapies under examination?
3. Therapist allegiance/conflict of interest: did the therapist have a vested interest for or against the therapies provided?

For cluster-RCTs and cross-over trials, we used the templates specifically designed to assess these types of trials, with the same five domains.

We judged the risk of bias for each domain within and across trials, and categorised this as low, unclear, or high risk of bias.

Two review authors independently assessed the risk of bias in included trials (EU, LR, ESa, ESo) and discussed any disagreements with a third review author (EU, LR, ESa, ESo, RC, DE). Where necessary, we contacted trial authors for further information. We presented all 'Risk of bias' data graphically, and narratively in the text.

Measures of treatment effect

Continuous outcomes

Where trials used the same outcome measure for comparison, we pooled data by calculating the mean difference (MD) and 95% confidence intervals (95% CIs). When trials used different measures to assess the same outcome, we pooled data calculating the

standardised mean difference (SMD) and 95% 95% CIs. We used both endpoint data and change from baseline data, depending on availability. If both were available, we used endpoint data. In accordance with the Cochrane Handbook, endpoint and change from baseline data were combined in one meta-analysis but included in different subgroups (Schünemann 2017a).

An SMD or MD of zero means that the intervention and control groups have equivalent treatment effects. We anticipated that, for most measures, a lower score will indicate greater improvement. For example, a lower score on depression symptom instruments such as the Hamilton Rating Scale for Depression (HRSD), Beck Depression Inventory (BDI) or Patient Health Questionnaire (PHQ-9) indicates an improvement in symptoms. In these cases, an SMD or MD less than zero indicates that the intervention has a greater effect than the control. An SMD or MD greater than zero indicates that the intervention has a smaller effect than the control. Interpretation of the SMD and MD is reversed in cases where a greater continuous score indicates greater improvement.

To facilitate interpretation of results in terms of their clinical relevance, we expressed SMDs for continuous outcomes in terms of units on a commonly used participant-rated outcome (BDI) and a commonly used clinician-rated instrument (HRSD). We calculated these re-expressed estimates according to guidance in the Cochrane Handbook (Schünemann 2017a).

Dichotomous outcomes

We analysed dichotomous outcomes by calculating risk ratios (RRs) and 95% CIs for each comparison in Review Manager 5 (Review Manager 2014).

In addition, we calculated the number needed to benefit (NNTB) with 95% CIs for all dichotomous outcomes to facilitate interpretation; this is the expected number of people who need to receive the intervention rather than the comparator for one additional person to achieve a beneficial outcome (Schünemann 2017a).

Unit of analysis issues

Cluster-randomised trials

We included cluster-randomised trials as long as proper adjustment for the intracluster correlation could be conducted in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Cross-over trials

We included trials employing a cross-over design in the review, but we only used data from the first active treatment phase.

Trials with multiple treatment groups

Multiple-arm trials (those with more than two intervention arms) can pose analytical problems in pair-wise meta-analysis. For trials with more than two eligible arms, we managed data in this review as follows.

Multiple experimental intervention groups versus a single control group

If studies compared multiple eligible experimental interventions with a single control group, we split the control group to enable pair-wise comparisons.

One or more experimental intervention groups versus multiple control groups

1. If studies used multiple 'active' comparator interventions, we combined these comparator groups to compare to the behavioural activation intervention group (objective 1/2).
2. If studies used multiple control groups including treatment as usual/ waiting list/ attention placebo/ psychological placebo, we combined the control groups to compare to the behavioural activation intervention group (objective 3).

Dealing with missing data

We managed missing dichotomous data through intention-to-treat (ITT) analysis, in which we assumed that participants who dropped out after randomisation had a negative outcome. We also conducted best/worse case scenarios for the clinical response outcome, in which we assumed that dropouts in the active treatment group had positive outcomes and those in the control group had negative outcomes (best-case scenario), and that dropouts in the active treatment group had negative outcomes and those in the control group had positive outcomes (worst-case scenario), thus providing boundaries for the observed treatment effect. We gave these best/worst case scenarios greater emphasis in the presentation of results if a large amount of information proved to be missing.

We analysed missing continuous data on an endpoint basis, including only participants with a final assessment, or by using the last observation carried forward (LOCF) to the final assessment, if trial authors reported LOCF data. When standard deviations (SDs) were missing, we attempted to obtain these data by contacting trial authors. When SDs were not available from trial authors, we calculated them from P values, t values, CIs or standard errors (SEs), if these were reported in the articles (Deeks 1997).

If a vast majority of SDs were available and only a minority of SDs were unavailable or unobtainable, we used the method devised by Furukawa and colleagues to impute SDs and calculate percentage responders (da Costa 2012; Furukawa 2005; Furukawa 2006). We planned to interpret these data with caution and take into account the degree of observed heterogeneity. We would also planned to undertake a sensitivity analysis to examine the effect of the decision to use imputed data. When conducting the review however, this method for imputing data was not used.

If additional figures were not available or obtainable and it was not deemed appropriate to use the Furukawa method as described above, we did not include the trial data in the comparison of interest.

Assessment of heterogeneity

We formally tested statistical heterogeneity using the Chi² test, which provides evidence of variation in effect estimates beyond that of chance. Because the Chi² test has low power to assess heterogeneity when a small number of participants or trials are included, we conservatively set the P value at 0.1 (Deeks 2017). We

also quantified heterogeneity using the I^2 statistic, which calculates the percentage of variability due to heterogeneity rather than to chance (Higgins 2003). We considered I^2 statistic values in the range of 50% to 90% to represent substantial statistical heterogeneity and explored these further. However, the importance of the observed I^2 statistic depends on the magnitude and direction of treatment effects and the strength of evidence for heterogeneity. Forest plots generated in Review Manager 5 will provide an estimate of τ^2 , the between-trial variance in a random-effects meta-analysis (Deeks 2017; Review Manager 2014).

Assessment of reporting biases

As far as possible, we minimised the impact of reporting biases by undertaking comprehensive searches of multiple sources (including trials registries), to identify unpublished material and including non-English language publications.

We also tried to identify outcome reporting bias in trials by recording all trial outcomes, planned and reported, and noting where outcomes were missing. If we found evidence of missing outcomes, we attempted to obtain any available data directly from the trial authors.

Where sufficient data were available, we constructed funnel plots to establish the potential influence of reporting biases and small-trial effects (Sterne 2017).

Data synthesis

We conducted a meta-analysis of included trials. Given the potential heterogeneity of behavioural activation approaches for inclusion, together with the likelihood of differing secondary comorbid mental disorders in the population of interest, we used a random-effects model in all analyses.

Subgroup analysis and investigation of heterogeneity

Clinical heterogeneity

We conducted the following subgroup analyses, depending on the availability of sufficient data for each outcome and comparison.

- Participant age: old age in particular can be expected to relate to treatment effect, as older people are more likely to suffer comorbidities. We conducted subgroup analyses with participants younger than 65 years and those aged 65 years or older.
- Level of therapist: one of the often mentioned potential benefits of less complex models of behavioural activation is that therapies can be delivered by a therapist with minimal training, or without a relevant accreditation. We expected that this analysis by level of therapist would also account for potential differences by intervention complexities. We conducted subgroup analyses according to the level of therapist delivering behavioural activation, classified as:
 - accredited/received formal training of several years (specialist); or
 - minimal training/lay counsellor (non-specialist); or
 - specialist in training; received substantial training but not yet an accredited therapist.
- Baseline depression severity: the severity of depression on entry into the trial is expected to have an impact on outcomes. We planned to categorise depression severity as subthreshold

depression, mild, moderate, or severe. As this was not possible in practice, we used the categories of subthreshold/ mild depression and moderate to severe depression instead (see [Differences between protocol and review](#)).

- Length of treatment: we categorised treatment into those delivered in one to three sessions and treatments of longer duration. We anticipated that the length of treatment could influence effectiveness.
- Type of psychological therapy comparison: the type of psychological therapy comparator used is likely to influence the observed effectiveness of the intervention. When possible, comparators were categorised as psychodynamic, behavioural, humanistic, integrative, or cognitive-behavioural.
- Type of control comparison: the type of control comparator used is likely to influence the observed effectiveness of the intervention. When possible, comparators were categorised as waiting list, treatment as usual/usual care, no treatment, attention placebo, or psychological placebo.

Sensitivity analysis

- Trial quality: we excluded low-quality trials in a sensitivity analysis, if we identified a number of higher-quality trials. As a marker of quality, we used the 'allocation concealment' criteria from the 'Risk of bias' assessment.
- Mode of delivery: we excluded therapies delivered through computer-based or electronic guidance without a substantial face-to-face component.
- Subthreshold depression: we planned to exclude trials of subthreshold depression to determine whether our decision to include non-clinical levels of depression had a substantial impact on the results. We did not conduct this analysis, as it would give the same results as subgroup analyses 3 (baseline depression severity).
- Group therapy: we excluded trials of group therapy for behavioural activation as the mode of delivery of psychotherapy could influence effectiveness of the therapy.

In addition to these planned sensitivity analyses, we performed several sensitivity analyses to further explore findings of the review. We removed one small study with a large weight ([Analysis 1.1](#)) and one outlier ([Analysis 10.3](#); [Analysis 10.4](#)). We also conducted fixed-effect rather than random-effects analyses for comparisons with smaller and larger studies and extreme estimates ([Analysis 6.3](#); [Analysis 6.5](#); [Analysis 10.3](#); [Analysis 10.4](#)) (see [Differences between protocol and review](#)).

'Summary of findings' tables

We constructed 'Summary of findings' tables to present the main findings of the review. We reported the outcomes listed below, when available, and presented standardised effect size estimates and 95% CIs. Review author EU performed an assessment of the certainty of the evidence for each outcome using the GRADE approach ([Schünemann 2017a](#)). We used GRADEproGDT to create our 'Summary of findings' tables ([GRADEpro 2015](#)), and followed standard methods as described in the *Cochrane Handbook for Systematic Reviews of Interventions* to prepare the tables ([Schünemann 2017b](#)). Review authors LR and NM checked GRADE assessments and 'Summary of findings' tables and tables were revised to reflect discussion between EU, LR, and NM.

For each of our main comparisons, we included the following outcomes (measured up to 24 months).

1. Treatment efficacy (number of participants responding to treatment).
2. Treatment acceptability (number of participants who dropped out).
3. Improvement in depression outcomes as a continuous score.
4. Quality of life.
5. Social adjustment/ functioning score.
6. Improvement in anxiety symptoms as a continuous score.

The 'Summary of findings' table was created before writing our discussion, abstract, and conclusions, so that the authors could jointly consider the potential impact of the certainty of the evidence for each outcome on the mean treatment effect and our confidence in these findings. Our confidence in the mean treatment effects based on the GRADE assessments was thus reflected in the interpretation of the results, which informed the abstract, lay summary, and discussion sections of the review.

RESULTS

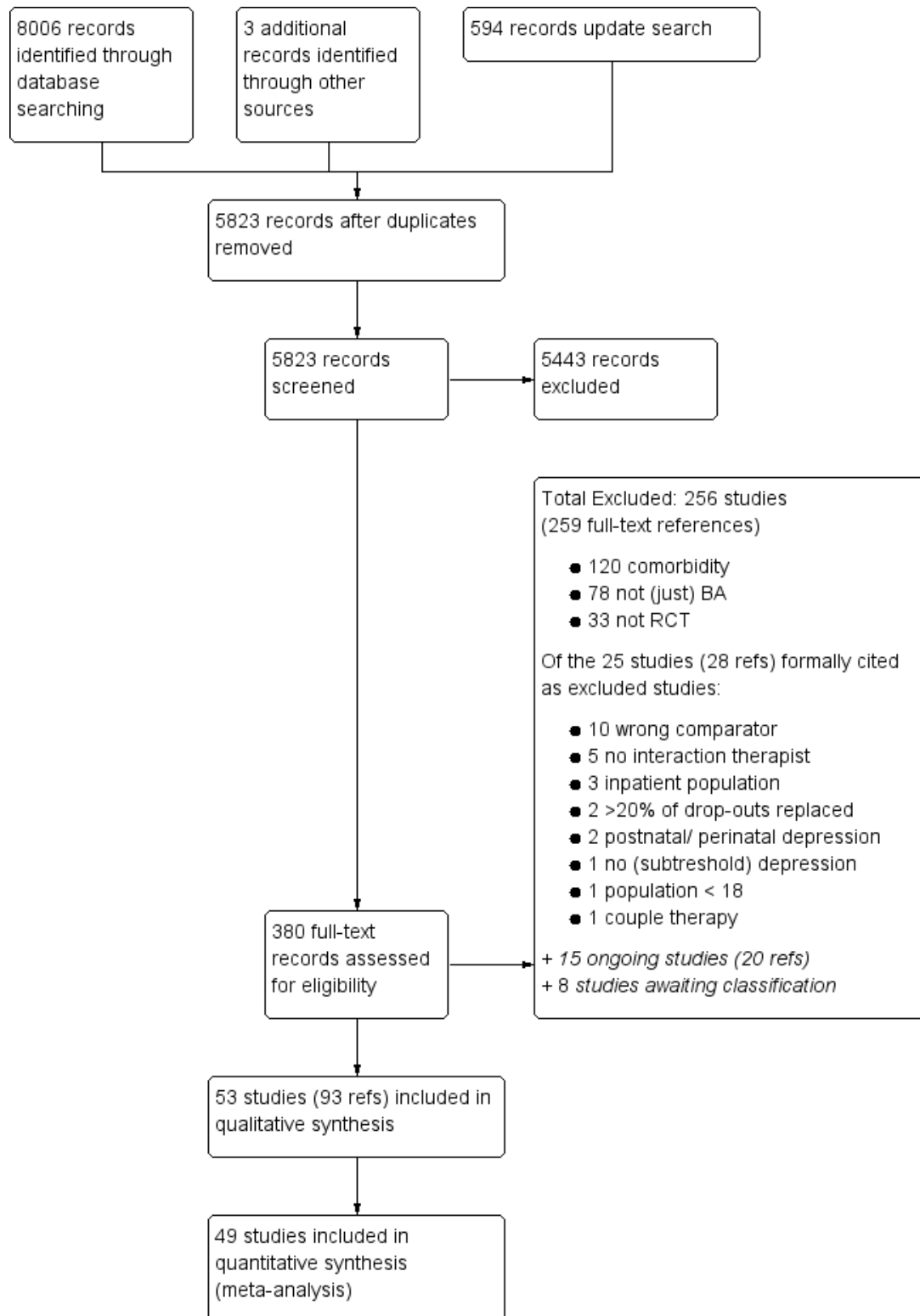
Description of studies

Results of the search

Searches in all pre-specified databases were performed by the Cochrane Common Mental Disorders' Information Specialist on 17 January 2019 and an update search was performed on 17 January 2020.

Figure 1 shows the selection of studies through screening of abstracts and full-text papers. After duplicates were removed, EU, SD, and LR screened titles and abstracts of 5823 records in duplicate. For 380 records, full-texts were obtained and screened in duplicate (EU, LR, ESo). Conflicts were resolved in discussion with DE, DR, and RC. After linking records belonging to the same study, 53 studies were included in the qualitative synthesis and 49 studies in meta-analyses. EU, LR, ESa, and ESo extracted data and assessed the risk of bias in duplicate.

Figure 1. Study flow diagram.



Included studies

We included 53 studies in this systematic review. Two of these studies were found as a result of the update search in January 2020.

Study design

Fifty-one studies were parallel group randomised controlled trials (RCTs) and two were cluster-RCTs (Fleming 1980; Luo 2018). One RCT allowed switching of placebo and medication treatment after

eight weeks depending on participant preference (Dimidjian 2006), and in one cross-over RCT treatments were switched between groups after six weeks (Kelly 1983). For these two trials employing a cross-over (Kelly 1983) and partial cross-over design (Dimidjian 2006), only outcome data for the first phase of the study are included in meta-analyses of this review as per protocol.

Most trials had two study arms, with either two active treatments or an active and a control group (31 studies). The other studies had three arms (13 studies), four arms (seven studies), five arms (two studies), or six arms (two studies). If study arms were variations of the same treatment, for example two types of behavioural activation, these data were combined in the meta-analyses of this review.

Sample size

The 53 included studies had 5495 participants, ranging from less than six participants per study arm (Skinner 1984) to an average of 352 participants per study arm (Gilbody 2017).

Setting

Many studies did not report on the setting and appear to have been conducted at a university or medical centre. Recruitment settings that were reported included: universities (Armento 2012; Cullen 2003; Gawrysiak 2009; Hammen 1975; Kelly 1983; McCluskey 2018; McIndoo 2016; McNamara 1986; Shaw 1977; Takagaki 2016; Taylor 1977; Weinberg 1978; Wilson 1983; Zeiss 1979; Zemestani 2016), medical centres including psychiatric outpatient facilities (Toghyani 2018; van den Hout 1995), community mental health services, primary care and community health centres (Bolton 2014; Bosanquet 2017; Bowe 2014; Chang 2018; Chowdhary 2016; Ekers 2011; Gilbody 2017; Nasrin 2017; Kanter 2015; Richards 2017), and nursing homes or facilities for older people (Luo 2020; Meeks 2008; Raue 2019). Several interventions were computer-based or phone-based and supported from a distance (Carlbring 2013; Carlbring 2013a; Ly 2014; Stiles-Shields 2019).

Studies were conducted in the USA (27 studies), UK (five studies), Iran (three studies), Sweden (three studies), Australia (two studies), Canada (two studies), India (two studies), Brazil (one study), China (one study), Hong Kong (one study), Indonesia (one study), Iraq (one study), Japan (one study), the Netherlands (one study), South Korea (one study), and Spain (one study).

Participants

We extracted data on participant age, sex, ethnic group, socioeconomic characteristics (household income, occupation/employment, education level), depression severity, and comorbid anxiety. In this section we briefly summarise the information available in study reports.

Age

Most studies included adult participants of all ages. Four studies included only adults up to 60 years old (Dimidjian 2006; Hemanny 2019; Nasrin 2017; Wilson 1983), seven studies included only participants aged 65 and over (Bosanquet 2017; Chang 2018; Gilbody 2017; Luo 2020; Meeks 2008; Raue 2019; Xie 2019), and in four studies samples were exclusively made up of young adult college/university students with an average age between 18 and 24 (Gawrysiak 2009; McIndoo 2016; Takagaki 2016; Zemestani 2016).

Differences in results for treatment efficacy and treatment acceptability by participant age (under 65 and aged 65 and over) are explored in subgroup analyses (Analysis 11.1; Analysis 11.2).

Sex

Six studies included only women (Fuchs 1977; Kornblith 1980; Padfield 1976; Rehm 1982; Thomas 1987; Toghyani 2018). Two studies included more men than women (39% and 38% women, respectively) (Cullen 2003; Takagaki 2016). In all other studies that reported on the sex of participants (36 studies), women represented between 58% and 93% of the sample.

Ethnicity

Five studies included participants of a specific region or ethnic group: people from various islands in Indonesia (Arjadi 2018), a sample of African American participants (Bowe 2014), Puerto Ricans (Comas Díaz 1981), and Latinos living in the USA (Collado 2016; Kanter 2015).

The other 14 studies reporting on participant ethnicity included predominantly White American or White British participants (58% to 99%), except for a study from Brazil reporting a mix of participants from three ethnic groups (Hemanny 2019).

Socioeconomic characteristics

Studies collected data on income, level of education, and employment status or occupation. It is difficult to compare study participants as these characteristics are time- and place-dependent. In many studies the sample represented a mix of people with various socioeconomic characteristics.

Some studies predominantly recruited participants of a higher socioeconomic status. For example, in the study by Ly and colleagues 7% of participants were unemployed and 63% had attended university (Ly 2014). Similarly, in the study by Carlbring and colleagues 9% of participants were unemployed and 62% had attended university (Carlbring 2013a), and in Arjadi 2018 unemployment was 8% and university attendance 55%.

Other studies had samples with predominantly people from a lower socioeconomic status, and some of these studies were conducted in low- and middle-income countries, or with people from such countries. For example, in seven studies a majority of participants had completed no more than primary education (Bolton 2014; Chang 2018; Chowdhary 2016; Comas Díaz 1981; Luo 2020; Weobong 2017; Xie 2019). In six studies levels of unemployment ranged from 50% to 100% (Bolton 2014; Chowdhary 2016; Comas Díaz 1981; Kanter 2015; Thomas 1987; Weobong 2017).

Severity of depression

For most studies, inclusion criteria specified a range or lower limit of depression symptoms using a commonly used screening tool such as the Patient Health Questionnaire (PHQ-9), Beck Depression Inventory (BDI), or Hamilton Rating Scale for Depression (HRSD).

In 25 studies, only people with diagnosed major depressive disorder or moderate to severe depression symptoms were included (Arjadi 2018; Bosanquet 2017; Bowe 2014; Chang 2018; Chowdhary 2016; Collado 2016; Cullen 2003; Dimidjian 2006; Hemanny 2019; McNamara 1986; Meeks 2008; Moradveisi 2015; Nasrin 2017; Padfield 1976; Rehm 1982; Richards 2017; Kanter 2015;

Shaw 1977; Stiles-Shields 2019; Thompson 1987; Toghiani 2018; van den Hout 1995; Weobong 2017; Xie 2019; Zemestani 2016).

In 16 studies, people with various levels of depression severity (mild, moderate, severe) were included (Armento 2012; Carlbring 2013a; Ekers 2011; Fleming 1980; Gawrysiak 2009; Hammen 1975; Kelly 1983; Ly 2014; McCluskey 2018; McIndoo 2016; Raue 2019; Skinner 1984; Taylor 1977; Thomas 1987; Weinberg 1978; Wilson 1983). Participants in 11 of these studies predominantly had major depressive disorder, or moderate to severe symptoms of depression (Armento 2012; Carlbring 2013a; Ekers 2011; Fleming 1980; Gawrysiak 2009; Kelly 1983; Ly 2014; McIndoo 2016; Raue 2019; Taylor 1977; Thomas 1987).

Three studies included only participants with subthreshold depression or minimal to mild symptoms (Gilbody 2017; Takagaki 2016; Vázquez 2014).

Based on this information from eligibility criteria and descriptions of the study samples, we can conclude that, in most studies, the majority of participants were suffering from moderate to severe levels of depression.

Anxiety

Most studies did not report on numbers of participants with comorbid anxiety. Anxiety disorder was an exclusion criteria in six trials (Chang 2018; Jacobson 1996; Kornblith 1980; Rehm 1982; Toghiani 2018; van den Hout 1995). In eight studies that reported on anxiety among participants, levels of anxiety disorder varied from 11% (Moradveisi 2015) to 65% (Collado 2016).

Intervention

Description of intervention

Behavioural activation interventions were described in different ways, and some were specifically designed for the study setting or population. All interventions are described in the [Characteristics of included studies](#) tables. Examples include the following.

1. Behavioural Activities Intervention (BE-ACTIV) for nursing home residents (Luo 2020; Meeks 2008)
2. Healthy Activity Programme (HAP) for treatment of moderate to severe depression in primary care in India (Chowdhary 2016; Weobong 2017)
3. Culturally Enhanced Behavioural Activation (CEBA) for African American communities (Bowe 2014)
4. Behavioural Activation for Latinos (BAL) for a low-income Spanish speaking Latino community (Kanter 2015)
5. Behavioural Activation of Religious Behaviors (BARB) (Armento 2012)

Others were described as behavioural activation or behavioural therapy based on Lewinsohns' approach (McNamara 1986; Padfield 1976; Shaw 1977; Skinner 1984; Taylor 1977; Thompson 1987; Vázquez 2014; Weinberg 1978), Behavioural Activation Treatment for Depression (BATD) (Bolton 2014; Collado 2016; Gawrysiak 2009; McCluskey 2018; Nasrin 2017), or behavioural activation based on the intervention evaluated by Fuch and Rehm (Fleming 1980; Fuchs 1977; Kornblith 1980; Rehm 1982; Thomas 1987; van den Hout 1995).

Level of therapist

For several trials, behavioural activation was delivered by a specialist in training (Carlbring 2013a; Fleming 1980; Fuchs 1977; Kelly 1983; McNamara 1986; Shaw 1977; Thomas 1987; Thompson 1987; Weinberg 1978; Zeiss 1979; Zemestani 2016), or a non-specialist (Arjadi 2018; Bolton 2014; Bosanquet 2017; Chang 2018; Chowdhary 2016; Collado 2016; Ekers 2011; Gilbody 2017; Luo 2020; Raue 2019; Richards 2017; Weobong 2017; Xie 2019), rather than a mental health specialist.

Trials published before the 1990s regularly used graduate or doctoral students to deliver interventions within the trial setting, even if the treatment would normally be delivered by accredited mental health specialists who completed formal training. In recent years, several behavioural activation interventions evaluated in trials have been delivered by non-specialists such as primary care workers or lay health workers, with a view to test an alternative therapy feasible for delivery in settings with limited resources.

Duration and format

Most of the interventions were delivered face-to-face. Four studies involved initial or occasional face-to-face contact, with most of the intervention delivered via phone calls (Armento 2012; Bosanquet 2017; Chang 2018; Gilbody 2017). One intervention was delivered through a series of conference calls (Vázquez 2014), three were delivered online (Arjadi 2018; Carlbring 2013a; Carlbring 2013), and two used a smartphone app in combination with contact via phone or email (Ly 2014; Stiles-Shields 2019). The exclusion of studies delivering interventions without a substantial face-to-face component is explored in sensitivity analyses (Analysis 20.1; Analysis 20.2; Analysis 21.1; Analysis 21.2).

Most interventions were delivered once or twice a week (Chowdhary 2016; Dimidjian 2006; Fleming 1980; Hemanny 2019; Moradveisi 2015; Richards 2017; Shaw 1977; Thompson 1987; Toghiani 2018), and a few interventions were delivered in only one session (Armento 2012; Gawrysiak 2009; Nasrin 2017). Most interventions were delivered over a period of four to 12 weeks, with the longest duration being 16 weeks (Richards 2017).

Therapy sessions were usually up to an hour in duration, with others lasting between 90 minutes and two hours (Bowe 2014; Comas Díaz 1981; Fleming 1980; Fuchs 1977; Gawrysiak 2009; Kornblith 1980; McCluskey 2018; Nasrin 2017; Rehm 1982; Shaw 1977; Toghiani 2018; van den Hout 1995; Vázquez 2014; Xie 2019; Zemestani 2016).

In most of the studies interventions were delivered to individuals, while 10 were delivered in a group format (Fleming 1980; Kornblith 1980; Rehm 1982; Shaw 1977; Thomas 1987; Toghiani 2018; van den Hout 1995; Vázquez 2014; Xie 2019; Zemestani 2016), and three used a mixed individual/group format (Bowe 2014; Fuchs 1977; Takagaki 2016). We performed sensitivity analyses to explore outcomes for the individual format only (Analysis 22.1; Analysis 22.2; Analysis 23.1; Analysis 23.2).

Comparators

Other psychological therapies

Psychological therapies other than behavioural activation, which were used as comparators, included the following.

- CBT (Bolton 2014; Dimidjian 2006; Hemanny 2019; Jacobson 1996; McNamara 1986; Rehm 1982; Richards 2017; Stiles-Shields 2019; Taylor 1977; Thomas 1987; Thompson 1987; Vázquez 2014; Weinberg 1978; Wilson 1983)
- Third-wave cognitive and behavioural therapies (Ly 2014; McIndoo 2016; Zemestani 2016)
- Humanistic therapy (Armento 2012; Collado 2016; McNamara 1986)
- Psychodynamic therapy (Thompson 1987)
- Interpersonal, cognitive analytic, and other integrative therapies (Kornblith 1980; Padfield 1976; Toghiani 2018; Weinberg 1978)

We categorised cognitive processing therapy and cognitive therapy as CBT. Emotional awareness training, general counselling, and general psychotherapy were included as an integrative therapies.

Other non-therapy comparators included the following.

1. Waiting list (Bolton 2014; Carlbring 2013a; Carlbring 2013; Cullen 2003; McIndoo 2016; Nasrin 2017; Taylor 1977; Stiles-Shields 2019; Weinberg 1978; Zemestani 2016)
2. Placebo; medical placebo (Dimidjian 2006), and attention placebo (Hammen 1975)
3. Medication (Dimidjian 2006; Moradveisi 2015)
4. No treatment (Gawrysiak 2009; Hammen 1975; McCluskey 2018; Takagaki 2016)
5. Treatment as usual (Bosanquet 2017; Ekers 2011; Gilbody 2017; Hemanny 2019; Kanter 2015; Luo 2020; Meeks 2008; Xie 2019)

If treatment as usual comprised medication or therapy it was added to the relevant medication or therapy comparisons. Online 'minimal psychoeducation', referral to mental health services and enhanced usual care (described as 'routine consultation and referral to services) were categorised as treatment as usual. Self-monitoring, described as 'no change from normal activities', was categorised as no treatment.

Outcomes

Studies reported data on all of the seven outcomes specified for this review. We report meta-analyses and forest plots for all outcomes at short-term, medium-term, and long-term endpoints, and subgroup analyses for primary outcomes treatment efficacy and treatment acceptability (dropouts) at short-term time endpoints.

Most data are available for depression symptoms, as measured by commonly used instruments for depression severity such as the BDI or HRSD. Depression symptom outcomes were more commonly reported than treatment efficacy. For treatment efficacy, we encountered multiple measures across studies, and sometimes multiple measures within one study. If a study reported multiple measures of treatment efficacy, we prioritised as follows: remission over clinically significant improvement, and recovery or remission over response.

For six studies data were missing and standard deviations could not be calculated (Bowe 2014; Comas Díaz 1981; Fleming 1980; Kelly 1983; Skinner 1984; Zeiss 1979). These studies are not included in any meta-analyses. For some studies data were missing but could be calculated (Fuchs 1977; Gardner 1981; McCluskey 2018; Shaw 1977; van den Hout 1995).

Data on adverse events are summarised narratively in Table 1.

Excluded studies

After obtaining full-text manuscripts, a total of 256 studies were excluded (259 full-text records) (Figure 1). Of the studies excluded at this stage, 120 studies were of participants with a physical comorbidity. These studies were included at the title and abstract screening stage as they informed a Cochrane review focussed on this population (Uphoff 2019b). A further 78 studies were excluded because the intervention was not behavioural activation, or behavioural activation was a component but not the key ingredient of the intervention. Another 33 studies were excluded because they were not RCTs. We were unable to exclude these studies at the stage of title and abstract screening because the abstracts did not clearly specify the study design and/or intervention. These records are not listed in this review.

Among the 25 studies (28 references) which are listed as Excluded studies in this review, the most common reasons for exclusion were wrong comparator ($k = 10$) and interventions with no interaction with a therapist ($k = 5$). Further reasons for exclusion are listed in the Characteristics of excluded studies table.

In addition to the excluded studies, authors were contacted to check whether studies identified through protocols had been published. Fifteen studies (20 references) are listed as ongoing (Characteristics of ongoing studies) and eight are awaiting classification (Studies awaiting classification).

Risk of bias in included studies

Out of 53 included studies, for 46 studies one or more risk of bias domains were initially rated as 'unclear' because information was missing from the study report and/or trial registration/ protocol. For 25 studies the author could not be contacted; 15 of these studies were published before 1990. Authors of two old studies replied but could no longer provide the requested information (Gardner 1981; Hammen 1975).

Allocation

Eighteen studies were rated as low risk of selection bias (Figure 2; Figure 3). The others, particularly older studies, either did not report sufficient information on randomisation and/or allocation concealment or were found to be at high risk of bias. In several studies randomisation was performed correctly, but a researcher involved in the study was aware of the allocation participant list (McIndoo 2016; Meeks 2008; Zemestani 2016).

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

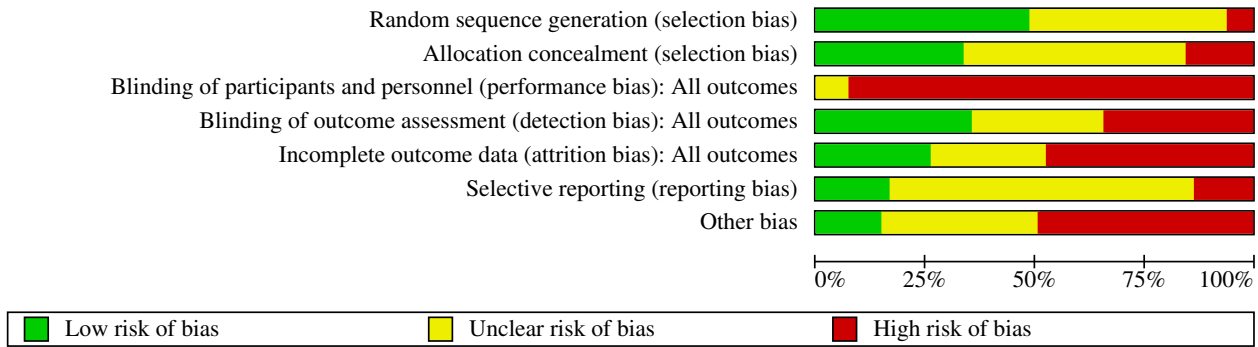


Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias): All outcomes	Blinding of outcome assessment (detection bias): All outcomes	Incomplete outcome data (attrition bias): All outcomes	Selective reporting (reporting bias)	Other bias
Arjadi 2018	+	+	-	+	-	+	+
Armento 2012	?	?	-	?	+	?	?
Bolton 2014	+	+	-	?	+	+	+
Bosanquet 2017	+	+	-	-	+	+	-
Bowe 2014	?	?	-	-	-	?	-
Carlbring 2013	+	+	-	-	+	?	-
Carlbring 2013a	+	?	-	-	-	-	-
Chang 2018	+	+	-	+	+	-	?
Chowdhary 2016	+	+	?	?	+	?	-
Collado 2016	+	+	-	+	-	-	+
Comas Díaz 1981	?	?	-	?	?	?	+
Cullen 2003	?	?	?	?	-	?	?
Dimidjian 2006	+	+	-	+	-	?	-
Ekers 2011	+	+	-	+	-	+	-
Fleming 1980	?	?	-	?	?	?	-
Fuchs 1977	?	-	-	?	?	?	-
Gardner 1981	?	?	-	-	-	?	?
Gawrysiak 2009	?	?	-	?	+	?	-
Gilbody 2017	+	+	-	-	-	+	-
Hammen 1975	?	?	?	?	?	?	?
Hemanny 2019	?	?	?	+	-	-	-
Jacobson 1996	+	+	-	+	+	?	?
Kanter 2015	+	+	-	+	-	?	-

Figure 3. (Continued)

Jacobson 1996	+	+	-	+	+	?	?
Kanter 2015	+	+	-	+	-	?	-
Kelly 1983	?	?	-	-	?	?	?
Kornblith 1980	-	-	-	+	-	?	-
Luo 2020	?	?	-	?	+	?	-
Ly 2014	+	+	-	+	+	-	-
McCluskey 2018	+	?	-	?	?	?	+
McIndoo 2016	+	-	-	?	+	-	-
McNamara 1986	?	?	-	-	-	?	-
Meeks 2008	+	-	-	+	-	-	-
Moradveisi 2015	+	+	-	-	-	?	?
Nasrin 2017	+	?	-	?	?	?	?
Padfield 1976	?	?	-	+	?	?	?
Raue 2019	?	-	-	-	-	+	-
Rehm 1982	?	?	-	+	-	?	+
Richards 2017	+	+	-	+	-	+	-
Shaw 1977	?	?	-	+	?	?	?
Skinner 1984	?	?	-	-	-	?	-
Stiles-Shields 2019	+	+	-	-	-	?	-
Takagaki 2016	+	+	-	+	+	?	+
Taylor 1977	-	-	-	-	?	?	?
Thomas 1987	?	?	-	-	-	?	?
Thompson 1987	?	?	-	?	-	?	-
Toghyani 2018	?	?	-	?	-	?	-
van den Hout 1995	?	?	-	-	?	?	?
Vázquez 2014	+	?	-	+	+	?	?
Weinberg 1978	-	-	-	-	?	?	?
Weobong 2017	+	+	-	+	?	+	?
Wilson 1983	?	?	-	+	-	?	+
Xie 2019	+	?	-	-	?	+	?
Zeiss 1979	?	?	-	?	-	?	-
Zemestani 2016	+	-	-	-	+	?	?

Blinding

Blinding of participants and personnel (performance bias) was not achieved in any of the included studies (Figure 2) and is rarely attempted for psychological therapy interventions. In 18 studies, authors limited the risk of detection bias through blinding of outcome assessors. Where outcome assessors were not blinded this was usually because participants self-completed questionnaires on symptoms of depression.

Incomplete outcome data

There was evidence of incomplete outcome data in 25 studies, and an assessment of 'unclear' risk of attrition bias in a further 14 studies. Issues included no or unclear reporting of participants who dropped out of the trial, unclear reasons for dropout, the exclusion of participants who dropped out from the analyses, or a substantial difference in dropout rates between the different study arms.

Selective reporting

For the majority of studies, no reference was made to a study protocol or online trial registration. Nine studies were rated as low risk of reporting bias, because a protocol or trial registration was available and no differences with the results were found. For seven studies, there were discrepancies in outcomes reported between the methods section, trial registration, or protocol, and the published study results (Carlbring 2013a; Chang 2018; Collado 2016; Hemanny 2019; Ly 2014; McIndoo 2016; Meeks 2008). For example, reporting of extra outcomes, no reporting of outcomes listed in the protocol, a change in the measures used, or differences in time points reported.

Other potential sources of bias

Other issues that were rated as a high risk of bias were identified for 26 studies. This included issues relevant to the conduct of trials in psychotherapy, such as low treatment fidelity of therapists,

researcher or therapist allegiance to one of the interventions, or a conflict of interest from researchers or therapists. For example, several trials were conducted by authors who were involved in the development of the intervention. Another common potential source of bias was any indication of inadequate randomisation, for example with extremely small sample sizes (less than 10 participants per study arm) and substantial differences in participant characteristics between study arms.

Effects of interventions

See: [Summary of findings 1](#) Behavioural activation compared with CBT for depression in adults; [Summary of findings 2](#) Behavioural activation compared with third-wave CBT for depression in adults; [Summary of findings 3](#) Behavioural activation compared with humanistic therapy for depression in adults; [Summary of findings 4](#) Behavioural activation compared with psychodynamic for depression in adults; [Summary of findings 5](#) Behavioural activation compared with interpersonal, cognitive analytic, integrative for depression in adults; [Summary of findings 6](#) Behavioural activation compared with waiting list for depression in adults; [Summary of findings 7](#) Behavioural activation compared with placebo for depression in adults; [Summary of findings 8](#) Behavioural activation compared with medication for depression in adults; [Summary of findings 9](#) Behavioural activation compared with no treatment for depression in adults; [Summary of findings 10](#) Behavioural activation compared with treatment as usual for depression in adults

Behavioural activation versus psychological therapies

Included studies compared behavioural activation with CBT, third-wave CBT, humanistic therapy, psychodynamic therapy, and interpersonal, cognitive analytic, and integrative therapy.

Comparison 1. Behavioural activation versus cognitive-behavioural therapy (CBT)

Short-term outcomes

Moderate- to very low-certainty evidence from randomised controlled trials (RCTs) showed no statistically significant differences in short-term (up to six months) outcomes between behavioural activation and CBT in terms of treatment efficacy (risk ratio (RR) 0.99, 95% CI 0.92 to 1.07; 5 RCTs, 601 participants; moderate-certainty evidence) ([Analysis 1.1](#)), treatment acceptability (RR 1.03, 95% CI 0.85 to 1.25; 12 trials, 1195 participants) ([Analysis 1.2](#); low certainty), depression symptoms (standardised mean difference (SMD) 0.12, 95% CI -0.08 to 0.32; high heterogeneity I^2 52%; 16 RCTs, 1205 participants) ([Analysis 1.3](#)), quality of life (SMD 0.04, 95% CI -0.20 to 0.28; 2 RCTs, 268 participants; moderate-certainty evidence) ([Analysis 1.4](#)), social adjustment and functioning (SMD -0.13, 95% CI -0.50 to 0.24; 2 RCTs, 111 participants; very low-certainty evidence) ([Analysis 1.5](#)), and anxiety symptoms (SMD -0.03, 95% CI -0.18 to 0.13; 4 RCTs, 646 participants; moderate-certainty evidence) ([Analysis 1.6](#)).

One small study ([Vázquez 2014](#)) has a high weight in the analyses comparing the treatment efficacy of behavioural activation and CBT because none of the participants had depression at follow-up. Removing this study made the pooled estimate less precise but did not substantially change the estimate (RR 0.94, 95% CI 0.81 to 1.10).

Medium- and long-term outcomes

One study ([Richards 2017](#)) compared outcomes between a behavioural activation and a CBT group in the medium term (seven to 12 months) and long term (>12 months), and found no evidence of a difference in treatment efficacy (medium term: RR 1.00, 95% CI 0.86 to 1.16; 364 participants, long term: (RR 0.93, 95% CI 0.81 to 1.08; 356 participants)), treatment acceptability (medium term: RR 1.25, 95% CI 0.97 to 1.62; 440 participants, long term: RR 1.16, 95% CI 0.90 to 1.49; 440 participants), depression symptoms (medium term: SMD -0.18, 95% CI -0.38 to 0.02; 380 participants, long term: (SMD 0.00, 95% CI -0.21 to 0.21; 364 participants), quality of life (medium term: SMD 0.15, 95% CI -0.07 to 0.37, long term: SMD 0.06, 95% CI -0.15 to 0.28), and anxiety symptoms (medium term: SMD 0.02, 95% CI -0.20 to 0.23; 337 participants, long term: SMD -0.10, 95% CI -0.31 to 0.12; 332 participants).

Adverse events

Adverse events was included as an outcome in two trials; one reported no adverse events ([Stiles-Shields 2019](#)), and the other reported three serious adverse events in the behavioural activation arm (two overdose, one self-harm) and eight serious adverse events in the CBT arm (seven overdose, one self-harm) ([Richards 2017](#) ([Table 1](#))).

Funnel plots revealed no indications of publication bias for treatment acceptability and depression symptoms.

Comparison 2. Behavioural activation versus third-wave CBT

Short-term outcomes

Three RCTs contributed low-certainty evidence comparing behavioural activation with third-wave CBT.

Low-certainty evidence showed no statistically significant differences for short-term (up to six months) outcomes between behavioural activation and third-wave CBT in terms of treatment efficacy (RR 1.10, 95% CI 0.91 to 1.33; 2 RCTs, 98 participants) ([Analysis 2.1](#)), treatment acceptability (RR 0.84, 95% CI 0.33 to 2.10; 3 RCTs, 147 participants) ([Analysis 2.2](#)), depression symptoms (SMD -0.14, 95% CI -0.47 to 0.18; 3 RCTs, 147 participants) ([Analysis 2.3](#)), quality of life (MD 0.02, 95% CI -0.96 to 1.00; 1 RCT, 81 participants) ([Analysis 2.4](#)), and anxiety symptoms (MD 0.69, 95% CI -0.68 to 2.06; 3 RCTs, 147 participants) ([Analysis 2.5](#)).

Data on social adjustment and functioning and adverse events were not reported.

Comparison 3. Behavioural activation versus humanistic therapy

Short-term outcomes

Three RCTs contributed moderate- to very low-certainty evidence on the comparison of short-term (up to six months) outcomes between behavioural activation and humanistic therapy.

Low-certainty evidence showed greater treatment efficacy for behavioural activation compared with humanistic therapy (RR 1.84, 95% CI 1.15 to 2.95; 2 RCTs, 46 participants) ([Analysis 3.1](#)). Three people would need to receive treatment for one person with depression to benefit.

Low- to very low-certainty evidence showed no statistically significant difference in treatment acceptability (RR 1.06, 95% CI

0.20 to 5.55; 2 RCTs, 96 participants, very low certainty) ([Analysis 3.2](#)), quality of life (MD 0.80, 95% CI -0.12 to 1.72; 1 RCT, 50 participants; low certainty) ([Analysis 3.4](#)), or anxiety symptoms (MD -1.30, 95% CI -6.10 to 3.50; 1 RCT, 50 participants; low certainty) ([Analysis 3.5](#)).

Moderate-certainty evidence indicated that depression symptoms improved more in those assigned to behavioural activation compared with those assigned to humanistic therapy (MD -3.75, 95% CI -6.72 to -0.78; 3 RCTs, 93 participants) ([Analysis 3.3](#)).

Data on social adjustment and functioning and adverse events were not reported.

Comparison 4. Behavioural activation versus psychodynamic therapy

Short-term outcomes

Very low-certainty evidence from one RCT (60 participants) showed no difference between behavioural activation and psychodynamic therapy for short-term outcomes treatment efficacy (RR 1.21, 95% CI 0.74 to 1.99) ([Analysis 4.1](#)), depression symptoms (MD -1.10, 95% CI -4.35 to 2.15) ([Analysis 4.2](#)), and social adjustment and functioning (MD 2.10, 95% CI -4.92 to 9.12) ([Analysis 4.3](#)).

Data on treatment acceptability, quality of life, anxiety symptoms, and adverse events were not reported.

Comparison 5. Behavioural activation versus interpersonal, cognitive analytic, and integrative therapy

Short-term outcomes

Very low-certainty evidence showed no difference between behavioural activation and interpersonal, cognitive analytic, and integrative therapies for short-term outcomes treatment acceptability (RR 0.84, 95% CI 0.32 to 2.20; 4 RCTs, 123 participants)

([Analysis 5.1](#)), depression symptoms (SMD -0.16, 95% CI -0.59 to 0.28; 4 RCTs, 103 participants) ([Analysis 5.2](#)), social adjustment and functioning (MD -3.92, 95% CI -16.78 to 8.93; 1 RCT, 39 participants) ([Analysis 5.3](#)), and anxiety symptoms (MD -0.39, 95% CI -11.78 to 11.00; 1 RCT, 15 participants) ([Analysis 5.4](#)).

Data on treatment efficacy and quality of life were not reported.

Adverse events

[Padfield 1976](#) reported there were no adverse events in the behavioural activation study arm and two suicide attempts and one case of suicidal thoughts in the comparator arm (low-certainty evidence) ([Table 1](#)).

Behavioural activation versus other comparators

Included studies compared behavioural activation with being on a waiting list, receiving a placebo, medication (anti-depressants), no treatment, or treatment as usual.

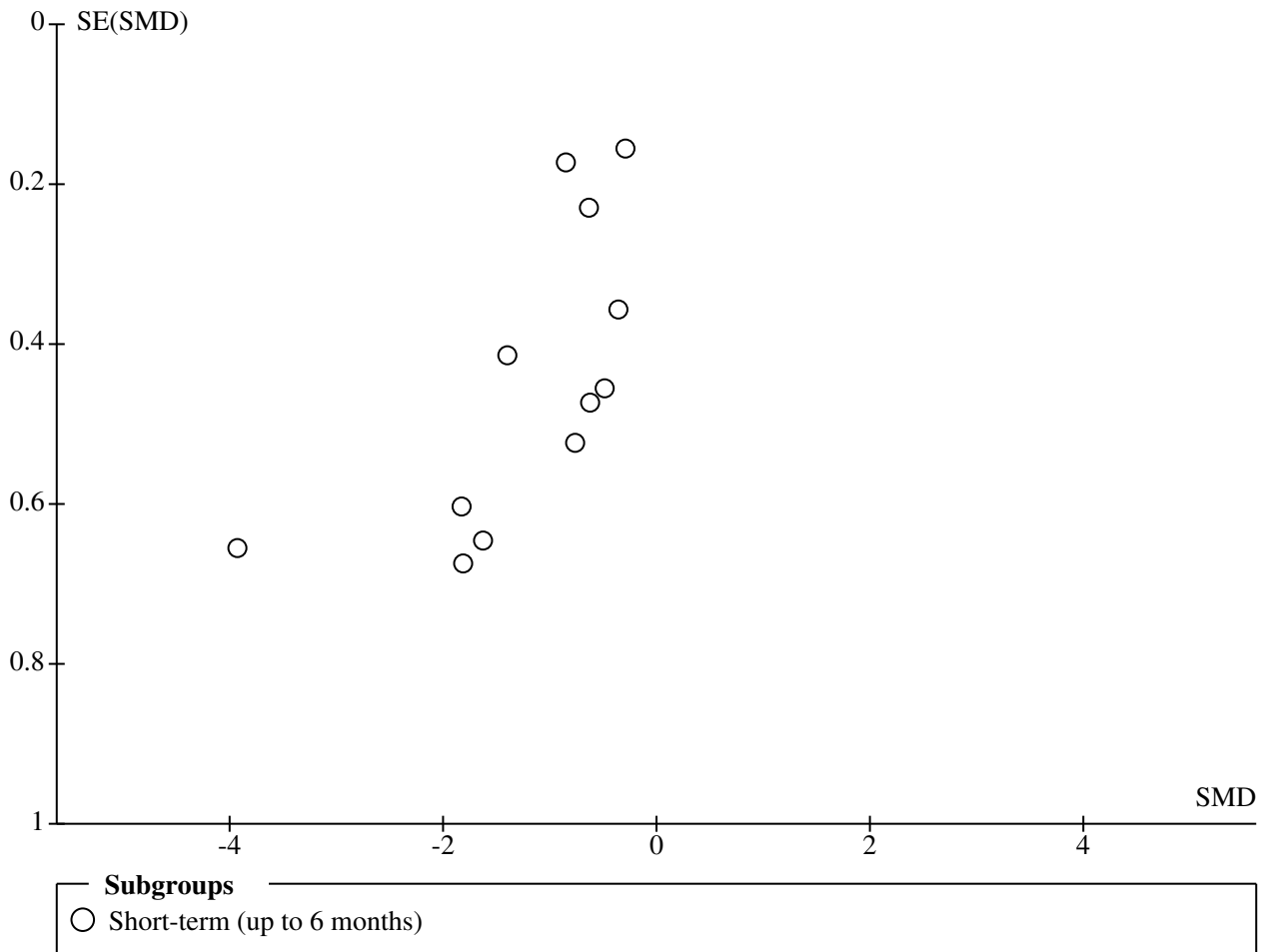
Comparison 6. Behavioural activation versus waiting list

Short-term outcomes

Moderate- to low-certainty evidence suggested there is no difference in treatment efficacy (RR 2.14, 95% CI 0.90 to 5.09; 1 RCT, 26 participants; low certainty) ([Analysis 6.1](#)) and treatment acceptability (RR 1.17, 95% CI 0.70 to 1.93; 8 RCTs, 359 participants; moderate certainty) ([Analysis 6.2](#)) in the short term (up to six months) between behavioural activation and waiting list.

Low-certainty evidence showed that those who received behavioural activation had a greater short-term reduction in depression symptoms than those on a waiting list (SMD -1.04, 95% CI -1.44 to -0.63; 12 RCTs, 619 participants) ([Analysis 6.3](#)). The funnel plot indicates that smaller studies with results favouring waiting list may be missing from these data ([Figure 4](#)).

Figure 4. Funnel plot of comparison: 6 behavioural activation versus waiting list, outcome: 6.3 depression symptoms.



Low-certainty evidence indicated benefits of behavioural activation compared with waiting list for anxiety symptoms (SMD -0.91, 95% CI -1.59 to -0.23; 5 RCTs, 424 participants) (Analysis 6.5), but not for quality of life (MD 0.03, 95% CI -0.70 to 0.76; 1 RCT, 80 participants) (Analysis 6.4).

No data were reported on social adjustment and functioning.

Estimates for depression symptoms and anxiety symptoms suggested a large effect and high level of heterogeneity (I^2 75% and 87%, respectively). To test how robust these findings are, we conducted sensitivity analyses with fixed-effect instead of random-effects models. The pooled estimates were reduced to SMD -0.72 (95% CI -0.89 to -0.55) for depression symptoms (Analysis 24.1) and SMD -0.54 (95% CI -0.74 to -0.33) for anxiety symptoms (Analysis 24.2).

Adverse events

The authors of a trial comparing behavioural activation to CBT and waiting list reported that no adverse events took place (Stiles-Shields 2019)(Table 1).

Comparison 7. Behavioural activation versus placebo

Short-term outcomes

Two RCTs contributed low-certainty evidence comparing behavioural activation to a placebo. One study used a medical placebo (Dimidjian 2006) and one used an attention placebo (Hammen 1975).

No difference between behavioural activation and placebo was found for treatment acceptability (RR 0.72, 95% CI 0.31 to 1.67; 1 RCT; 96 participants) (Analysis 7.1) and depression symptoms (SMD -0.18, 95% CI -0.57 to 0.20; 2 RCTs, 108 participants) (Analysis 7.2).

No data were reported for treatment efficacy, quality of life, anxiety symptoms, and social adjustment and functioning.

Adverse events

One RCT reported various physical side effects from the medication placebo, and no adverse events for the behavioural activation group (Dimidjian 2006) (Table 1).

Comparison 8. Behavioural activation versus medication

Short-term outcomes

One RCT (141 participants) on treatment efficacy, with treatment efficacy being higher for behavioural activation than medication (RR 1.77, 95% CI 1.14 to 2.76; 1 RCT, 141 participants) (Analysis 8.1). We judged this evidence to be of moderate certainty following the GRADE approach. However, because this evidence is based on data from one trial only, we were not able to assess inconsistency in results between trials.

Moderate-certainty evidence showed no difference between behavioural activation and medication in short-term treatment acceptability (RR 0.52, 95% CI 0.23 to 1.16; 2 RCTs, 243 participants) (Analysis 8.2). Low-certainty evidence showed no difference in short-term symptoms of depression (MD -1.42, 95% CI -4.80 to 1.96; 2 RCTs, 180 participants; I^2 83% indicating high heterogeneity) (Analysis 8.3).

No data were reported on quality of life, anxiety symptoms, and social adjustment and functioning.

Medium- and long-term outcomes

One RCT (reported medium-term (seven to 12 months) outcomes comparing behavioural activation to medication. There was no difference in treatment acceptability between the groups (RR 0.86, 95% CI 0.31 to 2.37; 100 participants) (Analysis 8.2). Symptoms of depression decreased more in the behavioural activation than the medication group (MD -2.34, 95% CI -3.84 to -0.84; 100 participants) (Analysis 8.3).

Adverse events

In one RCT comparing CBT, medication, and medical placebo to behavioural activation, a range of physical side effects were reported for the medication and placebo study arms (Dimidjian 2006). There was one case of suicide in the medication arm. No adverse events of behavioural activation were reported (Table 1). This information is also included in the behavioural activation and placebo comparison in Summary of findings 7.

Comparison 9. Behavioural activation versus no treatment

Short-term outcomes

Three RCTs contributed data on short-term (up to six months) outcomes to the comparison of behavioural activation versus no treatment.

Moderate-certainty evidence indicated there was no difference between behavioural activation and no treatment in treatment acceptability (RR 0.97, 95% CI 0.45 to 2.09; 3 RCTs, 187 participants) (Analysis 9.1).

Moderate-certainty evidence showed a benefit of behavioural activation in improvement in depression symptoms (MD -6.10, 95% CI -7.87 to -4.33; 3 RCTs, 187 participants) (Analysis 9.2), and high-certainty evidence showed greater improvements in quality of life for behavioural activation compared with no treatment (MD 0.07, 95% CI 0.03 to 0.11; 1 RCT, 118 participants) (Analysis 9.3). Low-certainty evidence indicated a greater reduction in anxiety symptoms for behavioural activation compared with no treatment (MD -5.50, 95% CI -10.01 to -0.99; 1 RCT, 30 participants) (Analysis 9.4).

No data were reported on treatment efficacy, social adjustment and functioning, and adverse events.

Medium- and long-term outcomes

One RCT reported on medium-term outcomes comparing behavioural activation to no treatment. Results showed no difference in treatment acceptability (RR 1.57, 95% CI 0.65 to 3.79; 124 participants) (Analysis 9.1). There was a greater reduction in depression symptoms for the behavioural activation group compared with the no treatment group (MD -2.83, 95% CI -5.32 to -0.34; 118 participants) (Analysis 9.2).

Comparison 10. Behavioural activation versus treatment as usual

Short-term outcomes

Fifteen RCTs contributed very low- to moderate-certainty evidence on short term (up to six months) outcomes for behavioural activation versus treatment as usual.

Moderate-certainty evidence indicated greater treatment efficacy for behavioural activation compared with treatment as usual (RR 1.40, 95% CI 1.10 to 1.78; 7 RCTs, 1533 participants) (Analysis 10.1), although this difference was not found in sensitivity analyses using a worst-case or intention-to-treat scenario (Analysis 26.1; Analysis 28.1). Moderate-certainty evidence suggested greater treatment acceptability, as indicated by dropouts, for treatment as usual, although results lacked precision (RR 1.64, 95% CI 0.81 to 3.31; 14 RCTs, 2518 participants) (Analysis 10.2).

Low-certainty evidence suggested a benefit of behavioural activation in terms of depression symptoms (SMD -0.78, 95% CI -1.05 to -0.51; 15 RCTs, 2208 participants) (Analysis 10.3), and social adjustment and functioning (SMD -1.27, 95% CI -1.74 to -0.81; 2 RCTs, 88 participants) (Analysis 10.5). Very low-certainty evidence suggested a greater improvement in quality of life for behavioural activation compared with treatment as usual (SMD 0.97, 95% CI 0.38 to 1.57; 6 RCTs, 1299 participants) (Analysis 10.4). Moderate-certainty evidence showed a greater improvement in anxiety symptoms for behavioural activation compared with treatment as usual (SMD -0.33, 95% CI -0.45 to -0.21; 4 RCTs, 1063 participants) (Analysis 10.6).

In the study by Luo and colleagues (Luo 2020), large effects were reported favouring behavioural activation over treatment as usual for depression symptoms and quality of life. Removing this study from the analyses changed the pooled estimate of depression symptoms (SMD -0.57, 95% CI -0.75 to -0.39) and quality of life (SMD 0.34, 95% CI 0.03 to 0.66).

Estimates for depression symptoms and quality of life suggested a large effect. To test how robust these findings are, we conducted sensitivity analyses with fixed-effect instead of random-effects models. The pooled estimates changed to SMD -0.48 (95% CI -0.57 to -0.39) for depression symptoms (Analysis 25.1) and SMD 0.25 (95% CI 0.14 to 0.37) for quality of life (Analysis 25.2).

Funnel plots reveal no indication of publication bias for treatment efficacy, treatment acceptability, and depression symptoms. The I^2 test statistic suggests high levels of statistical heterogeneity for short-term outcomes treatment efficacy (84%), acceptability (85%), depression symptoms (85%), and quality of life (95%), and

medium-term outcomes treatment acceptability (94%) and quality of life (72%).

Medium- and long-term outcomes

Five RCTs reported medium term (seven to 12 months) and/or long term (> 12 months) estimates comparing behavioural activation to treatment as usual.

There was evidence of a difference in medium term treatment efficacy (RR 1.23, 95% CI 1.07 to 1.42; 2 RCTs, 1012 participants) (Analysis 10.1), but not for treatment acceptability (RR 2.84, 95% CI 0.92 to 8.75; 4 RCTs, 1726 participants) (Analysis 10.2). Long-term treatment acceptability favoured treatment as usual (RR 2.17, 95% CI 1.39 to 3.39; 1 RCT, 485 participants).

Medium-term depression symptoms showed greater improvement for behavioural activation than treatment as usual (SMD -0.23, 95% CI -0.38 to -0.08; 4 RCTs, 1381 participants), while no difference was found for long term depression symptoms (SMD 0.02, 95% CI -0.19 to 0.23; 1 RCT, 343 participants).

There was no difference in quality of life in the medium term (SMD 0.14, 95% CI -0.12 to 0.40; 2 RCTs, 879 participants) and long term (SMD -0.09, 95% CI -0.30 to 0.13; 1 RCT, 325 participants).

A greater reduction in anxiety symptoms was found for behavioural activation compared with treatment as usual in the medium term (SMD -0.27, 95% CI -0.41 to -0.12; 2 RCTs, 851 participants), but not in the long term (SMD -0.08, 95% CI -0.29 to 0.14; 1 RCT; 332 participants).

Adverse events

Three studies with a 'treatment as usual' comparator reported on adverse events (Table 1). Two studies of participants aged 65 and older reported a large number of suspected or potential adverse events. In [Bosanquet 2017](#) there were 47 suspected adverse events in the behavioural activation group, and 34 in the treatment as usual group. In [Gilbody 2017](#) there were 37 adverse events in the behavioural activation group and 44 in the treatment as usual group, but none of these were thought to be related to the interventions. In a study of people with severe depression, there was one suicide attempt and 18 unplanned hospitalisations in the behavioural activation arm and one suicide attempt, 26 unplanned hospitalisations, and two deaths in the comparator arm ([Weobong 2017](#)).

Subgroup analyses

Inclusion of studies in subgroup analyses was dependent on the information provided within those studies. For some studies, we could not obtain the data needed to correctly categorise the study. Subgroup analyses were performed for the primary outcomes (up to six months) for the following comparisons with data available from more than one study.

- Behavioural activation versus other control groups (other than psychological therapies) by age (under 65 and 65 and over) (Analysis 11.1 Analysis 11.2)
- Behavioural activation versus other psychological therapies by type of therapist delivering behavioural activation (specialist, specialist in training, non-specialist) (Analysis 12.1; Analysis 12.2)

- Behavioural activation versus other control groups by type of therapist (specialist, specialist in training, non-specialist) (Analysis 13.1; Analysis 13.2)
- Behavioural activation versus other control groups by severity of depression symptoms (subthreshold/ moderate to severe depression) (Analysis 14.1; Analysis 14.2)
- Behavioural activation versus other control groups by length of therapy (one to three and more than three sessions) (Analysis 15.1)
- Behavioural activation versus other psychological therapies by type of comparator therapy (CBT, third-wave CBT, psychodynamic/humanist/integrative) (Analysis 16.1; Analysis 16.2)
- Behavioural activation versus other control groups by type of other control group (treatment as usual, waiting list, no treatment, placebo, other comparator) (Analysis 17.1; Analysis 17.2)

Comparison 11. Age

There was no difference between age groups in treatment efficacy (under 65: RR 2.03, 95% CI 1.49 to 2.75, 65 and over: RR 3.32, 95% CI 0.20 to 54.59) and treatment acceptability (under 65: RR 0.83, 95% CI 0.49 to 1.40, 65 and over: RR 1.30, 95% CI 0.26 to 6.38 for behavioural activation versus comparators other than psychological therapies.

Comparisons 12 and 13. Type of therapist

There was no difference between types of therapists in treatment efficacy (specialist: RR 1.11, 95% CI 0.93 to 1.32, specialist in training: RR 1.13, 95% CI 0.85 to 1.49, non-specialist: RR 1.30, 95% CI 0.86 to 1.98) and treatment acceptability for behavioural activation versus other psychological therapies (specialist: RR 0.88, 95% CI 0.62 to 1.25, specialist in training: RR 0.83, 95% CI 0.31 to 2.25, non-specialist: RR 1.05, 95% CI 0.84 to 1.31).

There was no difference between types of therapists in treatment efficacy (specialist: RR 1.71, 95% CI 1.08 to 2.70, specialist in training no data, non-specialist: RR 1.49, 95% CI 1.13 to 1.97) for behavioural activation versus comparators other than psychological therapies. Behavioural activation was less acceptable (higher percentage of dropouts) than other comparators for interventions delivered by non-specialists (RR 2.20, 95% CI 1.06 to 4.57), and more acceptable than other comparators for interventions delivered by specialists (RR 0.65, 95% CI 0.47 to 0.89). There was no difference with behavioural activation delivered by specialists in training (RR 1.35, 95% CI 0.42 to 4.35).

Comparison 14. Severity of depressions symptoms

Behavioural activation showed greater treatment efficacy than comparators other than psychological therapies for participants with moderate to severe depression (RR 1.62, 95% CI 1.41 to 1.85), than for those with subthreshold depression (RR 1.09, 95% CI 1.01 to 1.17).

There was no difference in the treatment acceptability of behavioural activation and other comparators between participants with subthreshold depression (RR 4.30, 95% CI 0.46 to 40.44) and those with moderate to severe depression (RR 1.04, 95% CI 0.55 to 1.97).

Comparison 15. Length of therapy

No data were available to compare the treatment efficacy of behavioural activation versus comparators other than psychological therapies between short and longer length therapy.

There was no difference for treatment acceptability of behavioural activation versus comparators other than psychological therapies between a short (RR 1.03, 95% CI 0.53 to 2.03) and a longer length of therapy (RR 1.35, 95% CI 0.76 to 2.37).

Comparison 16. Type of comparator therapy

Behavioural activation showed a greater treatment efficacy when compared with psychodynamic, humanist, or integrative therapies (RR 1.50, 95% CI 1.24 to 1.81) than when compared with CBT (RR 0.99, 95% CI 0.91 to 1.07), but there was no difference for behavioural activation versus third-wave CBT (RR 1.08, 95% CI 0.91 to 1.29).

There was no difference in treatment acceptability when comparing behavioural activation to CBT (RR 1.04, 95% CI 0.85 to 1.28), third-wave CBT (RR 0.86, 95% CI 0.54 to 1.36), or psychodynamic, humanist, or integrative therapies (RR 0.77, 95% CI 0.44 to 1.33).

Comparison 17. Other control groups

There was no difference in treatment efficacy when comparing behavioural activation to treatment as usual (RR 1.17, 95% CI 0.95 to 1.45), waiting list (RR 1.17, 95% CI 0.70 to 1.93), no treatment (RR 2.97, 95% CI 1.42 to 6.24), medication (RR 1.77, 95% CI 1.14 to 2.76), or another comparator (RR 1.59, 95% CI 1.38 to 1.83).

There was no difference in treatment acceptability when comparing behavioural activation to treatment as usual (RR 1.50, 95% CI 0.56 to 3.99), waiting list (RR 1.17, 95% CI 0.70 to 1.93), no treatment (RR 0.97, 95% CI 0.45 to 2.09), placebo (RR 0.72, 95% CI 0.31 to 1.67), medication (RR 0.37, 95% CI 0.18 to 0.75), or another comparator (RR 2.17, 95% CI 1.04 to 4.53).

Sensitivity analyses**Comparisons 18 and 19. Study quality**

Sensitivity analyses were carried out removing studies which scored 'unclear' or 'high' risk of bias for allocation concealment for the primary outcomes ([Analysis 18.1](#); [Analysis 18.2](#); [Analysis 19.1](#); [Analysis 19.2](#)).

Behavioural activation was no more or less effective than other psychological therapies (RR 1.20, 95% CI 0.95 to 1.51) and there was no difference in treatment acceptability (RR 1.04, 95% CI 0.84 to 1.29).

Behavioural activation was more effective than comparators other than psychological therapies (RR 1.49, 95% CI 1.16 to 1.90) and had lower treatment acceptability than other comparators (RR 2.22, 95% CI 1.00 to 4.95).

Comparisons 20 and 21. Mode of delivery

We analysed studies which were predominantly delivered face-to-face, removing 10 studies which evaluated interventions mostly delivered online, over the phone, or email ([Analysis 20.1](#); [Analysis 20.2](#); [Analysis 21.1](#); [Analysis 21.2](#)).

There was no difference in treatment efficacy (RR 1.09, 95% CI 0.92 to 1.29) or acceptability (RR 1.00, 95% CI 0.83 to 1.20) between behavioural activation and other psychological therapies.

Behavioural activation was more effective than other comparators (RR 1.76, 95% CI 1.50 to 2.05) and there was no difference in treatment acceptability (RR 0.85, 95% CI 0.67 to 1.08).

Severity of depression

We did not perform sensitivity analyses excluding studies with participants with subthreshold depression, because these analyses would have included the same study as those in the subgroup analyses for participants diagnosed with major depressive disorder or moderate to severe symptoms of depression ([Analysis 14.1](#); [Analysis 14.2](#)).

Comparisons 22 and 23. Individual therapy

We performed sensitivity analyses for the primary outcomes excluding nine studies delivered in a group format and three studies delivered in a mixed individual/ group format ([Analysis 22.1](#); [Analysis 22.2](#); [Analysis 23.1](#); [Analysis 23.2](#)).

There was no difference in treatment efficacy (RR 1.17, 95% CI 1.00 to 1.37) or acceptability (RR 1.05, 95% CI 0.91 to 1.22) between behavioural activation and other psychological therapies.

Behavioural activation was more effective than other comparators (RR 1.61, 95% CI 1.26 to 2.05) and there was no difference in treatment acceptability (RR 1.55, 95% CI 0.85 to 2.79).

Missing data

The impact of missing data on treatment efficacy was explored in three scenarios: intention-to-treat analysis, best-case scenario, and worst-case scenario. Not all studies contributed data to these analyses, as dropout rates were not consistently reported across trials.

Comparison 24. Intention-to-treat

In this scenario, we assumed that treatment was not effective for participants who dropped out after randomisation ([Analysis 26.1](#)).

There was no difference in treatment efficacy between behavioural activation and CBT (RR 0.93, 95% CI 0.83 to 1.05), behavioural activation and third-wave CBT (RR 1.17, 95% CI 0.91 to 1.52), and behavioural activation and treatment as usual (RR 1.29, 95% CI 0.99 to 1.68).

Behavioural activation was more effective than humanistic therapy (RR 2.33, 95% CI 1.09 to 5.00).

Comparison 25. Best-case scenario

In this scenario we assumed that treatment was effective for participants who dropped out of the behavioural activation study arm and that treatment was not effective for participants who dropped out of the comparator study arm ([Analysis 27.1](#)).

There was no difference in treatment efficacy between behavioural activation and CBT (RR 1.17, 95% CI 0.90 to 1.52). Behavioural activation was more effective than third-wave CBT (RR 1.41, 95% CI 1.12 to 1.76), humanistic therapy (RR 3.67, 95% CI 1.83 to 7.34), and treatment as usual (RR 1.63, 95% CI 1.29 to 2.04).

Comparison 26. Worst-case scenario

In this scenario we assumed that treatment was not effective for participants who dropped out of the behavioural activation study arm and that treatment was effective for participants who dropped out of the comparator study arm (Analysis 28.1).

There was no difference in treatment efficacy between behavioural activation and CBT (RR 0.82, 95% CI 0.58 to 1.17), third-wave CBT (RR 0.89, 95% CI 0.73 to 1.09), humanistic therapy (RR 0.78, 95% CI 0.53 to 1.15), and treatment as usual (RR 1.14, 95% CI 0.89 to 1.46).

DISCUSSION

Summary of main results

Results for each of the 10 comparisons are summarised in the 'Summary of findings' tables.

This review comprised 53 studies, including 26 studies published after previous reviews on this topic were conducted (Churchill 2013; Ekers 2014; Hunot 2013).

The objectives of this review were to examine the effects of behavioural activation for depression in adults compared with 1) all other psychological therapies, 2) medication, and 3) other comparators (treatment as usual, waiting list, placebo, no treatment).

Behavioural activation versus psychological therapies

Trials included in this review compared behavioural activation with cognitive-behavioural therapy (CBT), third-wave CBT, humanistic therapy, psychodynamic therapy, and interpersonal/ cognitive analytic/ integrative therapy for the treatment of depression. Most trials reported data on short-term outcomes only.

Primary outcomes

Moderate- to very low-certainty evidence showed no difference in treatment efficacy and acceptability (dropouts) between behavioural activation and other psychological therapies, except that behavioural activation may be more effective than humanistic therapy (low-certainty evidence).

Subgroup and sensitivity analyses

Subgroup analyses showed no difference in efficacy and acceptability when comparing behavioural activation to other psychological therapies by participant and treatment characteristics. Efficacy of behavioural activation was greater compared with psychodynamic, humanistic, and integrative therapies than it was for CBT. No difference by type of comparator therapy was found for treatment acceptability.

When considering high-quality studies only, behavioural activation was no more or less effective or acceptable than other psychological therapies.

When considering only face-to-face and only individual therapies, there was no difference between behavioural activation and other therapies in terms of treatment efficacy and treatment acceptability.

When using an intention-to-treat approach to missing data, treatment efficacy remained higher for behavioural activation

than for humanistic therapy. This was no longer the case when a worst-case scenario was used. In a, more realistic, intention-to-treat analysis, behavioural activation showed no difference in effectiveness compared with CBT and third-wave CBT.

We performed an unplanned sensitivity analysis removing one small study with a large weighting from comparison 1.1. This reduced the precision of the estimate, but did not change the finding that CBT is no more effective than behavioural activation in the treatment of depression.

Secondary outcomes

There was no evidence of a difference in our secondary outcomes between behavioural activation and other psychological therapies (moderate- to very low-certainty evidence), except for depression symptoms being reduced to a greater extent with behavioural activation compared with humanistic therapy (moderate-certainty evidence).

Adverse events were reported in various studies for participants receiving behavioural activation, CBT, general counselling, medication placebo, medication, and treatment as usual. These events included serious adverse events such as hospitalisation, suicide attempt, and suicide. Authors of various trials reported that adverse events were not thought to be related to the treatment received.

Behavioural activation versus medication

Two trials compared behavioural activation with medication for depression.

Primary outcomes

Moderate-certainty evidence from one study suggests that behavioural activation is probably more efficacious than medication. There was moderate-certainty evidence that behavioural activation and medication probably do not differ in terms of treatment acceptability.

Secondary outcomes

Low-certainty evidence suggests reduction in depression symptoms did not differ between behavioural activation and medication in the short term, but favoured behavioural activation in the medium term.

Behavioural activation versus other comparators

Included trials compared behavioural activation with waiting list, placebo, no treatment, or treatment as usual.

Primary outcomes

Moderate-certainty evidence showed better treatment efficacy for behavioural activation compared with treatment as usual in the short term and medium term. Low-certainty evidence on the treatment efficacy of behavioural activation compared with waiting list favours behavioural activation but lacks precision.

Moderate- to low-certainty evidence showed no difference in treatment acceptability between behavioural activation and comparison groups in the short term (waiting list, placebo, no treatment, treatment as usual). Treatment acceptability was higher

for treatment as usual than for behavioural activation, although the short- and medium term estimates lacked precision.

Planned subgroup and sensitivity analyses

Subgroup analyses for participant age, length of therapy, and type of comparator showed no differences in treatment efficacy and acceptability (dropouts).

Treatment efficacy was greater for behavioural activation versus other comparators for participants with moderate to severe depression compared with those with mild or subthreshold depression. No difference by severity of depression was found for treatment acceptability.

Treatment acceptability was higher for behavioural activation than for other comparators for interventions delivered by a specialist, but lower for interventions delivered by a non-specialist. This finding was driven by three trials of non-specialist interventions, for which the comparator group consisted of treatment as usual by a general practitioner or minimal psychoeducation.

Sensitivity analyses of high-quality studies, face-to-face therapy, and individual therapy showed benefits of behavioural activation versus other comparators for treatment efficacy, but not for treatment acceptability. When considering high-quality studies only, behavioural activation had a lower treatment acceptability than comparators.

When re-analysing data using three different approaches for missing data, behavioural activation was more effective than treatment as usual only when a best-case-scenario was used.

Secondary outcomes

Moderate- to low-certainty evidence suggested that depression symptoms were reduced more for behavioural activation when compared with waiting list, treatment as usual (short and medium term but not long term), and no treatment (short and medium term), but not when compared with a placebo.

Very low- to high-certainty evidence showed benefits of behavioural activation for short-term quality of life when compared with treatment as usual and no treatment, but not when compared with waiting list. Anxiety symptoms were reduced more for behavioural activation than waiting list, treatment as usual, and no treatment (low- to moderate-certainty evidence).

Low-certainty evidence showed a benefit of behavioural activation compared with treatment as usual for short-term social adjustment and functioning.

Unplanned sensitivity analyses

We removed one outlier in analyses of behavioural activation versus treatment as usual for depression symptoms and quality of life. The estimates for depression symptoms and quality of life were reduced as a result of this, but still showed a benefit of behavioural activation.

Analyses of behavioural activation versus waiting list and versus treatment as usual showed large beneficial effects of behavioural activation, based on a mix of studies including those with small sample sizes. We conducted fixed-effect analyses in addition to random-effects analyses to investigate the impact of small studies

on the results of two comparisons. The estimates of behavioural activation versus waiting list for depression symptoms ([Analysis 24.1](#)) and anxiety symptoms ([Analysis 24.2](#)) were reduced, but still favoured behavioural activation. The estimates of depression symptoms ([Analysis 25.1](#)), and quality of life ([Analysis 25.2](#)) for behavioural activation versus waiting list were reduced, but still showed a benefit of behavioural activation.

Overall completeness and applicability of evidence

Most of the evidence came from studies conducted in high-income countries, and from the USA in particular. This may make evidence from this review less applicable to Low and Middle Income Countries, where the majority of people with depression live.

In settings with less resources to deliver mental health interventions, behavioural activation may be delivered in a format which does not require a specialist, for example using lay health workers or community workers. Our subgroup analyses did not show a difference in treatment efficacy between behavioural activation delivered by specialists, specialists-in-training, or non-specialists. When comparing behaviour activation with other comparators, comparisons in which behavioural activation was delivered by specialists favoured behavioural activation, while in comparisons with behavioural activation delivered by non-specialists treatment acceptability was higher for other comparators.

We included studies of participants with moderate and severe depression, as well as subthreshold or mild symptoms of depression, to reflect variation in severity of symptoms found in clinical practice and in the general population. Subgroup analyses suggested that behavioural activation may be more effective than non-therapy comparators for people with moderate to severe depression rather than subthreshold or mild depression.

Trial participants were not necessarily representative of the population of people with depression. This makes it difficult to apply evidence from this review to clinical practice. People with mental health problems in addition to depression, such as anxiety disorder or substance abuse, were excluded from participating in some trials. This is problematic if trial participants are more amenable to treatment than people with depression not included in these trials. As for other participant characteristics, several population groups may be overrepresented. For example, some studies included only young adults attending college or university, while others included only women. Ethnicity of trial participants was not usually reported, and for most studies in which it was reported, the majority of participants were White American or White British. Socioeconomic characteristics were also poorly reported. For trials conducted in high-income countries there was mostly a mix of participants with different socioeconomic status, although it is difficult to assess to what extent these participant characteristics are representative of the population eligible for inclusion in trials of behavioural activation for depression.

Included trials were published between 1977 and 2020. Eligibility for inclusion was not based on date of publication in our review, in order to capture the entire evidence base. However, there may be differences in the way behavioural activation would be evaluated and offered in practice nowadays and in the past. Whereas behavioural therapy was initially based on the extraction of the behavioural component from CBT, more recently, behavioural

activation has been integrated into multidisciplinary treatments or collaborative care. In our review, we only included such trials if behavioural activation was clearly specified as the main component of the intervention (Bosanquet 2017; Gilbody 2017), rather than being only one of several elements of the treatment (Richards 2013). In a future update of this review, it would be worth reconsidering selection criteria, including the publication date and scope of the intervention.

Most studies reported short-term outcomes, within six months of starting treatment. We cannot be sure that any benefits of behavioural activation reported shortly after the treatment ends would continue over time.

Quality of the evidence

The certainty of the evidence was mostly low to moderate. This means that the effect sizes calculated in our review may deviate from the true effects of behavioural activation for depression in adults. For several comparisons, evidence for some outcomes was based on data from one trial only. This means we could not assess inconsistencies in the results between trials. For the comparison 'behavioural activation versus medication', this means the evidence for treatment efficacy was based on only one study but judged to be of moderate certainty.

The quality of the trials was limited by risk of bias relating to lack of blinding of participants and personnel, no published study protocol or trial report, missing information on incomplete outcome data, and potential conflicts of interest relating to the study authors being involved in the development of the intervention. We judged some of the estimates to be imprecise due to the limited availability of data for these outcomes.

Incomplete outcome data may have resulted in overestimation of the efficacy of behavioural activation compared with treatment as usual. In sensitivity analyses using a worst-case scenario or intention-to-treat scenario, the benefit effect of behavioural activation over treatment as usual was no longer clearly observed.

Sensitivity analyses of high-quality studies suggested that there was no difference in treatment efficacy and acceptability between behavioural activation and other psychological therapies. In these analyses, behavioural activation was more effective than non-therapy comparators and had lower treatment acceptability. However, we used allocation concealment as a crude proxy for quality in these analyses, and all studies included in the sensitivity analyses as 'high quality' had other domains for which risk of bias was assessed to be high.

Findings were frequently found to be imprecise due to a small number of studies per comparison, particularly for the primary outcomes, and a small number of participants per study. The majority of studies had less than 20 participants per study arm. This makes it difficult to determine whether behavioural activation performs as well as other psychological therapies.

Searches

Although we are confident that our search of the literature included the most important databases and sources of clinical trials on behavioural activation for depression, we cannot rule out the possibility that relevant data were missed. For example, our search did not include databases from low- and middle-income countries.

In years to come, behavioural activation may be rolled out in these countries as a feasible intervention to treat depression and other mental health conditions in settings where resources are limited, and an update of this review should therefore consider a broader search including such databases.

Missing data

We contacted authors of 44 included studies for information required to complete the extraction of key data and the 'Risk of bias' assessment. Authors of 23 studies could not be contacted and authors of two studies replied, but could no longer provide the requested information. Many of these studies were published more than 20 years ago; some nearly 40 years ago. This hindered our ability to retrieve all missing data, and as a consequence many 'Risk of bias' domains remained 'unclear'. For nine studies standard deviations or sample sizes required for meta-analyses were missing, and for four studies published between 1979 and 1983 this information could not be estimated or obtained.

Publication bias

The small number of studies for most comparisons made it difficult to assess the possibility of publication bias. There was an indication of publication bias in the comparison of behavioural activation versus waiting list for depressive symptoms, with small studies favouring waiting list missing from the review (Figure 4). This information was taken into account when assessing the certainty of the evidence, as summarised in Summary of findings 6. Funnel plots did not indicate publication bias for treatment acceptability or depression symptoms in the behavioural activation versus CBT comparison, nor for the treatment efficacy, acceptability, and depression symptoms in the behavioural activation versus treatment as usual comparison.

Primary outcome

Our primary outcome was treatment efficacy measured by the number of people who responded to treatment. We accepted trial authors' definitions of 'treatment response'. For some of the included trials a 50% or greater reduction in symptom severity measured on a validated depression scale was defined as response or clinically significant improvement, while other trials used recovery or remission (symptom level below the cut-off for clinically diagnosed depression). This may have led to heterogeneity in the results. However, because effect estimates are based on comparisons between intervention and control groups in each trial, we do not expect this to substantially bias the results.

Conflict of interest

Two authors on this review (DE, DR) have been involved in multiple included trials of behavioural activation. We have reported this potential conflict of interest in the 'Risk of bias' assessments pertaining to these studies in accordance with the Conflicts of interest and Cochrane Reviews policy. DE and DR were not involved in the data extraction, 'Risk of bias' assessments, and GRADE assessments of the certainty of the evidence for this review.

Agreements and disagreements with other studies or reviews

Conclusions regarding the effectiveness of behavioural activation have been limited in previous systematic reviews by the

absence of substantive, high-certainty evidence (Churchill 2013; Hunot 2013; Shinohara 2013). No difference had previously been found in effectiveness between behavioural activation and other psychological therapies (Shinohara 2013). Our review suggested similar efficacy between behavioural activation and other psychological therapies, although our confidence in these findings is limited due to concerns about the certainty of the evidence. Moderate- to low-certainty evidence suggested that behavioural activation was more effective than humanistic therapy, both in terms of depression as a binary outcome and symptoms of depression.

The most recent systematic review of behavioural activation for depression versus comparators other than psychological therapy found mostly low-quality evidence indicating that behavioural activation was superior to a wide range of control treatments, including medication (Ekers 2014). Our review also suggests a benefit of behavioural activation in terms of treatment efficacy or depression symptoms when compared with treatment as usual or no treatment. Our review also suggested that, compared with being on a waiting list, behavioural activation improved depression symptoms, but was not necessarily better in terms of treatment efficacy (although we found only one trial that looked at this). We found no difference between behavioural activation and placebo in terms of depression symptoms, although no data were available on treatment efficacy for this comparison. Behavioural activation performed better than medication in terms of treatment efficacy, but this was based on only one trial, and we found no difference between the two interventions in relation to decreasing symptoms of depression. Any differences between reviews are most likely due to the addition of new studies, minor differences in the selection criteria, and the choice of comparisons and outcomes.

AUTHORS' CONCLUSIONS

Implications for practice

In the UK, NICE guidance recommends behavioural activation for the treatment of subthreshold, mild, or moderate depression in adults, whilst recognising that the evidence for behavioural activation is less robust than for cognitive-behavioural therapy (CBT) and interpersonal therapy (NICE 2009). This systematic review suggests that behavioural activation may be more effective than humanistic therapy, medication, and treatment as usual, and that it may be no less effective than CBT, psychodynamic therapy, or being on a waiting list. However, our confidence in these findings is limited due to concerns about the certainty of the evidence.

Policy makers and practitioners may be able to use this evidence to inform decisions about whether or not to recommend or provide behavioural activation for the treatment of depression in adults, giving people with depression greater treatment choice. Other more established psychological therapies for depression rely on the availability of mental health professionals, often over a more extended period of time. Behavioural activation may offer an additional option, extending the range of available treatments in terms of type of therapist, format of delivery, and length of therapy, possibly within the context of a multidisciplinary collaborative care model.

Although sensitivity analyses of high-quality studies confirmed findings of no difference in effectiveness between therapies, the majority of the evidence on the efficacy of behavioural activation

was of limited quality and/or certainty. There may be differences between therapies we have not been able to demonstrate due to a lack of high-certainty evidence. There was more evidence available for improvement in symptoms of depression than for treatment efficacy (which was based on a clinical assessment of significant improvement, remission, or recovery).

Subgroup analyses suggested that behavioural activation may be more effective for moderate to severe depression than for subthreshold or mild depression when compared to control groups other than psychological therapies. Although this finding was based on data from only six studies, it is interesting given that behavioural activation is not currently recommended for moderate to severe depression in the UK (NICE 2009).

The choice between behavioural activation and another treatment for depression, for both people with depression and health care providers, will be influenced by factors other than evidence of short-term effectiveness. Evidence which was mostly moderate to low certainty did not suggest a difference in treatment acceptability, as indicated by dropout rates, between behavioural activation and other psychological therapies. People with depression may consider other aspects of treatment acceptability in their decision-making, such as the likelihood of side effects or acceptability of the format, or time commitment required. No adverse effects were identified for behavioural activation other than those unlikely to be related to the treatment. However, only seven out of 53 included studies collected and explicitly mentioned adverse events, and we therefore know relatively little about any potential negative impacts of this intervention.

Implications for research

This review has synthesised evidence from 53 studies, spanning four decades of research on behavioural activation for depression from a range of countries and settings. Despite this substantial amount of research, the evidence was mostly not of high certainty and for psychotherapy comparators in particular, a limited amount of data were available per comparator. More of the same research with the same populations is not likely to substantially improve the evidence base around behavioural activation. Considering the literature identified by this review, we see clear opportunities to improve the evidence base, including: enhancing the quality of trial methodology and reporting, using relevant comparators, measuring treatment acceptability as well as as well as adverse events, and better understanding which people with depression are most likely to benefit.

Strengthening the evidence base

Firstly, we have been limited in the conclusions that can be drawn from this review by the certainty of the evidence. Some issues are harder to overcome than others. For example, studies of psychological therapies are likely to be at risk of performance bias, because of the lack of a true placebo. However, an appropriate sample size, a longer follow-up, and transparency in the randomisation and allocation process would significantly improve the certainty of the evidence. We note that recent clinical trials are more likely to have achieved this than some of the older trials included in this review. In addition, involvement in the evaluation of interventions by researchers who developed the intervention caused a potential conflict of interest for several of the included trials.

Secondly, comparators should be selected based on their relevance for clinical practice. In the UK, NICE guidance recommends behavioural activation as one option for mild to moderate depression, alongside CBT, interpersonal therapy, couples therapy, counselling, or psychodynamic therapy (NICE 2009). In this setting, 'behavioural activation versus other therapies' may therefore be the most informative comparison to clinicians and patients. In settings where most people with depression remain untreated, the comparison between behavioural activation and no or minimal treatment may be of interest.

Thirdly, we used drop out from the study as a crude indicator of treatment acceptability, while treatment acceptability may be measured more comprehensively in other ways, for example through satisfaction surveys. The synthesis of existing evidence and the incorporation of such measures into trials could aid the implementation of behavioural activation in practice.

What works for whom

Evaluations of behavioural activation, as for most interventions in mental health, have generally focused on estimating an average effect of the intervention for the trial sample. Many questions on the most effective format or delivery of behavioural activation remain unanswered. Our review did not find any difference between interventions conducted face-to-face or online/over the phone, in an individual or group format, and with different durations. Studies explicitly investigating any such differences, whether through statistically powered clinical trials or qualitative evaluations, would be better placed to conclusively answer these questions and to determine what the most effective elements and formats of behavioural activation therapy are.

We aimed to explore differences in the effectiveness and acceptability of behavioural activation for various groups of the population, such as by participant age and severity of depression. These subgroup analyses were limited by the lack of relevant data reported in the included studies. To answer any questions

on treatment efficacy and acceptability for different groups of the population, detailed information on key participant characteristics should be collected and reported. This would allow researchers carrying out systematic reviews of the literature to assess what works for whom, and to better judge the applicability of the evidence for the diverse population of people with mental health problems.

Evidence from Low and Middle Income Countries, where resources to provide mental health support may be limited and behavioural activation may therefore offer a potential treatment option, is sparse. Well-conducted trials in Low and Middle Income Countries including diverse samples of participants may indicate whether behavioural activation could be an effective, acceptable, and feasible treatment for depression in these settings.

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 Behavioural activation therapies for depression in adults.

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES
Characteristics of included studies [ordered by study ID]

Arjadi 2018
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: participants were recruited from the Indonesian community through mass media advertisements (banners placed in various websites and places throughout the country), social media (online communities, forums, and pages about mental health), and referral from mental health institutions or mental health professionals (both flyers and word of mouth). Potential participants could access extensive information on the trial website, and, if they were interested, could complete the screening assessment (PHQ-9) via a linked Qualtrics online survey platform. No face-to-face screening methods were used.</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 31 male (19%), 128 female (81%) • <i>Ethnic group:</i> Java 69 (43%), Tionghoa 30 (19%), Sunda 21 (13%), Batak 8 (5%), Minangkabau 8 (5%), Other (19 ethnicities) 23 (14%) • <i>Household income:</i> - • <i>Occupation/employment:</i> unemployed 18 (11%), professional 3 (2%), private employee 56 (35%), civil employee 6 (4%), entrepreneur 4 (3%), freelancer 13 (8%), student 57 (36%), housewife 2 (1%) • <i>Education level:</i> junior high 3 (2%), senior high 61 (38%), vocational 6 (4%), Bachelor's degree 76 (48%), Master's degree 13 (8%) • <i>Comorbid anxiety:</i> N = 67 (42%) • <i>Depression severity:</i> 29% mild, 28% moderate, 43% severe • <i>Age:</i> 24.45 (SD 4.93) <p>Psychoeducation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 29 male (19%), 125 female (81%) • <i>Ethnic group:</i> Java 64 (42%), Tionghoa 18 (12%), Sunda 22 (14%), Batak 15 (10%), Minangkabau 6 (4%), Other (19 ethnicities) 29 (19%) • <i>Household income:</i> - • <i>Occupation/employment:</i> unemployed 6 (4%), professional 7 (5%), private employee 48 (31%), civil employee 3 (2%), entrepreneur 4 (3%), freelancer 17 (11%), student 63 (41%), housewife 6 (4%) • <i>Education level:</i> junior high 2 (1%), senior high 59 (38%), vocational 12 (8%), Bachelor's degree 73 (47%), Master's degree 8 (5%) • <i>Comorbid anxiety:</i> N = 75 (49%) • <i>Depression severity:</i> 25% mild, 36% moderate, 39% severe • <i>Age:</i> 24.52 (SD 5.22) <p>Overall</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> -

Arjadi 2018 (Continued)

- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Included criteria: aged 16 or older, scored 10 or above on PHQ 9, met criteria for major or persistent depressive disorders on DSM-5, were proficient in Bahasa Indonesia, and could use the internet.

Excluded criteria: current substance use disorders, current or previous manic or hypomanic episodes or psychotic disorder, attending psychological intervention at least weekly, and acute suicidality.

Pretreatment: baseline characteristics of enrolled participants were similar in both intervention groups.

Current medication: current medication treatment for mental health problems was allowed, and was checked at enrolment and again during the final interview. No participants were taking medications for mental health problems at enrolment or at their final interviews.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* online behavioural activation including counsellor support and psychoeducation
- *dose:* 30 to 45 minutes per module
- *frequency:* weekly
- *duration:* 8 weeks
- *level of therapist:* non-specialist
- *individual or group therapy:* individual
- *mode of delivery:* online with support from lay counsellor on the phone
- *modifications:* reduced text, replaced videos with illustrations, adapted to Indonesian context from original Dutch intervention

Psychoeducation

- *type of intervention:* comparator
- *specific intervention:* minimal psychoeducation; online psychoeducation without support
- *dose:* -
- *frequency:* -
- *duration:* 8 weeks
- *level of therapist:* -
- *individual or group therapy:* individual
- *mode of delivery:* online
- *modifications:* -

Outcomes

Depression symptoms

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** PHQ-9
- **Direction:** lower is better
- **Data value:** endpoint

Quality of life

Arjadi 2018 (Continued)

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** WHOQOL-brief
- **Direction:** higher is better
- **Data value:** endpoint

Depression remission

- **Outcome type:** dichotomous outcome
- **Reporting:** fully reported
- **Scale:** SCID-5 (DSM-5)
- **Direction:** higher is better
- **Data value:** endpoint

Dropouts

- **Outcome type:** dichotomous outcome
- **Reporting:** fully reported
- **Direction:** lower is better
- **Data value:** endpoint

Identification

Sponsorship source: this study is funded by the Indonesia Endowment Fund for Education (Lembaga Pengelola Dana Pendidikan), Ministry of Finance, Republic of Indonesia which provided a PhD scholarship and research funding for the first author. In addition, the University of Groningen also provided general funding support.

Country: Indonesia

Setting: community-based

Comments: -

Authors name: Prof Claudi L H Bockting

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Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Participants were randomly allocated (1:1) by a research assistant to GAF-ID or online psychoeducation via a web-based randomisation program built by an independent developer for this trial. Randomisation was done within a random permuted block design stratified by sex and depression severity (score 10–14 vs score ≥15 on PHQ-9)." Judgement comment: research assistant used web-based randomisation program
Allocation concealment (selection bias)	Low risk	Judgement comment: used different research assistants for randomisation and other aspects of the study. They were not aware of random block design. Web-based

Arjadi 2018 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding for participants. Although researchers tried to conceal which was the 'intervention of interest', the psychoeducation intervention was minimal in terms of support provided and substance of the intervention. This could have influenced participants' outcomes and chance of dropout.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The research assistants who did the clinical interviews after randomisation were not involved in the intervention process and were masked to participants' treatment condition (participants were also asked not to reveal their treatment condition during the interviews). At the end of the final interview (10 weeks after baseline), research assistants were asked to guess the treatment allocation of each participant they interviewed, and were then no longer blinded to allocation." Judgement comment: Efforts were made to conceal treatment allocation from research assistants who performed interviews, and outcomes were self-completed online. At the end of the trial, research assistants did correctly identify 68% of allocations, indicating blinding did not work completely, but this is unlikely to have influenced the results substantially.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: missing data were imputed but unclear how. People with milder symptoms more likely to drop out, which may have affected estimates. More dropouts in more intensive BA group than psychoeducation group, which may have led to a final sample of participants who responded well to treatment, and may have led to overestimation of positive results.
Selective reporting (reporting bias)	Low risk	Quote: "The trial protocol is publicly available, 6 and the trial was preregistered. The Tarumanagara University Human Research Ethics Committee (PPZ20152002), and the Research Ethics Committee at the Institute of Research and Community Service, Atma Jaya Catholic University of Indonesia (942/III/LPPM-PM.10.05/09/2016) provided ethical approval for the study." Judgement comment: all of the study's pre-specified outcomes have been reported. Outcomes and time points in protocol match study manuscript.
Other bias	Low risk	Treatment fidelity: Judgement comment: No assessment of treatment fidelity, but given that the intervention was mostly done on a computer there was limited potential for deviation from the intended treatments. Researcher allegiance/ conflict of interest: Quote: "Participants in the GAF-ID group received an internet-based behavioural activation intervention supported by lay counsellors. The intervention was made available via a secure online platform, which was built by an independent professional intervention website developer in the Netherlands." Judgement comment: last author C Bockting may have been involved in development of Dutch version of this intervention, but this is unlikely to be of great importance to the study results. Therapist allegiance/ conflict of interest: Judgement comment: minimal involvement from therapist.

Armento 2012
Study characteristics

Methods **Study design:** randomised controlled trial

Behavioural activation therapy for depression in adults (Review)

Armento 2012 (Continued)

Study grouping: parallel group

Recruitment:
Type of RCT (blind, double-blind, open-label): open-label

Participants

Baseline characteristics

Behavioural activation

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* 16.3 (9.0 SD)
- *Depression severity:* -
- *Age:* -

Supportive treatment

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* 11.6 (6.3 SD)
- *Depression severity:* -
- *Age:* -

Overall

- *Gender (N male, % male, N female, % female):* 19 male (38%), 31 female (62%)
- *Ethnic group:* 44 Caucasian (88%), 4 African American (8%), 1 Latino (2%), 1 American Indian/ Alaskan Native (2%)
- *Household income:* -
- *Occupation/employment:* 100% students
- *Education level:* 14 years (SD 1.38)
- *Comorbid anxiety:* -
- *Depression severity:* 29 major depression (58%), 10 dysthymia (20%)
- *Age:* 20.0 (SD 2.75)

Included criteria: age 18 or older and BDI-II greater than or equal to 14, no medication or stabilised on medication for at least 8 weeks

Excluded criteria: active suicidal intent, psychosis

Pretreatment: more participants in the ST group had a partner (N = 4 versus N = 0). Anxiety and depression scores seem slightly higher at baseline in BA compared to ST group.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* single session behavioural activation of religious behaviours
- *dose:* 60 minutes therapy session
- *frequency:* one session, telephone check in a week after intervention
- *duration:* one therapy session, 2-week interval given for activities

Armento 2012 (Continued)

- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: homework form, initial session face-to-face then telephone check in
- *modifications*: focus on religious activities

Supportive treatment

- *type of intervention*: comparator
- *specific intervention*: single session supportive treatment
- *dose*: 60 minutes
- *frequency*: one session, telephone check in a week later
- *duration*: one session
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: initial session face-to-face then telephone check in
- *modifications*: expressed depressive thoughts in a supportive environment but no therapy intervention used

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: BDI-II
- **Direction**: lower is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: lower is better
- **Data value**: endpoint
- **Notes**: unclear whether dropouts were included in ITT analysis or as-treated analysis

Anxiety symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: BAI
- **Direction**: lower is better
- **Data value**: endpoint
- **Notes**: Both BAI and STAI reported; chosen Becks Anxiety Inventory because Becks Depression Inventory was used as depression measure.

Quality of life

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: Quality of Life Inventory (QOLI)
- **Direction**: higher is better
- **Data value**: endpoint

Identification

- **Sponsorship source**: no information (thesis)
- **Country**: USA
- **Setting**: university

Armento 2012 (Continued)

Comments: -

Authors name: Derek Hopko

Institution: Department of Psychology, University of Tennessee

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Address: The University of Tennessee - Knoxville, Department of Psychology, 307 AustinPeay Building, Knoxville, TN 37996-0900.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement comment: not mentioned how they were randomised. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: participants not blinded, may have impacted if disagreed with intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: unclear who was collecting data from questionnaires. Author could not be contacted.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: two people dropped out, one for logistical issues and the other for illness. Both in BA group but no significant difference in attrition
Selective reporting (reporting bias)	Unclear risk	Judgement comment: protocol reference in dissertation is for different study.
Other bias	Unclear risk	<p>Judgement comment: group participating were more educated and less likely to be married compared to those who declined. This may indicate randomisation was unsuccessful and lead to biased estimates.</p> <p>Treatment fidelity:</p> <p>Quote: "All components of therapy were demarcated within the protocol and checked off by the therapist to indicate protocol adherence."</p> <p>Judgement comment: BARB group checked but ST group was told to continue as usual, unclear what this would have involved. Author could not be contacted.</p> <p>Researcher allegiance/ conflict of interest: Judgement comment: study appears to have been conducted, treatment provided, and results analysed, by one person as part of a dissertation. This reduces objectivity. However, no conflicts of interest reported.</p> <p>Therapist allegiance/ conflict of interest: Judgement comment: performed by one doctoral student in clinical psychology trained in BARB - may have an interest in showing effectiveness.</p>

Bolton 2014
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: May 2009 to June 2010 through referrals by doctors and nurses and through collaboration with former prisoner organisations who notified their members.</p> <p>Type of RCT (blind, double-blind, open-label): partly blind outcome assessments (85%)</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 49 Male (43%) 65 female (57%) • <i>Ethnic group:-</i> • <i>Household income: -</i> • <i>Occupation/employment:</i> 57 (50%) not employed, 25 (22%) in regular work, 32 (28%) self-employed/in irregular work • <i>Education level:</i> 59 (52%) none, 26 (23%) primary, 24 (21%) secondary, 5 (4%) bachelors/institutional degree or certificate • <i>Comorbid anxiety:</i> 1.25 mean (0.07 SE) • <i>Depression severity:</i> 1.6 (SD 0.5) • <i>Age:</i> 36.9 (SD 12.4) <p>Cognitive procession therapy (CPT)</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 59 female (58%) • <i>Ethnic group: -</i> • <i>Household income: -</i> • <i>Occupation/ employment:</i> 47 not working (48%), 32 regular work (33%), 18 self-employed/ irregular (19%) • <i>Education level:</i> 44 (44%) none, 30 (30%) primary, 13 (13%) secondary, 14 (14%) bachelors/institutional degree or certificate • <i>Comorbid anxiety:</i> 1.34 mean (0.06 SE) • <i>Depression severity:</i> 1.7 (SD 0.4) • <i>Age:</i> 41.5 (SD 13.7) <p>Waiting-list control</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 27 Male (41%) 39 Female (59%) • <i>Ethnic group: -</i> • <i>Household income: -</i> • <i>Occupation/employment:</i> 37 not working (56%), 20 regular work (30%), 9 self-employed/irregular (14%) • <i>Education level:</i> 38 (58%) none, 18 (27%) primary, 8 (12%) secondary, 2 (3%) bachelors/institutional degree or certificate • <i>Comorbid anxiety:</i> 1.18 mean (0.06 SE) • <i>Depression severity:</i> 1.5 (SD 0.3) • <i>Age:</i> 42.3 (SD 12.5) <p>Overall</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 118 Male (42%), 163 Female (58%) • <i>Ethnic group: -</i>

Bolton 2014 (Continued)

- *Household income:* -
- *Occupation/ employment:* 141 (50%) not employed, 77 (27%) in regular work, 59 (21%) self-employed/in irregular work
- *Education level:* 141 (50%) none, 74 (26%) primary, 45 (16%) secondary, 21 (7%) bachelors/institutional degree or certificate
- *Comorbid anxiety:* mean 1.26
- *Depression severity:* mean 1.6
- *Age:* mean 40.2

Included criteria: eligible persons were survivors of systematic violence living in the governorates of Erbil or Sulaimaniyah, aged 18 or over, fluent in Sorani Kurdish, reported significant depression symptoms on the adapted HSCL-25, had no current psychotic symptoms or active suicidality, and appeared mentally competent to consent.

Excluded criteria: inability to be interviewed due to a cognitive or physical disability, or severe suicidal ideation or behavior.

Pretreatment: mental health symptoms on several scales slightly higher in CPT group. Some other differences such as proportion of females, partnership status, and employment.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:*
- *dose:* -
- *frequency:*
- *duration:* -
- *level of therapist:* non-specialist
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* adapted for low literacy/extreme poverty and administration by paraprofessionals + culturally adapted to consider societal expectations and collective perspective

Cognitive procession therapy (CPT)

- *type of intervention:* comparator
- *specific intervention:* CPT
- *dose:* -
- *frequency:* 9 sessions
- *duration:* -
- *level of therapist:* non-specialist
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* adapted explanations to examples relevant to Kurdistan. Changed themes from esteem/intimacy to respect/caring. Reduced complexity of written material and included pictures. Used mobile phones to record homework and family members as scribe

Waiting-list control

- *type of intervention:* comparator
- *specific intervention:* waiting-list control
- *dose:* -
- *frequency:* -
- *duration:* approx 5 months
- *level of therapist:* non-specialist

Bolton 2014 (Continued)

- *individual or group therapy*: individual
- *mode of delivery*: -
- *modifications*: offered treatment after 5 months. contacted monthly for symptom check

Outcomes

Depression

- **Outcome type**: Continuous outcome
- **Reporting**: fully reported
- **Scale**: adapted HSCL-25
- **Range**: 0-3
- **Direction**: lower is better
- **Data value**: endpoint
- **Notes**: qualitative study data were used to adapt the Hopkins Symptom Checklist for Depression and Anxiety (HSCL-25), the Harvard Trauma Questionnaire (HTQ), and the Inventory of Traumatic Grief to measure symptoms of depression, anxiety, posttraumatic stress and traumatic grief. Adaptation included adding 13 locally relevant symptoms. Instrument reliability and validity were tested for all outcomes among local survivors of systematic violence (N = 128).

Anxiety

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: adapted HSCL-25
- **Range**: 0-3
- **Direction**: lower is better
- **Data value**: change from baseline
- **Notes**: qualitative study data were used to adapt the Hopkins Symptom Checklist for Depression and Anxiety (HSCL-25), the Harvard Trauma Questionnaire (HTQ), and the Inventory of Traumatic Grief to measure symptoms of depression, anxiety, posttraumatic stress and traumatic grief. Adaptation included adding 13 locally relevant symptoms. Instrument reliability and validity were tested for all outcomes among local survivors of systematic violence (N = 128).

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: lower is better
- **Data value**: endpoint

Identification

Sponsorship source: This study was solely funded by the USAID Victims of Torture Fund (VOT).

Country: Northern Iraq

Setting: government primary healthcare clinics

Comments: -

Authors name: Paul Bolton

Institution: John Hopkins Bloomberg School of Public Health

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Notes

Risk of bias

Bolton 2014 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization of CMHWs and participant IDs was done by JB using Stata's randomization function. Investigators kept a master list of each study ID's assignment for checking randomization fidelity." Judgement comment: Use of Stata's randomisation function
Allocation concealment (selection bias)	Low risk	Quote: "If a person consented the CMHW opened a sealed envelope attached to the consent form containing the participant's assignment." Judgement comment: sealed envelope
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Participants were not blinded to their own treatment/control status." Judgement comment: no blinding of participants. This might influence outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: outcome assessments were blinded in 85% of cases. 15% of unblinded interviews may have influenced results, as this was the group of patients that did not want further treatment, which may be related to their relationship with the assessor/therapist.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Multiple imputation by chained equations accounted for missing scale items and follow up scores among those lost to follow up [49]." Judgement comment: dropout reasons reported, and no obvious differences between groups. Slightly more people in BA group (28%) than CPT group (21%) started but did not complete treatment.
Selective reporting (reporting bias)	Low risk	Judgement comment: outcomes as reported in protocol (NCT00925262). Timing of follow-up assessment was different from proposed timing (3-6 months), but explained in the paper this is due to time taken to complete intervention and logistical challenges.
Other bias	Low risk	Judgement comment: none identified. Quote: "The authors declare that they have no competing interests." Judgement comment: therapists were community mental health workers; no reason to believe there would be conflicts of interest, although therapists may have preferred one treatment over another. Correspondence with author: "Providers received weekly supervision during which supervisors reviewed what actions providers took with each client that week and checked it against their training."

Bosanquet 2017
Study characteristics

Methods	Study design: randomised controlled trial
	Study grouping: parallel group
	Recruitment: from GP practices in the North of England: York, Leeds, Durham, Newcastle, and their surrounding areas. To start 15 Sept 2012.

Bosanquet 2017 (Continued)

Type of RCT (blind, double blind, open label):

Participants

Baseline characteristics

Behavioural activation

- *Gender (N male, % male, N female, % female):* 98 male (39.4%), 150 female (60.2%)
- *Ethnic group:* 241 (96.8%) white, 1 (0.4%) Asian, 1 (0.04%) black, 3(1.2%) other
- *Household income:* -
- *Occupation/ employment:* -
- *Education level:* 108 (43.4%) educated past 16y, 57 (22.9%) with degree/equivalent
- *Comorbid anxiety:* GAD-7 9.4 (5.03 SD)
- *Depression severity:* 1% none, 24% mild, 31% moderate, 28% moderate severe, 16% severe
- *Age:* 72.5 (SD 6.57)

Usual care

- *Gender (N male, % male, N female, % female):* 85 male (36.0%), 151 female (64.0%)
- *Ethnic group:* 233 White (99%), 2 other (1%)
- *Household income:* -
- *Occupation/ employment:* -
- *Education level:* 101 (42.8%) educated past 16y, 68 (28.8%) with degree/equivalent
- *Comorbid anxiety:* GAD-7 9.3 (4.92 SD)
- *Depression severity:* 2% none, 19% mild, 33% moderate, 32% moderate severe, 14% severe
- *Age:* 71.8 (SD 6.07)

Overall

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/ employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Included criteria: aged 65 years and over, screen-positive to at least one of the Whooley questions, and major depressive disorder (DSM IV) on further assessment with the MINI diagnostic tool and PHQ-9 questionnaire

Excluded criteria: known alcohol dependency (as recorded on GP records). Any known co-morbidity that would in the GP's opinion make entry to the trial inadvisable (for example, recent evidence of self-harm, known current thoughts of self-harm, significant cognitive impairment). Other factors that would make an invitation to participate in the trial inappropriate (for example, recent bereavement, terminal illness). Known to be experiencing psychotic symptoms (as recorded on GP records)

Pretreatment: people in the collaborative care group seemed more likely to answer feeling down/depressed/ hopeless and having little or no interest or pleasure in doing things in Whooley questions. No differences in PHQ-9 scores.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* manualised low-intensity programme of collaborative care using behavioural activation
- *dose:* -

Bosanquet 2017 (Continued)

- *frequency*: average 6 sessions
- *duration*: 8-9 weeks
- *level of therapist*: non-specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face, telephone
- *modifications*: collaborative care elements: telephone support, medication management, symptom monitoring, active surveillance. Designed specifically for adults > 65 with depression.

Usual care

- *type of intervention*: comparator
- *specific intervention*: usual care from GP (including prescription of necessary medication)
- *dose*: -
- *frequency*: -
- *duration*: -
- *level of therapist*: non-specialist
- *individual or group therapy*: individual
- *mode of delivery*: -
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: PHQ-9
- **Range**: 0-27
- **Direction**: lower is better
- **Data value**: endpoint

Anxiety symptoms

- **Outcome type**: ContinuousOutcome
- **Reporting**: Fully reported
- **Scale**: GAD-7
- **Range**: 0-21
- **Direction**: Lower is better
- **Data value**: Endpoint

Quality of life

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: SF-12 PCS score
- **Direction**: higher is better
- **Data value**: endpoint

Suspected adverse events

- **Outcome type**: adverse event
- **Reporting**: fully reported
- **Data value**: change from baseline
- **Notes**: all but 2 out of 81 suspected adverse events were found to be unrelated to the intervention, with the other 2 unlikely to be related. None of the 13 deaths were due to suicide. 47/196 suspected adverse events in BA arm, compared to 34/211 in usual care arm.

Dropouts

Bosanquet 2017 (Continued)

- **Outcome type:** dichotomous outcome
- **Reporting:** fully reported
- **Direction:** lower is better
- **Data value:** endpoint

Identification

Sponsorship source: this project was funded by the National Institute for Health Research HTA programme (project number 10/57/43)

Country: UK

Setting: primary care; 69 GP practices in North of England

Comments: four centres: (1) York centre (the core study centre) covering the York, Harrogate, Hull and the surrounding areas; (2) Leeds centre and the surrounding area; (3) Durham centre and the surrounding area; and (4) Newcastle upon Tyne centre, including Northumberland and North Tyneside

Authors name: Simon Gilbody

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Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation was carried out by the York Trials Unit Randomisation Service [www.yorkrand.com (accessed 23 June 2016)], accessed by a trained researcher from the study team. Participants were automatically randomised by a computer on a 1: 1 basis by simple unstratified randomisation to either the intervention group or control group, following the completion of a diagnostic interview. All diagnostic interviews were conducted over" Judgement comment: participants automatically randomised by computer, by the York Trials Unit Randomisation Service, on a 1:1 basis using simple unstratified randomisation after informed consent and baseline measures were collected
Allocation concealment (selection bias)	Low risk	Judgement comment: central allocation concealed from PI and participating GPs. By York Trials Unit randomisation service.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: not possible to blind, may affect outcomes if patients know they are just receiving usual care. Mental health workers in GP practices may have had a preference for BA, particularly given that the alternative was treatment as usual.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: outcomes completed by participants, mostly at home without interference from a researcher. This reduces risk of bias for researchers but not patients.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: higher percentage of people in the intervention group dropped out, and more had dropped out because they did not want to engage compared to usual care. However, dropout low overall.

Bosanquet 2017 (Continued)

Selective reporting (reporting bias)	Low risk	Judgement comment: slight differences in outcomes reported in trial registration, protocol, and trial report, but no change in primary outcomes.
Other bias	High risk	<p>Judgement comment: a purposive sample of sessions was audio-recorded from a range of case managers. However, no information on the outcome of this quality assurance process was reported. Case worker liaised with GP and recommended changes to patient care - unsure what changes were made by case workers.</p> <p>Judgement comment: several authors have been involved in multiple studies of BA. It can be assumed it is in their interest (status, funding) for findings of the trial to endorse BA as an effective intervention.</p>

Bowe 2014
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: the study team used ancillary recruitment strategies such as posting fliers at churches, other nursing centres and other resource centres in the African American community. In addition, study personnel actively recruited at the BOH one day per week during free-meal services by making announcements and talking about the group with individuals receiving food from the food line.</p> <p>Type of RCT (blind, double-blind, open-label):</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 3 male, 4 female • <i>Ethnic group:</i> African-American • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> - • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> - • <i>Age:</i> 50.86 (SD 6.54), range 44-63 <p>Waiting list</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> - • <i>Ethnic group:</i> African-American • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> - • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> - • <i>Age:</i> 44.71 (SD 9.07) <p>Overall</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> - • <i>Ethnic group:</i> -

Bowe 2014 (Continued)

- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Included criteria: African-American, ages of 18 and 65 inclusive, at least a fifth grade education level, ability to read and write in English, diagnosis of Major Depressive Disorder during the screen according to the Mini International Neuropsychiatric Interview and score 14 or greater on HADS at time of screening

Excluded criteria: current suicidal ideation, meet criteria for Bipolar Disorder, Schizophrenia according to the MINI during the screen, alcohol or substance dependence according to the MINI during the screen, currently receiving psychotherapy or medication for depression, already participated in Phase 1 of the study

Pretreatment:

Interventions	Intervention characteristics
	Behavioural activation <ul style="list-style-type: none"> • <i>type of intervention:</i> BA • <i>specific intervention:</i> culturally enhanced behavioural activation (CEBA) • <i>dose:</i> 2 hours • <i>frequency:</i> Weekly • <i>duration:</i> 12 weeks • <i>level of therapist:</i> specialist • <i>individual or group therapy:</i> individual + group • <i>mode of delivery:</i> Face-to-face, phone • <i>modifications:</i> Adapted to African-American culture Waiting list <ul style="list-style-type: none"> • <i>type of intervention:</i> comparator • <i>specific intervention:</i> waiting list • <i>dose:</i> - • <i>frequency:</i> - • <i>duration:</i> 12 weeks • <i>level of therapist:</i> - • <i>individual or group therapy:</i> individual + group • <i>mode of delivery:</i> - • <i>modifications:</i> -
Outcomes	Dropouts <ul style="list-style-type: none"> • Outcome type: dichotomous outcome • Reporting: fully reported • Direction: lower is better • Data value: endpoint Depression symptoms <ul style="list-style-type: none"> • Outcome type: continuous outcome • Scale: HAM-D • Direction: lower is better • Data value: endpoint

Bowe 2014 (Continued)

- **Notes:** only individual data is reported, for three patients who completed mid-treatment data collection, and one patient who completed endpoint data collection.

Identification	<p>Sponsorship source: Research Growth Initiative Grant awarded to J Kanter to fund this dissertation.</p> <p>Country: USA</p> <p>Setting: neighbourhood community health centre</p> <p>Comments: participants in BA group (no information on other group) were extremely disadvantaged (homelessness, shelter accomodation) and had a multitude of personal issues and comorbidities (diabetes, housing needs, suicide attempt, paranoia, alcoholism, gang violence).</p> <p>Authors name: William Michael Bowe</p> <p>Institution: University of wisconsin-Milwaukee</p> <p>Email: -</p> <p>Address: -</p>
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Notes	<p>Noortje Uphoff on 02/04/2019 19:19</p> <p>Select</p> <p>Can not include data for this study. It doesn't have any analysis of outcomes.</p>
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Following screening procedures described in more detail below, eight participants were randomized to the waitlist control group, and seven participants were randomized to the active group. The" Judgement comment: no information. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding not possible due to nature of intervention.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: self-completed measures and partly administered by study assessor.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: large number of dropouts: 6/8 from waiting list and 6/7 from active condition. At least 1 dropout related to not receiving intervention.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no protocol. Author could not be contacted.
Other bias	High risk	Judgement comment: participants in BA group were extremely disadvantaged (homelessness, shelter accommodation) and many comorbidities (diabetes, housing needs, suicide attempt, paranoia, alcoholism, gang violence). No information on other group. Extremely small sample sizes; randomisation unlikely to create balanced groups.

Bowe 2014 (Continued)

Judgement comment: researcher developed the treatment and may therefore likely to have an interest in it being effective. Therapists likely to have included the author.

Carlbring 2013
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Recruitment: participants were recruited from the general public by means of a 10 x 8 cm advertisement, published on a Sunday in January 2011, in a Swedish newspaper (Dagens Nyheter) with wide circulation.

Type of RCT (blind, double-blind, open-label): open

Participants

Baseline characteristics

Behavioural activation

- *Gender (N male, % male, N female, % female):* 9 male (22%), 31 female (77%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* armed forces 0, legislators/senior/managers 5 (12.5%), professionals 8 (20%), technicians/associate profs 8 (20%), clerks 2 (5%), service/shop sales workers 3 (7.5%), skilled agric/fish 0, craft/related trades 1 (2.5%), plant/machine operators 0, elementary 2 (5%), self-employed 1 (2.5%), other 1 (2.5%), retired 4 (10%), unemployed/sick 2 (5%), student 3 (7.5%)
- *Education level:* elementary school 1 (2.5%), upper secondary 11 (27.5%), vocational training 0, university ongoing 4 (10%), university completed 24 (60%)
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* 43.6 (SD 13.7)

Waiting list

- *Gender (N male, % male, N female, % female):* 5 male (12%), 35 female (87%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* armed forces 0, legislators/senior/managers 6 (15%), professionals 0, technicians/associate profs 10 (25%), clerks 2 (5%), service/shop sales workers 2 (5%), skilled agric/fish 0, craft/related trades 2 (5%), plant/machine operators 0, elementary 1 (2.5%), self-employed 2 (5%), other 0, retired 5 (12.5%), unemployed/sick 4 (10%), student 6 (15%)
- *Education level:* elementary school 2 (5%), upper secondary 2 (5%), vocational training 3 (7.5%), university ongoing 6 (15%), university completed 27 (67.5%)
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* 45.3 (SD 13.4)

Overall

- *Gender (N male, % male, N female, % female):* M 14 (17.5%), F 66 (82.5%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* armed forces 0, legislators/senior/managers 11 (13.8%), professionals 8 (10%), technicians/associate profs 18 (22.5%), clerks 4 (5%), service/shop sales workers 5 (6.3%),

Carlbring 2013 (Continued)

- skilled agric/fish 0, craft/related trades 3 (3.8%), plant/machine operators 0, elementary 3 (3.8%), self-employed 2 (2.5%), other 1 (1.3%), retired 9 (11.3%), unemployed/sick 6 (7.5%), student 9 (11.3%)
- *Education level:* elementary school 3 (3.8%), upper secondary 13 (16.3%), vocational training 3 (3.8%), university ongoing 10 (12.5%), university completed 51 (63.8%)
 - *Comorbid anxiety:* -
 - *Depression severity:* -
 - *Age:* 44.4 (SD 13.5)

Included criteria: (a) be at least 18 years of age; (b) live in Sweden; and (c) have a MADRS-S score in the range of 15 to 30. If the participant was on medication the dosage had to be kept constant for the past 3 months.

Excluded criteria: ongoing therapy, other primary diagnosis, just changed medication

Pretreatment: more men in BA group, higher educated in waiting list group

Interventions	Intervention characteristics
	<p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> BA • <i>specific intervention:</i> online programme 'Depressionshjälpen' with limited therapist interaction • <i>dose:</i> - • <i>frequency:</i> - • <i>duration:</i> 8 weeks • <i>level of therapist:</i> - • <i>individual or group therapy:</i> individual • <i>mode of delivery:</i> online • <i>modifications:</i> BA with components of Acceptance and Commitment Therapy (ACT) <p>Waiting list</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> comparator • <i>specific intervention:</i> waiting list • <i>dose:</i> - • <i>frequency:</i> - • <i>duration:</i> 8 weeks • <i>level of therapist:</i> - • <i>individual or group therapy:</i> individual • <i>mode of delivery:</i> online • <i>modifications:</i> -
Outcomes	<p><i>Depression symptoms</i></p> <ul style="list-style-type: none"> • Outcome type: continuous outcome • Reporting: fully reported • Scale: MADRS-S • Direction: lower is better • Data value: endpoint • Notes: self-rated MADRS <p><i>Quality of life</i></p> <ul style="list-style-type: none"> • Outcome type: continuous outcome • Reporting: fully reported • Scale: quality of life inventory • Direction: higher is better

Carlbring 2013 (Continued)

- **Data value:** endpoint

Identification

Sponsorship source: this study was sponsored in part by grants from the Swedish Science Foundation, the Swedish Council for Social Research and the Swedish Council for Work Life Research.

Country: Sweden

Setting: online/ at home

Comments: -

Authors name: Per Carlbring

Institution: Stockholm University

Email: per@carlbring.se

Address: Department of Psychology, Stockholm University, Stockholm, Sweden

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: the participants were divided into two groups – treatment or control – by an online true random-number service independent of the investigators and therapists
Allocation concealment (selection bias)	Low risk	Judgement comment: online random number service was used which was independent of investigators and therapists.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding possible. It is possible that self-reported outcomes were influenced by participants knowing whether they were receiving treatment or not.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: potential for bias because outcomes were self-reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: relatively low dropout rates; for post-intervention measurement at 8 weeks 40/40 and 38/40 participants in each group provided data. Missing data imputed.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol. No response from author.
Other bias	High risk	Quote: "Mats Dahlin and Kristofer Vernmark are employed by Psykologpartners, which is a company developing and selling products related to the research described in this paper. The other five authors have no conflict of interest." Judgement Comment: The practice by which two authors are employed offers online support programs for depression. This clinic also owns, developed, and sells the intervention (confirmed in personal correspondence with first author).

Carlbring 2013a

Study characteristics

Methods **Study design:** randomised controlled trial

Study grouping: parallel group

Recruitment: participants from Sweden were recruited between January 2013 and May 2014 through advertisements in newspapers, on various websites and through social media

Type of RCT (blind, double-blind, open-label): open

Participants **Baseline characteristics**

Physical exercise without treatment rationale

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* GAD-7 8.97
- *Depression severity:* PHQ-9: 12.01
- *Age:* -

Physical exercise with treatment rationale

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* GAD-7 8.97
- *Depression severity:* PHQ-9: 12
- *Age:* -

Behavioural activation Lewinshon's model

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* GAD-7 9.29
- *Depression severity:* PHQ-9: 12.5
- *Age:* -

Bbehavioural activation Martell's model

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* GAD-7 9.39
- *Depression severity:* PHQ-9: 13
- *Age:* -

Carlbring 2013a (Continued)

Waiting list

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/ employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity: PHQ-9:* 11.5
- *Age:* -

Overall

- *Gender (N male, % male, N female, % female):* 76% women, 24% men
- *Ethnic group:* -
- *Household income:* -
- *Occupation/ employment:* 54% working full time, 20% part-time, 11% student, 6% retired, 9% unemployed
- *Education level:* 3% elementary, 35% high school, 59% graduate school, 3% postgraduate
- *Comorbid anxiety: GAD-7* 9.28
- *Depression severity: PHQ-9:* 12.5
- *Age:* 42 (SD 13.5), range 20-80

Included criteria: mild to moderate depression (DSM-IV-TR), score between 15 to 35 on MADRS-S, be aged > 18 years, have a computer with access to the internet, be a resident in Sweden, and be able to read and write in Swedish.

Excluded criteria: individuals were excluded if they were regarded as suicidal or severely depressed (according to MADRS-S), presently participating in any other psychological treatment, had made changes in their anti-depressant medications (or other medications that may affect mood) during the last three months, were active exercisers (exercised more than once a week) or met criteria for another primary psychiatric diagnosis

Pretreatment: no baseline characteristics reported by group.

Interventions

Intervention characteristics

Physical exercise without treatment rationale

- *type of intervention:* comparator
- *specific intervention:* physical exercise programme without treatment rationale
- *dose:* 12 sessions
- *frequency:* once a week
- *duration:* 12 weeks
- *level of therapist:* professional (in training)
- *individual or group therapy:* individual
- *mode of delivery:* online interface with some therapist support
- *modifications:* -

Physical exercise with treatment rationale

- *type of intervention:* comparator
- *specific intervention:* physical exercise programme with rationale
- *dose:* 12 sessions
- *frequency:* once a week
- *duration:* 12 weeks
- *level of therapist:* professional (in training)
- *individual or group therapy:* individual

Carlbring 2013a (Continued)

- *mode of delivery*: online interface with some therapist support
- *modifications*: -

Behavioural activation Lewinshon's model

- *type of intervention*: BA
- *specific intervention*: behavioural activation (Lewinsohn)
- *dose*: 12 sessions
- *frequency*: once a week
- *duration*: 12 weeks
- *level of therapist*: professional (in training)
- *individual or group therapy*: individual
- *mode of delivery*: online interface with some therapist support
- *modifications*: -

Behavioural activation Martell's model

- *type of intervention*: BA
- *specific intervention*: behavioural activation (Martell)
- *dose*: 12 sessions
- *frequency*: once a week
- *duration*: 12 weeks
- *level of therapist*: professional (in training)
- *individual or group therapy*: individual
- *mode of delivery*: online interface with some therapist support
- *modifications*: -

Waiting list

- *type of intervention*: comparator
- *specific intervention*: waiting list
- *dose*: -
- *frequency*: -
- *duration*: 12 weeks
- *level of therapist*: -
- *individual or group therapy*: -
- *mode of delivery*: -
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: partially reported
- **Scale**: PHQ-9
- **Range**: 0-27
- **Direction**: lower is better
- **Data value**: endpoint
- **Notes**:

Anxiety symptoms

- **Outcome type**: continuous outcome
- **Reporting**: partially reported
- **Scale**: GAD-7
- **Direction**: lower is better
- **Data value**: endpoint

Carlbring 2013a (Continued)

 • **Notes:**

Identification

Sponsorship source: Swedish Council for Working Life and Social Research (FORTE 2011-0477).

Country: Sweden

Setting: internet-based

Comments: -

Authors name: Markus BT Nyström

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Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: block randomisation using a specially designed computer program.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information. No response from author.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding possible in this kind of intervention but still highly likely to interfere with outcomes.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: questionnaires were self-completed at home through an online interface, so influence by researchers is less likely but patient preference/ experience may bias outcomes.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: group differences in number of participants dropping out or with no follow-up data. For example, in BAL group 6% dropped out and for 11% there were no follow-up data, compared to 18% and 3% for BAM group. This may be related to differences in how effective treatment was perceived to be. No information reported on reasons for dropout.
Selective reporting (reporting bias)	High risk	Judgement comment: secondary outcomes on physical activity, quality of life, and general health are mentioned in the protocol but no data are reported.
Other bias	High risk	<p>Judgement comment: the interventions specified in the protocol do not match those in the report. The protocol specifies BA with treatment rationale versus BA without treatment rationale, instead of BAL versus BAM. This is worrying because it is unclear how interventions were developed and why this change was made. The analysis plan also differs substantially from the analyses reported. The sample size was substantially smaller from the proposed sample size (N = 286 versus 500).</p> <p>Judgement comment: In the protocol, one author reported a conflict of interest: "CM has written a self-help book similar to the treatment that will be in one of the treatment arms (BA). Consequently, CM will not be involved in any</p>

Carlbring 2013a (Continued)

of the informed consent procedures or analyses of outcome data." In the report, no conflicts of interest were reported.

Chang 2018
Study characteristics

Methods	<p>Study design: Randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: the study was conducted from August 2015 to January 2016 for adults with depression in geriatric community mental health centres located at Suwon and Gwangju, Republic of Korea</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 4 (8.5%) male • <i>Ethnic group:</i> 100% Korean • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> mean 4.2 yrs (SD 3.8) • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> 12.5 (SD 2.2) baseline GDS • <i>Age:</i> 78 (SD 6.0) <p>Usual care management</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 8 (17.4%) male • <i>Ethnic group:</i> 100% Korean • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> mean 4.5 yrs (SD 4.1) • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> 12.2 (SD 2.2) baseline GDS • <i>Age:</i> 77 (SD 7.2) <p>Overall</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 12 male (13%), 81 (87%) female • <i>Ethnic group:</i> 100% Korean • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> mean 4.4 yrs (SD 3.9) • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> 12.3 (SD 2.2) • <i>Age:</i> 78 (SD 6.6) <p>Included criteria: 1) those with non-psychotic, unipolar MDD DSM-IV diagnosis (Mini-International Neuropsychiatric Interview)13; 2) those with Montgomery Asberg Depression Rating Scale (MADRS) score of 17 or higher 14; and 3) those who were taking antidepressants at stable dosage for at least 6 weeks prior to study entry without any medical recommendation for medication change for the next 3 months.</p>

Chang 2018 (Continued)

Excluded criteria: 1) those with other Axis I psychiatric disorder; 2) those with acute or severe medical illness (e.g., metastatic cancer, liver failure); 3) those who were taking drugs known to cause depression; 4) those with advanced dementia; and 5) those with aphasia or inability to speak Korean.

Pretreatment: slightly more males in UCM

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* multi-domain prize based contingency management for lifestyle modification
- *dose:* -
- *frequency:* one phone call a week + 1 session of therapy a month
- *duration:* 12 weeks
- *level of therapist:* non-specialist
- *individual or group therapy:* individual
- *mode of delivery:* telephone and face-to-face
- *modifications:* Prizes for positive reinforcement in this study were symbolic gold medal stickers

Usual care management

- *type of intervention:* comparator
- *specific intervention:* Usual care management - supportive psychotherapy
- *dose:* -
- *frequency:* one phone call a week + 1 session of therapy a month
- *duration:* 12 weeks
- *level of therapist:* non-specialist
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face plus phone
- *modifications:* Focused on non-specific therapeutic factors such as facilitating expression of effect, conveying empathy, and imparting optimism.

Outcomes

Geriatric depression scale

- **Outcome type:** continuous outcome
- **Reporting:** partially reported
- **Scale:** Geriatric Depression Scale (GDS)
- **Direction:** lower is better
- **Data value:** endpoint

Dropouts

- **Outcome type:** dichotomous outcome
- **Reporting:** fully reported
- **Direction:** lower is better
- **Data value:** endpoint

Identification

Sponsorship source: this study was supported by a grant (HI15C1032) funded by a R&D Project of Korea Mental Health Technology.

Country: South Korea

Setting: geriatric community mental health centres located at Suwon and Gwangju, Republic of Korea.

Comments: -

Authors name: Ki Jung Chang

Chang 2018 (Continued)

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Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "informed consent. Randomization and masking Randomization was designed in blocks of four participants using SAS. The study coordinator sequentially allocated par-"
Allocation concealment (selection bias)	Low risk	Quote: "The study coordinator sequentially allocated participants to either usual care management (UCM) or lifestyle modification with contingency management" Judgement comment: sequentially allocated participants in block of four after randomisation by computer programme.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: group allocation not divulged to participants, although nurses were not blinded and feelings about treatment may affect outcome
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Raters were independent evaluators who were unaware of randomization status or study hypotheses."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: only a few dropped out during treatment, similar numbers in both groups
Selective reporting (reporting bias)	High risk	Quote: "(NCT03095820)." Judgement comment: study protocol states MADRS is primary outcome, but GDS is reported instead. Report did not include measurement at 8 weeks as mentioned in protocol.
Other bias	Unclear risk	Quote: "The intervention was carried out by trained health worker in mental health community center. For treatment fidelity, they received training on brief advising process, assessing activity level using a simple self-assessment tool, providing how to increase the activity level, and selecting adequate lifestyle modification goals. A manual was also provided to health workers with systematic introductions. Health workers followed the study's written protocols when making any intervention-related recommendations." Judgement comment: no evaluation of treatment fidelity

Chowdhary 2016
Study characteristics

Methods

Study design: randomised controlled trial

Behavioural activation therapy for depression in adults (Review)

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Chowdhary 2016 (Continued)

Study grouping: parallel group

Recruitment: participants were primary health centre attendees recruited between August 2013 and October 2013

Type of RCT (blind, double-blind, open-label):

Participants	Baseline characteristics
	Behavioural activation <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 11 male (35%), 20 female (64%) • <i>Ethnic group:</i> - • <i>Household income:</i> - • <i>Occupation/ employment:</i> Unemployed 19 (61.3%), manual 8 (25.8%), professional 3 (9.7%) no data 1 (3.2%) • <i>Education level:</i> None 6 (19.3%), primary 17 (54.8%), secondary or higher 8 (25.8%) • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> - • <i>Age:</i> 42.8 (SD 13.0)
	Enhanced usual care <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 6 male (25%), 18 female (75%) • <i>Ethnic group:</i> - • <i>Household income:</i> - • <i>Occupation/ employment:</i> Unemployed 12 (50.0%), manual 9 (37.5%), professional 2 (8.3%), no data 1 (4.2%) • <i>Education level:</i> 5 none (21%), 11 primary (46%), 8 higher than primary (33%) • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> - • <i>Age:</i> 37.6 (SD 10.2)
	Overall <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 17 male, 38 female • <i>Ethnic group:</i> - • <i>Household income:</i> - • <i>Occupation/ employment:</i> - • <i>Education level:</i> - • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> - • <i>Age:</i> - <p>Included criteria: > 14 on PHQ-9, aged above 17, resident in Goa, not requiring emergency treatment for any reason.</p> <p>Excluded criteria: -</p> <p>Pretreatment: not reported</p>
Interventions	Intervention characteristics
	Behavioural activation <ul style="list-style-type: none"> • <i>type of intervention:</i> BA • <i>specific intervention:</i> healthy Activity Program: brief psychological therapy based on behavioural activation for depression • <i>dose:</i> 30- to 40-minute session

Chowdhary 2016 (Continued)

- *frequency*: weekly or fortnightly
- *duration*: 6 to 8 weeks
- *level of therapist*: non-specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: modification of behavioural activation for depression to simplify language, improve cultural relevance and acceptability, and enhance feasibility for delivery by lay counsellors

Enhanced usual care

- *type of intervention*: comparator
- *specific intervention*: enhanced usual care
- *dose*: -
- *frequency*: -
- *duration*: -
- *level of therapist*: -
- *individual or group therapy*: -
- *mode of delivery*: -
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: partially reported
- **Scale**: BDI-II
- **Direction**: lower is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: lower is better
- **Data value**: endpoint

Remission

- **Outcome type**: dichotomous outcome
- **Reporting**: partially reported
- **Direction**: higher is better
- **Data value**: endpoint
- **Notes**: participants with PHQ<5

Identification

Sponsorship source: This research has been entirely funded by a Wellcome Trust Senior Research Fellowship to V.P. (Grant no. 091834/Z/10/Z).

Country: India

Setting: primary health centres

Comments: -

Authors name: Vikram Patel

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Chowdhary 2016 (Continued)

Address: H No 451 (168), Bhatkar Waddo, Succour, Porvorim, Bardez, Goa 403501, India

Notes Only adjusted risk ratios reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Those who consented were randomly allocated in a 1:1 ratio to receive either enhanced usual care (EUC) or EUC plus HAP using a computer-generated allocation sequence, stratified by primary health centre and gender."
Allocation concealment (selection bias)	Low risk	Quote: "Those who consented were randomly allocated in a 1:1 ratio to receive either enhanced usual care (EUC) or EUC plus HAP using a computer-generated allocation sequence, stratified by primary health centre and gender."
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Judgement comment: no blinding. Dropout may have been influenced by willingness of researchers to engage with participants, and by participants' preference for treatment arms.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: unclear who assessed outcomes. Presumably same as therapists. Information requested from author but only partially received.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: similar number of dropouts in treatment arm (86%) and comparator arm (91%).
Selective reporting (reporting bias)	Unclear risk	Judgement comment: protocol not available
Other bias	High risk	<p>Judgement comment: authors were responsible for the development of this intervention. Even if not financially, they would benefit from its success (status, recognition).</p> <p>Quote: "The quality of the delivery was enhanced by provision of checklists for use by counsellors during sessions. Examples were step-by-step guidelines in dealing with difficult situations (especially high suicide risk) and off-the-shelf solutions derived from experiences in the clinical case series for dealing with social problems. Finally, simplification of therapeutic tools was emphasised, such as doing activity monitoring in blocks of time (morning, afternoon, night) rather than hourly and the use of icons to represent specific activities and emotions for patients with limited literacy to track activities."</p> <p>Judgement comment: strategies to improve fidelity, but no monitoring or evaluation is reported. Not enough information to make judgement.</p>

Collado 2016
Study characteristics

Methods **Study design:** randomised controlled trial

Study grouping: parallel group

Collado 2016 (Continued)

Recruitment: a sample of Latinos with a Spanish-speaking preference was recruited from July 2013 to June 2014 primarily through community organisations and radio stations serving the Spanish-speaking community.

Type of RCT (blind, double-blind, open-label): open

Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 83% female • <i>Ethnic group: country of origin:</i> 22% El Salvador, 17% Guatemala, 17% Honduras • <i>Household income:</i> 45% ≤ USD 14999, 20% 15000-29999, 25% 30000-44999, 10% 45000 or higher • <i>Occupation/ employment:</i> 48% full-time, 9% part-time • <i>Education level:</i> mean grade 11 (SD 3.7) • <i>Comorbid anxiety:</i> 74% • <i>Depression severity:</i> BDI 29.9 (SD 9.26) • <i>Age:</i> 34 (SD 12.2) <p>Supportive counselling (SC)</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 87% female • <i>Ethnic group:</i> 35% El Salvador, 17% Mexico, 13% Guatemala • <i>Household income:</i> 47% ≤ USD 149,99, 35% 150,00 to 29,999, 18% 30,000 to 44,999, 0% 45,000 or higher • <i>Occupation/ employment:</i> 35% full-time, 14% part-time • <i>Education level:</i> mean grade 10 (SD 3.8) • <i>Comorbid anxiety:</i> 56% • <i>Depression severity:</i> BDI 29.5 (SD 11.5) • <i>Age:</i> 38 (SD 15.2) <p>Overall</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 85% female • <i>Ethnic group:</i> 28% El Salvador, 15% Guatemala, 13% Honduras, 13% Mexico • <i>Household income:</i> 46% ≤ USD 149,99, 27% 150,00 to 299,99, 22% 300,00 to 449,99, 5% 450,00 or higher • <i>Occupation/ employment:</i> 41% full-time, 11% part-time • <i>Education level:</i> mean grade 11 (SD 3.7) • <i>Comorbid anxiety:</i> 65% • <i>Depression severity:</i> - • <i>Age:</i> 36 (SD 13.8) <p>Included criteria: 1) be a minimum of 18 years of age, 2) Latino/a, 3) report Spanish-language preference, 4) meet MDD criteria, 5) not meet criteria for substance abuse or dependence, bipolar or psychotic disorders, 6) not be receiving psychotherapy, and 7) if taking antidepressants, demonstrate three or more consecutive months of use</p> <p>Excluded criteria: -</p> <p>Pretreatment: no statistically significant differences, but BATD group seems to have more previous treatment for depression and higher rates of comorbid anxiety disorder and PTSD, than SC group.</p>
Interventions	<p>Intervention characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> BA • <i>specific intervention:</i> Behavioural Activation Treatment for Depression (BATD) • <i>dose:</i> - • <i>frequency:</i> weekly

Collado 2016 (Continued)

- *duration*: 10 weeks
- *level of therapist*: non-specialist (students)
- *individual or group therapy*: individual
- *mode of delivery*: face to face, homework assignments
- *modifications*: manual translated into Spanish

Supportive counselling (SC)

- *type of intervention*: comparator
- *specific intervention*: supportive counselling
- *dose*: -
- *frequency*: weekly
- *duration*: 10 weeks
- *level of therapist*: non-specialist (students)
- *individual or group therapy*: individual
- *mode of delivery*: face to face, homework assignments
- *modifications*: manual translated into Spanish

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: BDI
- **Direction**: lower is better
- **Data value**: endpoint
- **Notes**: follow-up at 1 month seems to be 1 month from end of treatment (10 weeks).

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: lower is better
- **Data value**: endpoint

Depression remission

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Scale**: SCID-IV
- **Direction**: higher is better
- **Data value**: endpoint

Identification

Sponsorship source: the work was supported in part by the National Institute of Mental Health F31MH098512-02 awarded to Anahi Collado.

Country: USA

Setting: community

Comments: participants were paid \$125 throughout the course of the study for completing assessments and for travel.

Authors name: Anahí Collado

Institution: Center for Addictions, Personality, and Emotion Research (CAPER)

Email: acollado@umd.edu

Collado 2016 (Continued)

Address: Center for Addictions, Personality, and Emotion Research (CAPER), 2103 ColeField House, University of Maryland, College Park, MD 20742, USA

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "the assessments, participants receive compensation. At the first meeting, a staff member not involved in the study conducts the randomization using a computerized random number generator and informs the participant's therapist" Judgement comment: independent staff member conducts the randomisation using a computerised random number generator
Allocation concealment (selection bias)	Low risk	Judgement comment: independent staff conducting randomisation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding not possible. This may affect outcomes if researchers, therapists, or staff have a preference for the treatment versus control intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Judgement comment: the research assistant conducting assessments for a participant is blind to every participants' assigned treatment condition
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: 20/46 did not complete follow-up. Small number dropped out because of the intervention
Selective reporting (reporting bias)	High risk	Judgement comment: protocol mentions Hamilton Rating Scale for Depression to be measured in each session, but no results reported. Results for 1 month follow-up depression remission (SCID-IV) also not reported. Stigma checklist questionnaire not reported.
Other bias	Low risk	Judgement comment: no other types of bias identified.

Comas Díaz 1981
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: referred by local community agencies for treatment of depression</p> <p>Type of RCT (blind, double-blind, open-label):</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> Gender (N male, % male, N female, % female): - Ethnic group: -

Behavioural activation therapy for depression in adults (Review)

Comas Díaz 1981 (Continued)

- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Cognitive therapy

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Waiting list

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Overall

- *Gender (N male, % male, N female, % female):* 100% female
- *Ethnic group:* 100% Puerto Rican
- *Household income:* 100% low income
- *Occupation/employment:* 100% unemployed
- *Education level:* average 6 years
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* mean 38

Included criteria: depressed (classified by BDI and HAM-D) low socio-economic status, unemployed, Puerto Rican women who were recipients of government financial aid

Excluded criteria: women thought to be psychotic, addicted to drugs, organic, or severely suicidal were not considered for the investigation.

Pretreatment: no significant differences reported.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behaviour therapy; activity schedules, verbal contracts, and behavioral rehearsal techniques for training social skills and self-reinforcement
- *dose:* 1.5 hours per session
- *frequency:* 5 sessions

Comas Díaz 1981 (Continued)

- *duration*: 4 weeks
- *level of therapist*: -
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: -

Cognitive therapy

- *type of intervention*: comparator
- *specific intervention*: cognitive therapy (Beck's)
- *dose*: 1.5 hours per session
- *frequency*: 5 sessions
- *duration*: 4 weeks
- *level of therapist*: -
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: added elements of learned helplessness strategies (assertiveness and experience with success and failure)

Waiting list

- *type of intervention*: comparator
- *specific intervention*: waiting list
- *dose*: -
- *frequency*: -
- *duration*: 4 weeks
- *level of therapist*: -
- *individual or group therapy*: -
- *mode of delivery*: -
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: partially reported
- **Scale**: HRSD
- **Direction**: lower is better
- **Data value**: endpoint

Identification

Sponsorship source: none reported. Research completed as part of a PhD.

Country: USA

Setting: local community agencies

Comments: -

Authors name: Lillian Comas-Diaz

Institution: Yale University

Email: -

Address: Yale University School of Medicine, 464 Congress Avenue, New Haven, Connecticut 06519

Notes

Data not included in meta-analysis; not possible to estimate SD.

Risk of bias

Comas Díaz 1981 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "After matching the clients in age and severity of depression as measured by the Beck pretreatment scores, 8 women were randomly assigned to a cognitive therapy group, 8 to a behavior therapy group, and 10 to a waiting list/assessment group." Judgement comment: no further information on how randomisation was achieved. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information on allocation concealment. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding. All treatment provided by one therapist. Experience of therapy was found to be similar in the two treatment groups. Lack of blinding may influence outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: unclear who assessed outcomes. Author could not be contacted.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Judgement comment: no information provided re dropouts and missing data. Author could not be contacted.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no protocol available. Author could not be contacted.
Other bias	Low risk	Judgement comment: no other sources of bias identified. No evidence of conflict of interest. Therapist showed high fidelity to treatments.

Cullen 2003
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: adults seeking mental health services for Unipolar Depression recruited through public service announcements, newspaper advertisement, solicitations from community professionals, and other healthcare agencies</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): • Ethnic group: • Household income: • Occupation/employment: • Education level: • Comorbid anxiety: • Depression severity: BDI score 32.78 (SD 6.3)

Behavioural activation therapy for depression in adults (Review)

Cullen 2003 (Continued)

- Age:

Waiting list

- Gender (*N* male, % male, *N* female, % female):
- Ethnic group:
- Household income:
- Occupation/employment:
- Education level:
- Comorbid anxiety:
- Depression severity: BDI score 29.75 (SD 5.6)
- Age:

Overall

- Gender (*N* male, % male, *N* female, % female): 19 M (61.3%) , 12 F (38.7%)
- Ethnic group: 1 African American, 1 Hispanic, 1, 1 International, 1 Alaskan American, 26 Caucasian, 1 did not report
- Household income: Under \$10,000 per year = 8, \$10-\$20K per year = 7, \$20-\$30K per year = 7, over \$30k per year = 7, did not report = 2
- Occupation/employment:
- Education level: < 12 years = 2, 12 years or GED = 5, >12 <16 years = 13, 16 years = 3, 16 + years = 8
- Comorbid anxiety:
- Depression severity:
- Age: mean 37.9

Included criteria: MDD according to DSM-IV, at least 20 on BDI-II and 14 or greater on revised HRSD.

Excluded criteria: coexistent psychiatric disorders including bipolar or psychotic subtypes of depression, panic disorder, current alcohol or other substance abuse, past or present schizophrenia or schizotypal disorder, organic brain syndrome, obsessive compulsive disorder and mental retardation. Participants who were in some concurrent form of psychotherapy or who needed to be hospitalised because of imminent suicide potential or psychosis were deemed ineligible for the study

Pretreatment: baseline differences not reported by treatment arm

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural activation (Beck)
- *dose:* 1-hour sessions
- *frequency:* weekly
- *duration:* 10 weeks
- *level of therapist:* specialist
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:*

Waiting list

- *type of intervention:* comparator
- *specific intervention:* waiting list
- *dose:* one-hour sessions
- *frequency:* weekly
- *duration:* 6 weeks
- *level of therapist:* specialist

Cullen 2003 (Continued)

- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*:

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: BDI-II
- **Direction**: lower is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: lower is better
- **Data value**: endpoint

depression

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Scale**: MDD according to DSM-IV
- **Direction**: lower is better
- **Data value**: endpoint

Identification

Sponsorship source: none reported. PhD thesis.

Country: United States

Setting: University Psychology Clinic

Comments: PhD dissertation

Authors name: Jennifer M Cullen

Institution: Western Michigan University

Email: -

Address: Western Michigan University, Kalamazoo, Michigan

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement comment: "If they chose to participate, each person was assigned a research code number to be used on all subsequent forms and randomly assigned into an immediate treatment or waitlist control condition." Unclear how randomisation was achieved.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information on concealment of allocation.
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement comment: no information. Presumably not blinded.

Cullen 2003 (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: no information; presumably no blinding.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: data on dropouts are unclear and inconsistent: in the text; it is suggested that 5 participants dropped out after randomisation. In the tables it only shows 3 dropouts (in the treatment group). Further on in the text it is reported that only 3 participants finished treatment. Outcome data are also reported where none were collected (Table 3, follow-up WL group), and inappropriate imputation is performed; it appears missing outcome data from 14/17 participants were imputed using the mean score of the 3 remaining participants. Dropout rate appears high (14/27).
Selective reporting (reporting bias)	Unclear risk	Judgement comment: data on HRSD were inconsistently reported. No protocol available.
Other bias	Unclear risk	Judgement comment: data on dropouts and outcomes are unclear and inconsistent between tables and text.

Dimidjian 2006
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: recruitment occurred between 1998 and 2001; the majority of participants were recruited from media advertisements, a substantial minority by referral from local agencies, and the rest by word of mouth or other referral sources.</p> <p>Type of RCT (blind, double-blind, open-label): double-blind for medication/placebo groups but not for psychotherapy groups.</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: - • Depression severity: - • Age: - <p>Cognitive therapy</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: -

Dimidjian 2006 (Continued)

- *Depression severity:* -
- *Age:* -

Antidepressant medication

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Placebo

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Overall

- *Gender (N male, % male, N female, % female):* 159 female (66%)
- *Ethnic group:* 197 White (82%)
- *Household income:* -
- *Occupation/employment:* 171 (71%) employed outside the home
- *Education level:* 121 (50%) college graduate
- *Comorbid anxiety:* 57 (24%)
- *Depression severity:* 103 (43%) low (HRSD 14-19), 138 (57%) high (HRSD ≥ 20)
- *Age:* 39.9 (SD 10.97)

Included criteria: age 18 to 60, met criteria for major depression (DSM-IV) and scored 20 or higher on the BDI-II and 14 or greater on the HRSD.

Excluded criteria: lifetime diagnosis of psychosis or bipolar disorder, organic brain syndrome, or mental retardation. Suicide risk, alcohol or drug abuse/dependence, panic disorder, OCD, psychogenic pain disorder, anorexia, or bulimia, antisocial/borderline/schizotypal personality disorder, participants who had not responded favourably within the preceding year to an adequate trial of either CT or paroxetine also were excluded. Unstable medical condition, using any medication that would complicate the administration of paroxetine, allergy to paroxetine. Pregnant/breastfeeding

Pretreatment: people in the CT group seemed to have slightly lower levels of depression symptoms than people in the BA group at baseline, although any differences were small. There were fewer women in the BA group.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural activation
- *dose:* 50 minute sessions
- *frequency:* maximum 24 sessions. twice weekly for first 8 weeks, then once weekly for next 8 weeks

Dimidjian 2006 (Continued)

- *duration*: 16 weeks
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: -

Cognitive therapy

- *type of intervention*: comparator
- *specific intervention*: CT
- *dose*: 50 minute sessions
- *frequency*: maximum 24 sessions. twice weekly for first 8 weeks, then once weekly for next 8 weeks
- *duration*: 16 weeks
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: -

Antidepressant medication

- *type of intervention*: comparator
- *specific intervention*: paroxetine (SSRI)
- *dose*: 10 mg to 50 mg
- *frequency*: daily
- *duration*: 8 to 16 weeks
- *level of therapist*: -
- *individual or group therapy*: individual
- *mode of delivery*: self-administered, with weekly/biweekly check ups
- *modifications*: dose increased from 10 mg to 50 mg over course of follow-up. After 8 weeks placebo/medication groups were allowed to switch.

Placebo

- *type of intervention*: comparator
- *specific intervention*: placebo
- *dose*: -
- *frequency*: seen weekly for first 4 weeks then bi-weekly after that
- *duration*: 8-16 weeks
- *level of therapist*: -
- *individual or group therapy*: individual
- *mode of delivery*: self-administered, with weekly/ biweekly check ups
- *modifications*: After 8 weeks blinding was broken and placebo/ medication groups were allowed to switch.

 Outcomes

HRSD posttreatment - low-severity group

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: HRSD
- **Direction**: lower is better
- **Data value**: endpoint
- **Notes**: data presented separately for people with low severity (HRSD 14-19) and high severity (HRSD >=20) depression

Dropouts

Dimidjian 2006 (Continued)

- **Outcome type:** dichotomous outcome
- **Reporting:** fully reported
- **Direction:** lower is better
- **Data value:** endpoint

Side effects

- **Outcome type:** continuous outcome
- **Reporting:** fully reported

HRSD posttreatment - high-severity group

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** HRSD
- **Direction:** lower is better
- **Data value:** endpoint
- **Notes:** data presented separately for people with low severity (HRSD 14-19) and high severity (HRSD >=20) depression

Identification	<p>Sponsorship source: GlaxoSmithKline provided medications and pill placebos for the trial. The research was supported by National Institute of Mental Health Grant MH55502 (R01) first to Neil S. Jacobson and, after his death, to David L. Dunner.</p> <p>Country: USA</p> <p>Setting: community</p> <p>Comments: -</p> <p>Authors name: Sona Dimidjian</p> <p>Institution: University of Colorado</p> <p>Email: sona.dimidjian@colorado.edu</p> <p>Address: Department of Psychology, University of Colorado, Boulder, CO 80309-0345.</p>	
Notes	<p>Cross-over was allowed in medication and placebo groups after 8 weeks. Only data up to 8 weeks are included in meta-analyses.</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Quote: "Once eligibility was determined, participants were assigned by the participant coordinator to one of four acute treatment conditions using a computer-generated randomization list:"</p> <p>Judgement comment: unclear how randomisation was achieved; antidepressant medication group was twice the size of the other groups, which would not have happened by chance. Author contacted: confirms computer-generated list used.</p>
Allocation concealment (selection bias)	Low risk	<p>Judgement comment: participant co-ordinator used a list to randomise participants. It appears the coordinator was therefore not blinded to the allocation. Author contacted: research assistants were not aware of allocation.</p>
Blinding of participants and personnel (performance bias)	High risk	<p>Quote: "Pharmacotherapists, evaluators, and patients were blind to medication status, meaning that the pharmacological portion of the trial was conducted triple blind."</p>

Dimidjian 2006 (Continued)

All outcomes		Judgement comment: blinding of participants and personnel for medication/placebo arms but not for therapy arms. Possible that therapists had a preference for either CT or BA. High number of dropouts after randomisation in medication groups, possibly because participants did want medication.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Participants completed standard comprehensive outcome assessments, conducted by evaluators blind to treatment assignment, at mid- and post- treatment" Judgement comment: blinding
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "The rate of attrition for ADM (44%; n 44) was significantly higher than for either CT (13.3%; n 6), 2 (1, N 145) 12.92, p .001, or BA (16.3%; n 7), 2 (1, N 143) 10.07, p.002." Judgement comment: rate of attrition higher in ADM than in other groups, particularly in the first 8 weeks. Last observation carried forward for missing data.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to published protocol.
Other bias	High risk	Quote: "GlaxoSmithKline provided medications and pill placebos for the trial." Judgement comment: one of the authors, who managed the funding for this research in the later stages of the study, received funding from GlaxoSmithKline, who provided the medication and placebos for the trial.

Ekers 2011
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: recruited potential participants aged 18 or over from either general practices directly or from primary care mental health services over a 9-month period. Practices were based in a mix of rural and urban settings.</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Bbehavioural activation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 8 male (35%), 15 female (65%) • <i>Ethnic group:</i> - • <i>Household income:</i> - • <i>Occupation/ employment:</i> full time 13 (56.5%), part time 1 (4.3%), housewife 1 (4.3%), retired 3 (13%), unemployed 4 (17.4%), incapacity benefit 1 (4.3%) • <i>Education level:</i> • <i>Depression severity:</i> 35.57 (9.60) mild 1 (4.3%), moderate 13 (56.5%), severe 8 (34.8) • <i>Age:</i> 46.43 (24 to 63) <p>Usual care</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 10 male (42%), 14 female (58%) • <i>Ethnic group:</i> -

Behavioural activation therapy for depression in adults (Review)

Ekers 2011 (Continued)

- *Household income:* -
- *Occupation/ employment:* full time 8 (33.3%), part time 7 (29.2%), housewife 1 (4.2%), carer 1 (4.2%) retired 3 (12.5%), unemployed 2 (8.3%), incapacity benefit 2 (8.3%)
- *Education level:*
- *Depression severity:* 35.08 (9.60), mild 2 (8.3%), moderate 9 (37.5%), severe 13 (54.2%)
- *Age:* 43.08 (28 to 63)

Overall

- *Gender (N male, % male, N female, % female):* 18 male, 29 female
- *Ethnic group:* -
- *Household income:* -
- *Occupation/ employment:* 21 full-time, 8 part-time, 6 unemployed
- *Education level:* -
- *Comorbid anxiety:* 1 (2.1%)
- *Depression severity:* 35.32 (9.50), mild 3 (6.4%), moderate 22 (46.8%), severe 21 (44.7%)
- *Age:* 44.72 (24 to 63)

Included criteria: aged 18 or over, depression (ICD-10), stable or no dose of antidepressants for 6 weeks prior

Excluded criteria: suicidal risk, psychotic symptoms, diagnosis of bipolar disorder, organic brain disease or the use of alcohol/non-prescription drugs requiring clinical intervention.

Pretreatment: BA group more likely to be employed full-time, usual care group more likely to be employed part-time. 65% in BA group prescribed antidepressants, compared to 71% in usual care group.

Prescribed antidepressants BA 15 (65%), usual care 17 (71%): -

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural activation
- *dose:* 1 hour sessions
- *frequency:* 12 sessions
- *duration:* 3 months
- *level of therapist:* non-specialist
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* -

Usual care

- *type of intervention:* comparator
- *specific intervention:* usual care
- *dose:* -
- *frequency:* -
- *duration:* 3 months
- *level of therapist:* -
- *individual or group therapy:* -
- *mode of delivery:* -
- *modifications:* participants were allowed to take part in interventions offered as per normal practice.

Outcomes

Depression symptoms

- **Outcome type:** continuous outcome

Ekers 2011 (Continued)

- **Reporting:** fully reported
- **Scale:** BDI-II
- **Range:** 0 to 63
- **Direction:** lower is better
- **Data value:** endpoint

Dropouts

- **Outcome type:** dichotomous outcome
- **Reporting:** fully reported
- **Direction:** lower is better
- **Data value:** endpoint

Functioning

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** Work and Social Adjustment Scale (WSAS)
- **Range:** 0 to 40
- **Direction:** lower is better
- **Data value:** endpoint

Clinically significant improvement

- **Outcome type:** dichotomous outcome
- **Reporting:** fully reported
- **Scale:** BDI-II
- **Direction:** higher is better
- **Data value:** endpoint
- **Notes:** Jacobson & Truax procedures used for calculating reliable and clinically significant change to quantify clinical improvement in depressive symptoms on the BDI-II. Calculated for whole sample using last observation carried forward (LOCF) for missing data.

Identification

Sponsorship source: Tees Esk & Wear Valleys NHS Trust (UK)

Country: UK

Setting: health centres

Comments: -

Authors name: David Ekers

Institution: Durham University

Email: david.ekers@tevv.nhs.uk

Address: Mental Health Research Centre, Durham University, Health Centre, Chester Le Street, Co Durham, DH3 3UR, UK.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: "Following assessment, participants were randomised to two arms through an allocation concealment process independent of the study team using a block randomisation system in blocks of four."

Ekers 2011 (Continued)

Allocation concealment (selection bias)	Low risk	<p>Quote: "Following assessment, participants were randomised to two arms through an allocation concealment process independent of the study team using a block randomisation system in blocks of four. Taking"</p> <p>Judgement comment: not entirely clear how randomisation was performed, but authors state that independent person was used to perform randomisation.</p>
Blinding of participants and personnel (performance bias) All outcomes	High risk	<p>Quote: "participants were informed of allocation automatically by letter."</p> <p>Judgement comment: no blinding given nature of treatments. Evaluation of adherence of personnel mitigates risk of bias, but patients may have been influenced by knowing they were receiving the active treatment or usual care.</p>
Blinding of outcome assessment (detection bias) All outcomes	Low risk	<p>Quote: "Assessments were collected by a research worker masked to treatment allocation at baseline, 1-, 2- and 3-month follow-up. To reduce the risk of bias further we used self-completed assessments of depression symptom level, functioning and satisfaction."</p> <p>Judgement comment: considerable effort to reduce risk of bias, and outcome assessor was blinded.</p>
Incomplete outcome data (attrition bias) All outcomes	High risk	<p>Judgement comment: 7/23 and 2/24 participants dropped out but reasons not given.</p>
Selective reporting (reporting bias)	Low risk	<p>Judgement comment: all outcomes stated in the protocol are reported in the study results.</p>
Other bias	High risk	<p>Judgement comment: first author is also author of the present review. Several of the authors of this study have benefited in their career from evidence showing potential effectiveness of BA.</p>

Fleming 1980
Study characteristics

Methods	<p>Study design: cluster-randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: volunteer participants were recruited from the community through the mass media.</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: - • Depression severity: BDI 24.15 • Age: -

Fleming 1980 (Continued)

Cognitive therapy

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: BDI 23.46
- Age: -

Non-directive therapy

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: BDI 26.44
- Age: -

Overall

- Gender (N male, % male, N female, % female): 8 male, 25 female
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: -
- Age: mean 38 (SD 13.7)

Included criteria: at least 3 weeks of reported depression, no current involvement in psychotherapy, score ≥ 17 on BDI, score ≥ 14 on D-30 scale, and clinical judgment that depression was the major presenting problem.

Excluded criteria: psychotic symptoms

Pretreatment: no participant characteristics reported by group. BDI score slightly higher in non-directive therapy group.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural therapy (self-control therapy manual Fuchs and Rehm)
- *dose:* 2 hours a session
- *frequency:* twice a week
- *duration:* 4 weeks
- *level of therapist:* non-specialist
- *individual or group therapy:* group
- *mode of delivery:* face-to-face
- *modifications:* -

Cognitive therapy

Fleming 1980 (Continued)

- *type of intervention:* comparator
- *specific intervention:* cognitive therapy (cognitive modification manual Shaw)
- *dose:* 2 hours a session
- *frequency:* twice a week
- *duration:* 4 weeks
- *level of therapist:* non-specialist
- *individual or group therapy:* group
- *mode of delivery:* face-to-face
- *modifications:* -

Non-directive therapy

- *type of intervention:* comparator
- *specific intervention:* unstructured, non-directive therapy
- *dose:* 2 hours a session
- *frequency:* twice a week
- *duration:* 4 weeks
- *level of therapist:* non-specialist
- *individual or group therapy:* group
- *mode of delivery:* face-to-face
- *modifications:* -

Outcomes	<i>Depression symptoms</i> <ul style="list-style-type: none"> • Outcome type: continuous outcome • Reporting: partially reported • Scale: BDI • Direction: lower is better • Data value: endpoint 	
Identification	Sponsorship source: none reported. Masters thesis. Country: USA Setting: community Comments: - Authors name: Barbara M Fleming Institution: Michigan State University Email: - Address: Department of Psychology, Michigan State University, East Lansing, Michigan 48824	
Notes	Data not included in meta-analysis; not possible to estimate SD.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement comment: no information. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Quote: "To minimize the waiting period, groups were formed as soon as a sufficient number of subjects had been screened, and each group was randomly assigned to a treatment condition."

Fleming 1980 (Continued)

		Judgement comment: unclear whether and how allocation was concealed. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding not possible due to nature of treatments. It is likely that being aware of the therapy provided could influence outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: it appears participants completed questionnaires; unclear who processed them. As they were aware of the intervention they received, this may have introduced bias. Author could not be contacted.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Judgement comment: 5/40 participants dropped out. Unclear in which arm. Author could not be contacted.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no protocol available. Author could not be contacted.
Other bias	High risk	<p>Judgement comment: methods are not described in detail. No information on baseline characteristics and potential differences between study arms. Author could not be contacted.</p> <p>Issues specific to cluster RCTs:</p> <p>Quote: "To minimize the waiting period, groups were formed as soon as a sufficient number of subjects had been screened, and each group was randomly assigned to a treatment condition."</p> <p>Judgement comment: only 6 groups for 3 interventions. Groups were formed based on when they were recruited; unlikely to be random. No baseline characteristics reported</p>

Fuchs 1977
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: depressed women were sought as volunteer participant clients for an experimental therapy program through announcements in the mass media.</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 100% female • <i>Ethnic group:</i> - • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> - • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> baseline BDI 21.38 • <i>Age:</i> 26

Fuchs 1977 (Continued)

Non-specific therapy

- *Gender (N male, % male, N female, % female):* 100% female
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* baseline BDI 23.60
- *Age:* 28.5

Waiting list

- *Gender (N male, % male, N female, % female):* 100% female
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* baseline BDI 23.20
- *Age:* 31.1

Overall

- *Gender (N male, % male, N female, % female):* 100% female
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* 28.8, range 18 to 48

Included criteria: female, depressed, 18 to 60 years old. Depression based on criteria on the Minnesota Multiphasic Personality Inventory

Excluded criteria: no history of psychiatric hospitalisation, no serious suicidal ideation or attempt, no involvement in any other therapy for problems relating to psychological functioning within the past month, not suicidal or psychotic.

Pretreatment: authors report no statistically significant differences.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* self-control therapy with 3 phases placing emphasis on training, self-monitoring, self-evaluation and self-reinforcement skills
- *dose:* 2 hours a session
- *frequency:* once a week
- *duration:* 6 weeks
- *level of therapist:* specialist (in training)
- *individual or group therapy:* group
- *mode of delivery:* face-to-face, homework assignments
- *modifications:* -

Non-specific therapy

Fuchs 1977 (Continued)

- *type of intervention:* comparator
- *specific intervention:* non-directive
- *dose:* 2 hours a session
- *frequency:* once a week
- *duration:* 6 weeks
- *level of therapist:* specialist (in training)
- *individual or group therapy:* group
- *mode of delivery:* face-to-face, homework assignments
- *modifications:* -

Waiting list

- *type of intervention:* comparator
- *specific intervention:* waiting list
- *dose:* -
- *frequency:* -
- *duration:* -
- *level of therapist:* -
- *individual or group therapy:* -
- *mode of delivery:* informed by telephone
- *modifications:* told that they would retake some of the screening tests just before therapy; were assured of being seen. Follow-up data not collected as in therapy

Outcomes

Depression symptoms

- **Outcome type:** continuous outcome
- **Reporting:** partially reported
- **Scale:** BDI
- **Direction:** lower is better
- **Data value:** endpoint

Identification

Sponsorship source: none reported. Study part of PhD dissertation.

Country: USA

Setting: community

Comments: -

Authors name: Carilyn Z Fuchs

Institution: University of Pittsburgh

Email: -

Address: Clinical Psychology Center, Old Engineering Hall, University of Pittsburgh, Pittsburgh, Pennsylvania, 15260

Notes

Risk of bias
Bias
Authors' judgement
Support for judgement

Random sequence generation (selection bias)

Unclear risk

Quote: "Except where necessary to balance experimental conditions for mean age and severity of depression, subjects were randomly assigned to one of two therapists and one of three treatment conditions—self-control therapy, non-specific therapy, or waiting list control."

Fuchs 1977 (Continued)

		Judgement comment: unclear how they were randomised, participants were balanced within groups. Author could not be contacted.
Allocation concealment (selection bias)	High risk	Judgement comment: no mention of concealing allocation. It seems likely researchers did influence allocation, as they tried to maintain balance between the groups.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: not possible to blind, allocation especially to waiting list may affect outcome
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: unclear who was assessing outcomes. Author could not be contacted.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "Drop-out rate did not differ significantly between conditions, $x^2(2) = .29, p < .80$. Dropouts did not differ from remainders on age, Depression Inventory, MMPI D, or MMPI total elevation scores." Judgement comment: authors report dropouts were not different from participants who continued on some characteristics, but no information is available on the dropout rate per study arm. Author could not be contacted.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no protocol available. Author could not be contacted.
Other bias	High risk	Quote: "All therapy subjects were required to make a \$10 deposit, which was to be returned upon completion of the last session." Judgement comment: participants had to pay a deposit to take part. This may influence outcomes, for example if participants felt the need to respond in a more positive way. Not clear from the report how many participants started and finished in each group. Author could not be contacted. Baseline characteristics of participants by study arm not reported; there may have been important differences between the groups. Intervention was developed by the authors. It is therefore in their interest that the intervention is successful and effective.

Gardner 1981
Study characteristics

Methods	Study design: randomised controlled trial Study grouping: parallel group Recruitment: through advertisements in the local newspapers Type of RCT (blind, double-blind, open-label): open
Participants	Baseline characteristics Behavioural activation <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: -

Gardner 1981 (Continued)

- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: BDI 24.5
- Age: 19-65

Cognitive therapy

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: BDI 23
- Age: 19-65

Overall

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: -
- Age: 19 to 65

Included criteria: men and women aged 19 to 65 with depression.

Excluded criteria: no depression according to BDI criteria.

Pretreatment: no differences reported.

Interventions

Intervention characteristics

Behavioural activation

- type of intervention: BA
- specific intervention: behavioural therapy
- dose: -
- frequency: -
- duration: 6 weeks
- level of therapist: specialist
- individual or group therapy: individual
- mode of delivery: face-to-face
- modifications: -

Cognitive therapy

- type of intervention: comparator
- specific intervention: cognitive therapy using a rational emotive therapeutic approach
- dose: 6 sessions
- frequency: -
- duration: 6 weeks
- level of therapist: specialist
- individual or group therapy: individual

Gardner 1981 (Continued)

- *mode of delivery:* face-to-face
- *modifications:* -

Outcomes	<i>Depression symptoms</i> <ul style="list-style-type: none"> • Outcome type: continuous outcome • Reporting: partially reported • Scale: BDI • Direction: lower is better • Data value: endpoint • Notes: data extracted from figure with WebPlotDigitizer
Identification	Sponsorship source: none reported Country: Australia Setting: - Comments: - Authors name: P Gardner Institution: La Trobe University, Bundoora, Australia Email: - Address: Department of Psychology, La Trobe University, Bundoors, Australia 3083
Notes	<i>Noortje Uphoff on 25/09/2019 18:51</i> Included Author contacted to ask for clarifications about RoB assessment.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Based on the Beck Depressive Inventory, Ss were assigned to light, moderate and severe depressive levels and then were matched on these levels and on sex and allocated randomly after matching to the behavioral treatment group (BT) or the cognitive treatment group (CT)." Judgement comment: no information on randomisation method reported. Stratified by depression level and sex. Author contacted; no further information.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information. Author contacted; no further information.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: it is not reported if there were any attempts to blind participants or personnel but unlikely given nature of trial.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: BDI is self-report
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "Thirteen Ss withdrew at the end of the first baseline period."

Gardner 1981 (Continued)

Judgement comment: 13 participants withdrew during baseline measurement period. No other withdrawals are reported but unclear if all participants included in analysis.

Selective reporting (reporting bias)

Unclear risk

Judgement comment: no reference to protocol.

Other bias

Unclear risk

Judgement comment: no information on participant characteristics by study arm. No information on who therapists were or how therapist allegiance would be mitigated. Author contacted; no further information.

Gawrysiak 2009
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Recruitment: introductory psychology students recruited from a public Southeastern university who received credit for participation

Type of RCT (blind, double-blind, open-label): open

Participants

Baseline characteristics

Behavioural activation

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: BAI 13.4
- Depression severity: BDI 21.0
- Age: -

No treatment

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: BAI 16.1
- Depression severity: BDI 19.8
- Age: -

Overall

- Gender (N male, % male, N female, % female): 6 men (20%), 24 women (80%)
- Ethnic group: 21 Caucasian (70%) 4 African American (13%), 5 other (17%)
- Household income: -
- Occupation/employment: 100% university students
- Education level: currently at university first year (100%)
- Comorbid anxiety: -

Gawrysiak 2009 (Continued)

- *Depression severity:* -
- *Age:* mean 18.4 (SD 0.81)

Included criteria: participants 18 years and older who scored 14 or higher on the BDI-II and were not presently undergoing pharmacological or psychological treatment for depression were included in the study.

Excluded criteria: involved with psychotherapy within the past 2 years, active suicidal intent, current psychosis, bipolar disorder.

Pretreatment: no information on participant characteristics by study arm.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural activation treatment for depression (BATD)
- *dose:* 90-minute session
- *frequency:* 1 session + homework
- *duration:* 2 weeks
- *level of therapist:* specialist
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* one session treatment

No treatment

- *type of intervention:* comparator
- *specific intervention:* no treatment
- *dose:* -
- *frequency:* -
- *duration:* -
- *level of therapist:* -
- *individual or group therapy:* -
- *mode of delivery:* -
- *modifications:* -

Outcomes

Clinically significant improvement

- **Outcome type:** dichotomous outcome
- **Reporting:** fully reported
- **Scale:** BDI-II
- **Direction:** higher is better
- **Data value:** endpoint
- **Notes:** clinically significant improvement on BDI-II using reliable chance indices (RCI).

Dropouts

- **Outcome type:** dichotomous outcome
- **Reporting:** fully reported
- **Direction:** lower is better
- **Data value:** endpoint

Depression symptoms

- **Outcome type:** continuous outcome
- **Reporting:** fully reported

Gawrysiak 2009 (Continued)

- **Scale:** BDI-II
- **Direction:** lower is better
- **Data value:** endpoint

Anxiety symptoms

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** BAI
- **Direction:** lower is better
- **Data value:** endpoint

Identification

Sponsorship source: none reported; study part of a thesis

Country: USA

Setting: University of Tennessee psychology clinic

Comments: -

Authors name: Derek R Hopko

Institution: University of Tennessee

Email: dhopko@utk.edu

Address: University of Tennessee, Knoxville, Department of Psychology, Room 301D, Austin Peay Building, Knoxville, TN 37996-0900

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement comment: no information about how randomisation was achieved. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information about efforts to conceal allocation. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: patients knew whether they were received an intervention or not, as did personnel. It is likely that this influences outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: unclear whether outcome assessors were blinded. It appears patients completed questionnaires, which may cause bias due to experiences/ preferences. Author could not be contacted.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: researchers report there was no attrition.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol. Author could not be contacted.
Other bias	High risk	Judgement comment: no information on participant characteristics by study arm, making it hard to establish whether randomisation was successful. Author could not be contacted.

Gawrysiak 2009 (Continued)

Quote: "Behavioral Activation Treatment for Depression (BATD; Lejuez, Hopko, & Hopko, 2001; Hopko & Lejuez, 2007)."

Judgement comment: author Hopko developed the intervention tested (BATD) and therefore has an interest in it being effective.

Gilbody 2017

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Recruitment: participants aged 65 years or older from 32 primary care practices in the North of England gave written informed consent between March 2011 and July 2013. Potential participants were identified by postal questionnaire and were eligible if they reported depressive symptoms on a standardized brief 2-item case-finding tool

Type of RCT (blind, double-blind, open-label): open

Participants

Baseline characteristics

Behavioural activation

- *Gender (N male, % male, N female, % female):* 159 male (46%), 185 female (54%)
- *Ethnic group:* 340 (98.8%) white, 2 (0.6%) Asian, 1 (0.3%) other
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* 52% education beyond 16 years, 33% degree or equivalent professional
- *Comorbid anxiety:* mean GAD-7 score 5.7 (SD 4.8)
- *Depression severity:* mean PHQ-9 score 7.8 (SD 4.7)
- *Age:* mean 77.1 (SD 7.09)

Usual GP care

- *Gender (N male, % male, N female, % female):* 139 male (38%), 222 female (61%)
- *Ethnic group:* 358 (99.2%) white, 2 (0.6%) black
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* 51% education beyond 16 years, 29% degree or equivalent professional
- *Comorbid anxiety:* mean GAD-7 score 5.7 (SD 4.4)
- *Depression severity:* mean PHQ-9 score 7.8 (SD 4.6)
- *Age:* mean 77.5 (SD 7.18)

Overall

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Gilbody 2017 (Continued)

Included criteria: aged ≥ 75 years during the pilot phase or ≥ 65 years during the main trial identified by a GP practice as being able to take part in collaborative care, subthreshold depression according to DSM-IV (MINI 5.0)

Excluded criteria: known alcohol dependency, psychotic symptoms, comorbidity making entry into trial inadvisable, other factors that would make an invitation to participate in a trial inappropriate.

Pretreatment: No important differences found between the groups.

Interventions	Intervention characteristics
	Behavioural activation <ul style="list-style-type: none"> • <i>type of intervention:</i> BA • <i>specific intervention:</i> collaborative care using behavioural activation • <i>dose:</i> half an hour sessions • <i>frequency:</i> weekly sessions, 6 on average • <i>duration:</i> 8 to 10 weeks • <i>level of therapist:</i> non-specialist (mental health/ IAPT worker) • <i>individual or group therapy:</i> individual • <i>mode of delivery:</i> 1st session face-to-face, then telephone • <i>modifications:</i> programme designed for those aged ≥ 65 years with subthreshold depression and to accommodate long-term physical health problems
	Usual GP care <ul style="list-style-type: none"> • <i>type of intervention:</i> comparator • <i>specific intervention:</i> usual care • <i>dose:</i> - • <i>frequency:</i> - • <i>duration:</i> - • <i>level of therapist:</i> - • <i>individual or group therapy:</i> - • <i>mode of delivery:</i> - • <i>modifications:</i> initiate medication only in response to increasing depressive symptoms
Outcomes	<i>Depression symptoms</i> <ul style="list-style-type: none"> • Outcome type: continuous outcome • Reporting: fully reported • Scale: PHQ-9 • Range: 0-27 • Direction: lower is better • Data value: endpoint • Notes: data for unadjusted analysis; other analyses were reported. <i>Dropouts</i> <ul style="list-style-type: none"> • Outcome type: dichotomous outcome • Reporting: fully reported • Direction: lower is better • Data value: endpoint <i>Cases of depression</i> <ul style="list-style-type: none"> • Outcome type: dichotomous outcome • Reporting: fully reported • Scale: PHQ-9

Gilbody 2017 (Continued)

- **Direction:** lower is better
- **Data value:** endpoint
- **Notes:** PHQ-9 score of ≥ 10 indicating moderate to severe depression.

Quality of life - SF12 PCS

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** SF-12 PCS
- **Range:** 0 to 100
- **Direction:** higher is better
- **Data value:** endpoint

Quality of life - SF12 MCS

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** SF-12 MCS
- **Range:** 0 to 100
- **Direction:** higher is better
- **Data value:** endpoint

Anxiety symptoms

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** GAD-7
- **Range:** 0-21
- **Direction:** lower is better
- **Data value:** endpoint

Adverse events

- **Outcome type:** adverse event
- **Reporting:** fully reported
- **Data value:** endpoint
- **Notes:** 81 suspected adverse events; 37 in 33 patients in the collaborative care arm and 44 in 43 patients in the usual care arm. None of the adverse events were possibly, probably, or definitely related to the study. None of the deaths were suicides.

Identification

Sponsorship source: this project was funded by the NIHR Health Technology Assessment programme (reference: 08/19/04)

Country: UK

Setting: 32 primary care centres in the UK

Comments: -

Authors name: Simon Gilbody

Institution: Department of health sciences, University of York

Email: simon.gilbody@york.ac.uk

Address: Department of Health Sciences, Seebohm Rowntree Building, University of York, Heslington, York, YO10 5DD, UK

Notes

Gilbody 2017 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: randomisation through computer programme at York trials unit. Participants were allocated in a 1:1 ratio by simple randomisation without blocking or stratification.
Allocation concealment (selection bias)	Low risk	Judgement comment: use of computer programme ensured automatic randomisation without intervention by a researcher. Treatment allocation was concealed from study researchers at the point of recruitment using an automated computer data entry system, administered remotely by the York Trials Unit, which used a computer-generated code
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: due to the nature of the intervention this was an open trial. Participants in particular may have been influenced by knowing whether they were in the intervention or usual care group.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: most participants completed self-reported questionnaires and those who did not respond were asked to complete the PHQ-9 over the phone. Bias can occur because patients were aware of the intervention.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: similar rates of non-response across arms, but in the collaborative care arm participants were more likely to withdraw from the trial or follow-up at either 4 or 12 months. Many of those states 'no time', 'too busy' or 'does not wish to engage', which may be related to the intervention and participants left in the trial may therefore be better responders than those who did not complete the study. Authors did perform analysis adjusting for factors associated with non-response, but other factors may not have been measured. Four-month retention was 83%, with higher loss to follow-up in collaborative care (82/344 [24%]) vs usual care (37/361 [10%]).
Selective reporting (reporting bias)	Low risk	Judgement comment: reason for changing to 65 years justified, outcomes the same in protocol
Other bias	High risk	Judgement comment: trial is meant to include patients with subthreshold depression only (based on MINI), but a substantial proportion of participants report either severe/moderately severe depression or no depression at baseline based on the PHQ-9. Judgement comment: some of the authors have published extensively on the topic of behavioural activation, and it would be in their interest for the trial to show effectiveness of the intervention. The author team also developed the intervention they were evaluating.

Hammen 1975
Study characteristics

Methods	Study design: randomised controlled trial Study grouping: parallel group Recruitment: students enrolled in psychology classes at University Type of RCT (blind, double-blind, open-label): Open
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Hammen 1975 (Continued)

Participants

Baseline characteristics

Behavioural activation

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: -
- Age: -

Expectancy control

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: -
- Age: -

Self-monitoring

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: -
- Age:

No treatment

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: -
- Age: -

Overall

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: -
- Age: -

Hammen 1975 (Continued)

Included criteria: student in introductory psychology class, consistent signs of mild to moderate depression

Excluded criteria: -

Pretreatment: there were no significant differences between the groups on any of the depression measures

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* increase pleasant events
- *dose:* -
- *frequency:* -
- *duration:* 2 weeks
- *level of therapist:* -
- *individual or group therapy:* -
- *mode of delivery:* -
- *modifications:* -

Expectancy control

- *type of intervention:* comparator
- *specific intervention:* dietary change; attention placebo
- *dose:* -
- *frequency:* -
- *duration:* 2 weeks
- *level of therapist:* -
- *individual or group therapy:* -
- *mode of delivery:* -
- *modifications:* -

Self-monitoring

- *type of intervention:* comparator
- *specific intervention:* no changes from normal activities
- *dose:* -
- *frequency:* -
- *duration:* 2 weeks
- *level of therapist:* -
- *individual or group therapy:* -
- *mode of delivery:* -
- *modifications:* -

No treatment

- *type of intervention:* comparator
- *specific intervention:* no treatment
- *dose:* -
- *frequency:* -
- *duration:* 2 weeks
- *level of therapist:* -
- *individual or group therapy:* -
- *mode of delivery:* -

Hammen 1975 (Continued)

- *modifications*: retesting at end of study

Outcomes	<p><i>Depression symptoms</i></p> <ul style="list-style-type: none"> • Outcome type: continuous outcome • Reporting: Partially reported • Scale: Depression Adjective Checklist • Direction: lower is better • Data value: endpoint
Identification	<p>Sponsorship source: None reported</p> <p>Country: USA</p> <p>Setting: University</p> <p>Comments: -</p> <p>Authors name: Constance L. Hammen</p> <p>Institution: University of California</p> <p>Email: -</p> <p>Address: Department of Psychology, University of California, Los Angeles, California</p>
Notes	Data reported for Depression Adjective Checklist is daily average over treatment period rather than endpoint.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement comment: no information on randomisation. Author contacted; was not able to provide information.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information on how allocation was performed or concealed. Author contacted; was not able to provide information.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	<p>Quote: "The study was depicted as an investigation of mood changes in college students; subjects were not told that they had been selected on the basis of depressed mood. Ten subjects were randomly assigned to each of four groups."</p> <p>Judgement comment: no blinding reported. Unclear whether participants were aware of study arms. Author contacted; was not able to provide information.</p>
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: no information on how performed outcome assessments. Author contacted; was not able to provide information.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Judgement comment: dropouts and missing data not reported. Author contacted; was not able to provide information.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol. Author contacted; was not able to provide information.

Hammen 1975 (Continued)

Other bias	Unclear risk	Judgement comment: no description of baseline characteristics of participants. Baseline depression scores not reported. No outcomes reported for no-treatment group. Author contacted; was not able to provide information.
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Hemanny 2019
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment:</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>Gender:</i> 87% female • <i>Ethnic group:</i> 29% White, 33% Brown, 38% Black • <i>Household income:</i> - • <i>Occupation/employment:</i> 63% employed • <i>Education level:</i> 38% high school, 62% higher education • <i>Comorbid anxiety:</i> 25% • <i>Depression severity:</i> HAM-D: 22.38 (SD 5.8), BDI: 32.38 (SD 8.6) • <i>Age:</i> mean 40.9 (SD 11.0) <p>Trial-based cognitive therapy (TBCT)</p> <ul style="list-style-type: none"> • <i>Gender:</i> 88% female • <i>Ethnic group:</i> 27% White, 54% Brown, 19% Black • <i>Household income:</i> - • <i>Occupation/employment:</i> 73% employed • <i>Education level:</i> 27% high school, 73% higher education • <i>Comorbid anxiety:</i> 54% • <i>Depression severity:</i> HAM-D: 20.62 (SD 5.3), BDI: 31.38 (SD 7.1) • <i>Age:</i> mean 39.6 (SD 10.4) <p>Inclusion criteria: on antidepressant medication for at least 2 months, 18 to 60 years old, met MDD criteria (DSM-IV/ICD-10) assessed with MINI, >15 HDRS score/ >20 BDI.</p> <p>Exclusion criteria: mood stabilising drugs, bipolar disorder, psychotic disorders, current abuse or dependence on psychoactive substances.</p> <p>Pretreatment: more recurrent depression, GAD, and comorbidities in TBCT group. Also more likely to be an employee. TAU group lower baseline scores of anxiety and related measure (BAI, CD-Quest).</p>

Interventions	<p>Intervention characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> BA • <i>specific intervention:</i> behavioural activation (+antidepressants) • <i>dose:</i> - • <i>frequency:</i> weekly
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Hemanny 2019 (Continued)

- *duration*: 12 weeks
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: adapted for 12 sessions

Trial based cognitive therapy (TBCT)

- *type of intervention*: comparator
- *specific intervention*: trial based cognitive therapy (+ antidepressants)
- *dose*: -
- *frequency*: weekly
- *duration*: 12 weeks
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: -

Treatment as usual

- *type of intervention*: comparator
- *specific intervention*: treatment as usual (+ antidepressants)
- *dose*: -
- *frequency*: N/A
- *duration*: 12 weeks
- *level of therapist*: N/A
- *individual or group therapy*: N/A
- *mode of delivery*: N/A
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: HRSD
- **Direction**: lower is better
- **Data value**: mean, SD

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Scale**: -
- **Direction**: lower is better
- **Data value**: n/N

Anxiety symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: BAI
- **Direction**: lower is better
- **Data value**: mean, SD

Quality of life (physical domain)

- **Outcome type**: continuous outcome

Hemanny 2019 (Continued)

- **Reporting:** fully reported
- **Scale:** WHOQOL-BREF
- **Direction:** higher is better
- **Data value:** mean, SD

Social functioning

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** CD-Quest
- **Direction:** lower is better
- **Data value:** mean, SD

Identification	<p>Sponsorship source: not reported in paper or protocol.</p> <p>Country: Brazil</p> <p>Setting: not reported</p> <p>Comments: all participants received antidepressants throughout study.</p> <p>Authors name: Curt Hemanny</p> <p>Institution: Health Sciences Institute, Federal University of Bahia</p> <p>Email: hemanny@gmail.com</p> <p>Address: Postgraduate Program of Interactive Processes of Organs and Systems, Health Sciences Institute, Federal University of Bahia, Brazil</p>	
Notes	All participants also received antidepressants	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>Quote: "When eligible, participants were assigned by the research coordinator, through a randomization list, to 1 of 3 intervention groups".</p> <p>Judgement comment: randomisation list used but not clear how generated</p>
Allocation concealment (selection bias)	Unclear risk	Judgement comment: research co-ordinator performed randomisation using list and was not involved in treatment, but not clear whether they could have influenced allocation.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Judgement comment: unclear if attempts made to blind participants (described as 'single blind' but this may refer to outcome assessors) but unlikely that participants were blinded given nature of intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	<p>Quote: "All assessments were performed by a trained and blind evaluator."</p> <p>Judgement comment: assessor was blind to treatment allocation.</p>
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: dropout rates were relatively high (16/26 in TAU group) and more patients dropped out of TAU than other groups. Some reasons for drop out (not wanting to take part after being randomised to TAU group) are likely to be related to the interventions. Missing data were imputed and assumed to be missing at random; this might not be justified.

Hemanny 2019 (Continued)

Selective reporting (reporting bias)	High risk	JJudgement comment: primary outcome measure was BDI in protocol and HAM-D in paper. One-year measurements specified in protocol but not reported. Beck Anxiety Inventory not specified in protocol.
Other bias	High risk	JJudgement comment: potential conflict of interest; one of the authors developed the RBCT intervention. Therapist allegiance unclear.

Jacobson 1996
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: potential clients were referred by a Seattle area health maintenance organization (HMO) or self-referred through a newspaper advertisement soliciting participation in a depression treatment program.</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> N = 16 male (28%), N = 41 female (72%) • <i>Ethnic group:</i> African American 1 (1.9%), Hispanic 2 (3.7%), Caucasian 50 (92.6%), Native American 1 (1.9%), Asian 0 (0%) • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> N = 18 post college (32%), N = 36 college graduate (63%) • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> BDI 29.3 (SD 6.9), HRSD 17.4 (SD 3.8) • <i>Age:</i> mean 36.6 <p>Cognitive therapy</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> N = 12 male (24%), N = 38 female (76%) • <i>Ethnic group:</i> African American 3 (6%), Hispanic 0(0%), Caucasian 38 (76%), Native American 3 (6%), Asian 2 (4%) • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> N = 12 post college (24%), N = 27 college graduate (54%) • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> BDI 29.8 (SD 6.3), HRSD 19.1 (SD 4.4) • <i>Age:</i> mean 39.2 <p>Automatic thoughts</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 34 female (77%), 10 male (23%) • <i>Ethnic group:</i> 1 Hispanic (2%), 40 Caucasian (91%), 2 Native American (4%), 1 Asian (2%) • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> 22 college graduate (50%), 8 post college (18%) • <i>Comorbid anxiety:</i> -

Jacobson 1996 (Continued)

- *Depression severity*: BDI 29.2 (SD 6.6), HRSD 19.3 (SD 4.0)
- *Age*: mean 38.3

Overall

- *Gender (N male, % male, N female, % female)*: N = 28 male, N = 79 female
- *Ethnic group*: N = 88 Caucasian, N = 12 other
- *Household income*: -
- *Occupation/employment*: -
- *Education level*: -
- *Comorbid anxiety*: -
- *Depression severity*: -
- *Age*: -

Included criteria: all clients met the following inclusion criteria: a diagnosis of current major depression based on DSM-III-R, a score of 20 or higher on the BDI, a score of 14 or higher on the HAM-D, agreement to random assignment to one of three treatment conditions, and agreement to having therapy sessions audiotaped and to completing questionnaires and participating in follow-up interviews.

Excluded criteria: at imminent risk of suicide, within the previous 6 months they met criteria for an Axis I disorder of alcohol or drug abuse or dependence, anorexia, bulimia, or panic disorder; or they had ever met criteria for obsessive compulsive disorder, bipolar disorder, or schizophrenia.

Pretreatment: baseline HAM-D score higher in CT group. No other baseline characteristics reported in this paper. Used baseline characteristics from original paper (numbers slightly different).

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention*: BA
- *specific intervention*: behavioural activation
- *dose*: -
- *frequency*: -
- *duration*: 20 sessions in total
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: -

Cognitive therapy

- *type of intervention*: comparator
- *specific intervention*: cognitive therapy
- *dose*: -
- *frequency*: -
- *duration*: 20 sessions in total
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: -

Automatic thoughts

- *type of intervention*: comparator
- *specific intervention*: activation and the modification of dysfunctional thoughts
- *dose*: -
- *frequency*: -

Jacobson 1996 (Continued)

- *duration*: 20 sessions in total
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: elements of BA

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: HRSD
- **Direction**: lower is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: lower is better
- **Data value**: endpoint

Identification

Sponsorship source: Grants 2R01 MH44063- 06 and 5K02 MH00868-05 from the National Institute of Mental Health

Country: USA

Setting: -

Comments: -

Authors name: NS Jacobson

Institution: University of Washington

Email: -

Address: Department of Psychology, University of Washington, 1107 NE 45th Street, Seattle, Washington 98105-4631

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: no information. Contacted author: Used random numbers list.
Allocation concealment (selection bias)	Low risk	Judgement comment: no information. Contacted author: concealed from researchers; allocation by research co-ordinator.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding; outcome may be influenced by therapist and patient preference.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Contacted author: outcome assessors blinded.

Jacobson 1996 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: N = 1 in each group did not complete post-treatment HAM-D. Author contacted: probably 4 dropouts in BA, 5 in AT, and 3 in CT group (from memory).
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no protocol.
Other bias	Unclear risk	Judgement comment: numbers of participants in two papers of same trial do not add up. Author provided numbers but not reasons for dropout.

Kanter 2015
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: participants were low-income, monolingual Spanish-speaking Latinos who were referred for psychological services at the behavioral health clinic of the SSCHC over a 9-month period</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> Gender (N male, % male, N female, % female): 16 female (76%) Ethnic group: 14 (66.7%) Mexico, 6 (28.6%) Puerto Rico, 1 (4.8%) other Household income: 9 ≤ \$10,000 (43%), 6 10,000 to 20,000 (29%), 3 >20,000 to 30,000 (14%) Occupation/employment: 11 unemployed (52%) Education level: - Comorbid anxiety: - Depression severity: 6 low (29%), 15 high (71%) Age: 38.7 (SD 11.7) <p>Treatment as usual</p> <ul style="list-style-type: none"> Gender (N male, % male, N female, % female): 18 female (82%) Ethnic group: 15 (68.2%) Mexico, 3 (13.6%) Puerto Rico, 3 (13.6%) other Household income: 11 ≤ \$10,000 (50%), 5 10,000-20 to 000 (23%), 5 >20,000 to 30,000 (23%) Occupation/employment: 12 unemployed (54%) Education level: - Comorbid anxiety: - Depression severity: 11 low (50%), 11 high (50%) Age: 37.5 (SD 10.1) <p>Overall</p> <ul style="list-style-type: none"> Gender (N male, % male, N female, % female): 34 female (79%) Ethnic group: 29 (67.4%) Mexico. 9 (20.9%) Puerto Rico. 4 (9.3%) other Household income: 20 ≤ \$10,000 (46%), 11 10,000 to 20,000 (26%), 8 >20,000 to 30,000 (19%) Occupation/employment: 23 unemployed (53%) Education level: - Comorbid anxiety: -

Kanter 2015 (Continued)

- *Depression severity:* 17 low (39%), 26 high (60%)
- *Age:* 38.1 (SD 10.8)

Included criteria: Latino, age 18 to 65, score 16 or higher on modified 17 item HRSD, meeting criteria for major depressive disorder (DSM-IV-TR).

Excluded criteria: any problem requiring immediate inpatient hospitalisation, organic brain syndrome or an intellectual or developmental disability according to medical records, probable alcohol abuse, a lifetime diagnosis of psychosis or bipolar disorder as indicated by the MINI, a current diagnosis of panic disorder as indicated by the MINI, or being on an antidepressant medication at the time of eligibility assessment.

Pretreatment: no statistically significant differences. Severity seems slightly higher in behavioural activation group.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* Behavioural Activation for Latinos (BAL)
- *dose:* 50-minute sessions
- *frequency:* weekly
- *duration:* up to 12 sessions
- *level of therapist:* specialist
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* Adapted from Martell original BA model

Treatment as usual

- *type of intervention:* comparator
- *specific intervention:* treatment as usual; non-specified therapy
- *dose:* 50 minute sessions
- *frequency:* weekly
- *duration:* up to 12 sessions
- *level of therapist:* specialist
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* -

Outcomes

Dropouts

- **Outcome type:** dichotomous outcome
- **Reporting:** fully reported
- **Direction:** lower is better
- **Data value:** endpoint

Depression symptoms

- **Outcome type:** continuous outcome
- **Reporting:** partially reported
- **Scale:** HRSD
- **Direction:** lower is better
- **Data value:** endpoint
- **Notes:** outcomes only reported by number of sessions completed; no data for two arms by treatment group.

Kanter 2015 (Continued)

Quality of life - SF12 PCS

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** SF12 PCS
- **Direction:** higher is better
- **Data value:** endpoint

Quality of life SF-12 MCS

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** SF-12 MCS
- **Direction:** higher is better
- **Data value:** endpoint

Identification	<p>Sponsorship source: this study was supported by NIMH Grant (R34) MH085109-01A1 awarded to Jonathan W. Kanter and Azara L. Santiago-Rivera.</p> <p>Country: USA</p> <p>Setting: community health centre</p> <p>Comments: -</p> <p>Authors name: Jonathan W. Kanter</p> <p>Institution: University of Washington</p> <p>Email: jonkan@uw.edu</p> <p>Address: Department of Psychology, University of Washington, Box 351525, Seattle, Washington, 98105</p>
Notes	<p><i>Noortje Uphoff on 26/07/2019 18:13</i></p> <p>Included</p> <p>No outcomes by treatment arm; only by number of sessions.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Participants then were randomly assigned by the project coordinator to one of two acute treatment conditions, BAL or TAU, using a computerized adaptive biased-coin randomization procedure that uses the urn design (Wei & Lachin, 1988) balancing on gender, marital status, and depression severity, in that order. Participants were assigned to therapists within condition based on clinician availability."
Allocation concealment (selection bias)	Low risk	Judgement comment: computerised programme used by project co-ordinator
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding not possible due to nature of interventions. This may have led to bias for participants in particular.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Judgement comment: outcome assessor was blinded.

Kanter 2015 (Continued)

Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "BAL clients attended significantly more sessions over the course of therapy (M = 8.21, SD = 3.95) compared to TAU clients (M = 4.95, SD = 3.41)," Judgement comment: Dropout was higher in TAU group. Dropout in BAL group was more likely for those with higher baseline depression symptoms, and dropout in TAU group was more likely for those with lower baseline depression symptoms.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: author contacted; no pre-registration or protocol available.
Other bias	High risk	Judgement comment: TAU was a non-specified therapy, which shared elements of treatment with the behavioural activation therapy. Given that TAU was not specified and therapists were aware of the treatment they provided, the 'TAU' treatment may have been different from what it would have been outside the trial. For example, purposefully less focused on behavioural activation. Intervention developed by one of the authors (Kanter), who has published a book on behavioural activation. It is therefore likely he has an interest in the intervention being successful. Quote: "Both BAL and TAU therapists followed equivalent standard clinic procedures with respect to the scheduling of sessions and phone follow-ups with clients in the case of missed sessions" Quote: "Although both BAL and TAU therapists followed the same clinic protocols between sessions with respect to calling clients who missed sessions or to remind clients to attend sessions, BAL therapists likely worked harder in session to encourage session attendance." Judgement comment: BAL protocol specifically encouraged therapists to spend time in session discussing importance of attendance.

Kelly 1983
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: cross-over</p> <p>Recruitment: newspaper advertisement</p> <p>Type of RCT (blind, double-blind, open-label): 10-week intervention; active treatment started in week 3 and in week 7 cross-over was used.</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): • Ethnic group: • Household income: • Occupation/employment: • Education level: • Comorbid anxiety: • Depression severity: Mean BDI: 24 (from graph)

Kelly 1983 (Continued)

- Age:

Cognitive intervention approach

- Gender (*N* male, % male, *N* female, % female):
- Ethnic group:
- Household income:
- Occupation/employment:
- Education level:
- Comorbid anxiety:
- Depression severity: Mean BDI: 23.5 (from graph)
- Age:

Overall

- Gender (*N* male, % male, *N* female, % female): 5 males (31%), 11 females (69%)
- Ethnic group:
- Household income:
- Occupation/employment:
- Education level:
- Comorbid anxiety:
- Depression severity: BDI 10 to 40
- Age:

Included criteria: score between 10 and 40 on BD. ICommitment to attend 10 consecutive treatment sessions, commitment to complete all research forms requested

Excluded criteria: severe depression (40 to 60 on BDI). Very mild depressive symptoms (0 to 9 on BDI), unable to commit to full participation

Pretreatment: No information. Baseline depression level similar between groups.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural treatment programme
- *dose:* one hour sessions
- *frequency:* weekly
- *duration:* 10 weeks (active treatment 4 weeks)
- *level of therapist:* specialist in training (doctoral students with training in specific approach)
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* Exploratory sessions for first 2 weeks with no specific attempt to improve symptoms. Cognitive intervention from week 7.

Cognitive intervention approach

- *type of intervention:* comparator
- *specific intervention:* cognitive treatment
- *dose:* 1-hour sessions
- *frequency:* weekly
- *duration:* 10 weeks (active treatment 4 weeks)
- *level of therapist:* specialist in training (doctoral students with training in specific approach)
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face

Kelly 1983 (Continued)

- *modifications*: Exploratory sessions for first 2 weeks with no specific attempt to improve symptoms. Behavioural intervention from week 7.

Outcomes	<i>Depression symptoms</i> <ul style="list-style-type: none"> • Outcome type: continuous outcome • Reporting: partially reported • Scale: BDI • Direction: lower is better • Data value: endpoint • Notes: data extraction from graph using WebPlotDigitizer. 	
Identification	Sponsorship source : none reported. Country : USA Setting : training and research centre at a university Comments : Authors name : E. Thomas Dowd Institution : University of Nebraska Email : Address : Department of Educational Psychology and Social Foundations, Educational Psychology Clinic, University of Nebraska, 130 Bancroft Hall, Lincoln, Nebraska 68588, USA	
Notes	<i>Noortje Uphoff on 18/07/2019 19:38</i> Included Submitted and received inter-lending request through library. Data not included in meta-analysis; not possible to estimate SD.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement comment: no information on randomisation method provided. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information on randomisation method provided. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no attempts to blind participants or personnel reported and unlikely due to nature of trial.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: BDI is self-report
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Judgement comment: no information regarding dropout rates; presumably all participants completed the interventions. Author could not be contacted.

Kelly 1983 (Continued)

Selective reporting (re-reporting bias)	Unclear risk	Judgement comment: measures reported in methods section are not presented in results section. Result section does not fully report results of all analyses. No reference to protocol. Author could not be contacted.
Other bias	Unclear risk	Judgement comment: study design: first inactive treatment, then active treatment, then treatments are swapped. Results show that decline in depression symptoms in both groups start during inactive treatment. - No information regarding baseline characteristics of participants. - Participants may have been pressured to complete the study (inclusion criteria include commitment to complete intervention. Author could not be contacted.

Kornblith 1980

Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment:</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Comprehensive self-control (behavioural activation)</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: - • Depression severity: - • Age: - <p>Self-monitoring plus self-evaluation (behavioural activation)</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: - • Depression severity: - • Age: - <p>Principles-only (behavioural activation)</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: -

Kornblith 1980 (Continued)

- *Depression severity:* -
- *Age:* -

Psychotherapy

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Overall

- *Gender (N male, % male, N female, % female):* 100% women (N = 49)
- *Ethnic group:* -
- *Household income:* average USD 15,000 to 20,000
- *Occupation/employment:* 44.9% employed
- *Education level:* median 13.9 years of school. 98% high school graduates
- *Comorbid anxiety:* -
- *Depression severity:* mean BDI score 27.6
- *Age:* mean 37.9, range 19 to 59

Included criteria: women, 18 to 60 years old, not currently or in last 30 days in psychotherapy for depression, not taking antidepressants or major tranquilisers, no life-threatening illness, =>20 on BDI and met Research Diagnostic Criteria for Major Affective Disorder.

Excluded criteria: current suicidal crisis, mania, hypomania, or schizophrenia; organic brain syndrome; mental retardation; borderline syndrome; antisocial personality; anorexia nervosa; or, during the last 12 months: alcohol abuse, anxiety disorder, Briquet's syndrome, drug abuse, obsessive-compulsive disorder, panic disorder, or phobic disorder.

Pretreatment: psychotherapy group seemed to have lower baseline depression scores

Interventions	Intervention characteristics
	<p>Comprehensive self-control (behavioural activation)</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> BA • <i>specific intervention:</i> behavioural activation with principles, exercises, and homework based on Rehm principles • <i>dose:</i> 1.5 hours a session • <i>frequency:</i> weekly • <i>duration:</i> 12 weeks • <i>level of therapist:</i> specialist • <i>individual or group therapy:</i> group • <i>mode of delivery:</i> face-to-face • <i>modifications:</i> - <p>Self-monitoring plus self-evaluation (behavioural activation)</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> BA • <i>specific intervention:</i> behavioural activation with focus on self-reinforcement • <i>dose:</i> 1.5 hours a session • <i>frequency:</i> weekly • <i>duration:</i> 12 weeks

Kornblith 1980 (Continued)

- *level of therapist*: specialist
- *individual or group therapy*: group
- *mode of delivery*: face-to-face
- *modifications*: -

Principles-only (behavioural activation)

- *type of intervention*: comparator
- *specific intervention*: behavioural activation without homework (principles only)
- *dose*: 1.5 hours a session
- *frequency*: weekly
- *duration*: 12 weeks
- *level of therapist*: specialist
- *individual or group therapy*: group
- *mode of delivery*: face-to-face
- *modifications*: -

Psychotherapy

- *type of intervention*: comparator
- *specific intervention*: general psychotherapy without homework
- *dose*: 1.5 hours a session
- *frequency*: weekly
- *duration*: 12 weeks
- *level of therapist*: specialist
- *individual or group therapy*: group
- *mode of delivery*: face-to-face
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: HDRS - interviewer rates
- **Direction**: lower is better
- **Data value**: endpoint
- **Notes**: reporting BA and comparator groups only due to review inclusion criteria. Reporting interviewer rates instead of clinician rates.

Functioning

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: Global Assessment Scale
- **Direction**: higher is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: lower is better
- **Data value**: endpoint

Identification

Sponsorship source: the study was supported by NIMH grant R01 MH27822 to the second author, who also chaired the dissertation committee.

Kornblith 1980 (Continued)

Country: USA

Setting: community

Comments: -

Authors name: Lynn Rehm

Institution: University of Houston

Email: -

Address: Department of Psychology, University of Houston, Houston, Texas 77004.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Judgement comment: author contacted; allocation based on when participant was screened; not completely at random.
Allocation concealment (selection bias)	High risk	Judgement comment: author contacted; allocation based on when participant was screened; no concealment of group allocation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding possible due to nature of interventions. This may influence outcomes, particularly because patients were aware of treatment and may favour one treatment over another.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "All clinicians were blind as to treatment condition, and the second raters were blind as to the pre/post status of the subject's videotape." Judgement comment: assessed by two people, both blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "Of the 10 withdrawals who failed to continue in the program past session 9, 5 dropped from the 16 who began the Comprehensive Self-Control condition (31%), 0 dropped from the 12 who began the Self-Monitoring plus Self-Evaluation condition (0%), 4 dropped from the 15 who began the Principles-Only condition (27%), and 1 dropped from the 6 who began the Psychotherapy condition (17%)." Judgement comment: Dropout seemed higher in comprehensive self-control (BA) group than in psychotherapy group. This may be due to chance (small numbers) or because the psychotherapy was seen as more favourable.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: contacted author; no protocol or online registration available.
Other bias	High risk	Judgement comment: contacted author; no baseline characteristics of participants published but groups balanced on age and severity of depression symptoms according to author. One of the authors (Rehm) developed the model of treatment tested in this trial.

Luo 2020
Study characteristics
Behavioural activation therapy for depression in adults (Review)

Luo 2020 (Continued)

Methods

Study design: cluster-randomised controlled trial

Study grouping: parallel group

Recruitment: seven long-term care facilities managed by a single non government organisation were randomly assigned as experimental and control sites. Participants recruited from the experimental sites were invited to take part in the PMAL intervention, whereas participants from the control sites received care as usual. A list of potential participants who may benefit from PMAL intervention was generated from the most up-to-date record of the Minimum Data Set (MDS) 2.0

Type of RCT (blind, double-blind, open-label): open

Participants

Baseline characteristics

Behavioural activation

- *Gender (N male, % male, N female, % female):* 27 female (84%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* 13 (43.3%) no formal education, 12 (40%) primary school, 5 (16.7%) middle school or higher
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* 85.9 (SD 7.14)

Usual care

- *Gender (N male, % male, N female, % female):* 23 female (77%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* 18 (56.3%) no formal education, 12 (37.5%) primary school, 2 (6.3%) middle school or higher
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* 84.4 (SD 9.5)

Overall

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Included criteria: presence of a mood problem indicated by the Resident Assessment Protocol (RAP), where one or more symptoms from 17 listed symptoms indicates a mood problem, a Cognitive Performance Scale (CPS) score of 0 or 1 (intact or borderline intact), no other acute clinical variations; and voluntary participation.

Excluded criteria: low cognitive performance

Pretreatment: no obvious differences.

Interventions

Intervention characteristics
Behavioural activation therapy for depression in adults (Review)

Luo 2020 (Continued)

Behavioural activation

- *type of intervention*: BA
- *specific intervention*: Positive Mood and Active Life (PMAL) behavioural activation based on BE-ACTIV intervention
- *dose*: -
- *frequency*: 36 sessions in total
- *duration*: 12 weeks
- *level of therapist*: non-specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: social workers instead of specialists

Usual care

- *type of intervention*: comparator
- *specific intervention*: usual care
- *dose*: -
- *frequency*: -
- *duration*: 12 weeks
- *level of therapist*: non-specialist
- *individual or group therapy*: individual
- *mode of delivery*: -
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: Geriatric Depression Scale (GDS)
- **Direction**: lower is better
- **Data value**: endpoint
- **Notes**: estimates from three-level linear mixed model to account for clustering of time points within patients within nursing homes.

Dropouts

- **Outcome type**: dichotomous outcome
- **Direction**: lower is better
- **Data value**: endpoint
- **Notes**: baseline characteristics are presented for those who completed the study only.

Quality of life

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: WHOQoL
- **Direction**: higher is better
- **Data value**: endpoint

Identification

Sponsorship source: none reported

Country: Hong Kong, China

Setting: long-term care facilities

Comments: -

Luo 2020 (Continued)

Authors name: Vivian Lou

Institution: University of Hong Kong

Email: wlou@hku.hk

Address: Department of Social Work and Social Administration, Rm522, The Jockey Club Tower, Centennial Campus, The University of Hong Kong, Pokfulam Road, Hong Kong, China

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement comment: unclear how sites were randomised.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: participants and personnel were likely not blinded due to the nature of the intervention. It is possible that the active intervention was seen as favourable compared to 'care as usual', which may cause bias.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "The items of the project-tailored assessment were read to the residents by an experienced research assistant who was trained on the GDS-15 and WHOQoL-BREF by the principal investigator." Judgement comment: unlikely that outcome assessors who administered questionnaires were blinded, but not specified.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: dropout rates were low and for reasons unlikely to be related to the treatment (cognitive impairment, frailty, mortality).
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol
Other bias	High risk	Researchers developed the intervention, which means they have an interest in the intervention being successful. Issues specific to cluster RCTs: Judgement comment: 7 sites; unclear how randomised. Sites were all part of the same organisation. No large differences between samples in control and experimental group. No information about differences between sites.

Ly 2014
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Recruitment: mass media and advertisements in large Swedish newspapers. Those who were interested were directed to a web page with information about the study

Ly 2014 (Continued)

Type of RCT (blind, double blind, open label):

Participants

Baseline characteristics

Behavioural activation

- *Gender (N male, % male, N female, % female):* N = 12 male (30%), N = 28 female (70%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* 35 (87.5%) employed/student, 3 (7.5%) unemployed, 0 retired, 2 (6.3%) other
- *Education level:* 1 (2.5%) 9-year compulsory school, 11 (27.5%) secondary school, 27 (67.5%) college/university, 1 (2.5%) other
- *Comorbid anxiety:* N = 19 (47%)
- *Depression severity:* BDI-II 23.50 (7.85 SD)
- *Age:* mean 36.6 (10.5 SD), range 20 to 59 years

Mindfulness

- *Gender (N male, % male, N female, % female):* N = 12 male (29%), N = 29 female (71%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* 30 (73.2%) employed/student, 3 (7.3%) unemployed, 1 (2.4%) retired, 7 (17.1%) other
- *Education level:* 2 (4.9%) 9-year compulsory school, 14 (34.1%) secondary school, 24 (58.5%) college/university, 1 (2.4%) other
- *Comorbid anxiety:* N=10 (24%)
- *Depression severity:* BDI-II mean 24.68, SD 9.47
- *Age:* mean 35.6 (11.3 SD), range 21 to 61 years

Overall

- *Gender (N male, % male, N female, % female):* N = 24 male, N = 57 female
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* N = 65 employed, N = 6 unemployed, N = 10 other
- *Education level:* 3 (3.8%) 9-year compulsory school, 25 (30.9%) secondary school, 51 (63%) college/university, 2 (2.5%) other
- *Comorbid anxiety:* N = 29 (36%)
- *Depression severity:* -
- *Age:* mean 36.1 (10.8 SD), range 20 to 61 years

Included criteria: 18 years old, > 5 on PHQ-9, depressive symptoms according to DSM-IV, access to the internet and a smartphone, good knowledge of Swedish language.

Excluded criteria: change in psychiatric medication in the last month, any other current psychological treatment, severe comorbid psychiatric condition which could interfere with treatment e.g. bipolar or schizophrenia, primary medical problems that would need other treatment, severe alcohol problems, severe depression, suicidal ideation.

Pretreatment: BA group seems to have a slightly higher level of education, is less likely to be on medication, and more likely to have a diagnosis of dysthymia in addition to depression and generalized anxiety disorder.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA

Ly 2014 (Continued)

- *specific intervention*: smartphone delivered BA with minimal therapist contact
- *dose*: max 20 min per participant per week of therapist contact
- *frequency*: personal encouraging messages every other or every third day, weekly general educational messages, weekly reflections from participants
- *duration*: 8 weeks
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: smartphone + email
- *modifications*: app was not designed for depression but to register behaviours to increase everyday activation. BA treatment manual adapted for this intervention.

Mindfulness

- *type of intervention*: comparator
- *specific intervention*: smartphone delivered psychoeducation and mindfulness with minimal therapist contact
- *dose*: max 20-minutes per participant per week of therapist contact. 3 to 30 minutes guided audio tracks
- *frequency*: personal encouraging emails every other or every third day, weekly general educational emails, weekly reflections from participants
- *duration*: 8 weeks
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: smartphone + email
- *modifications*: emails rather than messages via the app, mindfulness adapted for this intervention

Outcomes

Recovery rates

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: higher is better
- **Data value**: endpoint
- **Notes**: recovery rates were defined as no longer fulfilling the criteria for depression according to the MINI

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Data value**: endpoint

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: BDI-II
- **Direction**: lower is better
- **Data value**: endpoint

Anxiety symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: Becks Anxiety Inventory
- **Direction**: lower is better
- **Data value**: endpoint

Ly 2014 (Continued)

Quality of life

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** QOLI
- **Direction:** higher is better
- **Data value:** endpoint

Identification	<p>Sponsorship source: the Swedish Research Council sponsored this study with funding 2011–2476.</p> <p>Country: Sweden</p> <p>Setting: community/ at home</p> <p>Comments: -</p> <p>Authors name: Kien Hoa Ly</p> <p>Institution: Department of Behavioural Sciences and Learning, Linköping University</p> <p>Email: kien.hoa.ly@liu.se</p> <p>Address: Department of Behavioural Sciences and Learning, Linköping University, Linköping, Sweden</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: allocated using an online randomisation tool, done by an independent person separate from staff conducting the study
Allocation concealment (selection bias)	Low risk	Judgement comment: randomisation done by independent person. Not specifically said there was allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: participants and therapists providing support via email were not blinded. Their preference may have influenced outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "At the 6-month follow-up, the interviews were conducted by other clinical psychology students who were blind to the participant's condition and the treatment they had been given." Judgement comment: Interviews conducted by students who were blinded to the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: similar numbers lost to post-assessment and 6-month follow-up in both groups, and included in ITT analysis.
Selective reporting (reporting bias)	High risk	Judgement comment: protocol states outcomes will be reported at 1 year instead of 6 months. Primary outcome measures same as protocol, didn't include TIC-P secondary outcome which was in protocol.
Other bias	High risk	Judgement comment: the research group developed the behavioural activation smartphone app, so it in their interest for the app to be successful.

McCluskey 2018
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Recruitment: flyers around university campus

Type of RCT (blind, double-blind, open-label): open

Participants

Baseline characteristics

Behavioural activation

- *Gender (N male, % male, N female, % female):* 76% female, 24% male
- *Ethnic group:* 90% White, 5% Black, 5% Asian
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* BDI-II 18.75, SD 8.08
- *Age:* 19.6, SD 1.27

No treatment

- *Gender (N male, % male, N female, % female):* 83% female, 17% male
- *Ethnic group:* 78% White, 11% Black, 6% Hispanic, 6% Asian
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* BDI-II 21.56, SD 6.05
- *Age:* 19.6, SD 1.46

Overall

- *Gender (N male, % male, N female, % female):* 81% female, 19% male
- *Ethnic group:* 90% White, 3% Black, 2% Hispanic, 4% Asian
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* BDI-II 18.67, SD 3.01
- *Age:* 19.61 (1.35)

Included criteria: aged 18 years of over with BDI 13-28 (mild-moderate depression). Individuals taking antidepressant medication were required to be stabilized for a period of 8 weeks prior to beginning the study

Excluded criteria: under 18, not fluent in English, not meeting depression score criteria, significant histories of suicidal thoughts, psychosis, substance abuse, or bipolar disorder. Participants taking antidepressants had to be stabilised for a minimum of 8 weeks prior to the study.

Pretreatment: no significant differences in outcome or demographic data between groups

Interventions

Intervention characteristics

Behavioural activation

McCluskey 2018 (Continued)

- *type of intervention*: BA
- *specific intervention*: brief behavioural activation treatment for depression (BATD-R) with homework
- *dose*: 90-minute BATD-R based intervention session with assigned homework plus 2 follow-up sessions every 2 weeks
- *frequency*: -
- *duration*: 1 month
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: Small changes to BATD protocol by Gawrysiak et al, 2009

No treatment

- *type of intervention*: comparator
- *specific intervention*: no treatment
- *dose*: -
- *frequency*: -
- *duration*: -
- *level of therapist*: -
- *individual or group therapy*: -
- *mode of delivery*: -
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: partially reported
- **Direction**: lower is better
- **Data value**: endpoint
- **Notes**: extracted data for ITT analysis (last observation carried forward for missing data). Data extracted from figure.

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: lower is better
- **Data value**: endpoint

Identification

Sponsorship source: none reported. PhD dissertation.

Country: USA

Setting: psychological centre at University

Comments: -

Authors name: D Lee McCluskey

Institution: West Virginia University

Email: -

Address: Department of Psychology, West Virginia University Morgantown, WV

Notes

Risk of bias

McCluskey 2018 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "computer-based random number generator."
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information provided. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding due to nature of intervention. This may have influenced scores, for example leading to lower scores in no treatment arm.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: outcome assessors not specified. Author could not be contacted.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Judgement comment: attrition did not differ between groups. Missing data were imputed (last observation carried forward). It is unclear whether this is a valid method in this case, given that scores tended to go down at the first time point but up before follow-up.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: protocol not available. Author could not be contacted.
Other bias	Low risk	Judgement comment: no other sources of bias identified.

McIndoo 2016
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: recruited through general psychology courses using a research participation website (96%) and fliers posted on campus (4%). Recruitment took place between August 2013 and January 2014.</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 11 females (69%) • <i>Ethnic group:</i> 88% White, 6% Asian American, 6% Indian/ Middle Eastern • <i>Household income:</i> 3 (19%) < 20,000. 2 (12%) 20,000 to 40,000. 3 (19%) 40,000 to 60,000. 4 (25%) 60,000 to 80,000. 3 (19%) 80,000 to 100,000. 1 (6%) >100,000 • <i>Occupation/ employment:</i> 100% students • <i>Education level:</i> 100% college students • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> 63% major depressive disorder • <i>Age:</i> 19.3 (SD 1.5) <p>Mindfulness-based therapy</p>

McIndoo 2016 (Continued)

- *Gender (N male, % male, N female, % female):* 12 females (60%)
- *Ethnic group:* 80% White, 5% African American, 5% Hispanic, 10% mixed
- *Household income:* 4 (20%) <\$20,000, 2 (10%) 20,000 to 40,000, 1 (5%) 40,000 to 60,000, 4 (20%) 60,000 to 80,000, 2 (10%) 80,000 to 100,000, 7 (35%) >100,000
- *Occupation/employment:* 100% students
- *Education level:* 100% college students
- *Comorbid anxiety:* -
- *Depression severity:* 70% major depressive disorder
- *Age:* 19.3 (SD 1.9)

Waiting list

- *Gender (N male, % male, N female, % female):* 8 females (57%)
- *Ethnic group:* 57% White, 7% African American, 7% Indian/Middle Eastern, 7% Hispanic, 22% mixed
- *Household income:* 2 (14%) <20,000, 2 (14%) 20,000 to 40,000, 2 (14%) 40,000 to 60,000, 4 (29%) 60,000 to 80,000, 3 (22%) 80,000 to 100,000, 1 (7%) >100,000
- *Occupation/employment:* 100% students
- *Education level:* 100% college students
- *Comorbid anxiety:* -
- *Depression severity:* 64% major depressive disorder
- *Age:* 19.0 (SD 1.5)

Overall

- *Gender (N male, % male, N female, % female):* 19 male (38%), 31 female (62%)
- *Ethnic group:* 76% White, 10% mixed race, 4% African American, 4% Asian American, 4% Indian/Middle Eastern, 2% Hispanic
- *Household income:* -
- *Occupation/employment:* 100% students
- *Education level:* 100% college students
- *Comorbid anxiety:* -
- *Depression severity:* 66% major depressive disorder
- *Age:* 19.2 (SD 1.67)

Included criteria: college students with depression (BDI-II ≥ 14), non-medicated or stabilised for 8 weeks, not receiving other psychotherapy or counselling.

Excluded criteria: psychosis, alcohol or substance dependence.

Pretreatment: depression severity slightly higher in mindfulness group

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural activation
- *dose:* 1 hour sessions
- *frequency:* weekly
- *duration:* 4 weeks
- *level of therapist:* specialist
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* minor modifications to suit population and reduction to 4 sessions

Mindfulness-based therapy

- *type of intervention:* comparator

McIndoo 2016 (Continued)

- *specific intervention*: mindfulness-based therapy modelled on MBSR (Kabat-Zinn, 1982)
- *dose*: 1 hour sessions
- *frequency*: weekly
- *duration*: 4 weeks
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: reduced length of programme from 8 to 4 weeks; individual rather than group based

Waiting list

- *type of intervention*: comparator
- *specific intervention*: waiting list
- *dose*:
- *frequency*:
- *duration*:
- *level of therapist*:
- *individual or group therapy*:
- *mode of delivery*:
- *modifications*: offered BA or mindfulness at end of treatment

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: HRSD
- **Direction**: lower is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: lower is better
- **Data value**: endpoint

Anxiety symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: BAI
- **Direction**: lower is better
- **Data value**: endpoint

Response

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Scale**: HRSD
- **Direction**: higher is better
- **Data value**: endpoint
- **Notes**: response defined as at least 50% reduction on HRSD

Remission

- **Outcome type**: dichotomous outcome
- **Reporting**: Fully reported

McIndoo 2016 (Continued)

- **Scale:** HRSD
- **Direction:** Higher is better
- **Data value:** Endpoint
- **Notes:** Remission defined as no longer meeting criteria for depression according to HRSD.

Clinically significant improvement

- **Outcome type:** Dichotomous outcome
- **Reporting:** fully reported
- **Scale:** HRSD
- **Direction:** higher is better
- **Data value:** endpoint
- **Notes:** reliable change index (RCI) calculated with HRSD scores

Identification

Sponsorship source:
Country: USA

Setting: Students at University of Tennessee

Comments: -

Authors name: Derek Hopko

Institution: University of Tennessee

Email: dhopko@utk.edu

Address: The University of Tennessee Knoxville, Department of Psychology, 307 Austin Peay Building, Knoxville, TN 37996-0900, USA.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "As indicated on the CONSORT Figure, if included following the comprehensive assessment, based on a randomization table, participants were assigned to BA (n ¼ 16), MBT (n ¼ 20), or the WLC" Judgement comment: randomisation table used.
Allocation concealment (selection bias)	High risk	Quote: "The principal investigator (DH) generated and concealed the randomization table and stored it in a secure area. When participants were officially included in the trial, respective therapists were then informed (by the PI) which therapy they would provide." Judgement comment: therapists were not involved in allocation procedure, but principal investigator was, which could have biased treatment outcomes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding due to nature of interventions. This could have influenced study outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: outcome assessors not specified; presumably therapists supervised patient-completed questionnaires as outcome questionnaires were completed following therapy sessions. Author could not be contacted.

McIndoo 2016 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: low attrition rates in all groups. Missing data imputed by multiple imputation.
Selective reporting (reporting bias)	High risk	Judgement comment: for remission/response and clinically relevant change, only post-treatment data were reported and not follow-up. Since these outcomes are based on HRSD scores collected at each time point, they could have been calculated and reported. Three fewer weeks of intervention compared to protocol so did not do behavioural contracting strategies.
Other bias	High risk	Judgement comment: one of the authors (Hopko) was involved in the development of the original intervention, and therefore has an interest in it being successful.

McNamara 1986
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: participants were invited from those seeking services at the counselling centre.</p> <p>Type of RCT (blind, double-blind, open-label): not reported</p>
Participants	<p>Baseline characteristics</p> <p>Cognitive therapy</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: - • Depression severity: BDI mean (SD): 24.80 (5.29) • Age: - <p>Behavioural activation</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: - • Depression severity: BDI mean (SD): 25.90 (4.04) • Age: - <p>Combined therapy</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: -

McNamara 1986 (Continued)

- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* BDI mean (SD): 22.11 (4.28)
- *Age:* -

High demand control

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* BDI mean (SD): 25.55 (8.35)
- *Age:* -

Overall

- *Gender (N male, % male, N female, % female):* 11 male (27%), 29 female (73%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* mean 23, range 19-31

Included criteria: seeking services at counselling centre, reported depressive episode of at least 2 weeks, BDI => 18 at intake, BDI =>16 at baseline, HRSD =>20, consented to participation

Excluded criteria: suicidal behaviour, psychosis, drug addiction, sociopathy, organicity, major medical illness

Pretreatment: no information on patient characteristics by study arm. BDI at screening seemed higher in the behaviour therapy group. At baseline, BDI scores were more similar but still slightly lower in the combined therapy group.

Interventions

Intervention characteristics

Cognitive therapy

- *type of intervention:* comparator
- *specific intervention:* cognitive therapy
- *dose:* 50 minute sessions
- *frequency:* weekly
- *duration:* 8 weeks
- *level of therapist:* specialist (in training)
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* No attempts made to modify participants' behaviours or environments

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behaviour therapy (Lewinsohn)
- *dose:* 50-minute sessions
- *frequency:* weekly
- *duration:* 8 weeks

McNamara 1986 (Continued)

- *level of therapist*: professional (in training)
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: No references made to cognitions as possible sources of depression

Combined therapy

- *type of intervention*: comparator
- *specific intervention*: CBT
- *dose*: 50-minute sessions
- *frequency*: weekly
- *duration*: 10 weeks
- *level of therapist*: specialist (in training)
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: -

High demand control

- *type of intervention*: comparator
- *specific intervention*: Rogerian person-centred humanistic therapy
- *dose*: 50-minute sessions
- *frequency*: weekly
- *duration*: 8 weeks
- *level of therapist*: specialist (in training)
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: -

Outcomes

Clinically significant improvement

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: higher is better
- **Data value**: endpoint
- **Notes**: BDI 9 or below was classed as 'normal'

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: BDI
- **Direction**: lower is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: partially reported
- **Direction**: lower is better
- **Data value**: endpoint

Identification

Sponsorship source: None reported

Country: United States

Setting: University counselling centre

McNamara 1986 (Continued)

Comments: -

Authors name: Kathleen McNamara

Institution: Colorado State University

Email: -

Address: Department of Psychology, Colorado State University, Fort Collins, Colorado 80523

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Whenever 4 clients met the screening criteria, they were randomly assigned without exception to one of the four treatment conditions." Judgement comment: unclear how sequence was generated. Allocation was in blocks of four. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: unclear how sequence was generated or concealed. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no information, but it seems unlikely participants and personnel were blinded. This may have influenced outcomes and dropout rates.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: no information on outcome assessors. Risk of bias for follow-up, as questionnaires were completed at home by participants themselves. Author could not be contacted.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: dropout seemed to be higher in some groups than others, particularly in control group, but information on number of participants in each arm at each time point is missing. It appears that, at follow-up, the number of participants in each arm is very small (< N = 10).
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol. Author could not be contacted.
Other bias	High risk	Judgement comment: no information on participant baseline characteristics. At baseline, depression symptoms seemed lower in the combined treatment group, but no formal assessment of differences and extremely small sample sizes. Judgement comment: fidelity was monitored but no evaluation of fidelity was reported. Authors speculate that therapists may not have been delivering BA therapy to sufficient standard. Quote: "At the time of recruitment, seven counselors were self-described as "cognitive-behavioral" in orientation; the eighth preferred the term "interpersonal" (cf. Strong, 1968). All counsellors had expressed complete willingness to follow the exact procedures required by this study, despite any idiosyncratic preferences that might occur." Judgement comment: 7/8 counsellors described themselves as 'cognitive-behavioural' in orientation, and may therefore have been biased towards this particular treatment.

McNamara 1986 (Continued)

Author could not be contacted.

Meeks 2008

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Recruitment: from six nursing homes in Louisville, Kentucky, metropolitan area.

Type of RCT (blind, double-blind, open-label): open

Participants

Baseline characteristics

Behavioural activation

- Gender (N male, % male, N female, % female):
- Ethnic group:
- Household income:
- Occupation/employment:
- Education level: 9.3 (SD 1.8)
- Comorbid anxiety:
- Depression severity: HRSD 18.0 (SD 7.9)
- Age: 76.9 (SD 11.5)

Treatment as usual

- Gender (N male, % male, N female, % female):
- Ethnic group:
- Household income:
- Occupation/employment:
- Education level: 13.0 (SD 2.6)
- Comorbid anxiety:
- Depression severity: HRSD 15.9 (SD 5.8)
- Age: 79.4 (SD 4.3)

Overall

- Gender (N male, % male, N female, % female):
- Ethnic group:
- Household income:
- Occupation/employment: retired
- Education level: 10.6 (SD 2.5)
- Comorbid anxiety:
- Depression severity: HRSD 17.2 (SD 7.1)
- Age: 75.4 (SD 10.1)

Included criteria: nursing home residents in long-term care beds with an expected stay of 3 months or more, Geriatric Depression Scale score of at least 11, meets DSM-IV criteria for major depressive disorder or research diagnostic criteria for minor depressive disorder

Excluded criteria: Mini Mental State Exam score below 14, referred to hospice care for a terminal condition, current unstable or terminal medical condition, suicidal, meets DSM-IV criteria for bipolar disorder

Meeks 2008 (Continued)

Pretreatment: Depression seemed more severe in treatment than treatment as usual group for HRSD and GDS, but very small sample sizes.

Interventions	<p>Intervention characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> BA • <i>specific intervention:</i> Behavioral Activities Intervention (BE-ACTIV) • <i>dose:</i> 30-40 minutes • <i>frequency:</i> weekly • <i>duration:</i> 10 weeks • <i>level of therapist:</i> specialist and non-specialist • <i>individual or group therapy:</i> individual • <i>mode of delivery:</i> face-to-face • <i>modifications:</i> <p>Treatment as usual</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> comparator • <i>specific intervention:</i> treatment as usual • <i>dose:</i> • <i>frequency:</i> • <i>duration:</i> 10 weeks • <i>level of therapist:</i> • <i>individual or group therapy:</i> • <i>mode of delivery:</i> • <i>modifications:</i>
Outcomes	<p><i>Depression symptoms</i></p> <ul style="list-style-type: none"> • Outcome type: continuous outcome <p><i>Dropouts</i></p> <ul style="list-style-type: none"> • Outcome type: dichotomous outcome
Identification	<p>Sponsorship source: this research was supported by Grant R21 MH63073 from the National Institute of Mental Health.</p> <p>Country: United States</p> <p>Setting: Nursing home</p> <p>Comments:</p> <p>Authors name: Suzanne Meeks</p> <p>Institution: University of Louisville</p> <p>Email: smeeks@louisville.edu</p> <p>Address: Department of Psychological & Brain Sciences, University of Louisville, Louisville, KY 40292.</p>
Notes	
Risk of bias	
Bias	Authors' judgement Support for judgement

Meeks 2008 (Continued)

Random sequence generation (selection bias)	Low risk	Quote: "randomly assigned" Judgement comment: no information. Contacted author: statistician used random numbers list.
Allocation concealment (selection bias)	High risk	Judgement comment: no information. Contacted author: Random numbers list used and not concealed.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding possible due to nature of interventions.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "A doctoral student blind to treatment condition and trained to be reliable on the SADS with the principal investigator and criterion training tapes conducted posttreatment interviews." Judgement comment: Outcome assessor was blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: dropout was 3/13 and 3/7 for treatment and control groups, respectively, Proportionate to small sample size, this is a high dropout rate. Morbidity and assessment burden cited as reasons for drop-out.
Selective reporting (reporting bias)	High risk	Judgement comment: outcomes specified in online trial registration include Dartmouth COOP scales, which was not reported, and does not include Global Assessment Scale and HDRS, which were reported.
Other bias	High risk	Judgement comment: extremely small sample sizes may have hindered randomisation creating balance across groups. BA intervention was developed by study author. The researcher who developed the intervention was also the lead therapist and supervised the intervention.

Moradveisi 2015
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: participants were recruited through the media and poster advertisements, word of mouth, and referral from other mental health clinics and general practitioners</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 45 female (90%) • <i>Ethnic group:</i> • <i>Household income:</i> • <i>Occupation/ employment:</i> employed outside home 16 • <i>Education level:</i> 13 college student (26%), 21 college graduate (42%) • <i>Comorbid anxiety:</i> 7 (14%) • <i>Depression severity:</i> HRSD 21.12 (SD 5.26) • <i>Age:</i> 30.12 (SD 7.47)

Moradveisi 2015 (Continued)

Sertaline (treatment as usual)

- *Gender (N male, % male, N female, % female):* 40 female (80%)
- *Ethnic group:*
- *Household income:*
- *Occupation/ employment:* employed outside home 19
- *Education level:* 10 college student (20%), 19 college graduate (38%)
- *Comorbid anxiety:* 4 (8%)
- *Depression severity:* HRSD 21.62 (SD 5.42)
- *Age:* 32.63 (SD 10.17)

Overall

- *Gender (N male, % male, N female, % female):* 85 female (85%)
- *Ethnic group:*
- *Household income:*
- *Occupation/ employment:*
- *Education level:* 23 college student (23%), 50 college graduate (40%)
- *Comorbid anxiety:* 11 (11%)
- *Depression severity:* HRSD 21.37 (SD 5.32)
- *Age:* 31.37 (SD 8.97)

Included criteria: depressed female patients from Sanandaj, Iran, between the ages of 18 to 60 years, with a primary diagnosis of MDD according to the DSM-IV-TR. Score of ≥ 19 on BDI-II and ≥ 14 on HRSD.

Excluded criteria: a lifetime diagnosis of bipolar disorder or psychosis; organic brain syndrome; intellectual disability; substantial and imminent suicide risk; a current (within the past 6 months) diagnosis of alcohol or drug misuse or dependence, or a positive toxicology screen; a primary diagnosis other than major depressive disorder; unfavourable antidepressant medication response within the preceding year; unstable medical condition; medication use that would complicate antidepressant administration; known allergy to antidepressant medication/sertraline; pregnancy or a plan to become pregnant; and inability to read and understand the study's instruments

Pretreatment: no statistically significant differences.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural activation (Martell)
- *dose:* 50 minutes a session, 16 sessions in total
- *frequency:* 1 to 2 sessions a week
- *duration:* 12 weeks
- *level of therapist:* specialist
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:*

Sertaline (treatment as usual)

- *type of intervention:* comparator
- *specific intervention:* antidepressant Sertraline (SSRI)
- *dose:* 25 mg to 100 mg (25 mg daily week 1, 50 mg daily week 2, 75 mg daily week 4, 100 mg daily weeks 6 to 12)
- *frequency:* daily
- *duration:* 12 weeks
- *level of therapist:*

Moradveisi 2015 (Continued)

- *individual or group therapy*: individual
- *mode of delivery*:
- *modifications*:

Outcomes

Dropouts

- **Outcome type**: dichotomous outcome

Depression remission

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: higher is better
- **Data value**: endpoint
- **Notes**: remission was defined as scores of ≤ 7 on the HRSD and ≤ 10 on the BDI.

Response

- **Outcome type**: dichotomous outcome
- **Direction**: higher is better
- **Data value**: endpoint
- **Notes**: at least a 50% reduction from baseline on both HRSD and BDI-II

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: HRSD
- **Direction**: lower is better
- **Data value**: change from baseline
- **Notes**: data imputed for missing values; last observation carried forward.

Identification

Sponsorship source: Medical University of Kurdistan and Maastricht University

Country: Iran

Setting:

Comments:

Authors name: Latif Moradveisi

Institution: Maastricht University

Email: latif.moradveisi@maastrichtuniversity.nl

Address: Department of Clinical Psychological Science, Faculty of Psychology and Neuroscience, Maastricht University, P.O. Box 616, 6200 MD Maastricht, The Netherlands

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: "randomised by an independent coordinator using a computer-generated list based on blocks of four"
Allocation concealment (selection bias)	Low risk	Quote: "Participants were randomized by an independent coordinator."

Moradveisi 2015 (Continued)

		Judgement comment: allocation probably concealed adequately as the procedure was performed by an independent researcher.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding due to nature of interventions. This may influence treatment outcomes.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "HRSD assessments were done by evaluators blind to treatment conditions. Independent assessors assessed the HRSD for TAU patients and the BDI for BA patients before every treatment session and supplied results to psychiatrists and therapists." Judgement comment: outcome assessors were independent, but clinicians were then informed of results. This may influence treatment.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "For participants who dropped out of treatment, we used the last observation with the associated time, and estimated missing HRSD scores (for those in the behavioural activation group) from changes on the BDI, and missing BDI scores (for those in the TAU group) from changes on the HRSD, using regression-derived equations (1 BDI unit = 1.3 HRSD unit). All treatment drop-out took place before the mid-treatment assessment. We repeated the analyses without these estimates as a sensitivity analysis." For the test of moderation" Judgement comment: patients were more likely to drop out of the medication (N = 15) rather than the behavioural activation (N = 5) group, and reasons for dropping out were related to dissatisfaction with treatments or side effects. Data were imputed by last observation carried forward, but patients who dropped out may have had worse outcomes at endpoint than at time of last observation.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol
Other bias	Unclear risk	Judgement comment: follow-up for a year, but after 3 months participants had to pay for medication, which may explain higher dropout rate in medication group. Unclear how many participants continued medication after 3 months. No information on treatment fidelity reported.

Nasrin 2017
Study characteristics

Methods	Study design: randomised controlled trial Study grouping: parallel group Recruitment: participants were recruited from two primary care psychological therapies services in South London. Type of RCT (blind, double-blind, open-label): open
Participants	Baseline characteristics Behavioural activation <ul style="list-style-type: none"> Gender (N male, % male, N female, % female): 13 female (65%)

Nasrin 2017 (Continued)

- *Ethnic group*: 11 White (55%), 3 Black African (15%), 2 Black Caribbean (10%), 4 other (20%)
- *Household income*: -
- *Occupation/employment*: full time 5 (25%), part-time 5 (25%), self-employed 1 (5%), unemployed 6 (30%), in education 3 (15%)
- *Education level*: high school 3 (15%), NVQs 2 (10%), A levels 6 (30%), diploma 1 (5%), undergraduate 5 (25%), postgraduate 3 (15%)
- *Comorbid anxiety*: -
- *Depression severity*: 7 moderate (35%), 5 moderate-severe (25%), 8 severe (40%)
- *Age*: 34.90 (SD 10.9)

Waiting list

- *Gender (N male, % male, N female, % female)*: 14 female (70%)
- *Ethnic group*: White 12 (60%), Black 3 (15%), Pakistani 1 (5%), Other 4 (20%)
- *Household income*: -
- *Occupation/employment*: full time 8 (40%), part-time 1 (5%), self-employed 2 (10%), unemployed 5 (25%), in education 4 (20%)
- *Education level*: high school 3 (15%), NVQs 6 (30%), A levels 0 (0%), diploma 2 (10%), undergraduate 5 (25%), postgraduate 4 (20%)
- *Comorbid anxiety*: -
- *Depression severity*: 5 moderate (25%), 12 moderate-severe (60%), 3 severe (15%)
- *Age*: 37.60 (SD 8.4)

Overall

- *Gender (N male, % male, N female, % female)*: -
- *Ethnic group*: -
- *Household income*: -
- *Occupation/employment*: -
- *Education level*: -
- *Comorbid anxiety*: -
- *Depression severity*: -
- *Age*: -

Included criteria: met diagnostic criteria for major depressive disorder, age 18 to 60, speaking fluent English, 10 or above on PHQ-9

Excluded criteria: history of psychosis or mania, recent self-harm (within the last 4 weeks), current diagnosis of eating disorder, obsessive compulsive disorder, current drug/alcohol/medication abuse or dependence, history of traumatic brain injury or epileptic seizures, unable to refrain from taking benzodiazepines 48 hours before completing the experimental tasks, and psychotherapy or counselling at a frequency of more than once a month

Pretreatment: no notable differences.

Participants currently taking antidepressants were included in the study, with the caveat that medication had not been changed during the 4 weeks before starting the study: -

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention*: BA
- *specific intervention*: brief behavioural activation
- *dose*: 1 session of 60 to 90 minutes
- *frequency*: 1
- *duration*: 1 week
- *level of therapist*: professional (in training)

Nasrin 2017 (Continued)

- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: Based on BATD manual, reduced to 1 session

Waiting list

- *type of intervention*: comparator
- *specific intervention*: waiting list
- *dose*: -
- *frequency*: -
- *duration*: -
- *level of therapist*: -
- *individual or group therapy*: -
- *mode of delivery*: -
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: PHQ-9
- **Direction**: lower is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome

Identification

Sponsorship source: This research received no specific grant from any funding agency, commercial or not-for-profit sectors.

Country: UK

Setting: two primary care psychological therapy services

Comments: -

Authors name: Thorsten Barnhofer

Institution: University of Exeter

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Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was conducted following a simple randomization protocol using sealed envelopes and a manually generated randomization sequence (permuted blocked randomization with blocks of size 4) achieved through shuffling of the envelopes that remained concealed until assignment to the groups. The sequence was generated by an independent statistician."

Nasrin 2017 (Continued)

Allocation concealment (selection bias)	Unclear risk	Judgement comment: sequence generated by independent statistician, but assignment to intervention by lead researcher. Not clear whether envelopes were opaque.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: assumed that no blinding was possible due to nature of intervention. This may have led to bias in drop out of participants and depression scores.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: unclear who performed outcome assessments; possibly first author who also delivered intervention.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Judgement comment: missing data N = 4 in each arm, no indication this is related to the intervention.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol.
Other bias	Unclear risk	Judgement comment: it appears the first author was both therapist and outcome assessor. If the first author was convinced of the benefit of the treatment, this might have biased results both through the delivery of the treatment and the assessment of outcomes.

Padfield 1976
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: recruited from welfare, schools, physicians and newspapers.</p> <p>Type of RCT (blind, double-blind, open=label): open</p>
Participants	<p>Baseline characteristics</p> <p>Relationship model</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: - • Depression severity: - • Age: - <p>Behavioural activation</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: -

Padfield 1976 (Continued)

- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Overall

- *Gender (N male, % male, N female, % female):* 100% female
- *Ethnic group:* -
- *Household income:* N=12 \$400 or less per month, N=11 > \$400 a month
- *Occupation/employment:* -
- *Education level:* 54% not finished high school
- *Comorbid anxiety:* -
- *Depression severity:* moderately depressed
- *Age:* 21 to 65

Included criteria: women of low socioeconomic status, moderately depressed (Zung self-rating depression scale > 1.5, interview), living in rural area, age 18 to 64.

Excluded criteria: depression not the major problem but attributable to alcoholism, drugs, organic causes, or temporary situational distress. In first 6 months postpartum.

Pretreatment: depression symptoms on Zung scale similar between groups at baseline. No other information on baseline characteristics by study arm.

Interventions

Intervention characteristics

Relationship model

- *type of intervention:* comparator
- *specific intervention:* general counselling
- *dose:* 50 minute sessions
- *frequency:* once a week
- *duration:* 12 weeks (+2 week diagnostic period)
- *level of therapist:* specialist
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* -

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* general counselling + BA (Lewinsohn)
- *dose:* 50 minute sessions
- *frequency:* once a week
- *duration:* 12 weeks (+ 2 weeks diagnostic period)
- *level of therapist:* specialist
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* -

Outcomes

Depression symptoms

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** Zung Self-Rating Depression Scale
- **Direction:** lower is better

Padfield 1976 (Continued)

- **Data value:** endpoint

Dropouts

- **Outcome type:** dichotomous outcome

Adverse events

- **Outcome type:** dichotomous outcome
- **Reporting:** partially reported
- **Direction:** lower is better
- **Data value:** endpoint

Identification

Sponsorship source: None reported. PhD dissertation.

Country: USA

Setting: -

Comments: -

Authors name: Marianne Nina Carter Padfield

Institution: University of Arizona

Email: -

Address: -

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "a period of 12 weeks. After the women had volunteered for participation, had taken part in a two-week diagnostic phase, and met the criteria, every two clients in order of appearance were randomly assigned to counselling with the relationship model (Group A) or the relationship model plus the behavioral model (Group B) by flipping a coin. The two-week diagnostic period allowed" Judgement comment: coin tossing is an acceptable method of randomisation, but unclear whether the 'order of appearance' would have been random.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information, probably not concealed. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding possible due to nature of interventions; this may have caused bias in the outcome estimates.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Judgement comment: the interviews were recorded and a second rater, a psychiatric nurse, after listening to the tapes without knowing which counselling approach the woman was receiving, made her assessment of the woman's depth of depression
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Judgement comment: 1 dropout but no other information provided. Author could not be contacted.

Padfield 1976 (Continued)

Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol. Author could not be contacted.
Other bias	Unclear risk	Judgement comment: no baseline characteristics presented by study arm; unclear whether arms were balanced on main characteristics. - Two week diagnostic phase before randomisation. Unclear whether any participants dropped out. Not specified who therapist was. Assumed to be first author. No evidence of conflict of interest. Author could not be contacted.

Raue 2019
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel</p> <p>Recruitment: From senior centres</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): • Ethnic group: • Household income: • Occupation/employment: • Education level: • Comorbid anxiety: • Depression severity: • Age: <p>Referral to mental health services</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): • Ethnic group: • Household income: • Occupation/employment: • Education level: • Comorbid anxiety: • Depression severity: • Age: <p>Overall</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): 83% female • Ethnic group: 11% non-Hispanic Black, 11% Black • Household income: • Occupation/employment: • Education level: Mean 15 (2.5) years • Comorbid anxiety: • Depression severity: 73% major depression, 14% minor depression, 13% subthreshold depression • Age: mean 76 (SD 8.3)

Raue 2019 (Continued)

Included criteria: attending one of two senior centres, age => 60, English speaking, PHQ => 10, MMSE => 24.

Excluded criteria: passive or active suicidal ideation and diagnoses of bipolar depression, psychosis, or current alcohol or substance abuse.

Pretreatment: not reported, except for depression scores, which were similar although slightly higher in intervention group.

Interventions	<p>Intervention characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> BA • <i>specific intervention:</i> Programme including activity scheduling and focus on pleasant events. • <i>dose:</i> • <i>frequency:</i> once a week • <i>duration:</i> 12 weeks • <i>level of therapist:</i> non-specialist • <i>individual or group therapy:</i> • <i>mode of delivery:</i> face-to-face • <i>modifications:</i> <p>Referral to mental health services</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> comparator • <i>specific intervention:</i> referral to mental health services • <i>dose:</i> • <i>frequency:</i> • <i>duration:</i> 12 weeks • <i>level of therapist:</i> • <i>individual or group therapy:</i> • <i>mode of delivery:</i> • <i>modifications:</i>
Outcomes	<p><i>Depression symptoms</i></p> <ul style="list-style-type: none"> • Outcome type: continuous outcome • Reporting: fully reported • Scale: HRSD • Direction: lower is better • Data value: endpoint <p><i>Dropouts</i></p> <ul style="list-style-type: none"> • Outcome type: dichotomous outcome
Identification	<p>Sponsorship source: National Institute of Mental Health, Grant/ Award Numbers: P30 MH085943 and R34 MH111849</p> <p>Country: USA</p> <p>Setting: Two age service settings in NYC</p> <p>Comments:</p> <p>Authors name: Patrick J Raue</p> <p>Institution: University of Washington</p>

Raue 2019 (Continued)

Email: praue@uw.edu

Address: Department of Psychiatry and Behavioral Sciences, School of Medicine, University of Washington, 110 Campus Parkway, Box 358017, Seattle, WA 98195

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "We randomized 18 depressed clients to receive the "Do More, Feel Better" intervention or referral to mental health services. Study" Judgement comment: no information. Contacted author: study coordinator performed randomisation and allocation and research assistants worked with participants.
Allocation concealment (selection bias)	High risk	Judgement comment: no information. Contacted author: study coordinator was aware of allocation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding due to nature of intervention. Research assistants were not aware of study aims.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "The RAs assessed depressive symptom severity with the HAM-D at baseline and week 12. We" Judgement comment: no blinding; research assistants were aware of allocation.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: although dropouts small (only 2 in each group), the sample size was small (18) so represents a significant dropout rate. Also reasons for dropout unknown as unable to contact participants.
Selective reporting (reporting bias)	Low risk	Judgement comment: outcomes match trial registration.
Other bias	High risk	Judgement comment: very small sample size; randomisation not likely to achieve balanced groups (higher baseline mean depression scores in intervention group although not statistically significant. The intervention was developed by the study authors.

Rehm 1982
Study characteristics

Methods	Study design: randomised controlled trial Study grouping: parallel group Recruitment: participants were solicited from the general community with media announcements seeking women between the ages of 18 and 60 who felt they had a significant problem with depression and who were interested in volunteering for a 10-week therapy program as part of a research project. Type of RCT (blind, double-blind, open-label): open-label
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Rehm 1982 (Continued)

Participants

Baseline characteristics

Behavioural activation

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/ employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Cognitive therapy

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/ employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Cognitive-behavioural therapy

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/ employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Overall

- *Gender (N male, % male, N female, % female):* 100% female
- *Ethnic group:* -
- *Household income:* median \$25,000
- *Occupation/ employment:* 67.3% employed
- *Education level:* mean 14.8 years
- *Comorbid anxiety:* -
- *Depression severity:* 16.3% single-episode, 27.6% episodic, 29.6% intermittent, and 26.5% chronic
- *Age:* mean 38.6

Included criteria: women aged 18 to 60, BDI > 20, T score =>70 on MMPI Depression Scale, non-psychotic, non-bipolar major affective disorder diagnosed in interview

Excluded criteria: psychotherapy for depression in last 30 days, antidepressant or major tranquilliser use, mania, hypomania, schizophrenia, organic brain syndrome, mental retardation, antisocial personality, anorexia nervosa, or (during the last 12 months) alcohol abuse, anxiety disorder, Briquet's syndrome, drug abuse, obsessive-compulsive disorder, panic disorder, or phobic disorder

Pretreatment: similar scores for depression severity at baseline. Baseline characteristics not reported by research arm.

Rehm 1982 (Continued)

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural therapy
- *dose:* 1.5 hour sessions
- *frequency:* weekly
- *duration:* 10 weeks
- *level of therapist:* professional
- *individual or group therapy:* group
- *mode of delivery:* face-to-face
- *modifications:* -

Cognitive therapy

- *type of intervention:* comparator
- *specific intervention:* cognitive therapy
- *dose:* 1.5 hour sessions
- *frequency:* weekly
- *duration:* 10 weeks
- *level of therapist:* professional
- *individual or group therapy:* group
- *mode of delivery:* face-to-face
- *modifications:* -

Cognitive-behavioural therapy

- *type of intervention:* comparator
- *specific intervention:* cognitive-behavioural therapy
- *dose:* 1.5 hour sessions
- *frequency:* weekly
- *duration:* 10 weeks
- *level of therapist:* professional
- *individual or group therapy:* group
- *mode of delivery:* face-to-face
- *modifications:* -

Outcomes

Depression symptoms

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** HRSD-interviewer rating
- **Direction:** lower is better
- **Data value:** endpoint
- **Notes:** interviewer rating and clinician rating was provided; reporting interviewer rating here as this may be less biased.

Dropouts

- **Outcome type:** dichotomous outcome

Identification

Sponsorship source: this study was supported by National Institute of Mental Health Grant 2R01 MH27822 to the first author

Country: USA

Rehm 1982 (Continued)

Setting: general community

Comments: -

Authors name: Lynn P Rehm

Institution: University of Houston

Email: -

Address: Psychology Department, University of Houston, Houston, Texas 77004

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement comment: no information. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding impossible due to nature of treatments; this may have affected results.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Interviewers were blind to all test results and to subjects' experimental conditions."
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: 34 participants withdrew prior to completion but reasons not stated. HRSD not presented at 6 months.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol. Author could not be contacted.
Other bias	Low risk	Judgement comment: no other sources of bias identified. Although researcher published extensively on the topic a clear preference for one treatment does not emerge from this paper.

Richards 2017
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Recruitment: adults aged ≥ 18 years who met DSM-IV criteria for a major depressive disorder recruited from primary care and psychological therapy services in Devon, Durham and Leeds between Sept 2012 to April 2014.

Type of RCT (blind, double-blind, open-label): open

Richards 2017 (Continued)

Participants

Baseline characteristics

Behavioural activation

- *Gender (N male, % male, N female, % female):* 79 male (36%), 142 female (64%)
- *Ethnic group:* 204 White British (92%)
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* 25 (11%) none, 36 (16%) GCSE, 28 (13%) A levels, 54 (24%) NVQ, 44 (20%) undergraduate, 28 (13%) postgraduate, 2 (1%) doctoral, 4 (2%) professional degree
- *Comorbid anxiety:* 131 (59%)
- *Depression severity:* PHQ < 19 118 (54%), PHQ ≥ 19 103 (46%)
- *Age:* 43.9 (SD 14.1)

Cognitive behavioural therapy (CBT)

- *Gender (N male, % male, N female, % female):* 71 male (32%), 148 female (68%)
- *Ethnic group:* 197 White British (90%)
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* 30 (14%) none, 3 (20%) GCSE, 22 (10%) A levels, 71 (32%) NVQ, 35 (16%) undergraduate, 14 (6%) postgraduate, 1 doctoral, 3 (1%) professional degree
- *Comorbid anxiety:* 141 (64%)
- *Depression severity:* PHQ < 19 118 (54%), PHQ ≥ 19 101 (46%)
- *Age:* 43.0 (SD 14.1)

Overall

- *Gender (N male, % male, N female, % female):* 150 (34%) male, 290 (66%) female
- *Ethnic group:* 401 White British (91%)
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* 55 (13%) none, 79 (18%) GCSE, 50 (11%) A levels, 125 (28%) NVQ, 79 (18%) undergraduate, 42 (10%) postgraduate, 3 (1%) doctoral, 7 (2%) professional degree
- *Comorbid anxiety:* 272 (62%)
- *Depression severity:* PHQ < 19 236 (54%), PHQ ≥ 19 204 (46%)
- *Age:* 43.5 (SD 14.1)

Included criteria: adults 18 or over who met DSM IV criteria for major depressive disorder

Excluded criteria: receiving psychological therapy, alcohol or drug dependent, acutely suicidal or attempted suicide in previous 2 months, cognitively impaired, bipolar disorder, or psychosis or psychotic symptoms.

Pretreatment: slightly lower comorbid anxiety in BA, but no evidence of statistically significant differences.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural activation
- *dose:* 1 hour sessions
- *frequency:* weekly. max 20 sessions. twice weekly for the first 2 months, then weekly
- *duration:* 16 weeks
- *level of therapist:* non-specialist

Richards 2017 (Continued)

- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: optional 4 booster sessions

Cognitive behavioural therapy (CBT)

- *type of intervention*: comparator
- *specific intervention*: cognitive behavioural therapy
- *dose*: 1 hour sessions
- *frequency*: weekly. max 20 sessions
- *duration*: 16 weeks
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: optional 4 booster sessions

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: PHQ-9
- **Range**: 0-27
- **Direction**: lower is better
- **Data value**: endpoint
- **Notes**: reporting data for intention-to-treat analysis

Anxiety symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: GAD-7
- **Direction**: lower is better
- **Data value**: endpoint

Recovery

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Scale**: PHQ-9
- **Direction**: higher is better
- **Data value**: endpoint
- **Notes**: recovery defined as follow-up score of ≤ 9 on the PHQ-9. There seems to be a typo in Table 9; recovery for BA group 6% of 221 is not 208.

Response

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Scale**: PHQ-9
- **Direction**: higher is better
- **Data value**: endpoint
- **Notes**: 50% or greater reduction in PHQ-9 score compared to baseline.

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported

Richards 2017 (Continued)

- **Direction:** lower is better
- **Data value:** endpoint

Quality of life SF-36 PCS

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** SF-36 V2 PCS
- **Direction:** higher is better
- **Data value:** endpoint

Quality of life SF-36 MCS

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** SF-36
- **Direction:** higher is better
- **Data value:** endpoint

Adverse events

- **Outcome type:** adverse event
- **Reporting:** fully reported
- **Data value:** endpoint

Identification

Sponsorship source: National Institute for Health Research (NIHR) Health Technology Assessment programme

CountryUK

Setting: three community mental health services

Comments: -

Authors name: Dave A Richards

Institution: University of Exeter Medical School

Email: d.a.richards@exeter.ac.uk

Address: University of Exeter Medical School, St Luke's Campus, Exeter, UK

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Quote: "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."</p> <p>Judgement comment: sequence generated at random for first 20 patients in each arm, and non-random after that. However, given that a computer programme was used bias is less likely.</p>

Richards 2017 (Continued)

Allocation concealment (selection bias)	Low risk	Quote: "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. DOI: 10.3310/hta21460 HEALTH TECHNOLOGY ASSESSMENT" Judgement comment: allocation done by trials unit independent of researchers
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding of patients and therapists was not possible due to nature of intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "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." Judgement comment: outcome assessors were blinded, except in instances where patients disclosed their received treatment despite instructions not to do so.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: Undertook both ITT and per protocol analysis. More declines and withdrawals in BA than CBT group. This may be related to success of the intervention.
Selective reporting (reporting bias)	Low risk	Judgement comment: all outcomes in protocol were reported.
Other bias	High risk	Several researchers are also authors of the current review, and have received funding to evaluate BA interventions. This means they have an interest in the intervention being effective.

Shaw 1977

Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: participants were recruited for the study by announcements made in undergraduate psychology classes and placed on student information boards and by referral from the Student Health Service</p> <p>Type of RCT (blind, double-blind, open-label): open-label</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): 2 male, 6 female • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: 100% at university • Comorbid anxiety: -

Shaw 1977 (Continued)

- *Depression severity*: BDI 25.6 (18 to 38)
- *Age*: 20.1 (range 19 to 24)

Cognitive modification

- *Gender (N male, % male, N female, % female)*: 3 male, 5 female
- *Ethnic group*: -
- *Household income*: -
- *Occupation/employment*: -
- *Education level*: 100% at university
- *Comorbid anxiety*: -
- *Depression severity*: BDI 30.1 (18 to 45)
- *Age*: 19.8 (range 17 to 26)

Non-directive control

- *Gender (N male, % male, N female, % female)*: 3 male, 5 female
- *Ethnic group*: -
- *Household income*: -
- *Occupation/employment*: -
- *Education level*: 100% at university
- *Comorbid anxiety*: -
- *Depression severity*: BDI 26.4 (18-42)
- *Age*: 20.5 (range 19-26)

Waiting list

- *Gender (N male, % male, N female, % female)*: 2 male, 6 female
- *Ethnic group*: -
- *Household income*: -
- *Occupation/employment*: -
- *Education level*: 100% at university
- *Comorbid anxiety*: -
- *Depression severity*: BDI 26.6 (19 to 43)
- *Age*: 19.9 (range 18 to 25)

Overall

- *Gender (N male, % male, N female, % female)*: -
- *Ethnic group*: -
- *Household income*: -
- *Occupation/employment*: -
- *Education level*: -
- *Comorbid anxiety*: -
- *Depression severity*: -
- *Age*: -

Included criteria: 18 to 26 year old students at University of Western Ontario, self-reported current depression of at least 3 weeks, interest in intervention, BDI 18 or more, depression major presenting psychopathology, symptoms not severe enough to warrant hospitalisation or risk of suicide, HRSD 20 or over, VAS 40 or higher.

Excluded criteria: psychotic symptoms, drug addiction, sociopathy, organicity, major medical problems.

Pretreatment: mean ages and BDI are not significantly different but groups were not successfully matched on the sex variables - more females in BA and waiting list group.

Shaw 1977 (Continued)

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural therapy (Lewinsohn)
- *dose:* 2 hours per sessions
- *frequency:* twice per week
- *duration:* 4 weeks
- *level of therapist:* specialist (in training)
- *individual or group therapy:* group
- *mode of delivery:* face-to-face
- *modifications:* -

Cognitive modification

- *type of intervention:* comparator
- *specific intervention:* cognitive therapy (Beck)
- *dose:* 2 hours per sessions
- *frequency:* twice per week
- *duration:* 4 weeks
- *level of therapist:* specialist (in training)
- *individual or group therapy:* group
- *mode of delivery:* face-to-face
- *modifications:* -

Non-directive control

- *type of intervention:* comparator
- *specific intervention:* non-directive therapy (attention control)
- *dose:* 2 hours per sessions
- *frequency:* twice a week
- *duration:* 4 weeks
- *level of therapist:* specialist (in training)
- *individual or group therapy:* group
- *mode of delivery:* face-to-face
- *modifications:* -

Waiting list

- *type of intervention:* comparator
- *specific intervention:* waiting list
- *dose:* -
- *frequency:* -
- *duration:* 4 weeks
- *level of therapist:* -
- *individual or group therapy:* -
- *mode of delivery:* -
- *modifications:* -

Outcomes

Depression symptoms

- **Outcome type:** continuous outcome
- **Reporting:** partially reported
- **Scale:** HRSD

Shaw 1977 (Continued)

- **Direction:** lower is better
- **Data value:** endpoint
- **Notes:** no SDs reported.

Identification **Sponsorship source:** None reported
Country: Canada
Setting: University of Western Ontario
Comments: -
Authors name: Brian F Shaw
Institution: University of Western Ontario
Email: -
Address: Department of Psychology, University Hospital, London, Ontario, Canada N6G 2K3.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement comment: "Assignment was done randomly". No more information. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: open-trial; this may lead to biased results if patients or therapist favour one treatment over another.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Judgement comment: ratings were done by clinical psychologists who were blind to allocation of treatments.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Judgement comment: no SDs reported. Follow-up only for two treatment groups. Unclear how many participants were included in follow-up data. Author could not be contacted.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol. Author could not be contacted.
Other bias	Unclear risk	Judgement comment: some differences at baseline (BDI highest in cognitive therapy group, number of females) which may indicate problem with randomisation.

Skinner 1984
Study characteristics

Methods **Study design:** randomised controlled trial

Skinner 1984 (Continued)

Study grouping: parallel group

Recruitment: ads in local newspapers throughout San Diego

Type of RCT (blind, double-blind, open-label):

Participants

Baseline characteristics

Cognitive-behaviour therapy

- *Gender (N male, % male, N female, % female):* 2 male, 5 female
- *Ethnic group:*
- *Household income:*
- *Occupation/employment:*
- *Education level:* range 12 to 16 years
- *Comorbid anxiety:*
- *Depression severity:*
- *Age:* range 24 to 40

Behavioural activation

- *Gender (N male, % male, N female, % female):* 3 male, 5 female
- *Ethnic group:*
- *Household income:*
- *Occupation/employment:*
- *Education level:* range 10 to 16 years
- *Comorbid anxiety:*
- *Depression severity:*
- *Age:* range 20 to 61

Control

- *Gender (N male, % male, N female, % female):* 3 male, 5 female
- *Ethnic group:*
- *Household income:*
- *Occupation/employment:*
- *Education level:* range 11 to 16 years
- *Comorbid anxiety:*
- *Depression severity:*
- *Age:* range 19 to 47

Self-intervention

- *Gender (N male, % male, N female, % female):*
- *Ethnic group:*
- *Household income:*
- *Occupation/employment:*
- *Education level:*
- *Comorbid anxiety:*
- *Depression severity:*
- *Age:*

Overall

- *Gender (N male, % male, N female, % female):*
- *Ethnic group:*
- *Household income:*

Skinner 1984 (Continued)

- *Occupation/employment:*
- *Education level:* Mean 14 years (range 10 to 18)
- *Comorbid anxiety:*
- *Depression severity:* BDI score 13 to 41
- *Age:* Mean 34 years (range 20 to 61)

Included criteria: BDI 13 or higher, depressive episode of at least 8 weeks, age 18 or older

Excluded criteria:

Pretreatment: not able to assess; no summary statistics by study arm.

Interventions

Intervention characteristics

Cognitive-behaviour therapy

- *type of intervention:* comparator
- *specific intervention:* Beck cognitive behaviour self-therapy
- *dose:* 60 minute meetings
- *frequency:* weekly meetings, daily self-intervention
- *duration:* 5 weeks
- *level of therapist:*
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:*

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* Lewinsohn behavioural self-therapy
- *dose:* 60 minute meetings
- *frequency:* weekly meetings, daily self-intervention
- *duration:* 5 weeks
- *level of therapist:*
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:*

Control

- *type of intervention:* comparator
- *specific intervention:* no intervention
- *dose:* 60 minute meetings
- *frequency:* weekly meetings, daily self-intervention
- *duration:* 2 weeks
- *level of therapist:*
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:*

Self-intervention

- *type of intervention:* comparator
- *specific intervention:* self-selected behavioural or cognitive self-therapy
- *dose:* 60 minute meetings
- *frequency:* weekly meetings, daily self-intervention
- *duration:* 5 weeks

Skinner 1984 (Continued)

- *level of therapist:*
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:*

Outcomes

Identification **Sponsorship source:** Not reported; dissertation.
Country: USA
Setting:
Comments:
Authors name: Donald Alan Skinner
Institution: United States International University
Email:
Address:

Notes *Noortje Uphoff* on 06/08/2019 20:20
Included
 No results by study arm; individual results only.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement comment: no information. Said to be random. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding not possible due to nature of interventions.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: outcomes were self-reported by participants
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: 10/50 participants dropped out for unknown reasons during baseline assessments.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no protocol.
Other bias	High risk	Judgement comment: author states that groups were not matched on key characteristics and were not similar.

Stiles-Shields 2019
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Recruitment: recruitment of participants occurred from September 2015 to January 2016 from online ads posted on Craigslist in major American cities.

Type of RCT (blind, double blind, open label): -

Participants

Baseline characteristics

Behavioural activation

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity: PHQ-9: 15.20 (SD 5.49)*
- *Age:* -

Cognitive therapy

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity: PHQ-9: 17.00 (SD 4.62)*
- *Age:* -

Waiting list

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity: PHQ-9: 16.10 (SD 3.76)*
- *Age:* -

Overall

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Stiles-Shields 2019 (Continued)

Included criteria: PHQ-9 score 10 or higher, QIDS score 11 or higher, able to speak and read English, at least 18 years old, owned an Android, no visual, hearing, voice, or motor impairment, not diagnosed with a comorbid diagnosis for which participation in the trial was inappropriate or dangerous, not severely suicidal, not receiving psychotherapy, not on antidepressant medication or on stable dose.

Excluded criteria: -

Pretreatment: no participant characteristics reported. Similar baseline depression scores.

Interventions	Intervention characteristics
	<p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> BA • <i>specific intervention:</i> app based on behavioural activation with coaching • <i>dose:</i> coaching session max 5 minUTES • <i>frequency:</i> weekly coaching sessions • <i>duration:</i> 6 weeks • <i>level of therapist:</i> professional • <i>individual or group therapy:</i> individual • <i>mode of delivery:</i> Computer (smartphone) & telephone or email • <i>modifications:</i> based on activity scheduling component of BA only <p>Cognitive therapy</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> comparator • <i>specific intervention:</i> app based on cognitive therapy with coaching • <i>dose:</i> coaching session max 5 minutes • <i>frequency:</i> weekly coaching sessions • <i>duration:</i> 6 weeks • <i>level of therapist:</i> professional • <i>individual or group therapy:</i> individual • <i>mode of delivery:</i> Computer (smartphone) & telephone or email • <i>modifications:</i> based on restructuring component of cognitive therapy only <p>Waiting list</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> comparator • <i>specific intervention:</i> waiting list • <i>dose:</i> - • <i>frequency:</i> - • <i>duration:</i> 10 weeks • <i>level of therapist:</i> - • <i>individual or group therapy:</i> - • <i>mode of delivery:</i> - • <i>modifications:</i> -
Outcomes	<p><i>Depression symptoms</i></p> <ul style="list-style-type: none"> • Outcome type: continuous outcome • Reporting: fully reported • Scale: PHQ-9 • Direction: lower is better • Data value: endpoint <p><i>Dropouts</i></p> <ul style="list-style-type: none"> • Outcome type: dichotomous outcome

Stiles-Shields 2019 (Continued)

- **Reporting:** fully reported
- **Direction:** lower is better
- **Data value:** endpoint

Adverse events

- **Outcome type:** adverse event
- **Reporting:** fully reported
- **Data value:** endpoint

Identification

Sponsorship source: this research was supported by National Institute of Mental Health Grants R01 MH100482 (principal investigator [PI]: David C. Mohr) and F31 MH106321 (PI: Colleen Stiles-Shields). This project was also supported by National Institutes of Health (NIH)/National Center for Research Resources Colorado Clinical and Translational Sciences Institute Grant UL1 RR025780.

Country: USA

Setting: Smartphone app & phone

Comments: -

Authors name: Colleen Stiles-Shields

Institution: Loyola University Chicago

Email: estilesshields@luc.edu

Address: Department of Psychology, Loyola University Chicago, 1032 West Sheridan Road, Chicago, IL 60660

Notes
Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was created using PROC PLAN in SAS Version 9.2, with participants randomly assigned in randomization blocks of six to either Boost Me (n 10) or Thought Challenger (n 10) or to wait-list control (n 10). The randomized block design was used to ensure equal numbers were randomized to each group at a given time, should the study end early or if there were seasonal effects." Judgement comment: computer-generated randomisation, block sizes of 6
Allocation concealment (selection bias)	Low risk	Quote: "Once generated, this list was uploaded to Research Electronic Data Capture (REDCap), where study personnel were blinded to allocation prior to randomization, and participants would be randomized once eligibility was determined." Judgement comment: limited detail on how allocation concealment was achieved but seems to be via software for allocation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding due to nature of interventions; this may have led to bias in the results.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "To maximize blinding, we administered only self-report measures beyond the baseline assessment. Self-report assessments occurred at baseline, at Weeks 3 and 6 (midtreatment and end of treatment), and at Week 10

Stiles-Shields 2019 (Continued)

(1 month posttreatment follow-up) via REDCap, electronic data capture tools hosted at the university (Harris et al., 2009)."

Judgement comment: blinding was not possible. This may introduce bias.

Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "All Boost Me participants received the intervention. Three Thought Challenger participants did not receive the intervention; one reported not having enough device memory to download the app, and two were unresponsive to contact following randomization."
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Judgement comment: all 3 dropouts were in the Thought Challenger intervention; unclear whether this was related to the intervention.

Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol. Author could not be contacted.
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Other bias	High risk	Judgement comment: participant characteristics are not reported. The authors state there were no differences at baseline, but no information is provided. Author could not be contacted.
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Quote: "David C. Mohr also receives honoraria from Optum Behavioral Health and has an ownership interest in Actualize Therapy Ltd."

Judgement comment: all authors work for centre that developed the two apps. A study by the same authors evaluating the usability of the CBT app is cited, suggesting they may have been involved in development. One of the authors has ownership interest in Actualize Therapy Ltd (mobile technology for depression/anxiety). Therapist delivering coaching to both groups was also one of the researchers.

Takagaki 2016

Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: the participants were recruited over a 2-year period between 2013 and 2014 at Hiroshima University via email on a public information sharing platform</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
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Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): 24 female, 38 male • Ethnic group: - • Household income: - • Occupation/employment: 100% university students • Education level: attending university • Comorbid anxiety: N = 7 • Depression severity: BDI 12.76 (SD 6.66) • Age: 18.23 (SD 0.42) <p>No treatment</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): 21 female, 35 male
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Takagaki 2016 (Continued)

- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* 100% university students
- *Education level:* attending university
- *Comorbid anxiety:* N = 14
- *Depression severity:* BDI 13.30 (SD 5.95)
- *Age:* 18.20 (SD 0.40)

Overall

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Included criteria: 18 to 19-year-old first-year university student at Hiroshima University, BDI-II score ≥ 10 according to earlier studies, no major depressive episode (CIDI interview), and not undergoing psychopharmacological or psychological treatment.

Excluded criteria: a diagnosis of major depressive disorder (MDD) during the past year, a lifetime history of bipolar disorder, currently taking psychiatric medications or undergoing psychotherapy, possibility of acute suicide attempts, difficulty in understanding the purpose of the study, difficulty in completing the self-report scales due to a serious mental condition, or severe physical illness

Pretreatment: more participants with recent history of anxiety in control group, but depression severity similar between groups.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural activation
- *dose:* 60 minute sessions
- *frequency:* weekly
- *duration:* 5 weeks
- *level of therapist:* specialist
- *individual or group therapy:* individual + group
- *mode of delivery:* face-to-face
- *modifications:* based on CBT programme

No treatment

- *type of intervention:* comparator
- *specific intervention:* no treatment
- *dose:* -
- *frequency:* -
- *duration:* 5 weeks
- *level of therapist:* -
- *individual or group therapy:* -
- *mode of delivery:* -
- *modifications:* -

Takagaki 2016 (Continued)

Outcomes

Depression symptoms

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** BDI
- **Direction:** lower is better
- **Data value:** endpoint
- **Notes:** both ITT and complete case analysis are reported. Results reported here are from ITT analysis.

Dropouts

- **Outcome type:** dichotomous outcome

Quality of life

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** HRQOL
- **Direction:** higher is better
- **Data value:** endpoint

Identification

Sponsorship source: Supported by a Grant-in-Aid for Scientific Research on Innovative Areas from Japan Society for the Promotion of Science, JSPS (grants 16H06395 and 16H06399), and grant 23118004 from the Ministry of Education, Culture, Sports, Science and Technology, Japan. This work was partially supported by the programme for Brain Mapping by Integrated Neurotechnologies for Disease Studies (Brain/MINDS) by Japan Agency for Medical Research and Development, AMED (grant 15dm0207012h0002) and Integrated Research on Depression, Dementia and Development Disorders by AMED (grant 16dm0107093h0001)

Country: Japan

Setting: University

Comments: -

Authors name: Yasumasa Okamoto

Institution: Hiroshima University

Email: oy@hiroshima-u-ac.jp

Address: Department of Psychiatry and Neurosciences, Hiroshima University, 1-2-3 Kasumi, Minami-ku, Hiroshima 734-8551, Japan.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Microsoft Excel randomization function." Judgement comment: random numbers table used.
Allocation concealment (selection bias)	Low risk	Quote: "An expert of the Department of Clinical Research, who was independent of the research team that conducted this study, developed a sequential assignment list using computer-generated random numbers to allocate the participants to a treatment or a control group randomly at a 1:1 ratio. The random sequence was stratified by sex and depression severity during screening

Takagaki 2016 (Continued)

(BDI-II score #13, BDI-II score \$14). The group allocation was masked in the entry and in the CIDI assessment."

Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding not possible in this trial due to the nature of the intervention. This may have caused bias in the outcome estimates.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Participants received telephone interviews by CIDI and completed self-report scales via the Internet 1 year after the assessment by blind testers who did not know the allocation. In CIDI assessment of 1-year follow-up, allocation to the treatment group or control group was masked." Judgement comment: blinding of outcome assessors but some scales were self-reported by participants.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: dropout slightly higher in treatment group. ITT analysis (imputation) and completers only presented separately. These results were compared in sensitivity analyses.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: trial registration provided. Secondary outcomes reported post-treatment only. Unclear whether study authors had planned to report secondary outcomes at 1 year follow-up.
Other bias	Low risk	Judgement comment: none identified.

Taylor 1977
Study characteristics

Methods	Study design: Randomised controlled trial Study grouping: parallel group Recruitment: Type of RCT (blind, double-blind, open-label): open
Participants	Baseline characteristics Cognitive therapy <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: - • Depression severity: - • Age: - Behavioural activation <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: -

Taylor 1977 (Continued)

- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Cognitive and behavioural therapy

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Waiting list

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Overall

- *Gender (N male, % male, N female, % female):* 8 male, 20 female
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* undergraduate or graduate students
- *Comorbid anxiety:* -
- *Depression severity:* BDI 21.2 (mild-moderate)
- *Age:* 22.4 (SD 2.6, range 18 to 26)

Included criteria: 1. Self-reported depression of not less than two weeks duration. 2. Beck Depression Inventory (BDI) scores of not less than 13; the figure suggested by Beck (1967) as the cut-off point between de-pressed and non-depressed patients. 3. D-30 Scale (Dempsey, 1964), T scores of not less than 70. 4. Not currently receiving medication or other treatment. 5. Willingness to take part in a treatment and research program.

Excluded criteria: -

Pretreatment: -

Interventions

Intervention characteristics

Cognitive therapy

- *type of intervention:* comparator
- *specific intervention:* cognitive therapy based on Beck and Ellis
- *dose:* 40 minute sessions
- *frequency:* 6 sessions
- *duration:* 5 weeks
- *level of therapist:* specialist

Taylor 1977 (Continued)

- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: -

Behavioural activation

- *type of intervention*: BA
- *specific intervention*: behavioural therapy based on Lewinsohn, Ferster, and Lazarus
- *dose*: 40 minute sessions
- *frequency*: 6 sessions
- *duration*: 5 weeks
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: -

Cognitive and behavioural therapy

- *type of intervention*: comparator
- *specific intervention*: combined cognitive-behavioural treatment
- *dose*: 40-minute sessions
- *frequency*: 6 sessions
- *duration*: 5 weeks
- *level of therapist*: specialist
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: -

Waiting list

- *type of intervention*: comparator
- *specific intervention*: waiting list
- *dose*: -
- *frequency*: -
- *duration*: 5 weeks
- *level of therapist*: -
- *individual or group therapy*: -
- *mode of delivery*: -
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: BDI
- **Direction**: lower is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: lower is better
- **Data value**: endpoint
- **Notes**: in the waiting list group, 2 patients did receive treatment. The other 5 were then given the combined treatment.

Taylor 1977 (Continued)

Identification

Sponsorship source: none reported

Country: Canada

Setting: University

Comments: -

Authors name: Frederick G Taylor

Institution: Queen's University

Email: -

Address: Queen's University, Kingston, Ontario, Canada

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "Subjects were randomly assigned in order of acceptance to one of four groups:" Judgement comment: it seems that allocation was in order of appearance, which is not completely random.
Allocation concealment (selection bias)	High risk	Judgement comment: it seems that allocation was in order of appearance, which is not thought to be random. This also means allocation was not likely to be concealed, and could be easily manipulated.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding due to nature of interventions; this may lead to bias.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: self-assessment of outcome measures, which may lead to bias based on participant preference for treatment and satisfaction with the treatment received.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Judgement comment: no dropouts reported in active treatment groups; it has to be assumed that all participants randomised completed the study. In the waiting list group, 2 participants did receive treatment and therefore the other 5 were provided with the combined treatment. Unclear why this decision was made. Author could not be contacted.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol. Author could not be contacted.
Other bias	Unclear risk	Judgement comment: very small sample sizes (N = 7 per arm) and no description of patient characteristics by study arm, making it impossible to ascertain whether randomisation was successful. Unclear at which times post-treatment and follow-up measures were completed. Author could not be contacted. Quote: "All treatments (six 40-min. sessions) were administered individually by a single therapist (the senior author)," Judgement comment: no evidence of therapist allegiance.

Thomas 1987
Study characteristics

Methods **Study design:** randomised controlled trial
 Study grouping: parallel group
 Recruitment: mass media
 Type of RCT (blind, double-blind, open-label): open

Participants **Baseline characteristics**

Behavioural activation

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* BDI 25.09 (SD 2.38)
- *Age:* -

Cognitive therapy

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* BDI 20.40 (SD 2.11)
- *Age:* -

Overall

- *Gender (N male, % male, N female, % female):* N = 30 (100%) female
- *Ethnic group:* predominantly White
- *Household income:* -
- *Occupation/employment:* predominantly middle-class, 50% unemployed
- *Education level:* mode: high school graduate, range: 10th grade to college graduate
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* mean 35, range 18 to 60

Included criteria: women, MMPI score F-K <11 and D > 69, BDI 11 or more, no history of psychiatric hospitalisation, serious suicidal ideation or attempts, and no involvement in any other psychological therapy in the past month, clinical judgement of depression as major psychopathology, depression of at least 4 months duration, not psychotic or suicidal.

Excluded criteria: -

Pretreatment: patients in the self-control group had a higher pretest BDI score at baseline, although authors say this was not statistically significant. No other baseline characteristics reported by study arm.

Thomas 1987 (Continued)

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention*: BA
- *specific intervention*: behavioural therapy according to Fuchs & Rehm 1977
- *dose*: -
- *frequency*: weekly
- *duration*: 6 weeks
- *level of therapist*: specialist (in training)
- *individual or group therapy*: group
- *mode of delivery*: face-to-face
- *modifications*: -

Cognitive therapy

- *type of intervention*: comparator
- *specific intervention*: cognitive therapy (Beck)
- *dose*: -
- *frequency*: weekly
- *duration*: 6 weeks
- *level of therapist*: specialist (in training)
- *individual or group therapy*: group
- *mode of delivery*: face-to-face
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: BDI
- **Direction**: lower is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: partially reported
- **Direction**: lower is better
- **Data value**: endpoint

Identification

Sponsorship source: none reported

Country: USA

Setting: -

Comments: -

Authors name: J Randy Thomas

Institution: Medical College of Virginia

Email: -

Address: PO Box 253, MCV Station, Richmond, Virginia 23298.

Notes

Thomas 1987 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The 30 subjects were randomly assigned to one of six groups, with the re-straint that five subjects were in each group." Judgement comment: no information. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Therapists were told that subjects were selected on the basis of locus of control scores and matched to treatment. The purpose of this was to distract - - the therapist from the obvious cognitive versus self-control treatment comparison and to limit any personal bias that may have resulted, intentional or not. The misdirection appeared effective, as on debriefing the therapists said they felt they had identified the different locus of control groups and the matching that had occurred." Judgement comment: no blinding due to nature of interventions. This may have led to bias. Therapists were told that matching had occurred, when in reality it had not. It is unlikely this is an effective way to prevent bias.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: questionnaires were completed by patients themselves; possibly in the presence of the therapist. This may have led to bias if patients had a preference for a particular treatment, or based on satisfaction with their treatment.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: almost half of all participants dropped out before the study finished (4 in one group, 5 in the other group). It is unclear why this was the case, and at what point in the study participants dropped out. Authors state there were no significant differences between drop-outs and completers, but it would have been hard to find differences for such small sample sizes.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol. Author could not be contacted.
Other bias	Unclear risk	Judgement comment: sample sizes at follow-up are extremely small (N = 6 and N = 5), and any differences in outcomes may therefore have occurred by chance. Randomisation unlikely to have been effective. No information on treatment fidelity. Author could not be contacted.

Thompson 1987
Study characteristics

Methods	Study design: randomised controlled trial Study grouping: parallel group Recruitment: participants were 725 elderly individuals who telephoned our research center between January 1, 1982, and January 1, 1984, to inquire about participation in the psychotherapy outcome study (Breckenridge 1985) Type of RCT (blind, double-blind, open-label): open
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Thompson 1987 (Continued)

Participants

Baseline characteristics

Behavioural activation

- *Gender (N male, % male, N female, % female):* 8 male, 17 female
- *Ethnic group:* -
- *Household income:* -
- *Occupation/ employment:* 7 employed, 18 not employed
- *Education level:* mean 14.16 years (SD 2.37)
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* 66.88 (SD 5.17)

Cognitive therapy

- *Gender (N male, % male, N female, % female):* 11 male, 16 female
- *Ethnic group:* -
- *Household income:* -
- *Occupation/ employment:* 3 employed, 24 not employed
- *Education level:* 13.96 (SD 2.17)
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* 67.07 (SD 6.48)

Brief psychodynamic therapy

- *Gender (N male, % male, N female, % female):* 8 male, 16 female
- *Ethnic group:* -
- *Household income:* -
- *Occupation/ employment:* 3 employed, 21 not employed
- *Education level:* 14.62 (SD 2.12)
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* 66.71 (SD 6.16)

Delayed treatment

- *Gender (N male, % male, N female, % female):* 4 male, 15 female
- *Ethnic group:* -
- *Household income:* -
- *Occupation/ employment:* 4 employed, 15 not employed
- *Education level:* 15.31 (SD 1.34)
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* 67.63 (SD 5.56)

Overall

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/ employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Thompson 1987 (Continued)

Included criteria: 60 or older, diagnosed with major depressive disorder (RDC), no or stable medication for minimum of 3 months, not concurrently in psychotherapy, no evidence of psychosis, alcoholism, immediate suicidal risk, or bipolar disorder, not exhibiting evidence of significant cognitive impairment, minimum score 17 on BDI and 14 on HRSD.

Excluded criteria: -

Pretreatment: there were no significant differences across modalities on any of the background variables

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural therapy (Lewinsohn)
- *dose:* 16 to 20 sessions
- *frequency:* twice a week for first 4 weeks and once a week thereafter
- *duration:* -
- *level of therapist:* specialist (in training)
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* -

Cognitive therapy

- *type of intervention:* comparator
- *specific intervention:* cognitive therapy (Beck)
- *dose:* 16 to 20 sessions
- *frequency:* twice a week for first 4 weeks and once a week thereafter
- *duration:* -
- *level of therapist:* specialist (in training)
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* -

Brief psychodynamic therapy

- *type of intervention:* comparator
- *specific intervention:* brief psychodynamic therapy (Horowitz)
- *dose:* 16 to 20 sessions
- *frequency:* twice a week for first 4 weeks and once a week thereafter
- *duration:* -
- *level of therapist:* specialist (in training)
- *individual or group therapy:* individual
- *mode of delivery:* face-to-face
- *modifications:* Prescribed outline with some variations depending on patient progress

Delayed treatment

- *type of intervention:* comparator
- *specific intervention:* waiting list
- *dose:* -
- *frequency:* -
- *duration:* 6 weeks
- *level of therapist:* -
- *individual or group therapy:* -

Thompson 1987 (Continued)

- *mode of delivery:* -
- *modifications:* -

Outcomes

Depression symptoms

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** HRSD
- **Direction:** lower is better
- **Data value:** endpoint

Functioning

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** Global Assessment Scale
- **Direction:** higher is better
- **Data value:** endpoint

Social adjustment

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** Social Adjustment Scale
- **Direction:** lower is better
- **Data value:** endpoint

Depression remission

- **Outcome type:** dichotomous outcome
- **Reporting:** fully reported
- **Direction:** higher is better
- **Data value:** endpoint
- **Notes:** Remission according to 1) reliable change index and 2) deviation from normative elderly sample

Identification

Sponsorship source: this research was supported by Grant R01-MH37196 from the National Institute of Mental Health to the first author.

Country: USA

Setting: -

Comments: this study refers to Breckenridge 1985, which is not an RCT. It appears this is not the same study, but similar recruitment methods were used, and the funding source is the same.

Authors name: Larry W Thompson

Institution: Veterans Administration Medical Center

Email: -

Address: Veterans Administration Medical Center (182C/MP), 3801 Miranda Avenue, Palo Alto, California 94304,

Notes

Risk of bias

Thompson 1987 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement comment: no information. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: No information. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement Comment: no blinding due to nature of interventions. This may have biased estimates.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: unclear who performed outcome assessments. Author could not be contacted.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: patients were dropped from analyses if treatment fidelity was found to be insufficient (N = 5). More patients were reported to have dropped out in the cognitive (N = 10) than other groups (N = 4 each), and more patients in the cognitive group dropped out because of dissatisfaction with treatment. Data on dropouts are inconsistent throughout text and tables.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: not all prespecified outcomes are reported at the pre-specified time points. No reference to protocol. Author could not be contacted.
Other bias	High risk	Judgement comment: <ul style="list-style-type: none"> patients on the waiting list were re-randomised to one of three treatments halfway through the study, and these participants were analysed as belonging to one of the treatment groups at the end of the study, even though they had received no treatment at first. this study seems partly based on Breckenridge 1985, with the same source of funding. unclear treatment duration, and unclear when post-treatment follow-up was. it seems that 5 participants were dropped from the analysis due to issues with patient adherence, although this is not entirely clear from the text. Author could not be contacted.

Toghyani 2018
Study characteristics

Methods	Study design: randomised controlled trial Study grouping: parallel group Recruitment: patients were recruited from psychological services centres. Type of RCT (blind, double-blind, open-label): open
Participants	Baseline characteristics Behavioural activation

Toghyani 2018 (Continued)

- *Gender*: 100% female
- *Ethnic group*: -
- *Household income*: -
- *Occupation/employment*: 25% employed, 25% student, 50% housewife
- *Education level*: 50% high school, 50% university degree
- *Comorbid anxiety*: excluded
- *Depression severity*: BDI mean 30.17 (SD 9.60)
- *Age*: mean 33.4 (SD 8.73)

ILPI

- *Gender*: 100% female
- *Ethnic group*: -
- *Household income*: -
- *Occupation/employment*: 33% student, 67% house wife
- *Education level*: 33% primary school, 9% secondary school, 33% high school, 25% university degree
- *Comorbid anxiety*: excluded
- *Depression severity*: BDI mean 25.37 (SD 11.46)
- *Age*: mean 35.8 (SD 9.57)

Inclusion criteria: 20 to 50 years old, diagnosis of MDD (DSM-V), mild to moderate symptoms (BDI), physical and cognitive ability to write and give consent.

Exclusion criteria: suffering from any other psychological disorders, under psychotherapy or medicine for major depressive disorder.

Pretreatment: significantly higher levels of education and employment in BA group. Depression, hopelessness and worry higher in BA group at baseline (statistical significant not reported).

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention*: BA
- *specific intervention*: behavioural activation
- *dose*: 90 minutes
- *frequency*: weekly
- *duration*: 8 weeks
- *level of therapist*: specialist
- *individual or group therapy*: group
- *mode of delivery*: face-to-face
- *modifications*: group therapy

ILPI

- *type of intervention*: comparator
- *specific intervention*: Islamic lifestyle psychoeducational intervention (ILPI)
- *dose*: 90-minute sessions
- *frequency*: weekly
- *duration*: 10 weeks
- *level of therapist*: not reported
- *individual or group therapy*: group
- *mode of delivery*: face-to-face
- *modifications*: -

Outcomes

Depression symptoms

Toghyani 2018 (Continued)

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** BDI-II
- **Direction:** lower is better
- **Data value:** mean, SD

Dropouts

- **Outcome type:** dichotomous outcome
- **Reporting:** fully reported
- **Scale:** -
- **Direction:** lower is better
- **Data value:** n/N

Identification

Sponsorship source: this work was supported by the Center of Excellence for Spirituality and Happiness in the University of Isfahan [grant number 5863].

Country: Iran

Setting: Recruitment from psychological services centres

Comments:

Authors name: Mojtaba Toghyani

Institution: University of Isfahan

Email: m.b.kaj@edu.ui.ac.ir

Address: Department of Psychology, Faculty of Education and Psychology, University of Isfahan, Isfahan, Iran

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were equally and randomly assigned to the Islamic lifestyle psychoeducational intervention (ILPI) or behavioural activation (BA) treatment group" Judgement comment: no information on sequence generation.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information on allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: assumed to be not blinding due to nature of interventions.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: outcome assessors not specified.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: 3 participants did not complete treatment and were excluded from analysis in each group and not included in table of baseline characteristics. Reasons not given.

Toghyani 2018 (Continued)

Selective reporting (reporting bias)	Unclear risk	Judgement comment: protocol mentioned but no link to protocol or trial registration.
Other bias	High risk	Judgement comment: the researcher who delivered ILPI is also the first author and may have favoured this approach. This therapist and researcher allegiance may have led to bias. No details on treatment fidelity.

van den Hout 1995
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: patients receiving treatment at outpatient centre</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 6 males (39%), 9 females (62%) • <i>Ethnic group:</i> - • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> - • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> 54% major depression; 31% major depression superimposed on dysthymia • <i>Age:</i> 33.8 years (SD 10.2) <p>Treatment as usual</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 6 males (42%), 8 females (59%) • <i>Ethnic group:</i> - • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> - • <i>Comorbid anxiety:</i> 0 • <i>Depression severity:</i> 42% major depression; 50% major depression superimposed on dysthymia • <i>Age:</i> 34.2 years (SD 8.8) <p>Overall</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 10 males (40%), 15 females (60%) • <i>Ethnic group:</i> - • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> - • <i>Comorbid anxiety:</i> 0% (anxiety disorder was exclusion criteria) • <i>Depression severity:</i> 11 (38%) major depression superimposed on pre-existing dysthymia; 15 (52%) major depression; 3 (10%) dysthymia • <i>Age:</i> 34 years

van den Hout 1995 (Continued)

Included criteria: major depression and/or dysthymia on SCID-III-R \geq 50 on Zung's Self-rating Depression Scale

Excluded criteria: bipolar mood disorder Psychotic disorder Alcohol or drug dependence Anxiety disorder or post-traumatic stress disorder when clearly preceding the depressive episode Illiteracy

Pretreatment: participants in the experimental group were more likely to have major depression, whereas participants in the control group were more likely to have a diagnosis of dysthymia.

Interventions	<p>Intervention characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> BA • <i>specific intervention:</i> self-control therapy/ behavioural therapy (Rehm) + standard treatment • <i>dose:</i> 90-minute sessions (+5-day treatment as usual programme) • <i>frequency:</i> weekly • <i>duration:</i> 12 weeks • <i>level of therapist:</i> - • <i>individual or group therapy:</i> group • <i>mode of delivery:</i> face-to-face • <i>modifications:</i> - <p>Treatment as usual</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> comparator • <i>specific intervention:</i> treatment as usual (including social skills training etc.) • <i>dose:</i> - • <i>frequency:</i> - • <i>duration:</i> 5 days • <i>level of therapist:</i> - • <i>individual or group therapy:</i> group • <i>mode of delivery:</i> face-to-face • <i>modifications:</i> -
Outcomes	<p><i>Depression symptoms</i></p> <ul style="list-style-type: none"> • Outcome type: continuous outcome • Scale: Zung Self-rating Depression Scale • Direction: higher is better • Data value: endpoint
Identification	<p>Sponsorship source: not reported</p> <p>Country: the Netherlands</p> <p>Setting: psychiatric outpatient centre</p> <p>Comments: -</p> <p>Authors name: JHC van den Hout</p> <p>Institution: University of Limburg</p> <p>Email: -</p> <p>Address: Department of Medical Psychology, University of Limburg, P.O. Box 616, NL-6200 MD Maastricht, the Netherlands</p>

van den Hout 1995 (Continued)

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>Quote: "According to the randomized pre- and posttest control group design, 29 selected subjects were randomly assigned to either standard treatment (control condition, n = 14), or standard treatment plus self-control therapy (experimental condition, n = 15). Standard treatment (ST)."</p> <p>Judgement comment: no detail on randomisation method. Author could not be contacted.</p>
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	<p>Quote: "Although patients in both conditions were treated with care and attention, patients in the SCT condition could have been affected by the knowledge of being participants of a new therapy that focused especially on their depressive complaints. Because of the absence of an attention placebo control, this study fails to control for such effects. Furthermore, though both conditions participated"</p> <p>Judgement comment: Presumably no blinding; this may have led to bias in the estimates if patients or therapists had a preference for one treatment.</p>
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement Comment: self-rating scales were completed; this may have led to bias depending on participant preference for treatment and their satisfaction with the treatment.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	<p>Quote: "Three subjects dropped out between pre- and posttest. The remaining sample consisted of 25 subjects, 10 males and 15 females. The mean age of all subjects was 34 years (range 20-59). One subject dropped out between posttest and follow-up."</p> <p>Judgement comment: it is unclear how many participants dropped out in each study arm; 4 participants dropped out during treatment and 1 during follow-up. Author could not be contacted.</p>
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol. Author could not be contacted.
Other bias	Unclear risk	<p>Quote: "To control for possible bias caused by medication, the number of weeks medication was administered from pre- to posttest and from pretest to follow-up was included as a covariate in posttest and follow-up ANCOVAs, respectively. Univariate analysis outcomes at posttest and follow-up were comparable to those acquired when medication was not added as a covariate. For this reason, medication was not included in the analyses presented in this article. Furthermore, at pre-test, patients who received antidepressant medication did not have higher depression scores than those who did not."</p> <p>Quote: "There were no significant differences between the two groups in number of antidepressant medication-using patients (Table 1)."</p> <p>Judgement comment: some participants took antidepressants during trial. Although there was no significant difference between group and taking medication was not found to make a difference in analyses, rates of medication use</p>

van den Hout 1995 (Continued)

were higher in the BA group than the control during the intervention and follow-up period.

Vázquez 2014
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment:</p> <p>Type of RCT (blind, double-blind, open-label): open</p>
Participants	<p>Baseline characteristics</p> <p>Cognitive-behavioural therapy</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 18 female (90%), 2 male (10%) • <i>Ethnic group:</i> • <i>Household income:</i> • <i>Occupation/employment:</i> 12 housework (60%), 8 other (40%) • <i>Education level:</i> 13 less than high school (65%), 7 high school or university (35%) • <i>Comorbid anxiety:</i> • <i>Depression severity:</i> subthreshold • <i>Age:</i> 59.3 (SD 9.7) <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 22 female (100%), 0 male • <i>Ethnic group:</i> • <i>Household income:</i> • <i>Occupation/employment:</i> 15 housework (68%), 7 other (32%) • <i>Education level:</i> 13 less than high school (59%), 9 high school or university (41%) • <i>Comorbid anxiety:</i> • <i>Depression severity:</i> subthreshold • <i>Age:</i> 59.7 (SD 8.1) <p>Usual care</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 17 female (89%), 2 male (10%) • <i>Ethnic group:</i> • <i>Household income:</i> • <i>Occupation/employment:</i> 12 housework (63%), 7 other (37%) • <i>Education level:</i> 14 less than high school (74%), 5 high school or higher (26%) • <i>Comorbid anxiety:</i> • <i>Depression severity:</i> subthreshold • <i>Age:</i> 55.9 (SD 5.4) <p>Overall</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> 57 female (93%), 4 male (7%) • <i>Ethnic group:</i> • <i>Household income:</i> • <i>Occupation/employment:</i> 39 housework (64%), 22 other (36%)

Vázquez 2014 (Continued)

- *Education level:* 40 less than high school (66%), 21 high school or university (34%)
- *Comorbid anxiety:*
- *Depression severity:* subthreshold
- *Age:* 58.4 (SD 8.0)

Included criteria: (1) be a non-professional primary caregiver of a person whose dependence was officially recognised, (2) have a telephone, (3) pre-treatment score of at least 16 on the Spanish CES-D, (4) not meet the diagnostic criteria for a major depressive episode, (5) have no history of major depression and (6) give informed consent.

Excluded criteria: (1) had received psychological or psycho-pharmacological treatment within the last two months, (2) had mental or medical conditions that could act as confounders in the study (e.g. symptoms due to the direct physiological effects of a substance or a medical, metabolic or psychiatric condition in women participants), (3) presented medical or mental problems of such gravity that they either required immediate intervention (e.g. suicidal ideation) or precluded participation in the study (e.g. severe hearing impairment), (4) were caring for a person with a grave or terminal prognosis or (5) planned to change their domicile or institutionalise the person for whom they were caring.

Pretreatment: there were no remarkable or clinically relevant baseline differences

Interventions

Intervention characteristics

Cognitive-behavioural therapy

- *type of intervention:* control
- *specific intervention:* cognitive-behavioural therapy (Lewinsohn)
- *dose:* 90-minute sessions
- *frequency:* once a week
- *duration:* 5 weeks
- *level of therapist:* specialist
- *individual or group therapy:* group
- *mode of delivery:* conference call
- *modifications:*

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural activation (Lewinsohn/ Vazquez)
- *dose:* 90-minute sessions
- *frequency:* once a week
- *duration:* 5 weeks
- *level of therapist:* specialist
- *individual or group therapy:* group
- *mode of delivery:* conference call
- *modifications:*

Usual care

- *type of intervention:* control
- *specific intervention:* usual care; no intervention or educational materials
- *dose:*
- *frequency:*
- *duration:* 5 weeks
- *level of therapist:*
- *individual or group therapy:*
- *mode of delivery:*
- *modifications:*

Vázquez 2014 (Continued)

Outcomes

Depression symptoms

- **Outcome type:** continuous outcome
- **Reporting:** fully reported
- **Scale:** CES-D
- **Direction:** lower is better
- **Data value:** endpoint

Dropouts

- **Outcome type:** dichotomous outcome
- **Direction:** lower is better
- **Data value:** endpoint

Depression

- **Outcome type:** dichotomous outcome
- **Reporting:** fully reported
- **Scale:** DSM-IV
- **Direction:** lower is better
- **Data value:** endpoint

Identification

Sponsorship source: Ministry of Economy and Competitiveness of Spain [2012-PN162 (PSI2012-37396)]

Country: Spain

Setting:

Comments:

Authors name: Fernando Vazquez

Institution: University of Santiago de Compostela

Email: fernandolino.vazquez@usc.es

Address: Department of Clinical Psychology and Psychobiology, University of Santiago de Compostela, Santiago de Compostela, Spain

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "An independent statistician randomly assigned participants to groups using a table of random numbers." Judgement comment: random numbers table used by independent researcher.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: unclear who performed allocation based on random numbers table. Contacted author who states 'allocation concealment technique was used' but unclear how.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding not possible due to nature of interventions.

Vázquez 2014 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "All pre- and post-treatment assessments were conducted face-to-face by trained interviewers not directly involved in the research study and who were blind to the group to which each participant had been assigned." Judgement comment: outcome assessors were blinded and independent of researchers.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: small number of participants dropped out; reasons for dropout reported.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: protocol reported for full trial but not for this feasibility trial.
Other bias	Unclear risk	Quote: "The BAC intervention was also adapted from Vazquez et al. (2014) but in this case the intervention focused solely on the behavioral activation component." Judgement comment: intervention adapted from those developed by study author.

Weinberg 1978
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: from introductory psychology courses at college</p> <p>Type of RCT (blind, double-blind, open-label): open-label</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural activation</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: - • Depression severity: - • Age: - <p>Cognitive therapy</p> <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: - • Depression severity: - • Age: -

Weinberg 1978 (Continued)

Emotional Awareness Training

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/ employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: -
- Age: -

Waiting List

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/ employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: -
- Age: -

Overall

- Gender (N male, % male, N female, % female): 35 female, 5 male
- Ethnic group: -
- Household income: -
- Occupation/ employment: -
- Education level: University
- Comorbid anxiety: -
- Depression severity: -
- Age: -

Included criteria: at least moderate depression (score ≥ 8 BDI)

Excluded criteria: -

Pretreatment: no information on baseline characteristics by study arm. Depressions scores at baseline similar.

Interventions

Intervention characteristics

Behavioural activation

- *type of intervention:* BA
- *specific intervention:* behavioural therapy (Lewinsohn)
- *dose:* 1-hour sessions
- *frequency:* weekly
- *duration:* 4 weeks
- *level of therapist:* specialist (in training)
- *individual or group therapy:* group
- *mode of delivery:* face-to-face + homework
- *modifications:* -

Cognitive therapy

- *type of intervention:* comparator
- *specific intervention:* cognitive therapy (Goldfried)

Weinberg 1978 (Continued)

- *dose*: 1 hour sessions
- *frequency*: weekly
- *duration*: 4 weeks
- *level of therapist*: specialist (in training)
- *individual or group therapy*: group
- *mode of delivery*: face-to-face + homework
- *modifications*: -

Emotional Awareness Training

- *type of intervention*: comparator
- *specific intervention*: sensitivity treatment focused on awareness of emotions
- *dose*: 1-hour sessions
- *frequency*: weekly
- *duration*: 4 weeks
- *level of therapist*: specialist (in training)
- *individual or group therapy*: group
- *mode of delivery*: face-to-face + homework
- *modifications*: -

Waiting list

- *type of intervention*: comparator
- *specific intervention*: waiting list
- *dose*: -
- *frequency*: -
- *duration*: 4 weeks
- *level of therapist*: -
- *individual or group therapy*: -
- *mode of delivery*: -
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: BDI
- **Direction**: lower is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome

Anxiety symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: Trait Anxiety Scale
- **Direction**: lower is better
- **Data value**: endpoint

Identification

Sponsorship source: none reported- PhD dissertation.

Country: USA

Setting: University

Weinberg 1978 (Continued)

Comments: -

Authors name: Leslie Weinberg

Institution: State University of New York at Stony Brook

Email: -

Address: -

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Judgement comment: no information on sequence generation. One participant who dropped out after randomisation was replaced by a participant from the waiting list group; unclear to which group. Allocation was altered 'for scheduling' and to ensure similar baseline scores. Author could not be contacted.
Allocation concealment (selection bias)	High risk	Judgement comment: very probably not concealed to researcher because they made alterations to the randomisation. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding not possible due to nature of interventions; it is likely that knowledge of the intervention affects the estimates.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: BDI was self-reported; unclear who was present at the time of completion. This may lead to bias as patients were aware of intervention received. Author could not be contacted.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Judgement comment: one person dropped out before treatment and was replaced by a person from the waiting list group; unclear why and how this decision was made. A further 3 participants dropped out; unclear why. Author could not be contacted.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no link to protocol. Author could not be contacted.
Other bias	Unclear risk	Judgement comment: no information on baseline characteristics of participants; given small sample sizes it is likely that there would have been differences at baseline, that may also correlate with effect of interventions. No information on treatment fidelity. Author could not be contacted.

Weobong 2017
Study characteristics

Methods	Study design: randomised controlled trial Study grouping: parallel group Recruitment: from primary health centre Type of RCT (blind, double-blind, open-label): open
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Weobong 2017 (Continued)

Participants

Baseline characteristics

Enhanced usual care

- *Gender (N male, % male, N female, % female):* 191 female (77%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* unemployed 140 (56%), unskilled manual 97 (39%) skilled manual 4 (2%), clerical and professional 7 (3%)
- *Education level:* 55 none (22%), 135 primary (54%), 40 secondary (16%), 11 higher secondary (4%), 7 graduate or above (3%)
- *Comorbid anxiety:* -
- *Depression severity:* 187 moderately-severe (75%), 61 severe (25%)
- *Age:* 42.6 (SD 12.0)

Behavioural activation

- *Gender (N male, % male, N female, % female):* 188 female (76%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* unemployed 152 (62%), unskilled manual 77 (31%), skilled manual 3 (1%), clerical and professional 13 (5%)
- *Education level:* 75 none (31%), 114 primary (46%), 38 secondary (16%), 13 higher secondary (5%), 5 graduate or above (2%)
- *Comorbid anxiety:* -
- *Depression severity:* 185 moderately-severe (76%), 60 severe (24%)
- *Age:* 42.4 (SD 12.1)

Overall

- *Gender (N male, % male, N female, % female):* -
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* -

Included criteria: 18 to 65, probably diagnosis of moderately severe to severe depression (PHQ>14), gave informed consent

Excluded criteria: pregnant women, severe medical conditions requiring urgent medical attention, hearing/ speech difficulties.

Pretreatment:

Interventions

Intervention characteristics

Enhanced usual care

- *type of intervention:* comparator
- *specific intervention:* routine consultation and access to referral services
- *dose:* -
- *frequency:* -
- *duration:* -
- *level of therapist:* -

Weobong 2017 (Continued)

- *individual or group therapy*: -
- *mode of delivery*: -
- *modifications*: -

Behavioural activation

- *type of intervention*: BA
- *specific intervention*: Healthy Activity Programme (HAP): brief psychological therapy based on behavioural activation
- *dose*: 30- to 40-minute sessions
- *frequency*: weekly
- *duration*: 8 weeks
- *level of therapist*: non-professional
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face
- *modifications*: adapted for local context

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: partially reported
- **Scale**: BDI-II
- **Direction**: lower is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome

Adverse events

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: lower is better
- **Data value**: endpoint

Depression remission

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Scale**: PHQ-9
- **Direction**: higher is better
- **Data value**: endpoint
- **Notes**: remission as defined by a PHQ-9 score < 10

Identification

Sponsorship source: Wellcome Trust Senior Research Fellowship grant to VP (091834)

Country: India

Setting: primary care rural and peri-urban settings

Comments: -

Authors name: Vikram Patel

Institution: Harvard Medical School

Email: vikram.patel@hms.harvard.edu

Weobong 2017 (Continued)

Address: -

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "An independent statistician generated a randomisation list in randomly sized blocks (block size four to six [two to four for men because we anticipated relatively fewer men on the basis of the epidemiology of the prevalence of depression and did not want imbalance between groups]), stratified by PHC and sex. Assignments were sealed in sequential numbered opaque envelopes by independent support staff that were opened as each consenting eligible patient was enrolled 21 by trained health assistants."
Allocation concealment (selection bias)	Low risk	Quote: "Physicians providing EUC were masked to allocation status, as were the independent assessors who did outcome assessments, and these people had no contact with the PHCs or other team members. All authors, apart from the data manager (BB), were masked until the trial results were unmasked in the presence of the Trial Steering Committee and Data Safety and Monitoring Committee on March 7, 2016."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding of those who delivered the intervention and participants was not possible, but those who provided enhanced usual care were blinded, and had no contact with researchers.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Instances of unmasking of outcome assessors in the HAP group will be summarised on the basis of overall prevalence and the exact point during the interview that the interviewer was unmasked." Judgement comment: outcome assessors were blinded in most circumstances, and were independent from the research team.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Judgement comment: N = 5 refused follow-up in the control group, compared to N = 12 in the treatment (HAP) group. Unclear why this was the case, but this may be related to how the intervention was perceived. In this case, even multiple imputation of these missing data may have led to biased estimates.
Selective reporting (reporting bias)	Low risk	Judgement comment: protocol matches study reports.
Other bias	Unclear risk	Judgement comment: depression remission figures do not match up: a smaller sample is reported at 3 months than at 12 months. Numbers and percentages for 12 months don't match total sample size. Small differences; unclear whether this could have influenced results.

Wilson 1983
Study characteristics

Methods **Study design:** randomised controlled trial

Study grouping: parallel group

Wilson 1983 (Continued)

Recruitment: participants were obtained from the general population of Sydney through announcements of a depression treatment-research program in the media.

Type of RCT (blind, double-blind, open-label): -

Participants

Baseline characteristics

Behavioural activation

- *Gender (N male, % male, N female, % female):* 2 males (25%), 6 females (75%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* HAM-D: 13.89 (SD 3.22)
- *Age:* -

Cognitive therapy

- *Gender (N male, % male, N female, % female):* 1 male (12%), 7 females (88%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* HAM-D: 13.62 (SD 2.40)
- *Age:* -

Waiting list

- *Gender (N male, % male, N female, % female):* 2 males (22%), 7 females (78%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* -
- *Comorbid anxiety:* -
- *Depression severity:* HAM-D: 13.22 (SD 4.08)
- *Age:* -

Overall

- *Gender (N male, % male, N female, % female):* 5 males (20%), 20 females (80%)
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* N = 19 completed at least secondary school
- *Comorbid anxiety:* -
- *Depression severity:* -
- *Age:* 39.5, range 20 to 58

Included criteria: 20 to 60 years Score \geq 17 on BDI self-reported duration of depression of \geq 3 months

Excluded criteria: previous or concurrent treatment with major tranquillisers or lithium. Major physical or psychiatric disorders (including bipolar affective disorders). Suicidal intention or ideation.

Wilson 1983 (Continued)

Pretreatment: pre-treatment depression scores were similar for HRSD, but not for BDI: highest in cognitive therapy and lowest in behaviour therapy group.

Interventions	Intervention characteristics
	<p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> BA • <i>specific intervention:</i> behavioural therapy (Lewinsohn) • <i>dose:</i> 1-hour sessions • <i>frequency:</i> 8 sessions • <i>duration:</i> 8 weeks • <i>level of therapist:</i> specialist • <i>individual or group therapy:</i> individual • <i>mode of delivery:</i> face-to-face • <i>modifications:</i> - <p>Cognitive therapy</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> comparator • <i>specific intervention:</i> cognitive therapy (Beck) • <i>dose:</i> 1-hour sessions • <i>frequency:</i> 8 sessions • <i>duration:</i> 8 weeks • <i>level of therapist:</i> specialist • <i>individual or group therapy:</i> individual • <i>mode of delivery:</i> face-to-face • <i>modifications:</i> - <p>Waiting list</p> <ul style="list-style-type: none"> • <i>type of intervention:</i> comparator • <i>specific intervention:</i> waiting list • <i>dose:</i> - • <i>frequency:</i> - • <i>duration:</i> 8 weeks • <i>level of therapist:</i> - • <i>individual or group therapy:</i> - • <i>mode of delivery:</i> - • <i>modifications:</i> -
Outcomes	<p><i>Depression symptoms</i></p> <ul style="list-style-type: none"> • Outcome type: continuous outcome • Reporting: fully reported • Scale: HRSD • Direction: lower is better • Data value: endpoint <p><i>Dropouts</i></p> <ul style="list-style-type: none"> • Outcome type: dichotomous outcome • Reporting: fully reported • Direction: lower is better • Data value: endpoint • Notes: dropouts were replaced.

Wilson 1983 (Continued)

Identification

Sponsorship source: not reported

Country: Australia

Setting: University psychology clinic

Comments: -

Authors name: Peter H Wilson

Institution: University of Sydney

Email: -

Address: Department of Psychology, University of Sydney, N.S.W., Australia 2006

Notes

Noortje Uphoff on 12/08/2019 22:07
Outcomes

No data extracted for BDI as HRSD was our preferred measure.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Twenty-five subjects were randomly allocated to one of three experimental conditions" Judgement comment: no details on randomisation method reported. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement Comment: No blinding possible due to nature of intervention; this may cause bias, for example if participants or researchers/therapists have a preference for one treatment over another.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Interviews were tape-recorded and independently assessed by one rater who was blind to both treatment condition and assessment occasion." Judgement comment: it appears that the therapist administered the HRSD, and it was independently assessed by one blinded rater.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: 4/25 participants were replaced without randomisation. Most dropouts (N = 3) occurred in the cognitive therapy group.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no link to protocol. Author could not be contacted.
Other bias	Low risk	Quote: "it is possible that the therapists in the present study failed to administer the treatments in a sufficiently distinct manner. Although every effort was made to distinguish clearly between the two approaches, no independent checks were made on the adherence of therapists to the treatment manuals." Judgement comment: fidelity not monitored. Authors speculate treatments may not have been adhered to correctly. Author could not be contacted.

Xie 2019

Study characteristics

Methods **Study design:** randomised controlled trial

Study grouping: parallel group

Recruitment: 317 left-behind older adults from 17 villages in Yankou Town were asked to complete the Geriatric Depression Scale (GDS) by the local health service centre.

Type of RCT (blind, double-blind, open-label): open-label

Participants

Baseline characteristics

Behavioural activation

- *Gender (N male, % male, N female, % female):* 17 male, 23 female
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* 35 no schooling (97%), 5 elementary school (12%)
- *Comorbid anxiety:* -
- *Depression severity:* mean GDS 16.1 (SD 1.8)
- *Age:* 71.9 (SD 3.9)

Regular care

- *Gender (N male, % male, N female, % female):* 16 male, 24 female
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* 40 no schooling (100%)
- *Comorbid anxiety:* -
- *Depression severity:* mean GDS 15.8 (SD 1.6)
- *Age:* 71.8 (SD 3.7)

Overall

- *Gender (N male, % male, N female, % female):* 33 male, 47 female
- *Ethnic group:* -
- *Household income:* -
- *Occupation/employment:* -
- *Education level:* 75 no schooling (94%), 5 some schooling (6%)
- *Comorbid anxiety:* -
- *Depression severity:* mean GDS 16.0 (SD 1.7)
- *Age:* 71.9 (SD 3.8)

Included criteria: GDS scores 11 to 25, over 65 years of age, only one participant from each family, left-behind for longer than 6 months

Excluded criteria: psychiatric and medical co-morbidities that are potentially life threatening or expected to severely limit client participation or adherence, currently seeing a cognitive-behavioral therapist, psychotherapist or counsellor or currently receiving antidepressant drug treatment.

Pretreatment: baseline characteristics are remarkably similar. Similar baseline depression and anxiety scores.

Interventions

Intervention characteristics

Xie 2019 (Continued)

Behavioural activation

- *type of intervention*: BA
- *specific intervention*: modified BA + regular care
- *dose*: 2-hour sessions
- *frequency*: weekly
- *duration*: 8 weeks
- *level of therapist*: non-professional
- *individual or group therapy*: group
- *mode of delivery*: face-to-face
- *modifications*: modified to suit population

Regular care

- *type of intervention*: comparator
- *specific intervention*: regular care with some education and physical checks
- *dose*: -
- *frequency*: weekly
- *duration*: 8 weeks
- *level of therapist*: non-professional
- *individual or group therapy*: -
- *mode of delivery*: face-to-face
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: Geriatric Depression Scale
- **Direction**: lower is better

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: lower is better
- **Data value**: endpoint

Anxiety symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: Becks Anxiety Inventory
- **Direction**: lower is better
- **Data value**: endpoint

Depression remission

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Scale**: GDS
- **Direction**: higher is better
- **Data value**: endpoint
- **Notes**: remission defined as score < 11 on GDS ('normal' range).

Identification

Sponsorship source: this study was supported by the China Family Foundation Health Fellowship Program of Yale-China Association and the National Natural Science Foundation of China (NO.81502701).

Xie 2019 (Continued)

Country: China

Setting: 17 villages in Yanuka Town recruited through local health service centres

Comments: -

Authors name: Jianda Zhou

Institution: Central South University

Email: doctorzhoujianda@163.com

Address: Department of Orthopedic, The Third Xiangya Hospital, Central South University, Changsha, People's Republic of China.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Eighty participants were randomly numbered using a random number table and then divided into two groups randomly with 40 in the experimental group receiving MBAT intervention plus regular care, and 40 cases in the control group receiving regular care only." Judgement comment: random numbers table used.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information. Not clear who performed randomisation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Based on randomization procedures, each facilitator worked with one of the four groups of participants in the intervention period in close collaboration with the investigator. To ensure competent provision of intervention, all facilitators met for weekly individual supervision sessions with the investigator." Judgement comment: only one active treatment group, and investigator was aware of who was receiving treatment. Blinding not possible due to nature of intervention; this may have influenced outcomes.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "These scales were administered by trained investigators." Judgement comment: it appears assessments were not blinded. Unclear whether same person administered post-treatment and follow-up assessment.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Judgement comment: 5/40 participants dropped out in each group; reasons for discontinuing not all related to intervention (N = 4 lack of interest/ too busy). These participants were dropped from the analysis.
Selective reporting (reporting bias)	Low risk	Judgement comment: trial registration (http://www.chictr.org.cn/com/25/showprojen.aspx?proj=19204) lists depression as primary objective, and anxiety as secondary. In trial report, anxiety is listed as a primary outcome. However, all outcomes mentioned in trial registration have been reported.
Other bias	Unclear risk	Judgement comment: unclear whether regular care is truly 'regular'; patients received some education and physical checks. No information on treatment fidelity.

Zeiss 1979
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Recruitment: through announcement offering therapy for depression as part of a research project. This announcement was widely disseminated at the University of Oregon and in the surrounding metropolitan area.</p> <p>Type of RCT (blind, double-blind, open-label): open-label</p>
Participants	<p>Baseline characteristics</p> <p>Interpersonal behaviour therapy</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> - • <i>Ethnic group:</i> - • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> - • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> - • <i>Age:</i> - <p>Behavioural activation</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> - • <i>Ethnic group:</i> - • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> - • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> - • <i>Age:</i> - <p>Cognitive therapy</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> - • <i>Ethnic group:</i> - • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> - • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> - • <i>Age:</i> - <p>IPT waiting list</p> <ul style="list-style-type: none"> • <i>Gender (N male, % male, N female, % female):</i> - • <i>Ethnic group:</i> - • <i>Household income:</i> - • <i>Occupation/employment:</i> - • <i>Education level:</i> - • <i>Comorbid anxiety:</i> - • <i>Depression severity:</i> -

Zeiss 1979 (Continued)

- Age: -

BA waiting list

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: -
- Age: -

CT waiting list

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: -
- Age: -

Overall

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: 33% employed, 13% unemployed, 21% homemaker, 28% student, 4% retired
- Education level: mean 14.3 years
- Comorbid anxiety: -
- Depression severity: Moderate to severe
- Age: mean 33.9, range 19 TO 68

Included criteria: D equal to or greater than 70 and D > all other clinical scales (not Lie, Test-Taking Attitude, Masculinity and Femininity, Hypomania, or Social Introversion) on MMPI and one or more factor scores > 1.0 or mean factor score > 0.7 on Grinker interview rating

Excluded criteria: individuals who appeared to have a manic-depressive cycle were excluded from this study. Individuals currently in psychotherapy elsewhere were also excluded unless they chose to terminate the other therapy.

Pretreatment: no participant characteristics reported by study arm. Depression scores at baseline seem higher in the pleasant events group and lower in the cognitive group.

Interventions

Intervention characteristics

Interpersonal behaviour therapy

- *type of intervention:* comparator
- *specific intervention:* interpersonal therapy
- *dose:* -
- *frequency:* 12 sessions
- *duration:* 1 month
- *level of therapist:* professional (in training)
- *individual or group therapy:* individual

Zeiss 1979 (Continued)

- *mode of delivery*: face-to-face + homework
- *modifications*: -

Behavioural activation

- *type of intervention*: BA
- *specific intervention*: behavioural activation through increasing (enjoyment of) pleasant activities (Lewinsohn)
- *dose*: -
- *frequency*: 12 sessions
- *duration*: 1 month
- *level of therapist*: professional (in training)
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face + homework
- *modifications*: -

Cognitive therapy

- *type of intervention*: comparator
- *specific intervention*: cognitive therapy
- *dose*: -
- *frequency*: 12 sessions
- *duration*: 1 month
- *level of therapist*: professional (in training)
- *individual or group therapy*: individual
- *mode of delivery*: face-to-face + homework
- *modifications*: -

IPT waiting list

- *type of intervention*: comparator
- *specific intervention*: waiting list
- *dose*: -
- *frequency*: -
- *duration*: 1 month
- *level of therapist*: -
- *individual or group therapy*: -
- *mode of delivery*: -
- *modifications*: -

BA waiting list

- *type of intervention*: comparator
- *specific intervention*: waiting list
- *dose*: -
- *frequency*: -
- *duration*: 1 month
- *level of therapist*: -
- *individual or group therapy*: -
- *mode of delivery*: -
- *modifications*: -

CT waiting list

- *type of intervention*: comparator
- *specific intervention*: waiting list

Zeiss 1979 (Continued)

- *dose*: -
- *frequency*: -
- *duration*: 1 month
- *level of therapist*: -
- *individual or group therapy*: -
- *mode of delivery*: -
- *modifications*: -

Outcomes
Depression symptoms

- **Outcome type**: continuous outcome
- **Reporting**: partially reported
- **Scale**: MMPI Depression Scale
- **Direction**: lower is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: partially reported
- **Direction**: lower is better
- **Data value**: endpoint

Identification

Sponsorship source: supported in part by National Institute of Mental Health Grant MH24477

Country: USA

Setting: Outpatient, university of Oregon

Comments: -

Authors name: Antonette M Zeis

Institution: Arizona State University

Email: -

Address: Department of Psychology, Arizona State University, Tempe, Arizona 85281

Notes

Data not included in meta-analysis; not possible to estimate SD.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Depressed participants were randomly assigned to one of the three treatment projects, and they were randomly assigned to begin therapy either immediately or after a 1-month waiting period." Judgement comment: no information. Author could not be contacted.
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information. Author could not be contacted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: no blinding possible due to nature of interventions. This may lead to bias in estimates.

Zeiss 1979 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: unclear who assessors were. Author could not be contacted.
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: dropouts per study arm not clearly described. Five participants dropped out of waiting list groups; authors state this might be due to them seeking treatment elsewhere. This may mean that those who were less motivated to receive therapy remained in the study, which may bias results. 22/66 participants dropped out in total.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: no reference to protocol. Author could not be contacted.
Other bias	High risk	Judgement comment: <ul style="list-style-type: none"> • participant characteristics are not reported by study arm. • number of participants is small (66 across 6 study arms) and randomisation has resulted in differences in depression symptoms at baseline between study arms. • Peter Lewinsohn developed behavioural therapy as a standalone therapy; he may therefore have an interest in demonstrating its effectiveness.

Zemestani 2016
Study characteristics

Methods	Study design: randomised controlled trial Study grouping: parallel group Recruitment: at university Type of RCT (blind, double-blind, open-label): -
Participants	Baseline Characteristics Behavioural activation <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: - • Depression severity: BDI-II: 28.77 (SD 3.37) • Age: - Metacognitive therapy <ul style="list-style-type: none"> • Gender (N male, % male, N female, % female): - • Ethnic group: - • Household income: - • Occupation/employment: - • Education level: - • Comorbid anxiety: - • Depression severity: BDI-II: 29.28 (SD 3.24)

Zemestani 2016 (Continued)

- Age: -

Waiting list

- Gender (N male, % male, N female, % female): -
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: -
- Comorbid anxiety: -
- Depression severity: BDI-II: 29.35 (SD 3.56)
- Age: -

Overall

- Gender (N male, % male, N female, % female): 16 male (39%), 25 female (61%)
- Ethnic group: -
- Household income: -
- Occupation/employment: -
- Education level: 100% university students
- Comorbid anxiety: 4 panic disorder, 6 social phobia, 9 GAD
- Depression severity: all major depressive disorder
- Age: mean 24.2, range 18 to 30

Included criteria: Bachelor students at university, DSM-IV diagnosis of major depression (clinical interview), BDI-II > 19.

Excluded criteria: lifetime or current bipolar I or II disorder, schizophrenia, delusional disorder, brain injuries, OCD, PTSD, or Axis II disorders (SCID-II), alcohol or drug abuse or dependence within last six months, imminent risk of suicide or homicide, having a medical condition underlying depression, and use of psychotropic medications or involvement in concurrent psychotherapy.

Pretreatment: slightly lower depression score (BDI-II) for BA group than other groups and shorter duration of depressive episode for MCT group than other groups (statistical significance not reported)

Interventions

Intervention characteristics

Behavioural activation

- type of intervention: BA
- specific intervention: behavioural activation (Dimidjian/ Martell manual)
- dose: 90-minute sessions
- frequency: weekly
- duration: 8 sessions
- level of therapist: professional (in training)
- individual or group therapy: group
- mode of delivery: face-to-face
- modifications: -

Metacognitive therapy

- type of intervention: comparator
- specific intervention: metacognitive therapy (third-wave CBT, Wells manual)
- dose: 90 minute sessions
- frequency: weekly
- duration: 8 sessions
- level of therapist: professional (in training)
- individual or group therapy: group

Zemestani 2016 (Continued)

- *mode of delivery*: face-to-face
- *modifications*: -

Waiting list

- *type of intervention*: comparator
- *specific intervention*: waiting list
- *dose*: -
- *frequency*: -
- *duration*: -
- *level of therapist*: -
- *individual or group therapy*: -
- *mode of delivery*: -
- *modifications*: -

Outcomes

Depression symptoms

- **Outcome type**: Continuous outcome
- **Reporting**: fully reported
- **Scale**: BDI-II
- **Direction**: lower is better
- **Data value**: endpoint

Dropouts

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Direction**: lower is better
- **Data value**: endpoint

Anxiety symptoms

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Scale**: BAI
- **Direction**: lower is better
- **Data value**: endpoint

Identification

Sponsorship source: none reported

Country: Assumed to be Iran

Setting: university

Comments: -

Authors name: Medhi Zemestani

Institution: University of Kurdistan

Email: m.zemestan@gmail.com

Address: Department of Clinical Psychology, Faculty of Humanities & Social Sciences, University of Kurdistan, Sanandaj, Iran.

Notes

Risk of bias

Zemestani 2016 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Fifteen individuals were randomly allocated to each group (MCT, BA, and control). Random allocation was achieved by the use of a computer generated randomisation list without any attempt to match the groups." Judgement comment: computer-generated randomisation
Allocation concealment (selection bias)	High risk	Judgement comment: no information in study. Contact with author: researcher was aware of allocation list.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "treatments were delivered by a member of the research team, who was not blind to the hypotheses." Judgement comment: blinding not possible due to nature of interventions. This may lead to biased estimates.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: BDI-II and BAI self-reported. No attempt to blind outcome assessors reported for treatment acceptability
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "There were no dropouts," Judgement comment: no dropouts during treatment. 4 participants missed sessions, but were included in the ITT analysis.
Selective reporting (reporting bias)	Unclear risk	Quote: "The trial was not pre-registered in a clinical trial registry." Judgement comment: contact with author: retrospective trial registration (IRCT2013030912753N1), no protocol.
Other bias	Unclear risk	Quote: "Interventions were conducted by a PhD student in psychology who concluded a 2-year training in CBT and a 6-month training in MCT for depression." Judgement comment: therapist was first author and was reported to receive more training for one treatment than the other.

BA: Behavioural activation; **BA:** Behavioural activation; **BAL:** Behavioural Activation for Latinos; **BATD:** Behavioural Activation Treatment for Depression; **BDI:** Becks Depression Inventory; **CT:** cognitive therapy; **DSM:** Diagnostic and Statistical Manual of Mental Disorders; **GAD:** Generalised Anxiety Disorder; **GDS:** Geriatric Depression Scale; **HADS:** Hospital Anxiety and Depression Scale; **HAM:** Hamilton Anxiety Scale; **HRSd:** Hamilton Rating Scale for Depression; **ILPI:** Islamic lifestyle psychoeducational intervention; **ITT:** intention-to-treat; **MADRS:** Montgomery Asberg Depression Rating Scale; **MDD:** Major Depressive Disorder; **MMSE:** Mini-Mental State Examination; **OCD:** obsessive-compulsive disorder; **PHQ_9:** Patient Health Questionnaire; **SD:** standard deviation; **SE:** standard error; **SSRI:** serotonin reuptake inhibitor; **STAI:** State-Trait Anxiety Inventory; **VAS:** visual analogue scale; **WHOQL:** World Health Organization Quality of Life.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Almeida 2018	Inpatient population
Arjadi 2018a	Population < 18
Bagnall 2014	Postnatal/perinatal depression
Barrera 1979	Wrong comparator

Behavioural activation therapy for depression in adults (Review)

Study	Reason for exclusion
Cernin 2009	No (subthreshold) depression
Clignet 2012	Inpatient population
Dimidjian 2017	Postnatal/perinatal depression
Egede 2018	Wrong comparator
Farrand 2014	Wrong comparator
Gallagher 1983	>20% of dropouts replaced
Lambert 2018	Online only - no interaction with therapist
Luxton 2012	Wrong comparator
Ly 2015	Wrong comparator
Mausbach 2018	Online only - no interaction with therapist
McKendree Smith 2000	Online only - no interaction with therapist
McLean 1973	Couple therapy
McLean 1979	> 20% of dropouts replaced
Moss 2012	Online only - no interaction with therapist
Pentecost 2015	Wrong comparator
Rehm 1981	Wrong comparator
Shapiro 1974	Inpatient population
Soucy 2018	Online only - no interaction with therapist
Stein 2017	Wrong comparator
Turner 1979	Wrong comparator
Watkins 2016	Wrong comparator

Characteristics of studies awaiting classification *[ordered by study ID]*

Bolin 1974

Methods	Unclear
Participants	Unclear
Interventions	Unclear; behaviour modification techniques.
Outcomes	Unclear; relating to mental health.

Bolin 1974 *(Continued)*

Notes	No full-text could be obtained. No contact details.
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Bollenbach 1983

Methods	RCT
Participants	Self-referred depressed students (experiment 1)
Interventions	Unclear; possibly only the cognitive components of CBT
Outcomes	Depression symptoms (experiment 1)
Notes	Conference abstract. No contact details.

Central South University

Methods	RCT
Participants	Rural left behind elderly with GDS score between 11 and 25
Interventions	Behavioural activation and control (enhanced usual care)
Outcomes	Primary: depression (GDS)
Notes	No contact details. Unclear whether trial has been completed.

Jalili 2014

Methods	RCT
Participants	University students with depressive symptoms
Interventions	Behavioural activation and control
Outcomes	Depressive symptoms, dysfunctional attitudes
Notes	Awaiting Persian translation.

Naeem 2015

Methods	Pilot RCT
Participants	Adults with depression
Interventions	ACE-4 behavioural activation + treatment as usual and treatment as usual
Outcomes	Primary: anxiety and depression (HADS). Secondary: Clinical Outcome in Routine Evaluation (CORE), Brief Disability Questionnaire (BDQ).

Naeem 2015 *(Continued)*

Notes	No results published yet (personal correspondence with author F Naeem)
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Pace 1978

Methods	RCT
Participants	Primary unipolar depressed females (study 2/3)
Interventions	Unclear; Sensory Awareness Training, Relaxation Training, control (study 2) and Relaxation Training versus Task Assignment (study 3) and possibly waiting list and Client-Oriented Therapy.
Outcomes	Depression
Notes	Dissertation. ProQuest Dissertations and Theses Global: "This graduate work is not available to view or purchase". No author contact details.

Steffen 1998

Methods	RCT
Participants	Women with major depressive disorder
Interventions	Pleasant events class or problem-solving skills
Outcomes	Diagnosis, emotional distress.
Notes	Paper is based on two studies; one is an RCT of BA. Original trial of BA could not be identified.

Weiss 2010

Methods	Unclear; possibly RCT.
Participants	Adults with depression
Interventions	Behavioural activation + medication and medication
Outcomes	Primary: PHQ-9. Secondary: anxiety symptoms (GAD-7), physical health (SF-12), mental health (SF-12), BADS, substantial improvement PHQ-9, depression remission (PHQ-9).
Notes	Contacted author to enquire whether results have been published.

BA: Behavioural activation; **GAD-7:** Generalised Anxiety Disorder; **GDS:** Geriatric Depression Scale; **HADS:** Hospital Anxiety and Depression Scale; **PHQ_9:** Patient Health Questionnaire; **RCT:** randomised controlled trial; **SF-12:** Short Form.

Characteristics of ongoing studies *[ordered by study ID]*

Almeida 2016

Study name	Randomised controlled trial to determine whether a greater proportion of older people with major depression living in remote and regional Western Australia who receive a behavioural activation intervention experience remission of the depressive episode, compared with usual care.
Methods	RCT
Participants	Depressed older adults living in regional and remote areas in Western Australia
Interventions	Behavioural activation and usual care
Outcomes	Remission of symptoms at 12 weeks
Starting date	Unclear
Contact information	Professor Osvaldo Almeida: osvaldo.almeida@uwa.edu.au
Notes	No results published yet.

Banerjee 2019

Study name	Cognitive control training for depression
Methods	RCT
Participants	Adults with major depressive disorder
Interventions	Cognitive control training and behavioural activation
Outcomes	BDI, CGI, Spatial Span, Digit Span
Starting date	October 2017
Contact information	Ms Meenakshi Banerjee; meenakshi.banerjee@gmail.com
Notes	Estimated to be completed in October 2019

Botella 2015

Study name	Efficacy of two internet delivered intervention programs for depression: behavioral activation vs physical activity (PROMETEOII)
Methods	RCT
Participants	Adults with major depressive disorder and adjustment disorder with depressive symptomatology
Interventions	Behavioural activation, physical activity, and waiting list
Outcomes	Primary: PHQ-9 and BDI. Secondary: EQ-5D-5L, QLI, OASIS, PANAS, Happiness Scale, Satisfaction with Life Scale, Ryff Scale of Psychological Wellbeing, BADS-SF, EROS, BDI-II
Starting date	April 2018

Botella 2015 *(Continued)*

Contact information	Christina Botella: botalla@uji.es
Notes	Estimated completion date February 2019 (trial registry)

Daphne 2017

Study name	Development and testing of a behavioral activation mobile therapy for elevated depressive systems
Methods	RCT
Participants	Adults with elevated depressive symptoms
Interventions	Moodivate (behavioural activation), CBT, and treatment as usual
Outcomes	Primary: BDI. Secondary: client treatment adherence, user feasibility and acceptability, PANAS, EROS, POMS, BADS, SHAPS, BAI, ASI, FTND, timeline follow back (drug/tobacco use), contemplation ladder (tobacco use).
Starting date	1 June 2016
Contact information	Carl W. Lejuez, Professor, University of Maryland, College Park
Notes	

Haynes 2018

Study name	Reducing depressive symptoms among rural African Americans (REJOICE)
Methods	Cross-over RCT
Participants	African-American adults with mild to moderate depression
Interventions	REJOICE (behavioural activation) and usual care (educational materials)
Outcomes	Primary: depression symptoms (BDI)
Starting date	May 2016
Contact information	Tiffany F Haynes, tfhaynes@uams.edu
Notes	Estimated completion date April 2021 (trial registration)

Isometsä 2016

Study name	Effectiveness of add-on group behavioral activation treatment for depression in psychiatric care
Methods	RCT
Participants	Adults with major depressive disorder

Behavioural activation therapy for depression in adults (Review)

Isometsä 2016 *(Continued)*

Interventions	Behavioural activation, usual care (talking therapy and antidepressant medication), and peer support
Outcomes	Primary: depression symptoms (PHQ-9) at 8 weeks. Secondary: response, remission, functional impairment, depression score at 6 months.
Starting date	18/01/2016
Contact information	Professor Erkki Isometsä: erkki.isometsa@helsinki.fi
Notes	Estimated publication early 2020 (personal correspondence)

Janssen 2017

Study name	Behavioural activation delivered by mental health nurses versus treatment as usual for late-life depression in primary care.
Methods	RCT
Participants	Older adults with PHQ-9 score > 9
Interventions	Behavioural activation and treatment as usual
Outcomes	Primary: depression severity (Q-IDS). Secondary: EQ-5D-5L and TiC-P (cost-effectiveness)
Starting date	7 January 2016
Contact information	GJ Hendriks: ghendriks@ggznijmegen.nl
Notes	Data expected in Autumn 2020 (personal correspondence)

Massoudi 2017

Study name	BLENDING: Blended care vs. usual care in the treatment of depressive symptoms and disorders in general practice
Methods	RCT
Participants	Adults with depressive disorder or symptoms of depression
Interventions	Online + face-to-face self-management through behavioural activation and care as usual
Outcomes	Primary: depression symptoms at 3 months. Secondary: depression symptoms at 12 months, response, remission, antidepressant use, use of other psychotropics, functional impairment, health care utilisation, general health status, treatment satisfaction, Ecological Momentary Assessment.
Starting date	September 2014
Contact information	Dr H Burger: H.Burger@rug.nl
Notes	

Ruzickova 2019

Study name	Effects of behavioural activation on emotional cognition and mood
Methods	RCT
Participants	Low mood
Interventions	Behavioural activation, active monitoring, and waiting list
Outcomes	Emotional attention and memory, depression severity, environmental rewards, social support
Starting date	-
Contact information	Tereza Ruzickova
Notes	

Sakai 2017

Study name	Randomised controlled trial of behavioral activation group therapy for depression in undergraduate students
Methods	RCT
Participants	Undergraduate students with depression
Interventions	Behavioural activation group therapy and no treatment
Outcomes	Primary: PHQ-9. Secondary: BDI, BADS, Reward Probability Index, Work and Social Adjustment Scale, WHO Quality of Life 26
Starting date	April 2018
Contact information	Tatsuya Yamamoto: tatsuya@lets.chukyo-u.ac.jp
Notes	

Samaan 2014

Study name	A pilot study to assess the effectiveness of Behavioural Activation group program in patients with depression: BRAVE (BRAVE)
Methods	Pilot study including RCT
Participants	Adults with a diagnosis of major depressive disorder.
Interventions	Behavioural activation and support group (enhanced usual care)
Outcomes	Primary: recruitment and retention, data completion, resource utilisation. Secondary: qualitative study feedback, EQ-5D-5L feasibility.

Samaan 2014 *(Continued)*

Starting date	March 2014
Contact information	Zainab Samaan (Zena), Assistant Professor, St. Joseph's Healthcare Hamilton
Notes	

Schaich 2018

Study name	Metacognitive therapy vs. behavioral activation a single-center randomized clinical trial (PRO*MDD)
Methods	RCT
Participants	People with major depressive disorder
Interventions	Behavioural activation and metacognitive therapy
Outcomes	Primary: depression severity (HRSD). Secondary: quality of life, psychosocial functioning and participation, comorbidity.
Starting date	September 2016
Contact information	Eva Faßbinder: eva.fassbinder@uksh.de
Notes	

University of Pennsylvania 2016

Study name	Feasibility of a behavioral activation trial
Methods	RCT
Participants	Adults with major depressive disorder
Interventions	Behavioural activation and treatment as usual (psychotherapy and medication)
Outcomes	Primary: patients refusing randomisation, patients completing 9 sessions, homework completed, monthly assessments obtained, opinions about treatment, Brief Alliance Inventory. Secondary outcomes available in trial registration.
Starting date	March 2016
Contact information	University of Pennsylvania, Philadelphia, Pennsylvania, United States, 19104
Notes	Estimated completion date April 2020 (trial registry)

VA Office of Research and Development 2014

Study name	Improving mood in veterans in primary care
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VA Office of Research and Development 2014 (Continued)

Methods	RCT
Participants	Veterans with depressive symptoms
Interventions	Brief behavioural activation and usual care
Outcomes	Primary: depression symptoms at 12 weeks. Secondary: quality of life, sleep disturbances, EROS, suicidal ideation.
Starting date	March 2015
Contact information	Jennifer Schum Funderburk, PhD
Notes	Data have added to online trial registration record after data extraction for this review finished.

Velasquez Reyes 2019

Study name	Behavioural activation in nursing homes to treat depression (BAN-Dep)
Methods	Cluster-RCT
Participants	Nursing home residents with depressive symptoms
Interventions	Behavioural activation + Beyondblue Professional Education to aged care and Beyondblue Professional Education to Aged Care
Outcomes	PHQ-9, GAD-7, Montreal Cognitive Assessment, SF-12, DeJong Gierveld Loneliness Scale, LSNS-6, KLLD-R
Starting date	-
Contact information	Professor Osvaldo P Almeida; osvaldo.almeida@uwa.edu.au
Notes	Estimated to be completed in 2022

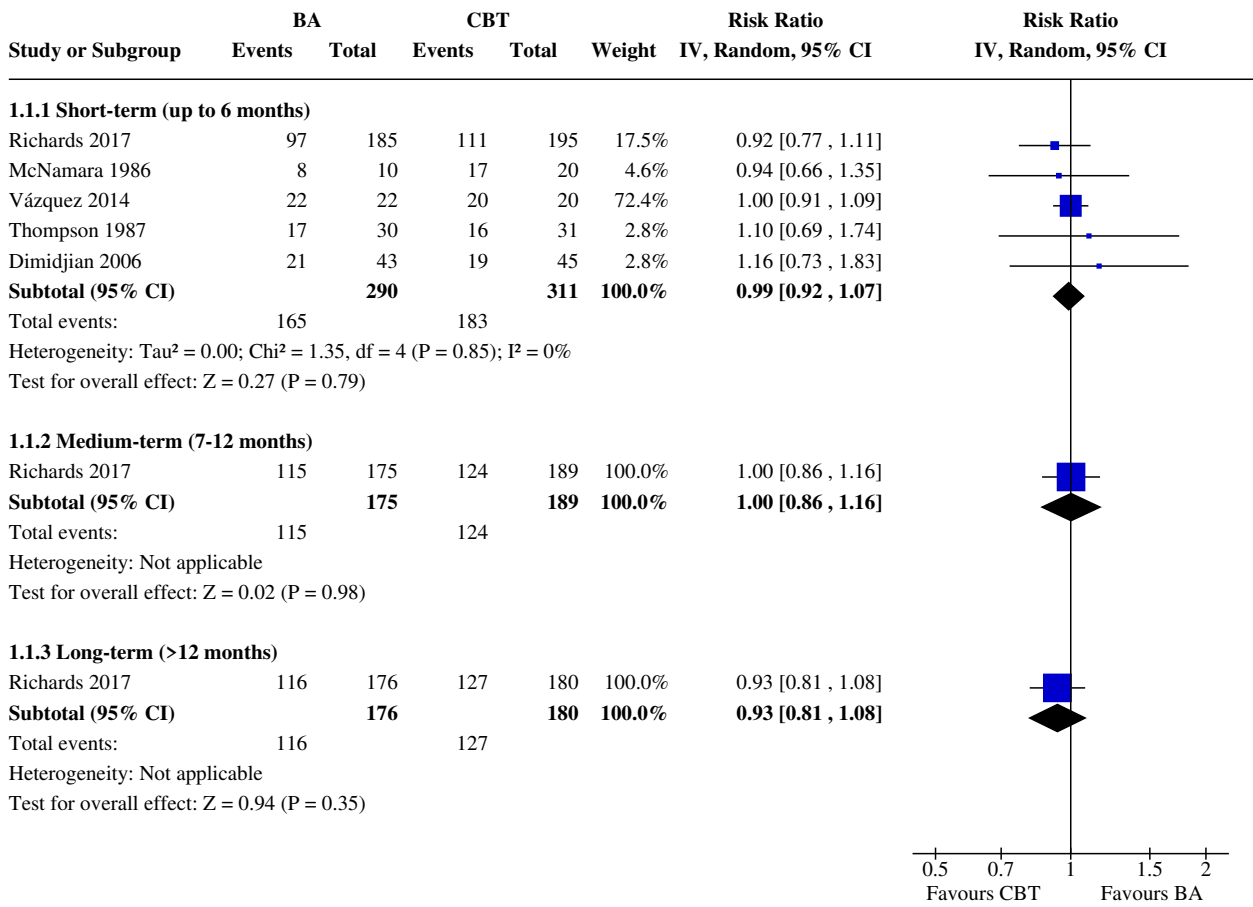
BA: Behavioural activation; **BAI:** Beck Anxiety Inventory; **BDI:** Beck Depression Inventory; **CBT:** cognitive-behavioural therapy; **GAD-7:** Generalised Anxiety Disorder; **PANAS:** Positive and Negative Affect Schedule; **PHQ_9:** Patient Health Questionnaire; **RCT:** randomised controlled trial; **WHO:** World Health Organization.

DATA AND ANALYSES
Comparison 1. behavioural activation vs CBT

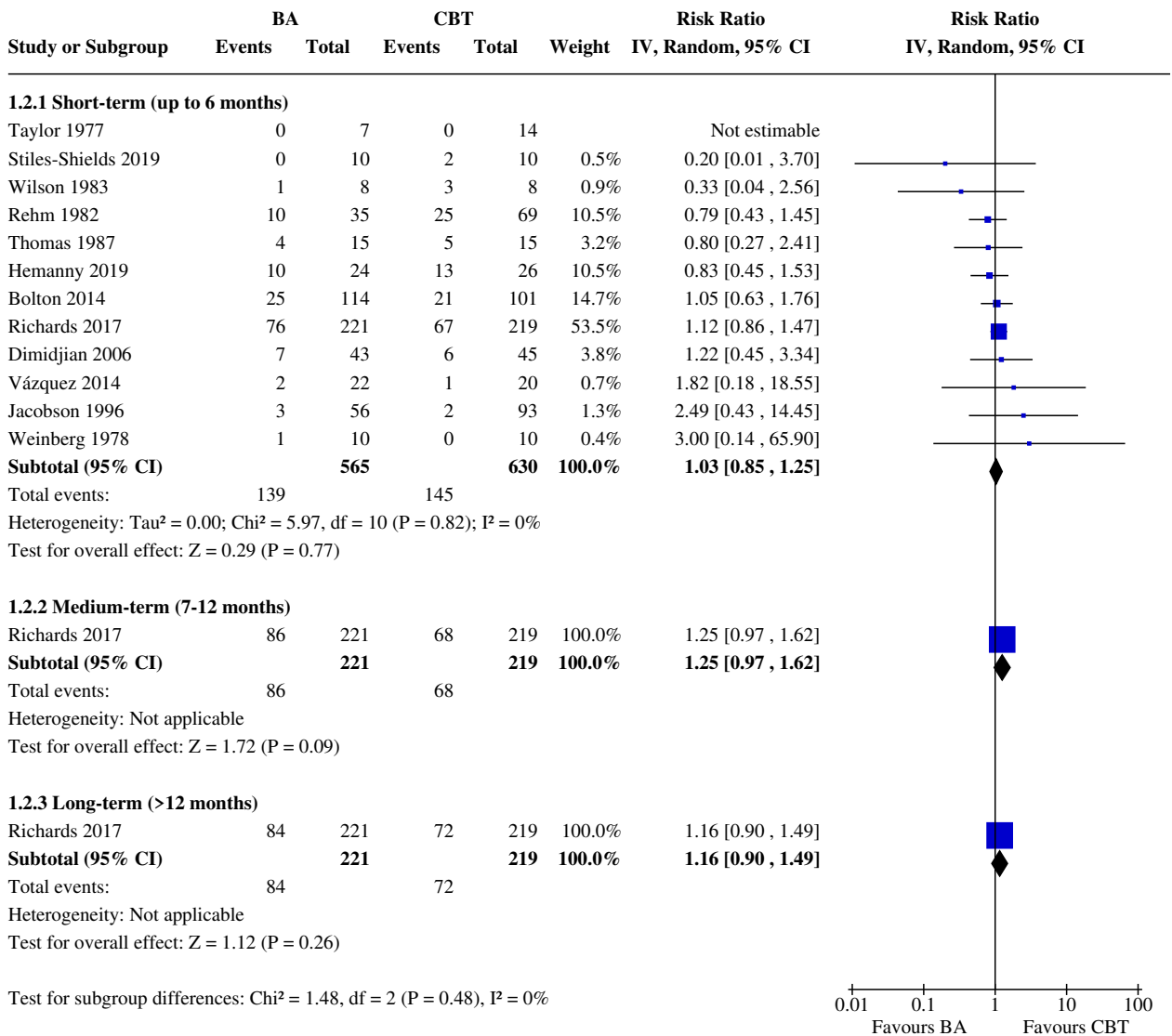
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 treatment efficacy	5		Risk Ratio (IV, Random, 95% CI)	Subtotals only
1.1.1 Short-term (up to 6 months)	5	601	Risk Ratio (IV, Random, 95% CI)	0.99 [0.92, 1.07]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1.2 Medium-term (7-12 months)	1	364	Risk Ratio (IV, Random, 95% CI)	1.00 [0.86, 1.16]
1.1.3 Long-term (>12 months)	1	356	Risk Ratio (IV, Random, 95% CI)	0.93 [0.81, 1.08]
1.2 treatment acceptability (dropouts)	12		Risk Ratio (IV, Random, 95% CI)	Subtotals only
1.2.1 Short-term (up to 6 months)	12	1195	Risk Ratio (IV, Random, 95% CI)	1.03 [0.85, 1.25]
1.2.2 Medium-term (7-12 months)	1	440	Risk Ratio (IV, Random, 95% CI)	1.25 [0.97, 1.62]
1.2.3 Long-term (>12 months)	1	440	Risk Ratio (IV, Random, 95% CI)	1.16 [0.90, 1.49]
1.3 depression symptoms	16		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.3.1 Short-term (up to 6 months)	16	1205	Std. Mean Difference (IV, Random, 95% CI)	0.12 [-0.08, 0.32]
1.3.2 Medium-term (7-12 months)	1	380	Std. Mean Difference (IV, Random, 95% CI)	-0.18 [-0.38, 0.02]
1.3.3 Long-term (>12 months)	1	364	Std. Mean Difference (IV, Random, 95% CI)	0.00 [-0.21, 0.21]
1.4 quality of life	2		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.4.1 Short-term (up to 6 months)	2	268	Std. Mean Difference (IV, Random, 95% CI)	0.04 [-0.20, 0.28]
1.4.2 Medium-term (7-12 months)	1	318	Std. Mean Difference (IV, Random, 95% CI)	0.15 [-0.07, 0.37]
1.4.3 Long-term (>12 months)	1	327	Std. Mean Difference (IV, Random, 95% CI)	0.06 [-0.15, 0.28]
1.5 social adjustment and functioning	2		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.5.1 Short-term (up to 6 months)	2	111	Std. Mean Difference (IV, Random, 95% CI)	-0.13 [-0.50, 0.24]
1.6 anxiety symptoms	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.6.1 Short-term (up to 6 months)	4	646	Std. Mean Difference (IV, Random, 95% CI)	-0.03 [-0.18, 0.13]
1.6.2 Medium-term (7-12 months)	1	337	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.20, 0.23]
1.6.3 Long-term (>12 months)	1	332	Std. Mean Difference (IV, Random, 95% CI)	-0.10 [-0.31, 0.12]

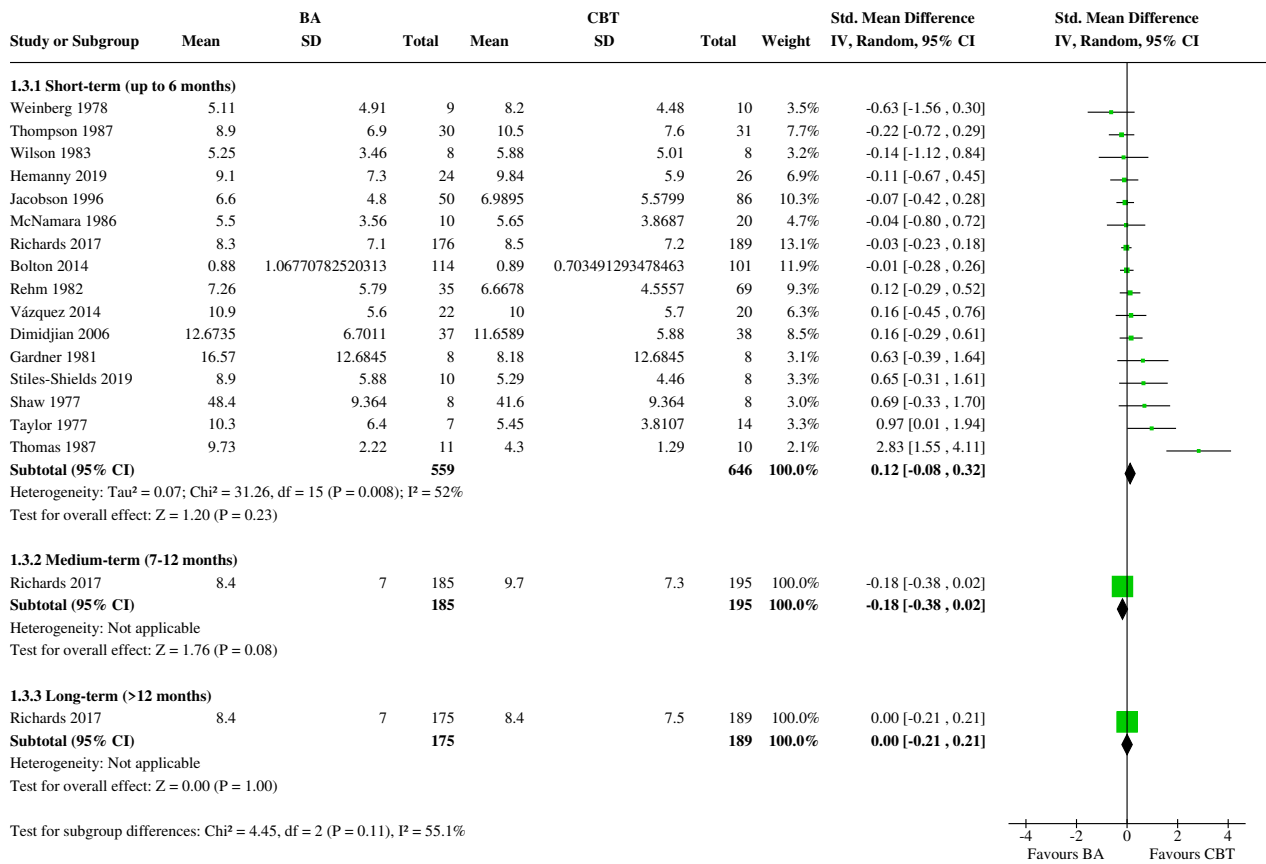
Analysis 1.1. Comparison 1: behavioural activation vs CBT, Outcome 1: treatment efficacy



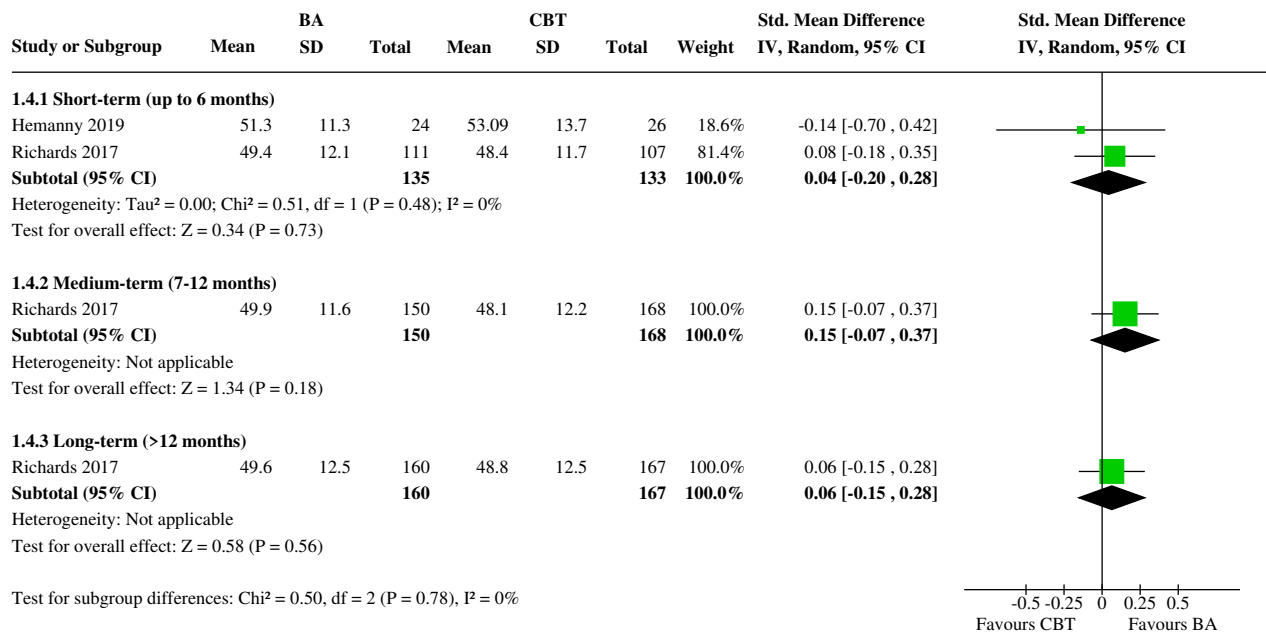
Analysis 1.2. Comparison 1: behavioural activation vs CBT, Outcome 2: treatment acceptability (dropouts)



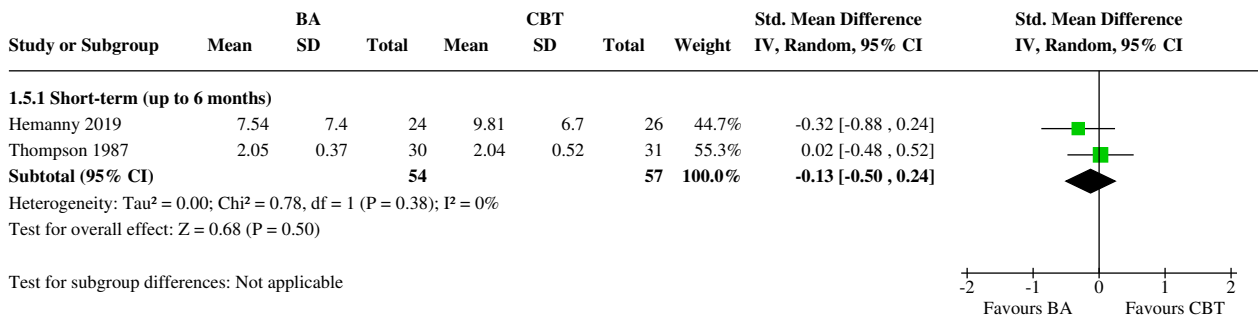
Analysis 1.3. Comparison 1: behavioural activation vs CBT, Outcome 3: depression symptoms



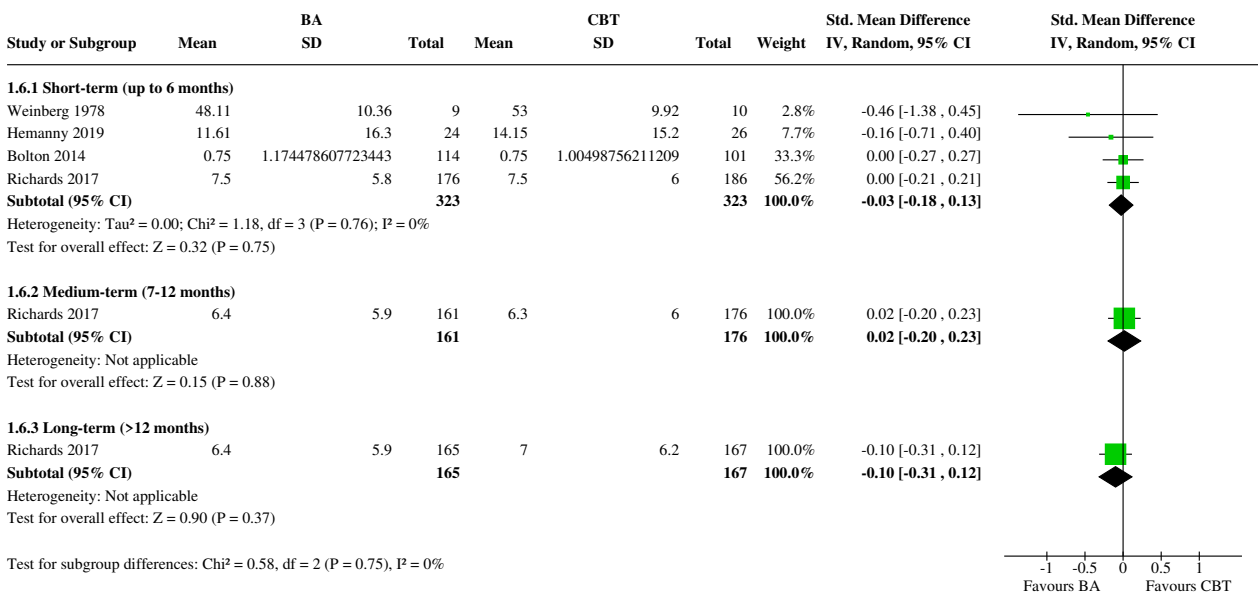
Analysis 1.4. Comparison 1: behavioural activation vs CBT, Outcome 4: quality of life



Analysis 1.5. Comparison 1: behavioural activation vs CBT, Outcome 5: social adjustment and functioning



Analysis 1.6. Comparison 1: behavioural activation vs CBT, Outcome 6: anxiety symptoms

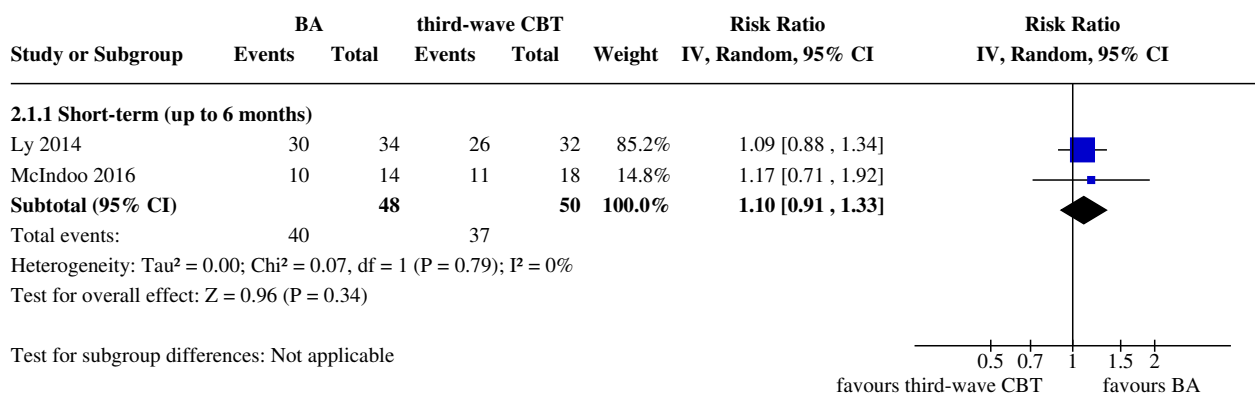


Comparison 2. behavioural activation vs third-wave CBT

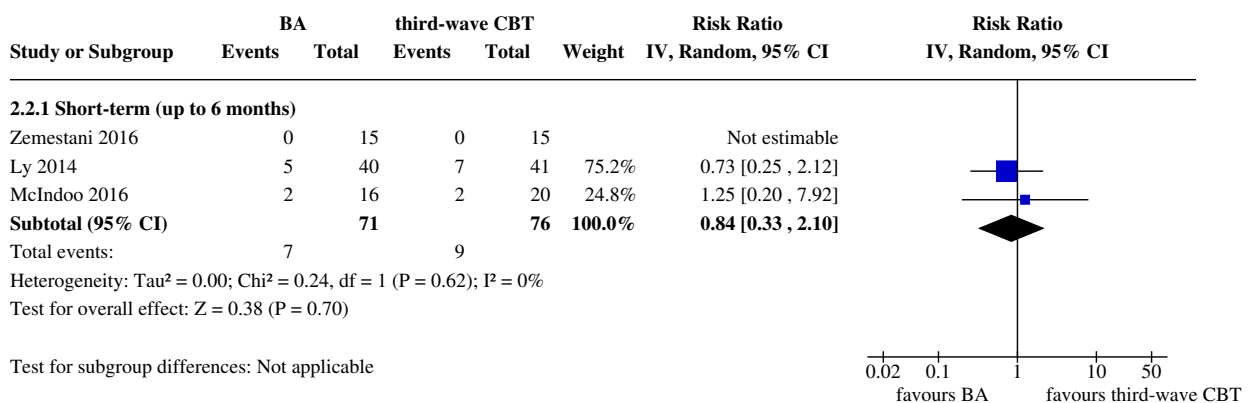
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 treatment efficacy	2		Risk Ratio (IV, Random, 95% CI)	Subtotals only
2.1.1 Short-term (up to 6 months)	2	98	Risk Ratio (IV, Random, 95% CI)	1.10 [0.91, 1.33]
2.2 treatment acceptability (dropouts)	3		Risk Ratio (IV, Random, 95% CI)	Subtotals only
2.2.1 Short-term (up to 6 months)	3	147	Risk Ratio (IV, Random, 95% CI)	0.84 [0.33, 2.10]
2.3 depression symptoms	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.3.1 Short-term (up to 6 months)	3	147	Std. Mean Difference (IV, Random, 95% CI)	-0.14 [-0.47, 0.18]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.4 quality of life	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.4.1 Short-term (up to 6 months)	1	81	Mean Difference (IV, Random, 95% CI)	0.02 [-0.96, 1.00]
2.5 anxiety symptoms	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.5.1 Short-term (up to 6 months)	3	147	Mean Difference (IV, Random, 95% CI)	0.69 [-0.68, 2.06]

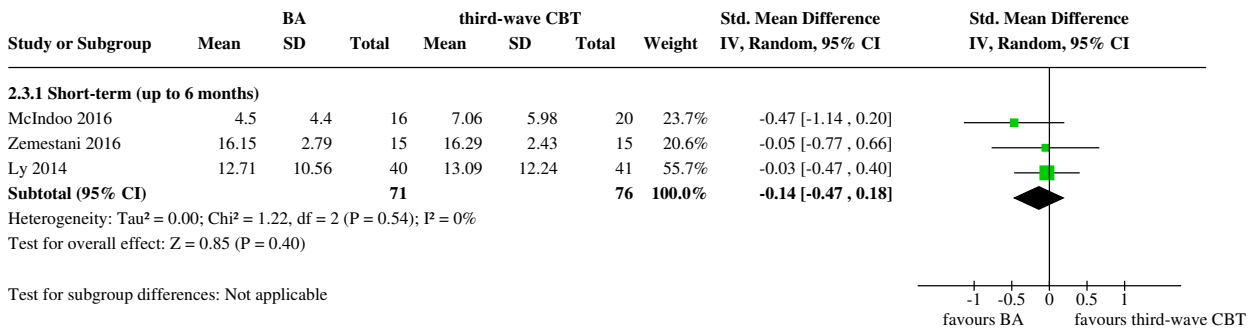
Analysis 2.1. Comparison 2: behavioural activation vs third-wave CBT, Outcome 1: treatment efficacy



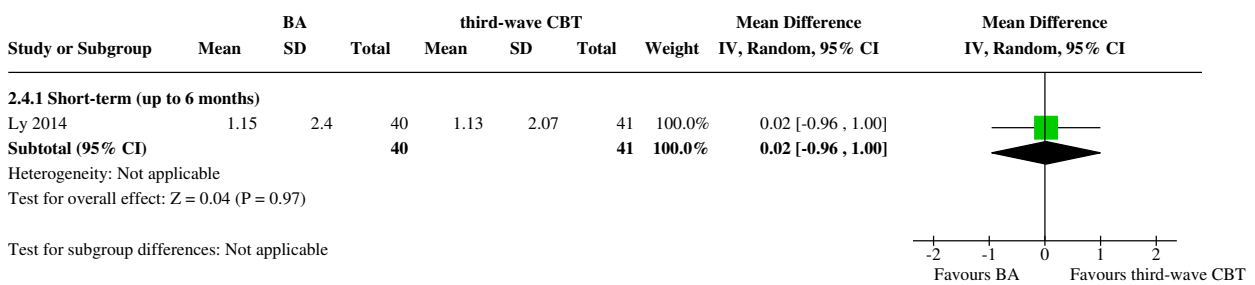
Analysis 2.2. Comparison 2: behavioural activation vs third-wave CBT, Outcome 2: treatment acceptability (dropouts)



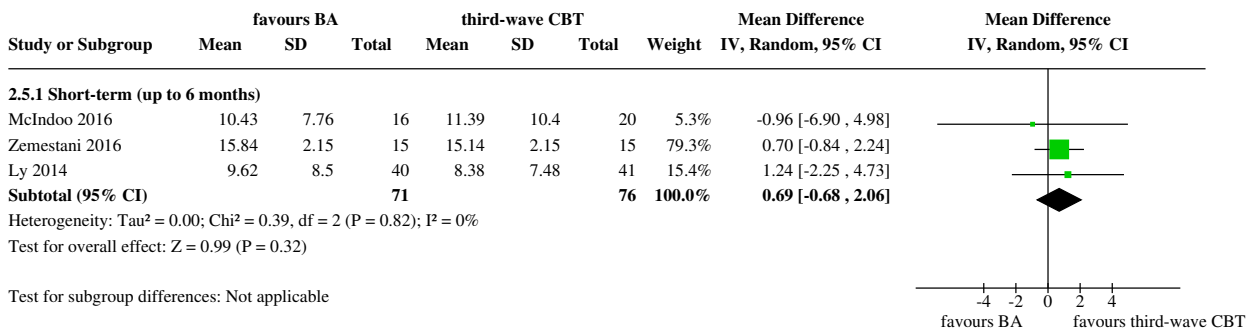
Analysis 2.3. Comparison 2: behavioural activation vs third-wave CBT, Outcome 3: depression symptoms



Analysis 2.4. Comparison 2: behavioural activation vs third-wave CBT, Outcome 4: quality of life



Analysis 2.5. Comparison 2: behavioural activation vs third-wave CBT, Outcome 5: anxiety symptoms

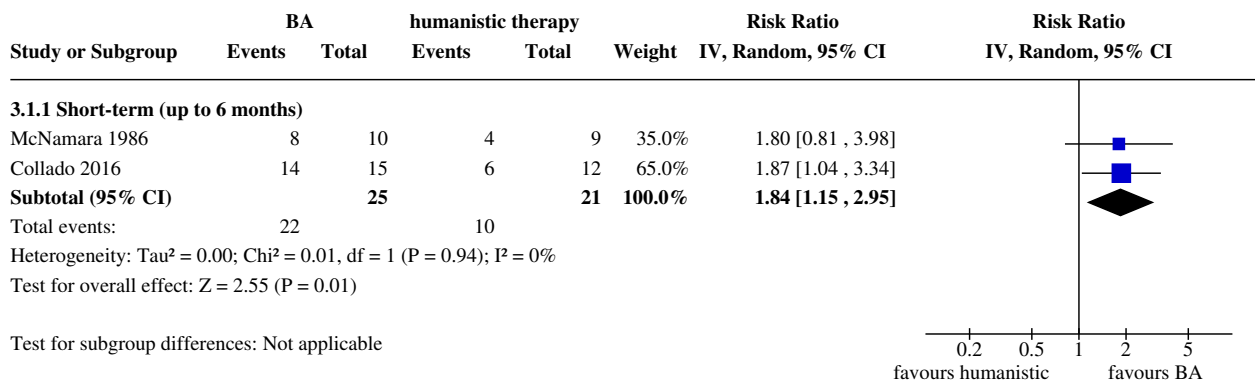


Comparison 3. behavioural activation vs humanistic therapy

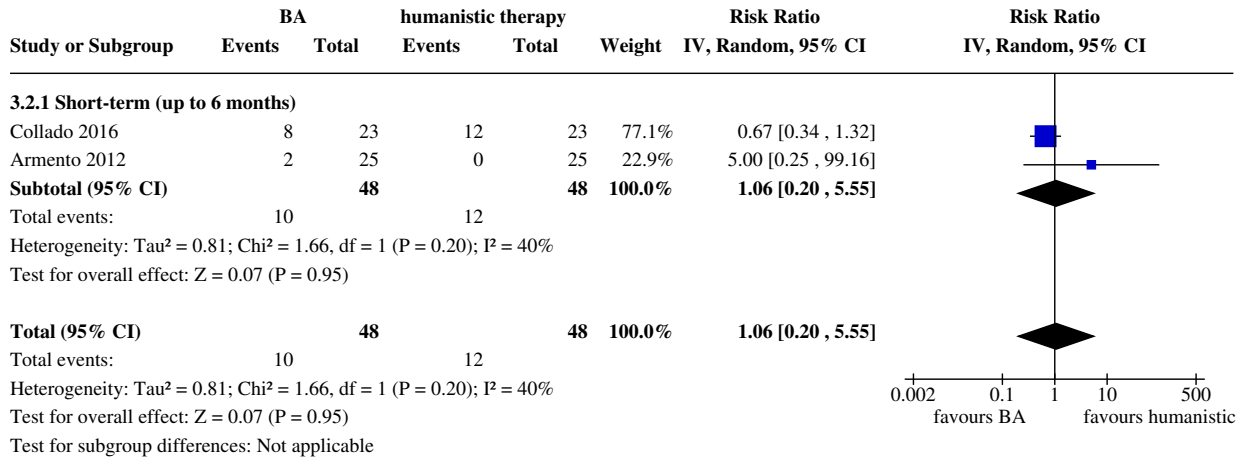
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 treatment efficacy	2		Risk Ratio (IV, Random, 95% CI)	Subtotals only
3.1.1 Short-term (up to 6 months)	2	46	Risk Ratio (IV, Random, 95% CI)	1.84 [1.15, 2.95]
3.2 treatment acceptability (dropouts)	2	96	Risk Ratio (IV, Random, 95% CI)	1.06 [0.20, 5.55]
3.2.1 Short-term (up to 6 months)	2	96	Risk Ratio (IV, Random, 95% CI)	1.06 [0.20, 5.55]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.3 depression symptoms	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
3.3.1 Short-term (up to 6 months)	3	93	Mean Difference (IV, Random, 95% CI)	-3.75 [-6.72, -0.78]
3.4 quality of life	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
3.4.1 Short-term (up to 6 months)	1	50	Mean Difference (IV, Random, 95% CI)	0.80 [-0.12, 1.72]
3.5 anxiety symptoms	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
3.5.1 Short-term (up to 6 months)	1	50	Mean Difference (IV, Random, 95% CI)	-1.30 [-6.10, 3.50]

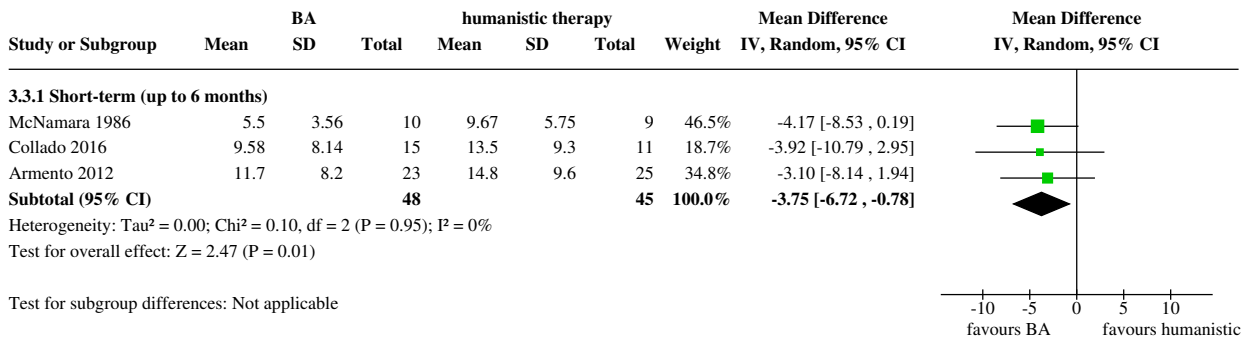
Analysis 3.1. Comparison 3: behavioural activation vs humanistic therapy, Outcome 1: treatment efficacy



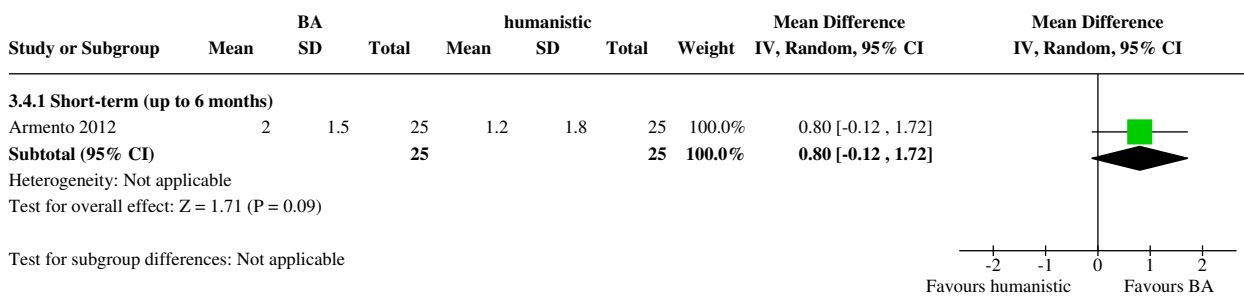
Analysis 3.2. Comparison 3: behavioural activation vs humanistic therapy, Outcome 2: treatment acceptability (dropouts)



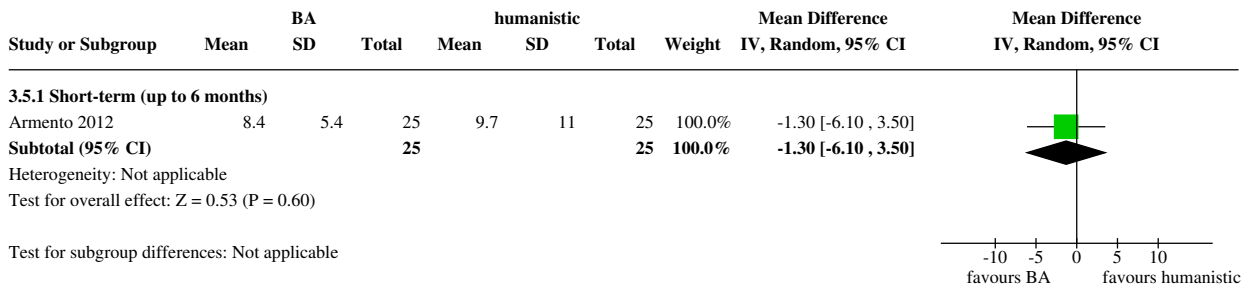
Analysis 3.3. Comparison 3: behavioural activation vs humanistic therapy, Outcome 3: depression symptoms



Analysis 3.4. Comparison 3: behavioural activation vs humanistic therapy, Outcome 4: quality of life



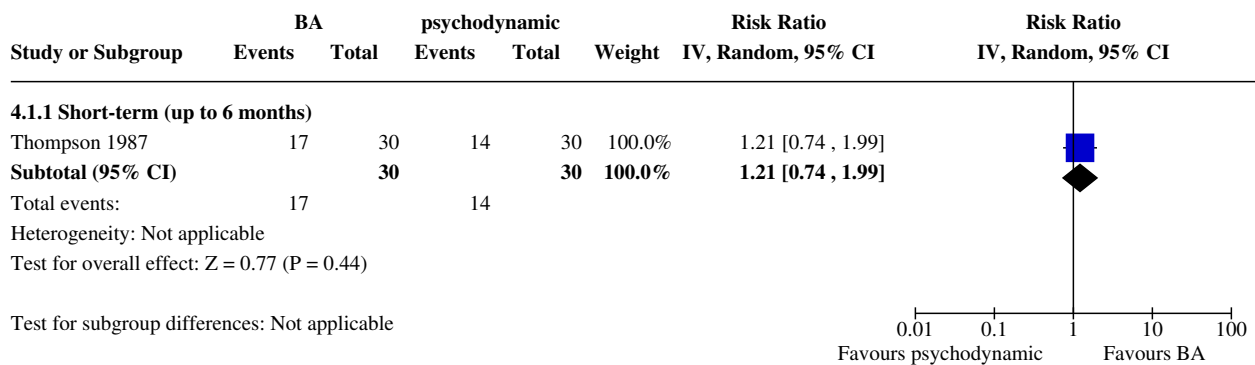
Analysis 3.5. Comparison 3: behavioural activation vs humanistic therapy, Outcome 5: anxiety symptoms



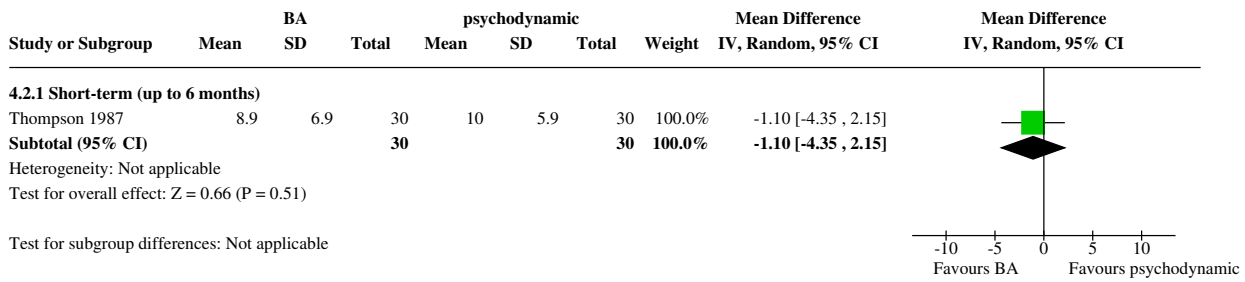
Comparison 4. behavioural activation vs psychodynamic

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 treatment efficacy	1		Risk Ratio (IV, Random, 95% CI)	Subtotals only
4.1.1 Short-term (up to 6 months)	1	60	Risk Ratio (IV, Random, 95% CI)	1.21 [0.74, 1.99]
4.2 depression symptoms	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.2.1 Short-term (up to 6 months)	1	60	Mean Difference (IV, Random, 95% CI)	-1.10 [-4.35, 2.15]
4.3 social adjustment and functioning	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.3.1 Short-term (up to 6 months)	1	60	Mean Difference (IV, Random, 95% CI)	2.10 [-4.92, 9.12]

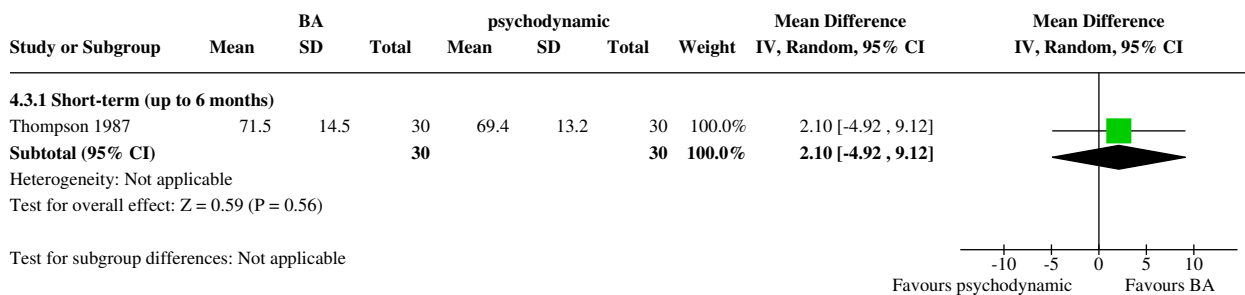
Analysis 4.1. Comparison 4: behavioural activation vs psychodynamic, Outcome 1: treatment efficacy



Analysis 4.2. Comparison 4: behavioural activation vs psychodynamic, Outcome 2: depression symptoms



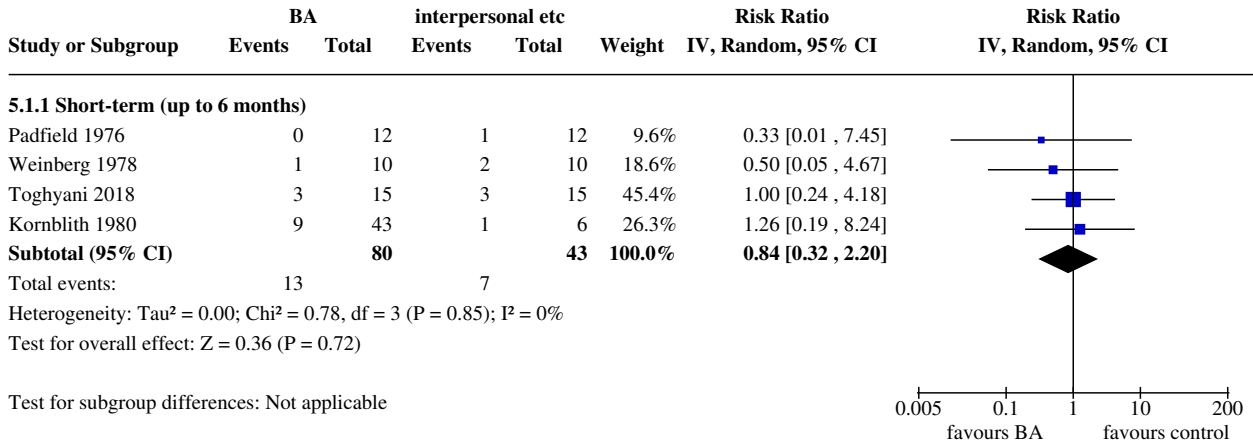
Analysis 4.3. Comparison 4: behavioural activation vs psychodynamic, Outcome 3: social adjustment and functioning



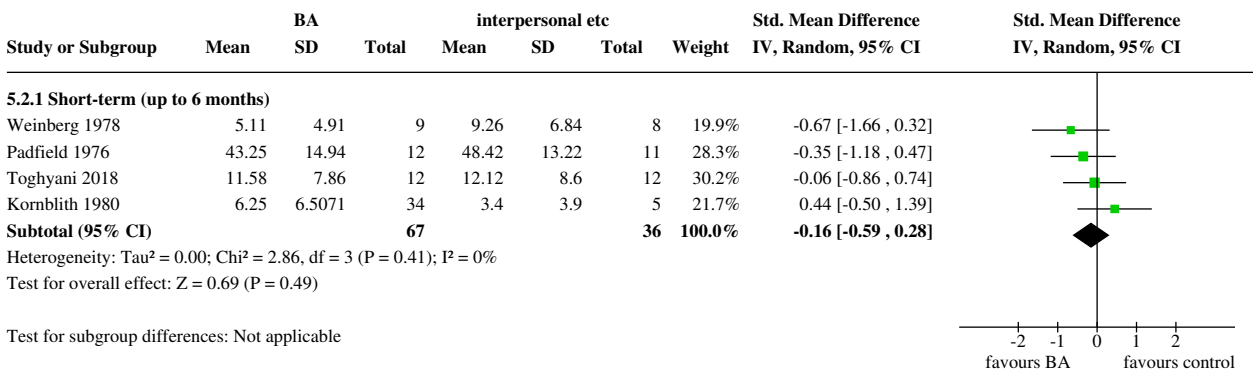
Comparison 5. behavioural activation vs interpersonal, cognitive analytic, integrative

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 treatment acceptability (dropouts)	4		Risk Ratio (IV, Random, 95% CI)	Subtotals only
5.1.1 Short-term (up to 6 months)	4	123	Risk Ratio (IV, Random, 95% CI)	0.84 [0.32, 2.20]
5.2 depression symptoms	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
5.2.1 Short-term (up to 6 months)	4	103	Std. Mean Difference (IV, Random, 95% CI)	-0.16 [-0.59, 0.28]
5.3 social adjustment and functioning	1	39	Mean Difference (IV, Random, 95% CI)	-3.92 [-16.78, 8.93]
5.3.1 Short-term (up to 6 months)	1	39	Mean Difference (IV, Random, 95% CI)	-3.92 [-16.78, 8.93]
5.4 anxiety symptoms	1	15	Mean Difference (IV, Fixed, 95% CI)	-0.39 [-11.78, 11.00]
5.4.1 Short-term (up to 6 months)	1	15	Mean Difference (IV, Fixed, 95% CI)	-0.39 [-11.78, 11.00]

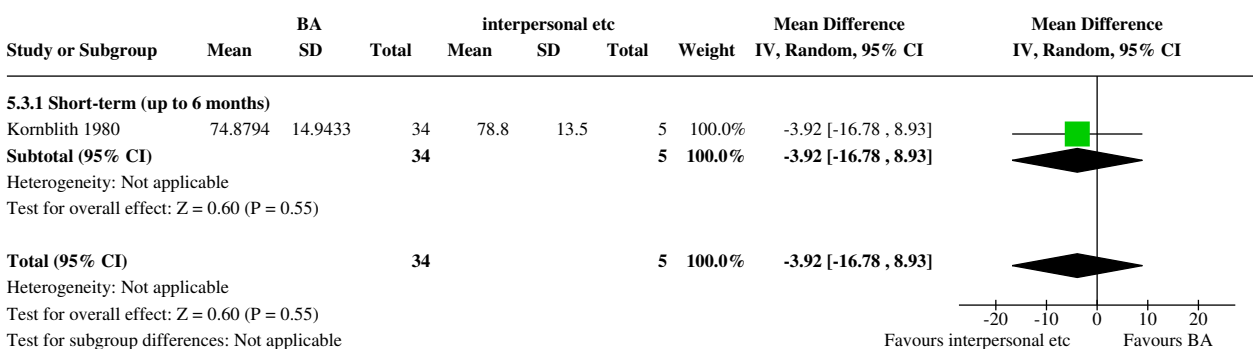
Analysis 5.1. Comparison 5: behavioural activation vs interpersonal, cognitive analytic, integrative, Outcome 1: treatment acceptability (dropouts)



Analysis 5.2. Comparison 5: behavioural activation vs interpersonal, cognitive analytic, integrative, Outcome 2: depression symptoms



Analysis 5.3. Comparison 5: behavioural activation vs interpersonal, cognitive analytic, integrative, Outcome 3: social adjustment and functioning



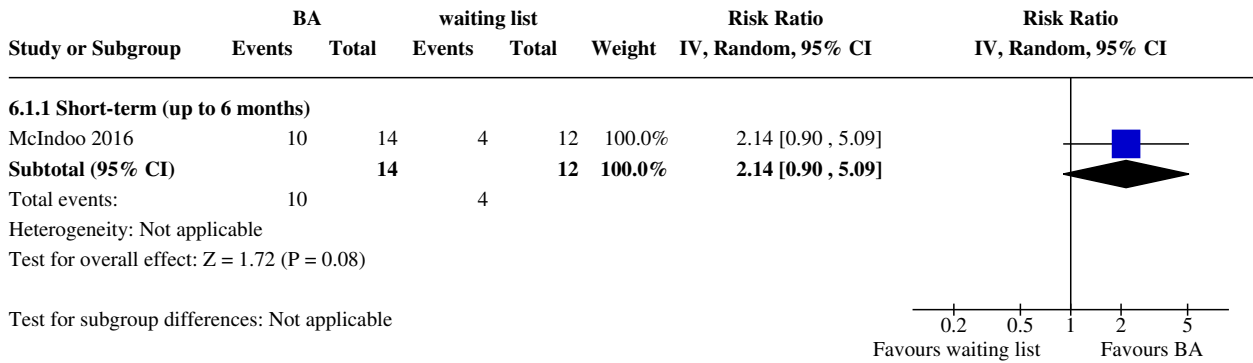
Analysis 5.4. Comparison 5: behavioural activation vs interpersonal, cognitive analytic, integrative, Outcome 4: anxiety symptoms

Study or Subgroup	behavioural activation			comparator			Weight	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
	Mean	SD	Total	Mean	SD	Total			
5.4.1 Short-term (up to 6 months)									
Weinberg 1978	48.11	10.36	7	48.5	12.15	8	100.0%	-0.39 [-11.78, 11.00]	
Subtotal (95% CI)			7			8	100.0%	-0.39 [-11.78, 11.00]	
Heterogeneity: Not applicable Test for overall effect: Z = 0.07 (P = 0.95)									
Total (95% CI)									
Heterogeneity: Not applicable Test for overall effect: Z = 0.07 (P = 0.95) Test for subgroup differences: Not applicable									

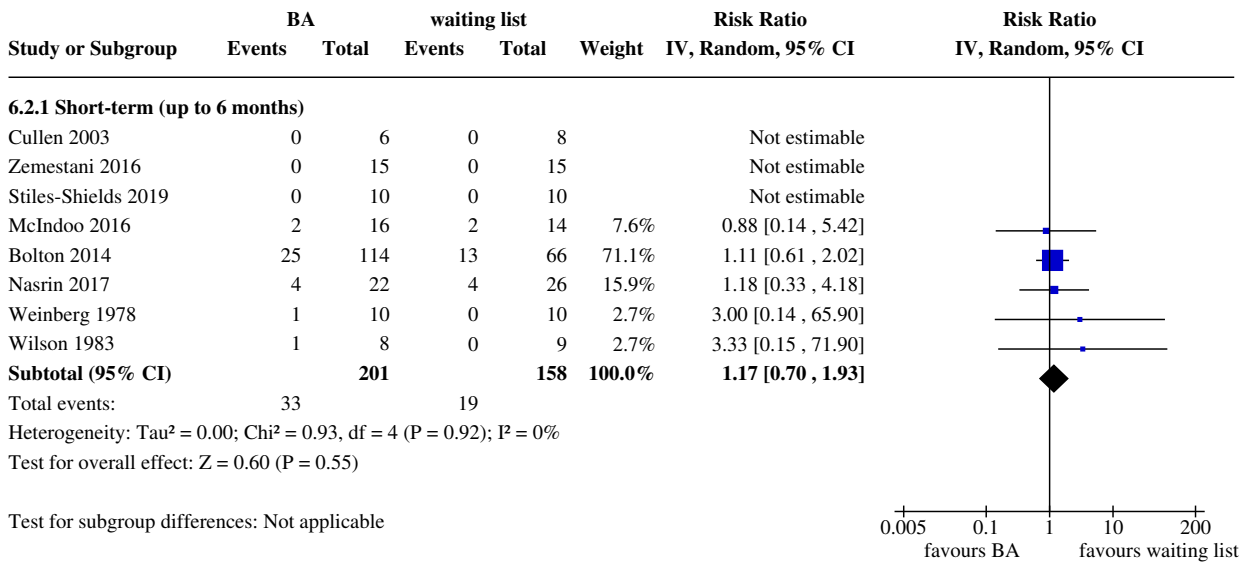
Comparison 6. behavioural activation vs waiting list

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 treatment efficacy	1		Risk Ratio (IV, Random, 95% CI)	Subtotals only
6.1.1 Short-term (up to 6 months)	1	26	Risk Ratio (IV, Random, 95% CI)	2.14 [0.90, 5.09]
6.2 treatment acceptability (dropouts)	8		Risk Ratio (IV, Random, 95% CI)	Subtotals only
6.2.1 Short-term (up to 6 months)	8	359	Risk Ratio (IV, Random, 95% CI)	1.17 [0.70, 1.93]
6.3 depression symptoms	12		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
6.3.1 Short-term (up to 6 months)	12	619	Std. Mean Difference (IV, Random, 95% CI)	-1.04 [-1.44, -0.63]
6.4 quality of life	1	80	Mean Difference (IV, Random, 95% CI)	0.03 [-0.70, 0.76]
6.4.1 Short-term (up to 6 months)	1	80	Mean Difference (IV, Random, 95% CI)	0.03 [-0.70, 0.76]
6.5 anxiety symptoms	5		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
6.5.1 Short-term (up to 6 months)	5	424	Std. Mean Difference (IV, Random, 95% CI)	-0.91 [-1.59, -0.23]

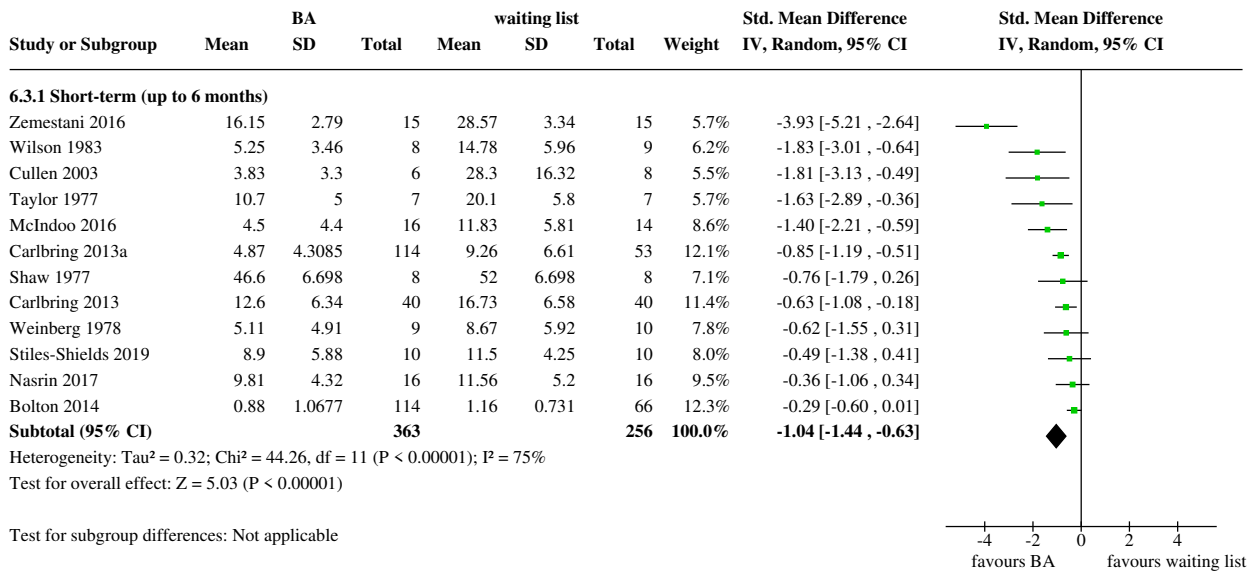
Analysis 6.1. Comparison 6: behavioural activation vs waiting list, Outcome 1: treatment efficacy



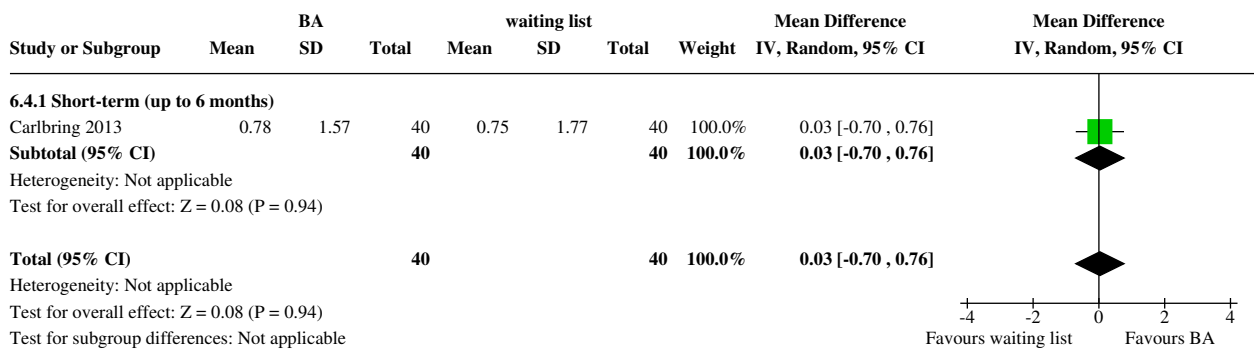
Analysis 6.2. Comparison 6: behavioural activation vs waiting list, Outcome 2: treatment acceptability (dropouts)



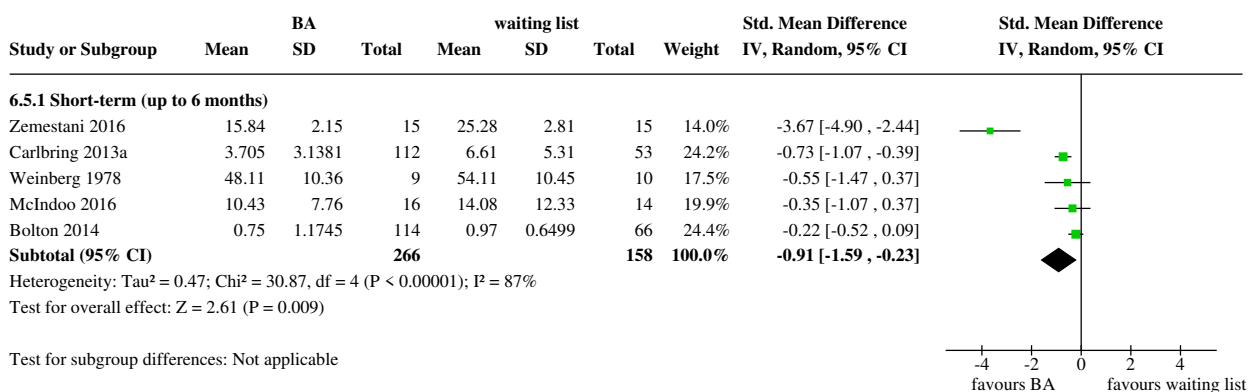
Analysis 6.3. Comparison 6: behavioural activation vs waiting list, Outcome 3: depression symptoms



Analysis 6.4. Comparison 6: behavioural activation vs waiting list, Outcome 4: quality of life



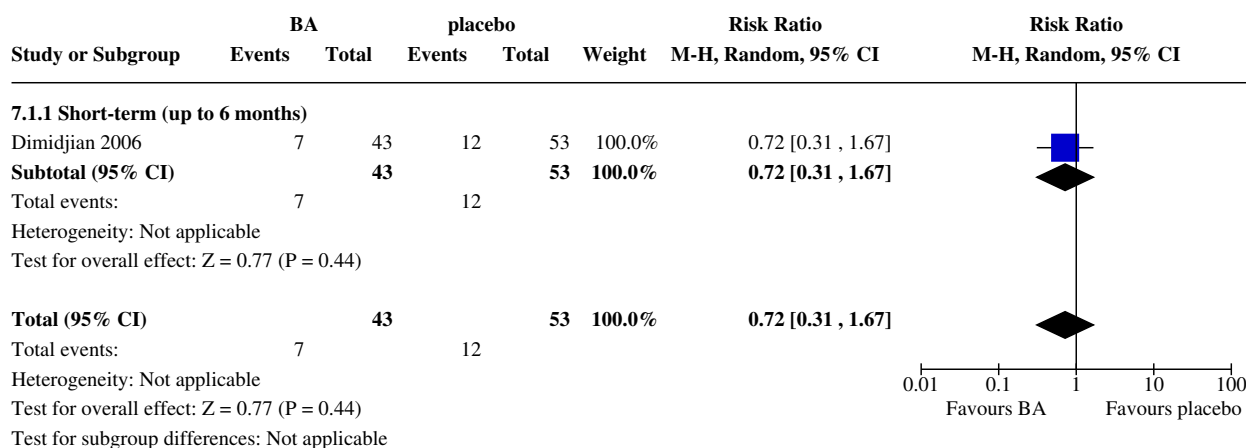
Analysis 6.5. Comparison 6: behavioural activation vs waiting list, Outcome 5: anxiety symptoms



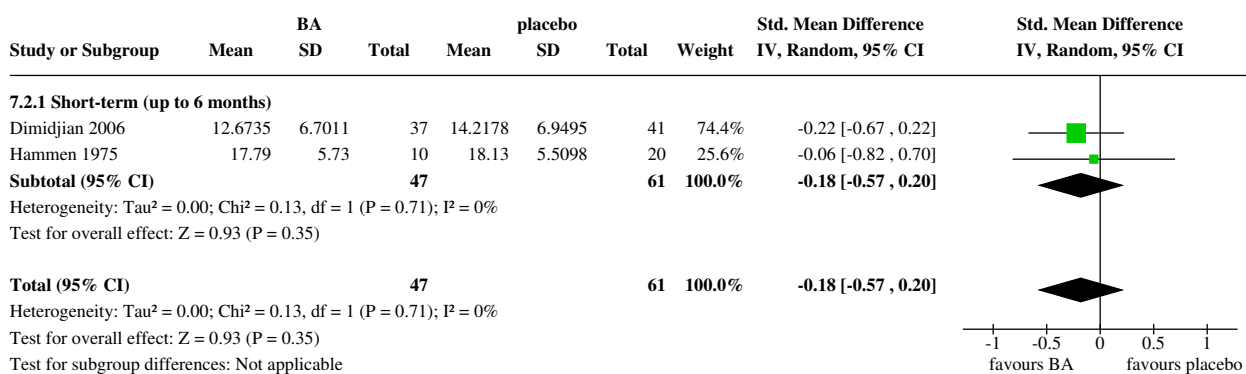
Comparison 7. behavioural activation vs placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.1 treatment acceptability (dropouts)	1	96	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.31, 1.67]
7.1.1 Short-term (up to 6 months)	1	96	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.31, 1.67]
7.2 depression symptoms	2	108	Std. Mean Difference (IV, Random, 95% CI)	-0.18 [-0.57, 0.20]
7.2.1 Short-term (up to 6 months)	2	108	Std. Mean Difference (IV, Random, 95% CI)	-0.18 [-0.57, 0.20]

Analysis 7.1. Comparison 7: behavioural activation vs placebo, Outcome 1: treatment acceptability (dropouts)



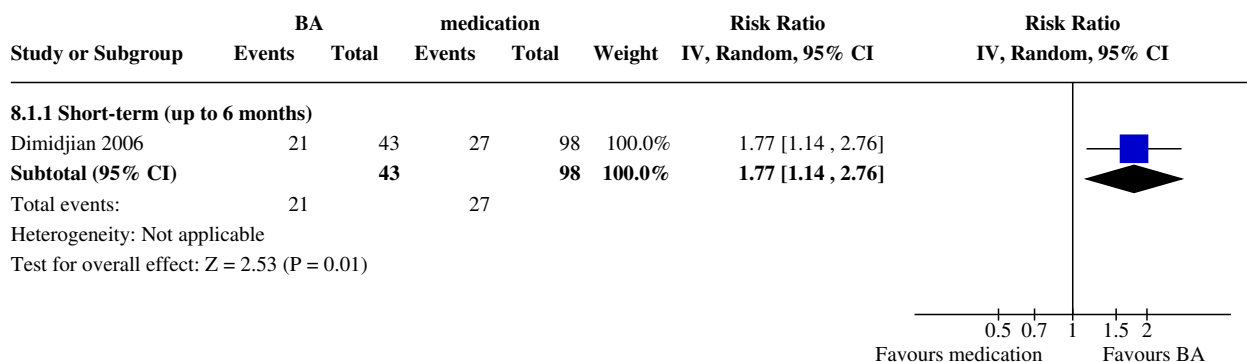
Analysis 7.2. Comparison 7: behavioural activation vs placebo, Outcome 2: depression symptoms



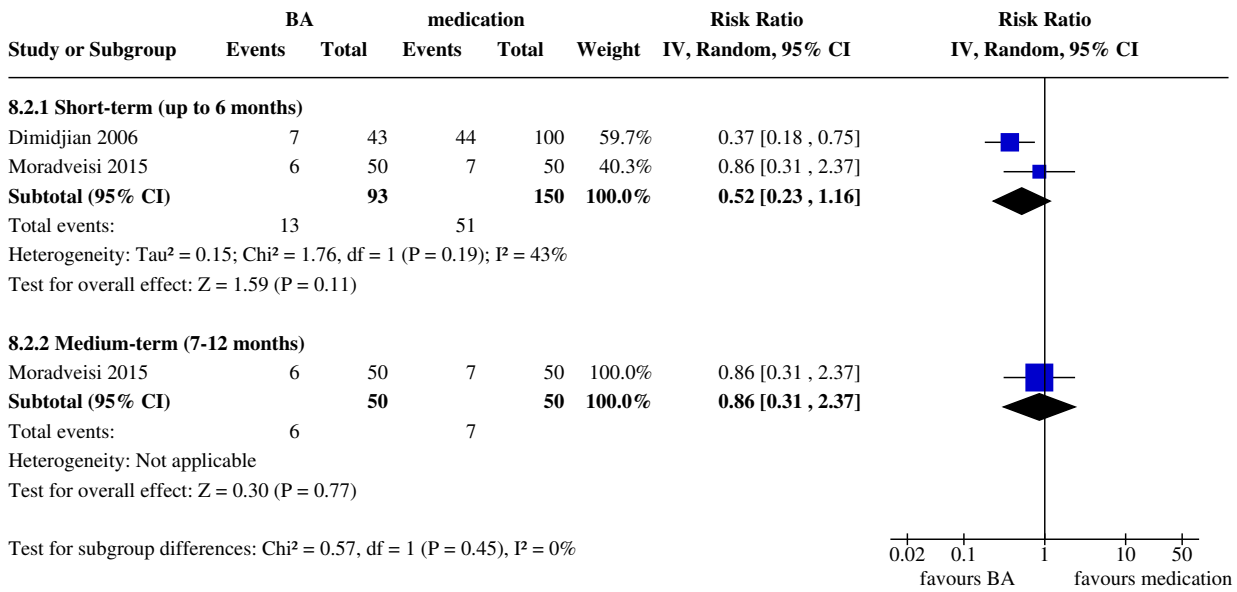
Comparison 8. behavioural activation vs medication

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.1 treatment efficacy	1		Risk Ratio (IV, Random, 95% CI)	Subtotals only
8.1.1 Short-term (up to 6 months)	1	141	Risk Ratio (IV, Random, 95% CI)	1.77 [1.14, 2.76]
8.2 treatment acceptability (dropouts)	2		Risk Ratio (IV, Random, 95% CI)	Subtotals only
8.2.1 Short-term (up to 6 months)	2	243	Risk Ratio (IV, Random, 95% CI)	0.52 [0.23, 1.16]
8.2.2 Medium-term (7-12 months)	1	100	Risk Ratio (IV, Random, 95% CI)	0.86 [0.31, 2.37]
8.3 depression symptoms	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
8.3.1 Short-term change from baseline (up to 6 months)	2	180	Mean Difference (IV, Random, 95% CI)	-1.42 [-4.80, 1.96]
8.3.2 Medium-term change from baseline (7-12 months)	1	100	Mean Difference (IV, Random, 95% CI)	-2.34 [-3.84, -0.84]

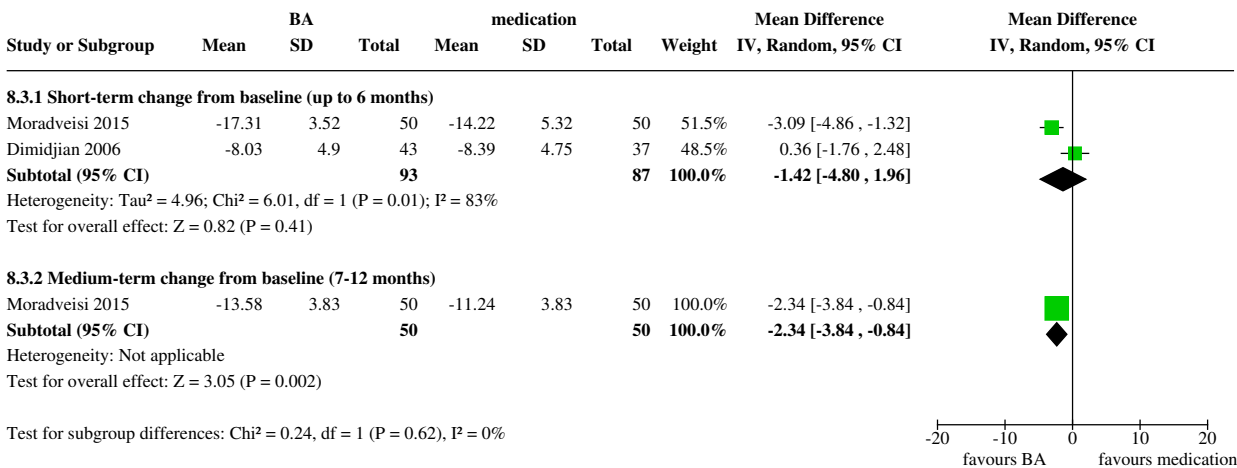
Analysis 8.1. Comparison 8: behavioural activation vs medication, Outcome 1: treatment efficacy



Analysis 8.2. Comparison 8: behavioural activation vs medication, Outcome 2: treatment acceptability (dropouts)



Analysis 8.3. Comparison 8: behavioural activation vs medication, Outcome 3: depression symptoms

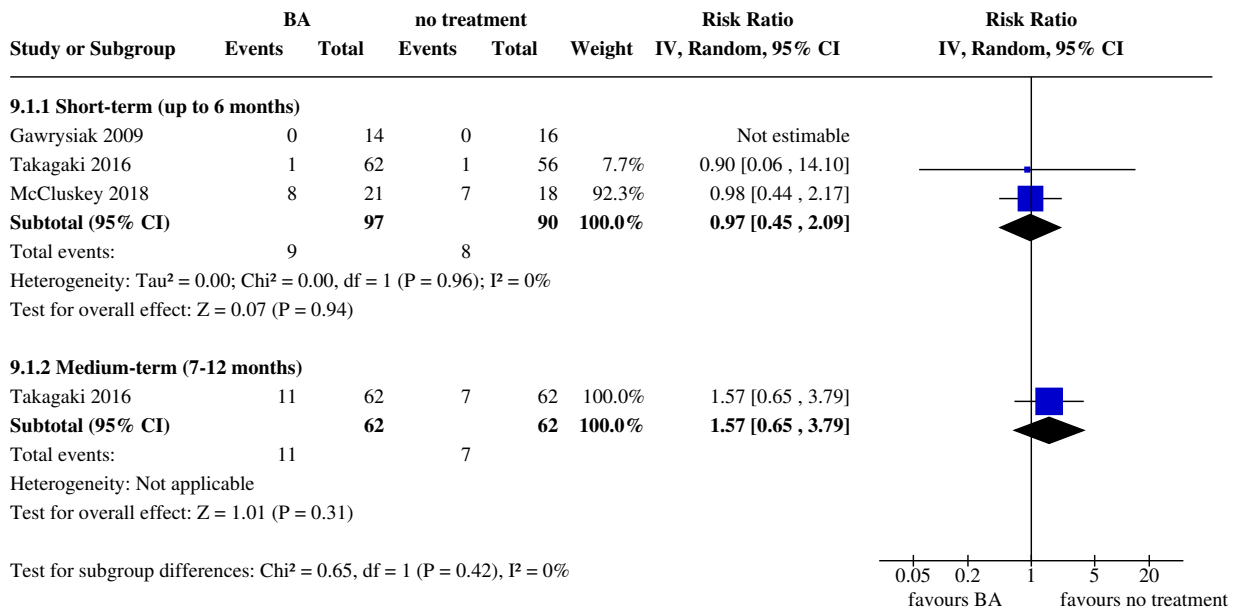


Comparison 9. behavioural activation vs no treatment

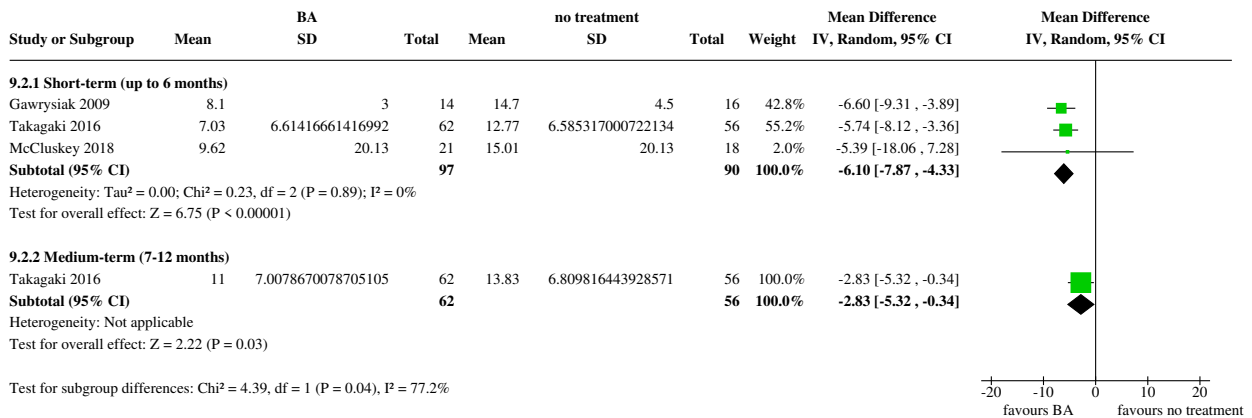
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
9.1 treatment acceptability (dropouts)	3		Risk Ratio (IV, Random, 95% CI)	Subtotals only
9.1.1 Short-term (up to 6 months)	3	187	Risk Ratio (IV, Random, 95% CI)	0.97 [0.45, 2.09]
9.1.2 Medium-term (7-12 months)	1	124	Risk Ratio (IV, Random, 95% CI)	1.57 [0.65, 3.79]
9.2 depression symptoms	3		Mean Difference (IV, Random, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
9.2.1 Short-term (up to 6 months)	3	187	Mean Difference (IV, Random, 95% CI)	-6.10 [-7.87, -4.33]
9.2.2 Medium-term (7-12 months)	1	118	Mean Difference (IV, Random, 95% CI)	-2.83 [-5.32, -0.34]
9.3 quality of life	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
9.3.1 Short-term (up to 6 months)	1	118	Mean Difference (IV, Random, 95% CI)	0.07 [0.03, 0.11]
9.4 anxiety symptoms	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
9.4.1 Short-term (up to 6 months)	1	30	Mean Difference (IV, Random, 95% CI)	-5.50 [-10.01, -0.99]

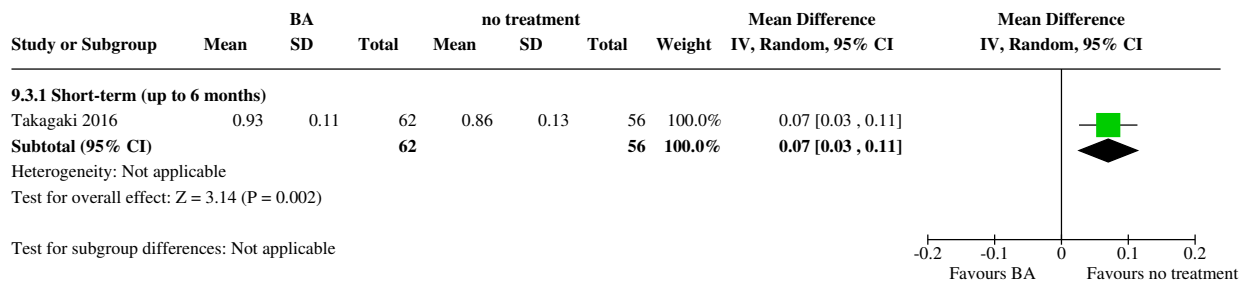
Analysis 9.1. Comparison 9: behavioural activation vs no treatment, Outcome 1: treatment acceptability (dropouts)



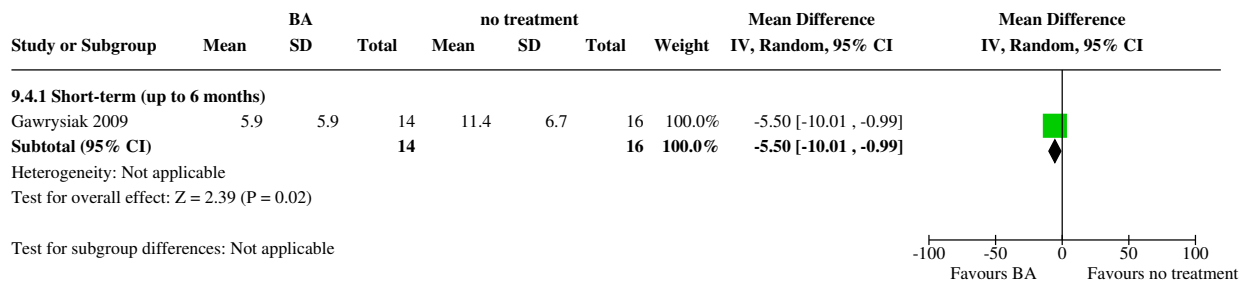
Analysis 9.2. Comparison 9: behavioural activation vs no treatment, Outcome 2: depression symptoms



Analysis 9.3. Comparison 9: behavioural activation vs no treatment, Outcome 3: quality of life



Analysis 9.4. Comparison 9: behavioural activation vs no treatment, Outcome 4: anxiety symptoms

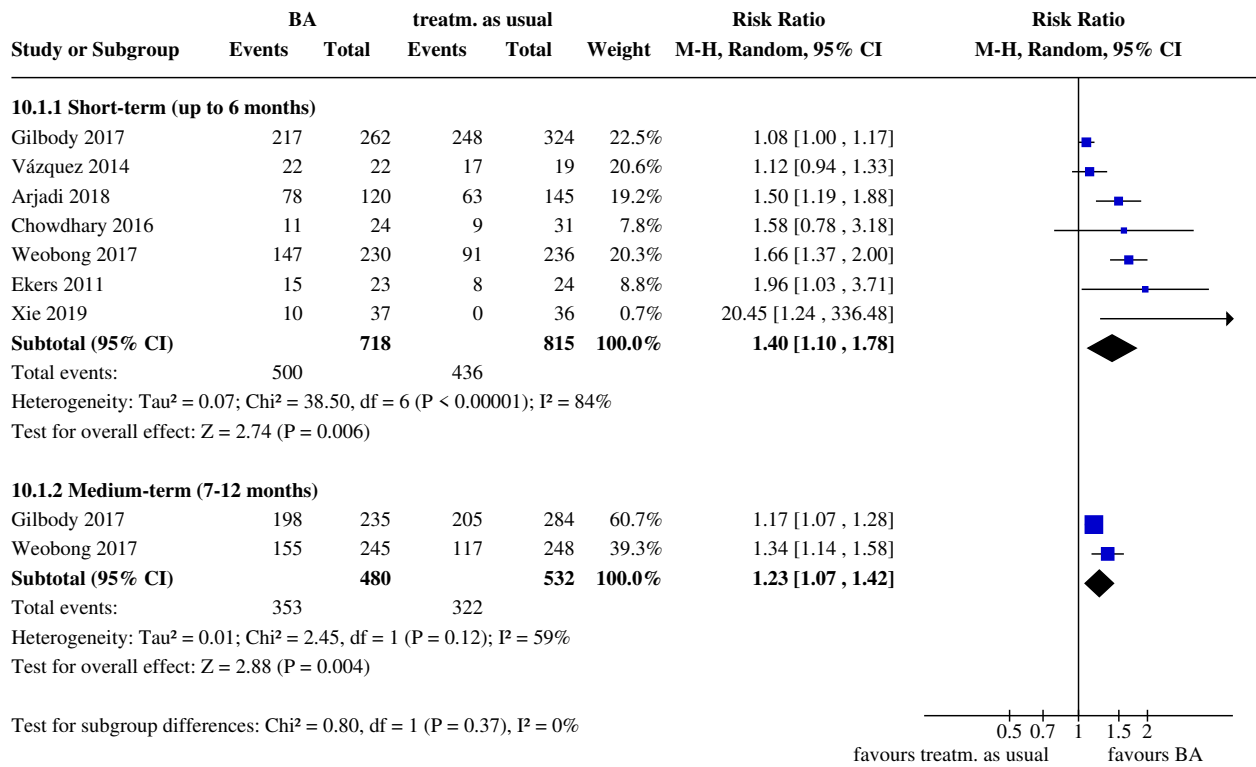


Comparison 10. behavioural activation vs treatment as usual

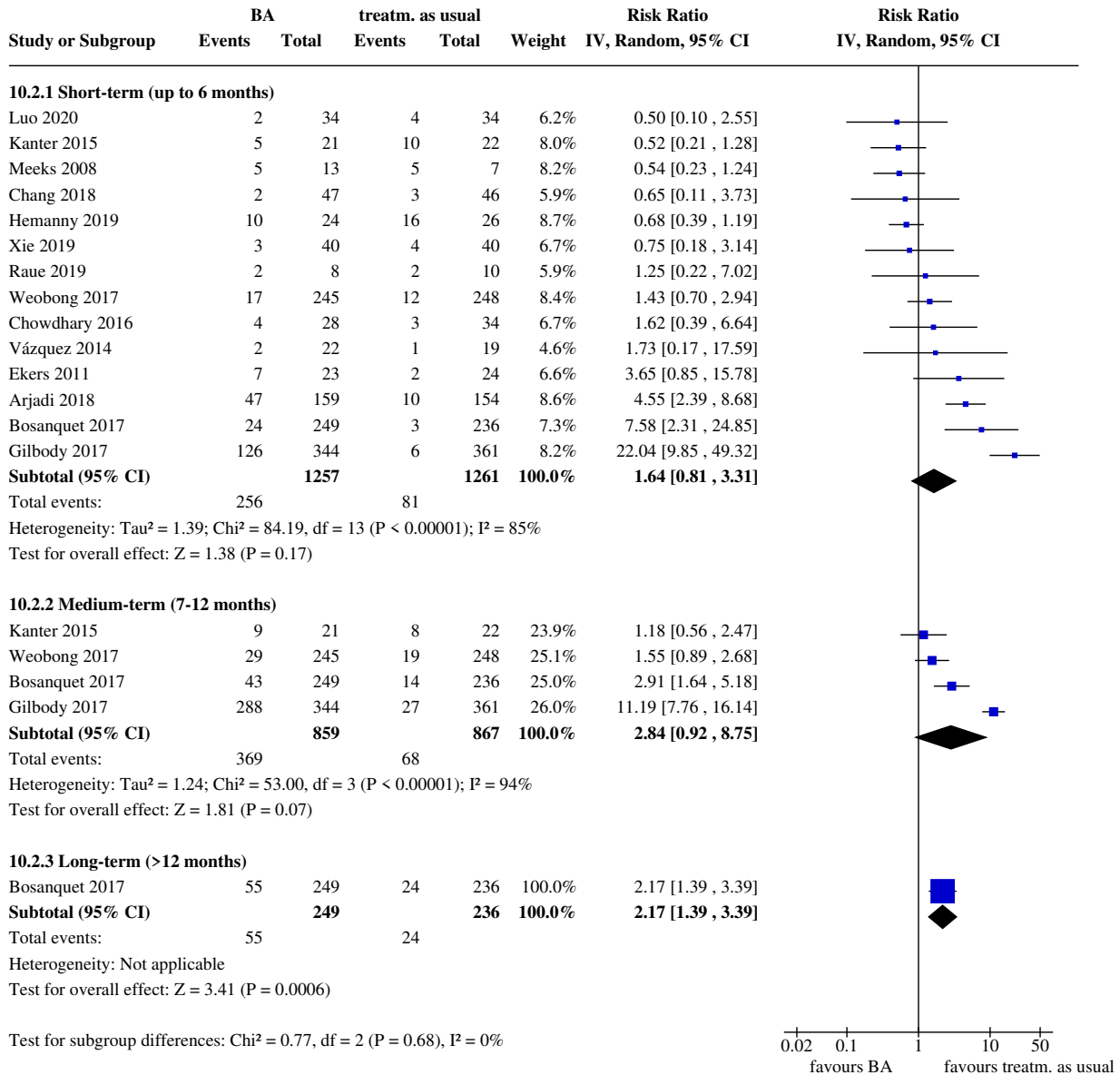
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
10.1 treatment efficacy	7		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
10.1.1 Short-term (up to 6 months)	7	1533	Risk Ratio (M-H, Random, 95% CI)	1.40 [1.10, 1.78]
10.1.2 Medium-term (7-12 months)	2	1012	Risk Ratio (M-H, Random, 95% CI)	1.23 [1.07, 1.42]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
10.2 treatment acceptability (dropouts)	14		Risk Ratio (IV, Random, 95% CI)	Subtotals only
10.2.1 Short-term (up to 6 months)	14	2518	Risk Ratio (IV, Random, 95% CI)	1.64 [0.81, 3.31]
10.2.2 Medium-term (7-12 months)	4	1726	Risk Ratio (IV, Random, 95% CI)	2.84 [0.92, 8.75]
10.2.3 Long-term (>12 months)	1	485	Risk Ratio (IV, Random, 95% CI)	2.17 [1.39, 3.39]
10.3 depression symptoms	15		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
10.3.1 Short-term (up to 6 months)	15	2208	Std. Mean Difference (IV, Random, 95% CI)	-0.78 [-1.05, -0.51]
10.3.2 Medium-term (7-12 months)	4	1381	Std. Mean Difference (IV, Random, 95% CI)	-0.23 [-0.38, -0.08]
10.3.3 Long-term (>12 months)	1	343	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.19, 0.23]
10.4 quality of life	6		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
10.4.1 short-term (up to 6 months)	6	1299	Std. Mean Difference (IV, Random, 95% CI)	0.97 [0.38, 1.57]
10.4.2 medium-term (7-12 months)	2	879	Std. Mean Difference (IV, Random, 95% CI)	0.14 [-0.12, 0.40]
10.4.3 long-term (>12 months)	1	325	Std. Mean Difference (IV, Random, 95% CI)	-0.09 [-0.30, 0.13]
10.5 social adjustment and functioning	2		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
10.5.1 Short-term (up to 6 months)	2	88	Std. Mean Difference (IV, Random, 95% CI)	-1.27 [-1.74, -0.81]
10.6 anxiety symptoms	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
10.6.1 Short-term (up to 6 months)	4	1063	Std. Mean Difference (IV, Random, 95% CI)	-0.33 [-0.45, -0.21]
10.6.2 Medium-term (7-12 months)	2	851	Std. Mean Difference (IV, Random, 95% CI)	-0.27 [-0.41, -0.12]
10.6.3 Long-term (>12 months)	1	332	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.29, 0.14]

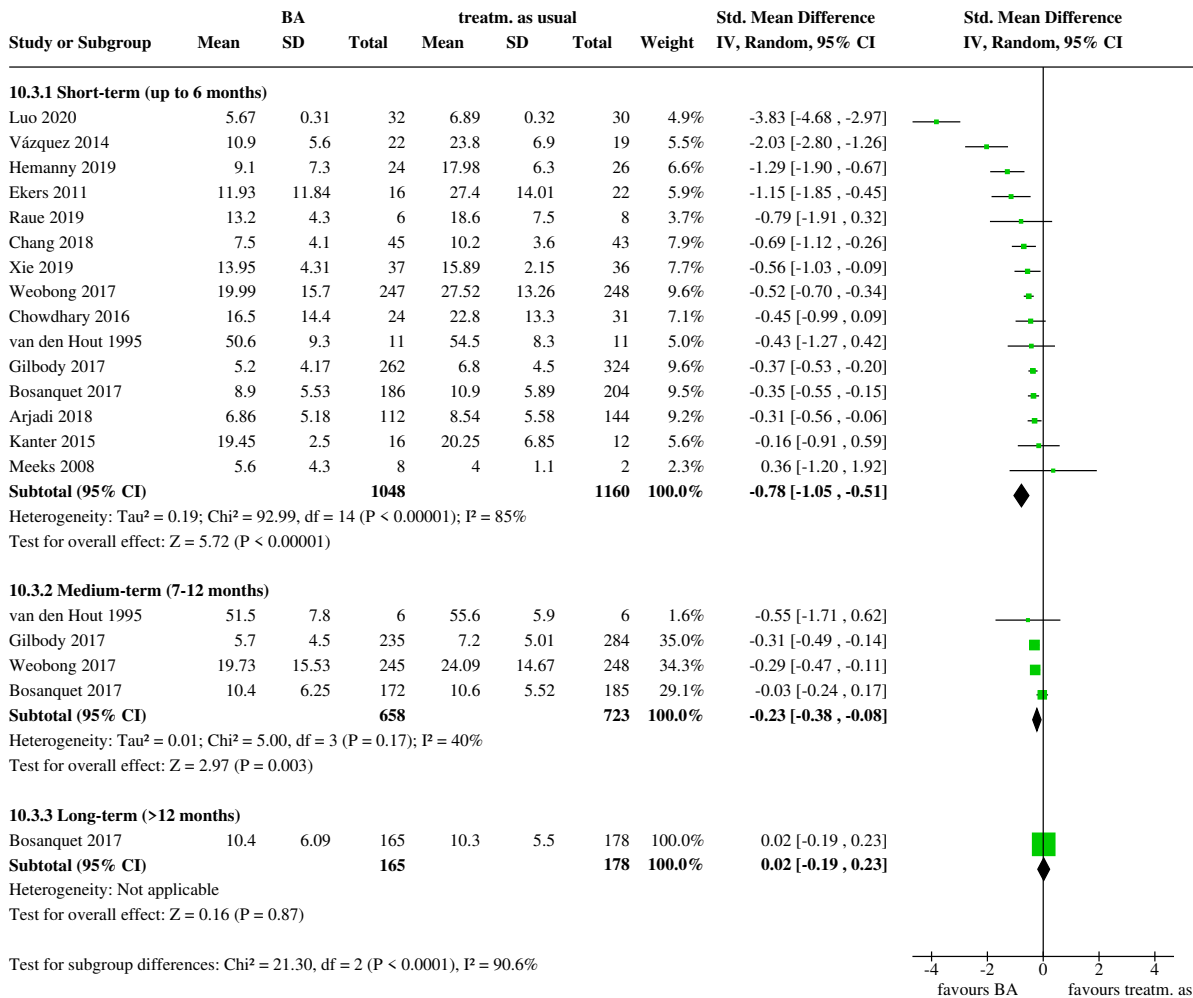
Analysis 10.1. Comparison 10: behavioural activation vs treatment as usual, Outcome 1: treatment efficacy



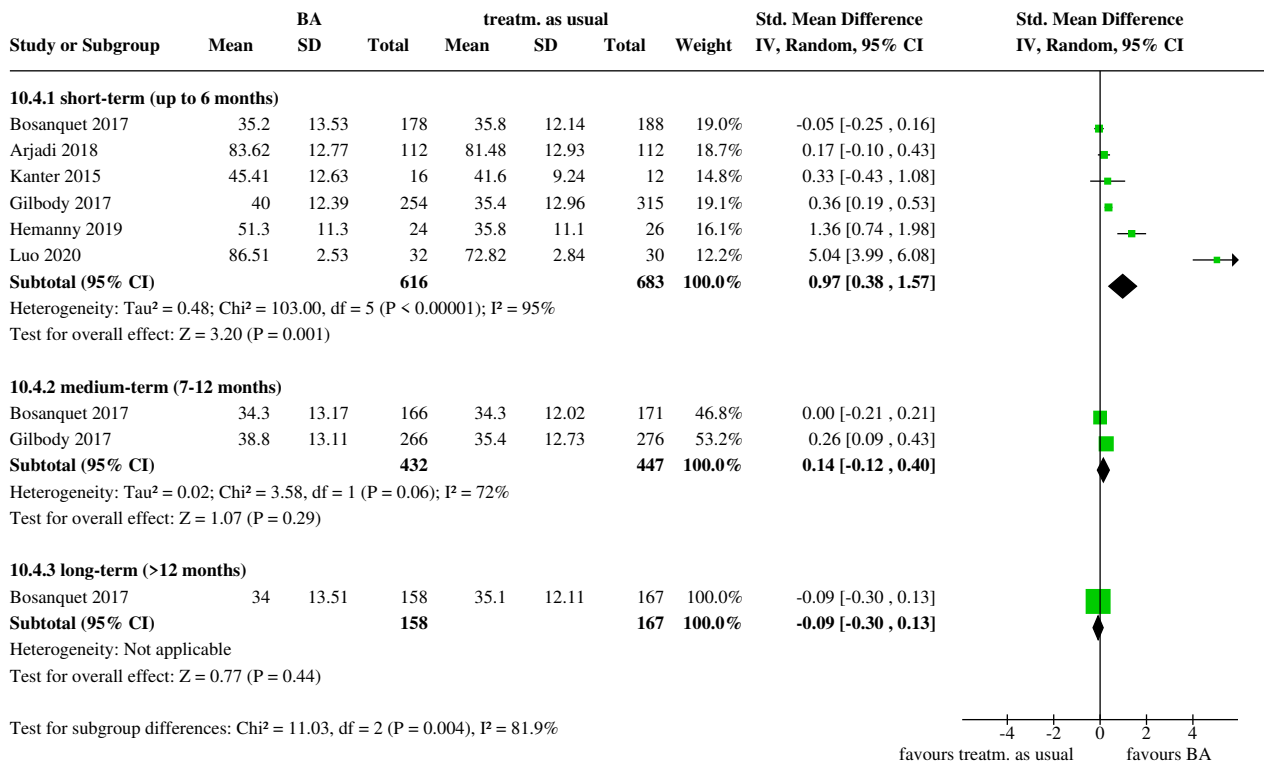
Analysis 10.2. Comparison 10: behavioural activation vs treatment as usual, Outcome 2: treatment acceptability (dropouts)



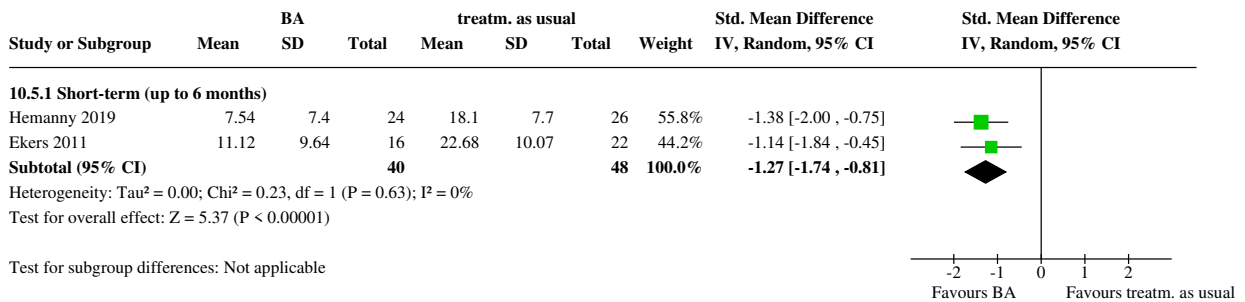
Analysis 10.3. Comparison 10: behavioural activation vs treatment as usual, Outcome 3: depression symptoms



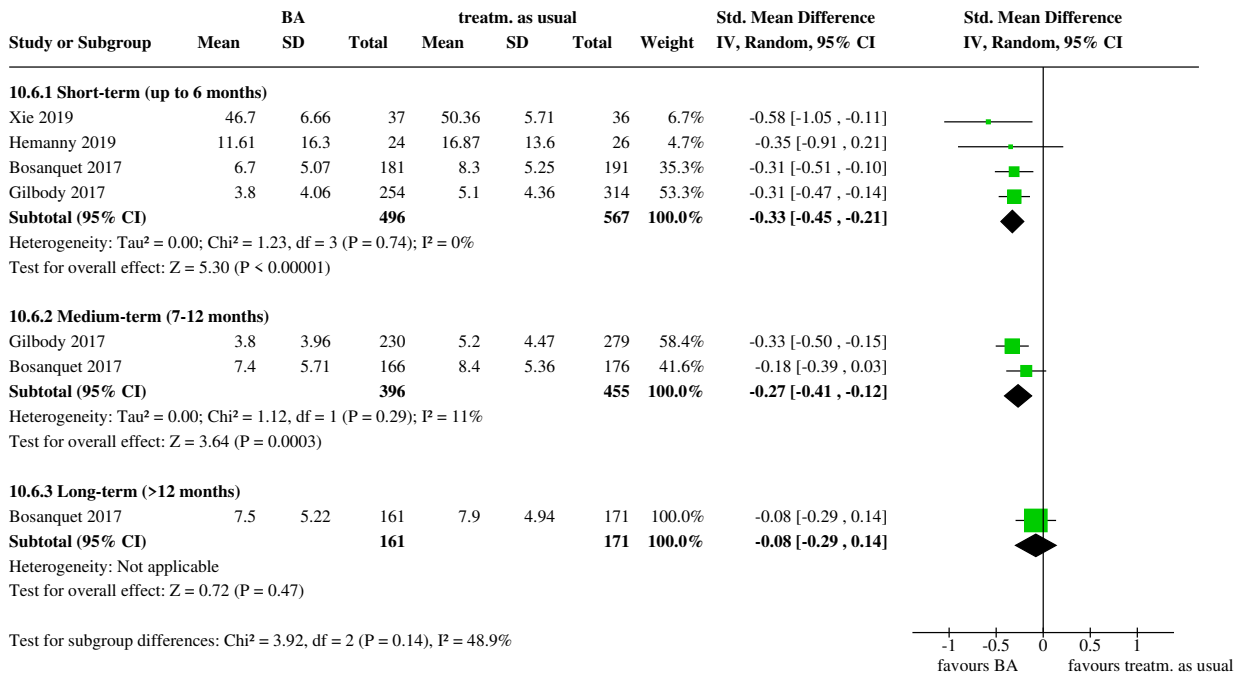
Analysis 10.4. Comparison 10: behavioural activation vs treatment as usual, Outcome 4: quality of life



Analysis 10.5. Comparison 10: behavioural activation vs treatment as usual, Outcome 5: social adjustment and functioning



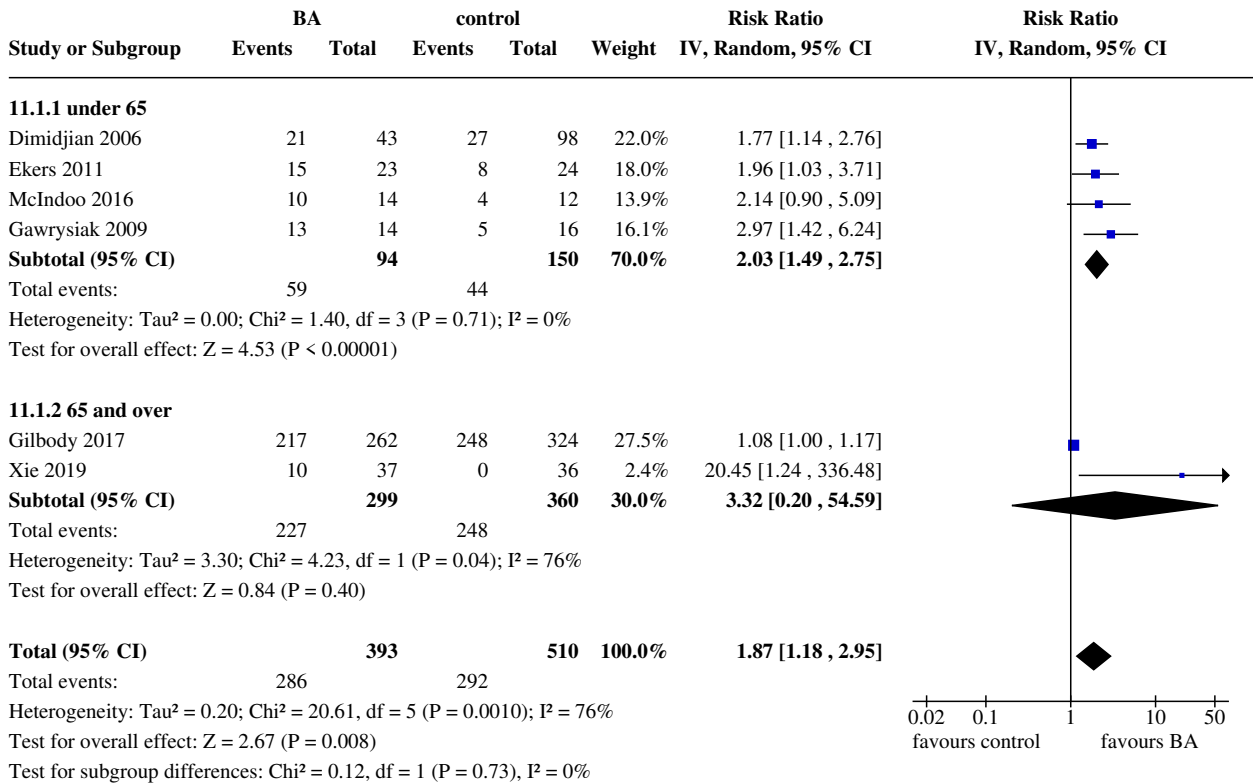
Analysis 10.6. Comparison 10: behavioural activation vs treatment as usual, Outcome 6: anxiety symptoms



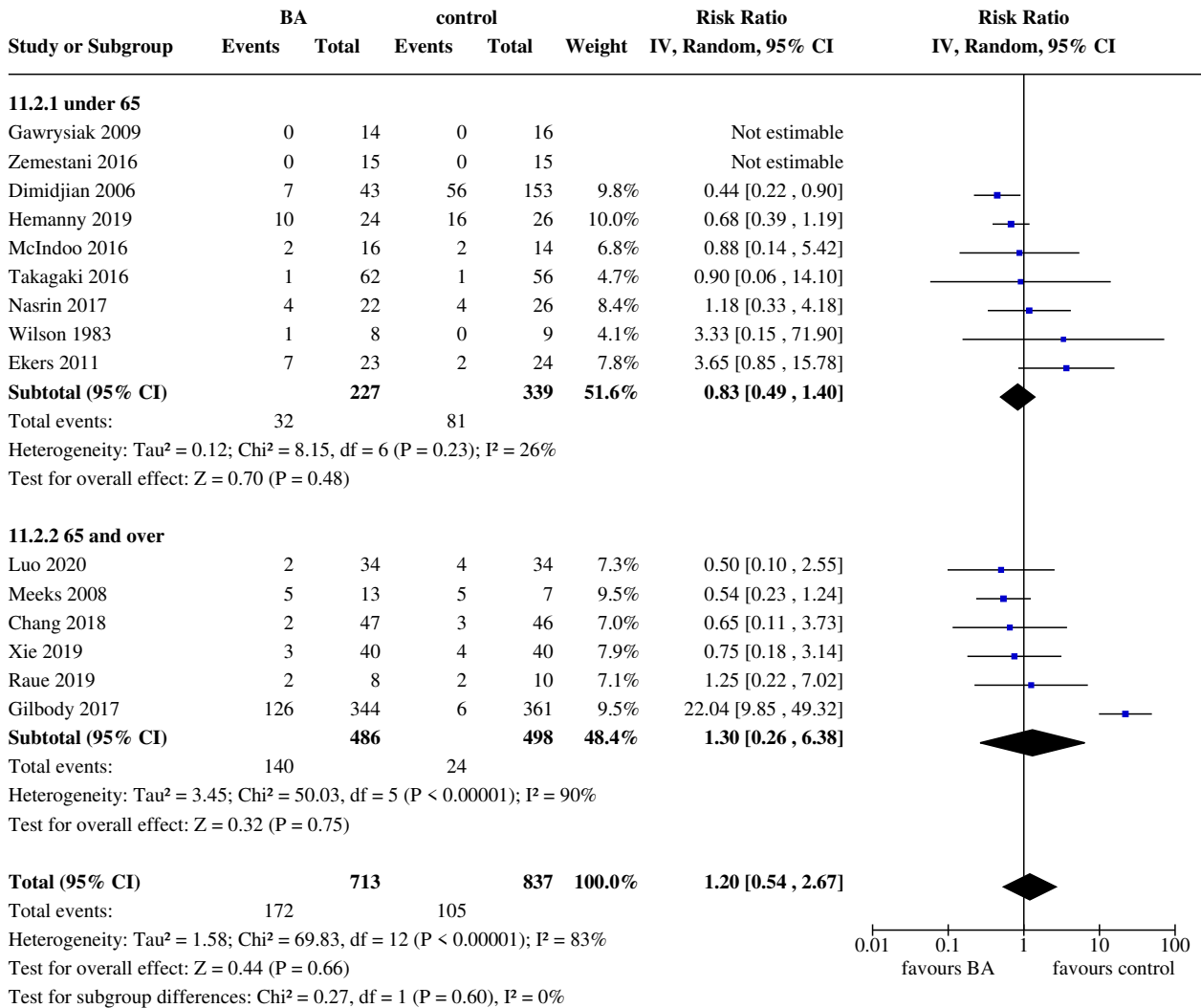
Comparison 11. SUBGROUP 1 AGE behavioural activation vs other controls (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11.1 treatment efficacy	6	903	Risk Ratio (IV, Random, 95% CI)	1.87 [1.18, 2.95]
11.1.1 under 65	4	244	Risk Ratio (IV, Random, 95% CI)	2.03 [1.49, 2.75]
11.1.2 65 and over	2	659	Risk Ratio (IV, Random, 95% CI)	3.32 [0.20, 54.59]
11.2 treatment acceptability (dropouts)	15	1550	Risk Ratio (IV, Random, 95% CI)	1.20 [0.54, 2.67]
11.2.1 under 65	9	566	Risk Ratio (IV, Random, 95% CI)	0.83 [0.49, 1.40]
11.2.2 65 and over	6	984	Risk Ratio (IV, Random, 95% CI)	1.30 [0.26, 6.38]

Analysis 11.1. Comparison 11: SUBGROUP 1 AGE behavioural activation vs other controls (up to 6 months), Outcome 1: treatment efficacy



Analysis 11.2. Comparison 11: SUBGROUP 1 AGE behavioural activation vs other controls (up to 6 months), Outcome 2: treatment acceptability (dropouts)

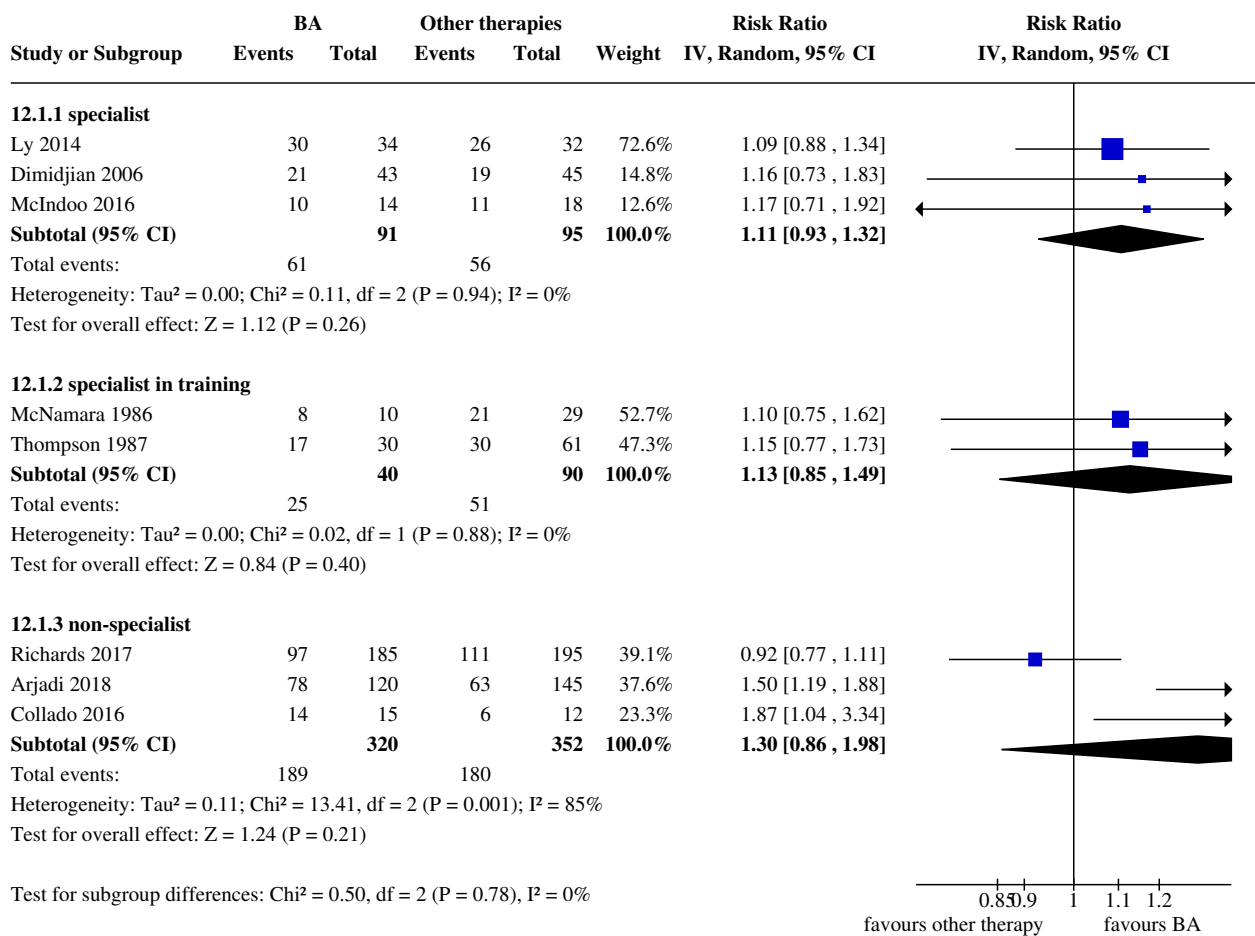


Comparison 12. SUBGROUP 2 THERAPIST behavioural activation vs other psychological therapies (up to 6 months)

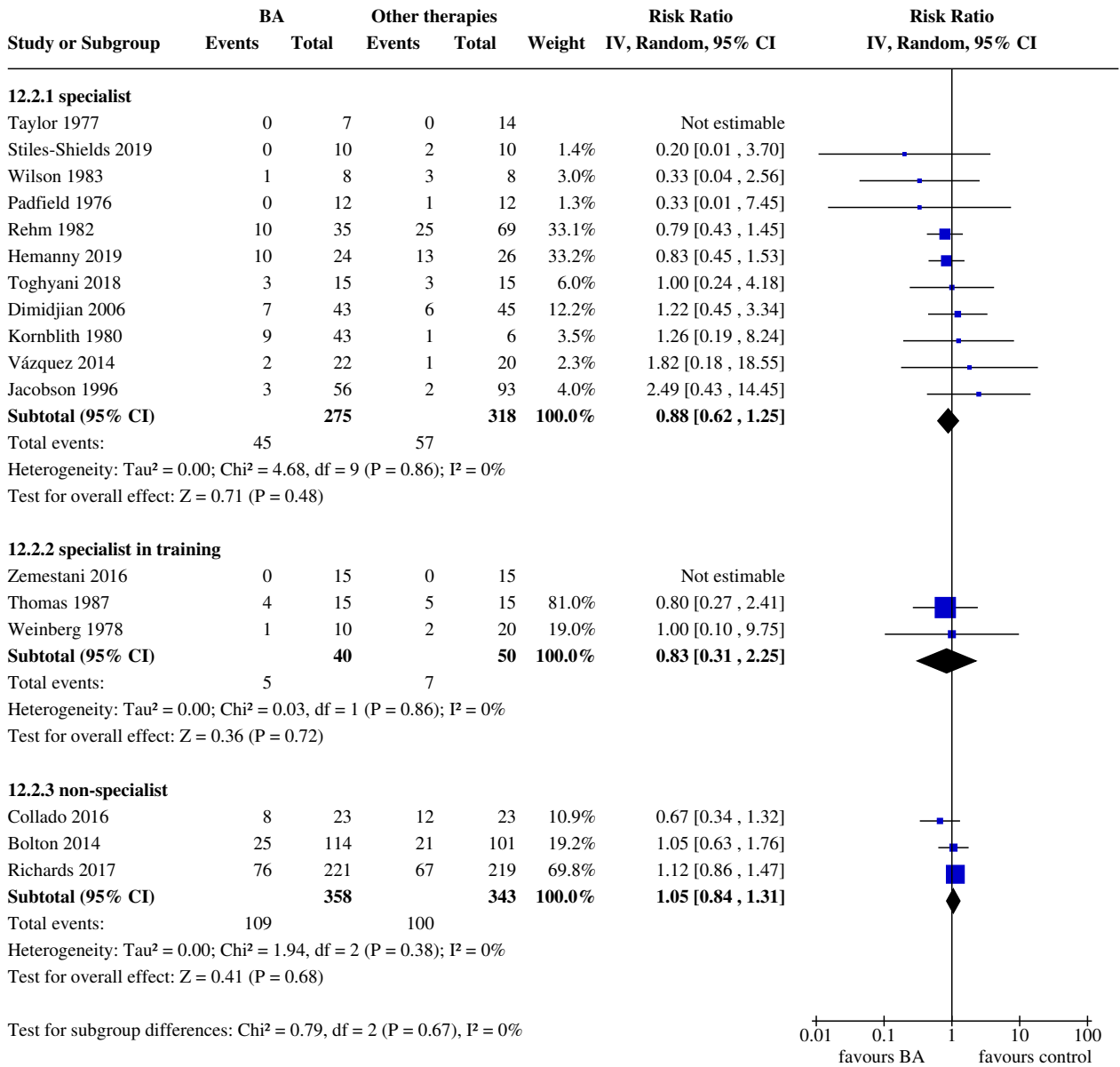
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
12.1 treatment efficacy	8		Risk Ratio (IV, Random, 95% CI)	Subtotals only
12.1.1 specialist	3	186	Risk Ratio (IV, Random, 95% CI)	1.11 [0.93, 1.32]
12.1.2 specialist in training	2	130	Risk Ratio (IV, Random, 95% CI)	1.13 [0.85, 1.49]
12.1.3 non-specialist	3	672	Risk Ratio (IV, Random, 95% CI)	1.30 [0.86, 1.98]
12.2 treatment acceptability (dropouts)	17		Risk Ratio (IV, Random, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
12.2.1 specialist	11	593	Risk Ratio (IV, Random, 95% CI)	0.88 [0.62, 1.25]
12.2.2 specialist in training	3	90	Risk Ratio (IV, Random, 95% CI)	0.83 [0.31, 2.25]
12.2.3 non-specialist	3	701	Risk Ratio (IV, Random, 95% CI)	1.05 [0.84, 1.31]

Analysis 12.1. Comparison 12: SUBGROUP 2 THERAPIST behavioural activation vs other psychological therapies (up to 6 months), Outcome 1: treatment efficacy



Analysis 12.2. Comparison 12: SUBGROUP 2 THERAPIST behavioural activation vs other psychological therapies (up to 6 months), Outcome 2: treatment acceptability (dropouts)

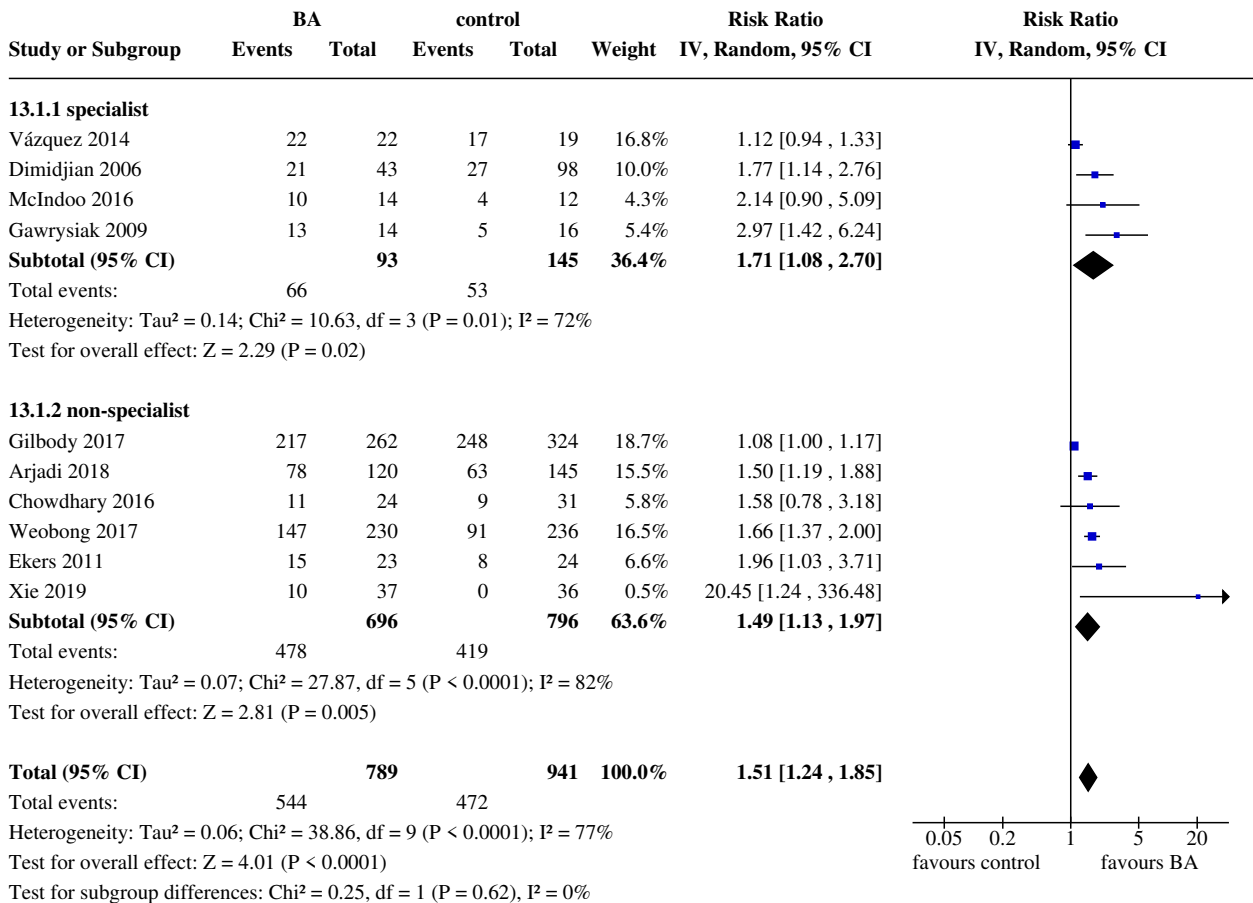


Comparison 13. SUBGROUP 2 THERAPIST behavioural activation vs other controls (up to 6 months)

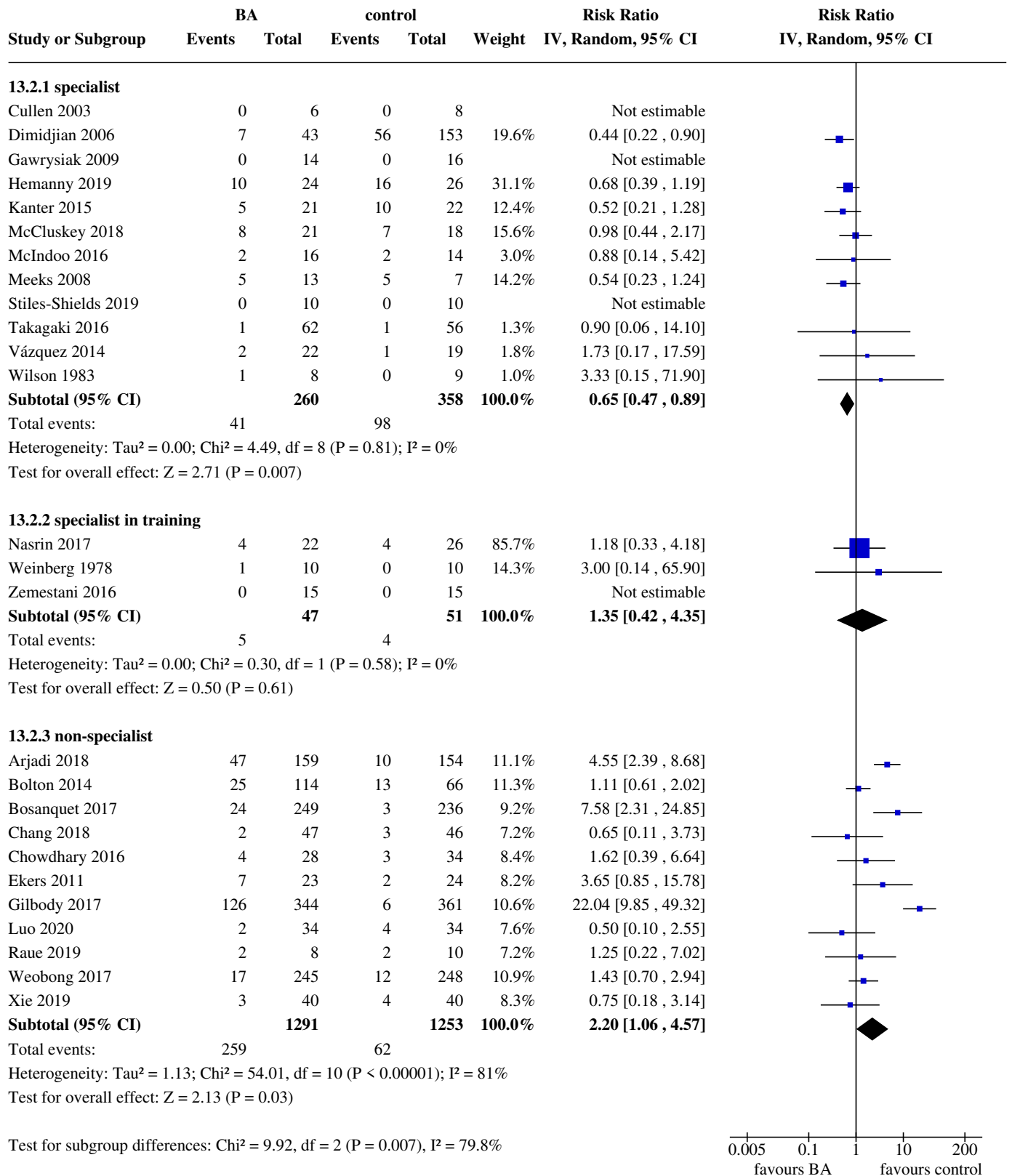
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
13.1 treatment efficacy	10	1730	Risk Ratio (IV, Random, 95% CI)	1.51 [1.24, 1.85]
13.1.1 specialist	4	238	Risk Ratio (IV, Random, 95% CI)	1.71 [1.08, 2.70]
13.1.2 non-specialist	6	1492	Risk Ratio (IV, Random, 95% CI)	1.49 [1.13, 1.97]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
13.2 treatment acceptability (dropouts)	26		Risk Ratio (IV, Random, 95% CI)	Subtotals only
13.2.1 specialist	12	618	Risk Ratio (IV, Random, 95% CI)	0.65 [0.47, 0.89]
13.2.2 specialist in training	3	98	Risk Ratio (IV, Random, 95% CI)	1.35 [0.42, 4.35]
13.2.3 non-specialist	11	2544	Risk Ratio (IV, Random, 95% CI)	2.20 [1.06, 4.57]

Analysis 13.1. Comparison 13: SUBGROUP 2 THERAPIST behavioural activation vs other controls (up to 6 months), Outcome 1: treatment efficacy



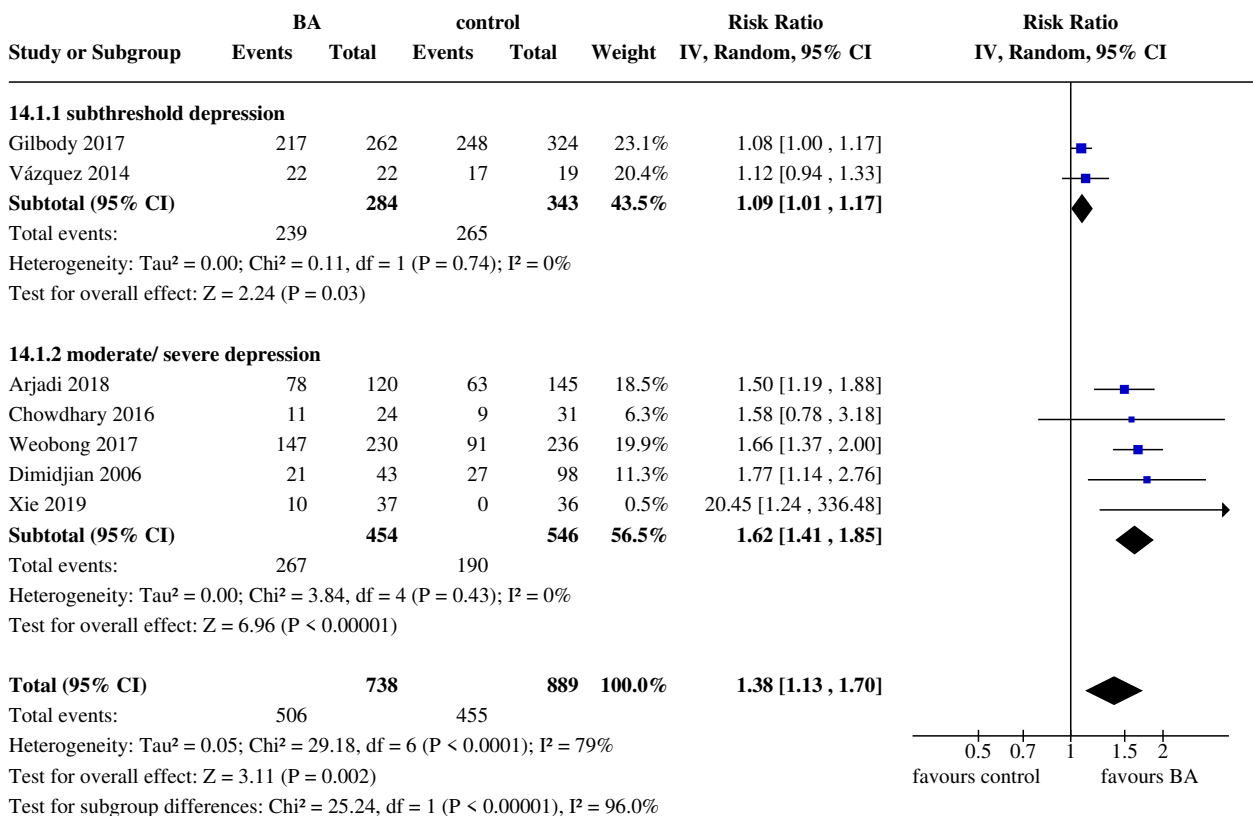
Analysis 13.2. Comparison 13: SUBGROUP 2 THERAPIST behavioural activation vs other controls (up to 6 months), Outcome 2: treatment acceptability (dropouts)



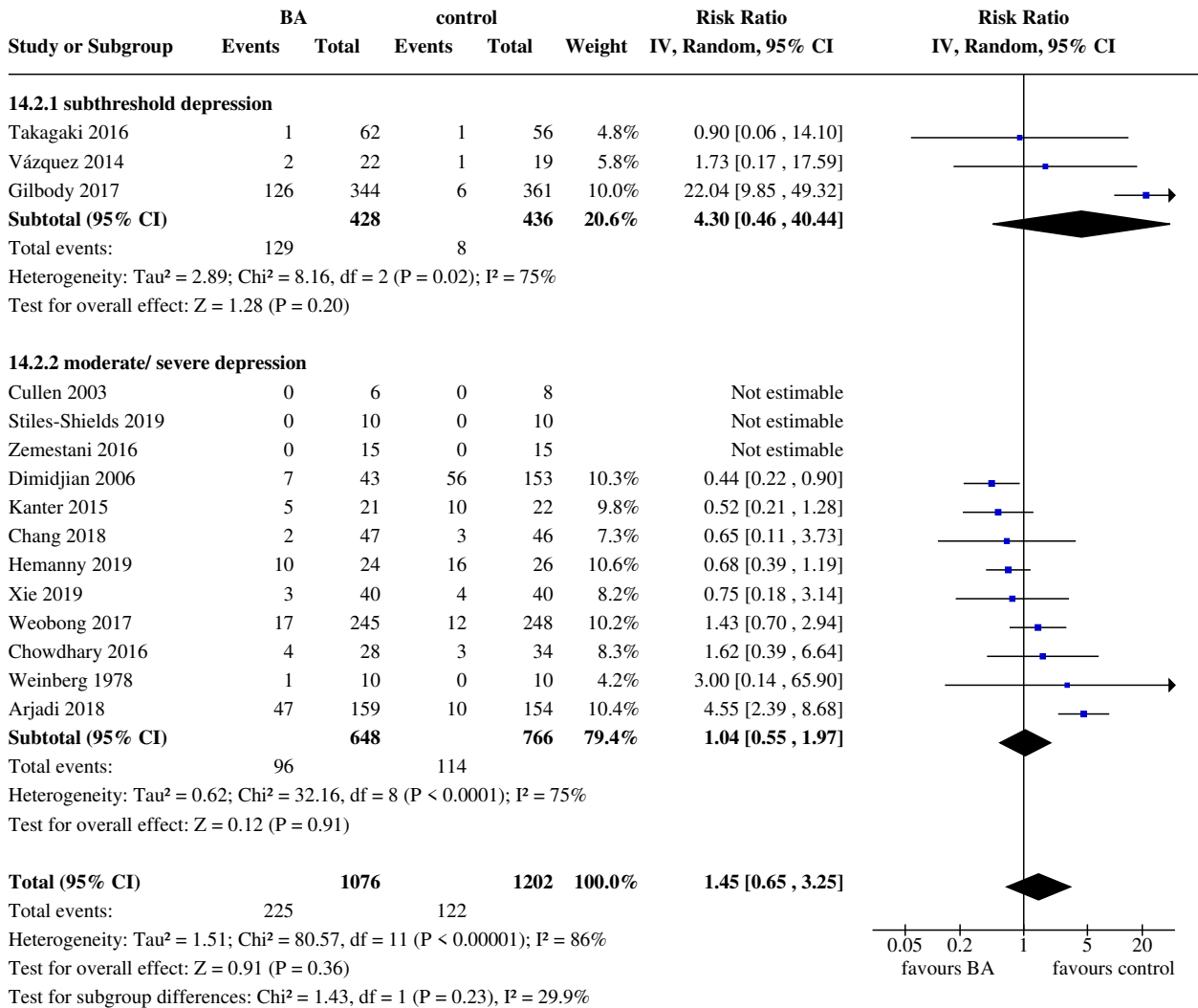
Comparison 14. SUBGROUP 3 SEVERITY behavioural activation vs other controls (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
14.1 treatment efficacy	7	1627	Risk Ratio (IV, Random, 95% CI)	1.38 [1.13, 1.70]
14.1.1 subthreshold depression	2	627	Risk Ratio (IV, Random, 95% CI)	1.09 [1.01, 1.17]
14.1.2 moderate/ severe depression	5	1000	Risk Ratio (IV, Random, 95% CI)	1.62 [1.41, 1.85]
14.2 treatment acceptability (dropouts)	15	2278	Risk Ratio (IV, Random, 95% CI)	1.45 [0.65, 3.25]
14.2.1 subthreshold depression	3	864	Risk Ratio (IV, Random, 95% CI)	4.30 [0.46, 40.44]
14.2.2 moderate/ severe depression	12	1414	Risk Ratio (IV, Random, 95% CI)	1.04 [0.55, 1.97]

Analysis 14.1. Comparison 14: SUBGROUP 3 SEVERITY behavioural activation vs other controls (up to 6 months), Outcome 1: treatment efficacy



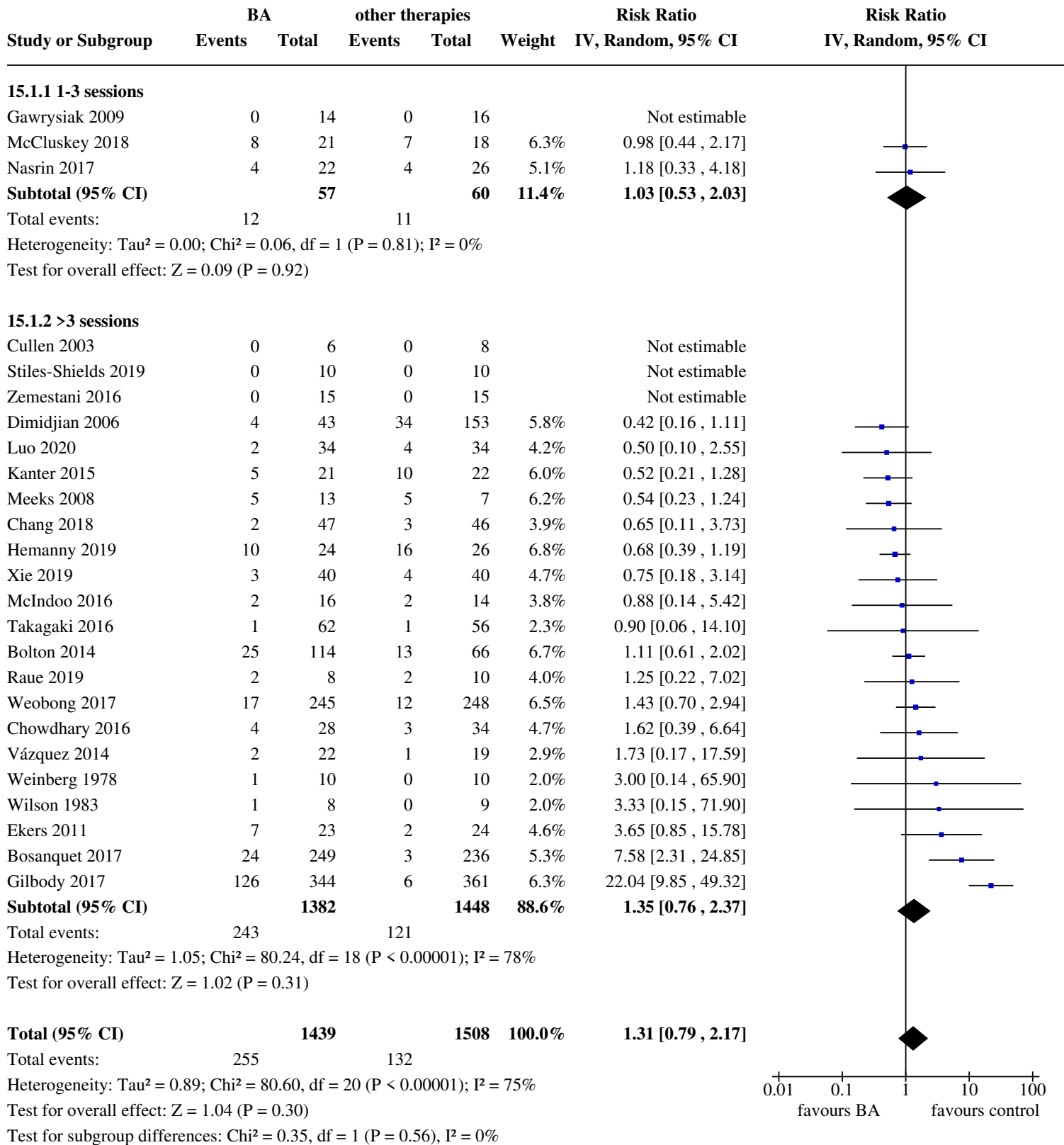
Analysis 14.2. Comparison 14: SUBGROUP 3 SEVERITY behavioural activation vs other controls (up to 6 months), Outcome 2: treatment acceptability (dropouts)



Comparison 15. SUBGROUP 4 LENGTH behavioural activation vs other controls (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
15.1 treatment acceptability (dropouts)	25	2947	Risk Ratio (IV, Random, 95% CI)	1.31 [0.79, 2.17]
15.1.1 1-3 sessions	3	117	Risk Ratio (IV, Random, 95% CI)	1.03 [0.53, 2.03]
15.1.2 >3 sessions	22	2830	Risk Ratio (IV, Random, 95% CI)	1.35 [0.76, 2.37]

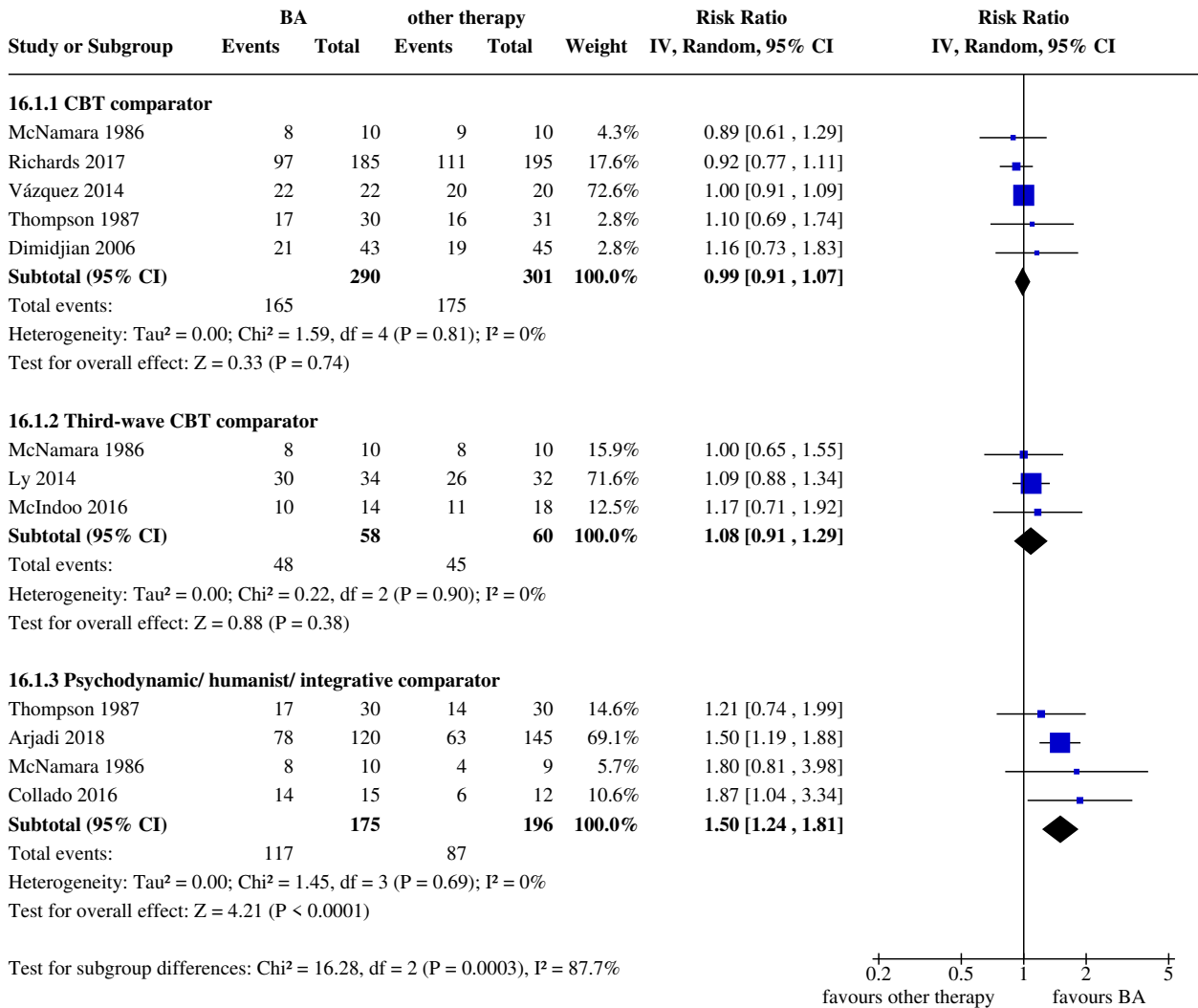
Analysis 15.1. Comparison 15: SUBGROUP 4 LENGTH behavioural activation vs other controls (up to 6 months), Outcome 1: treatment acceptability (dropouts)



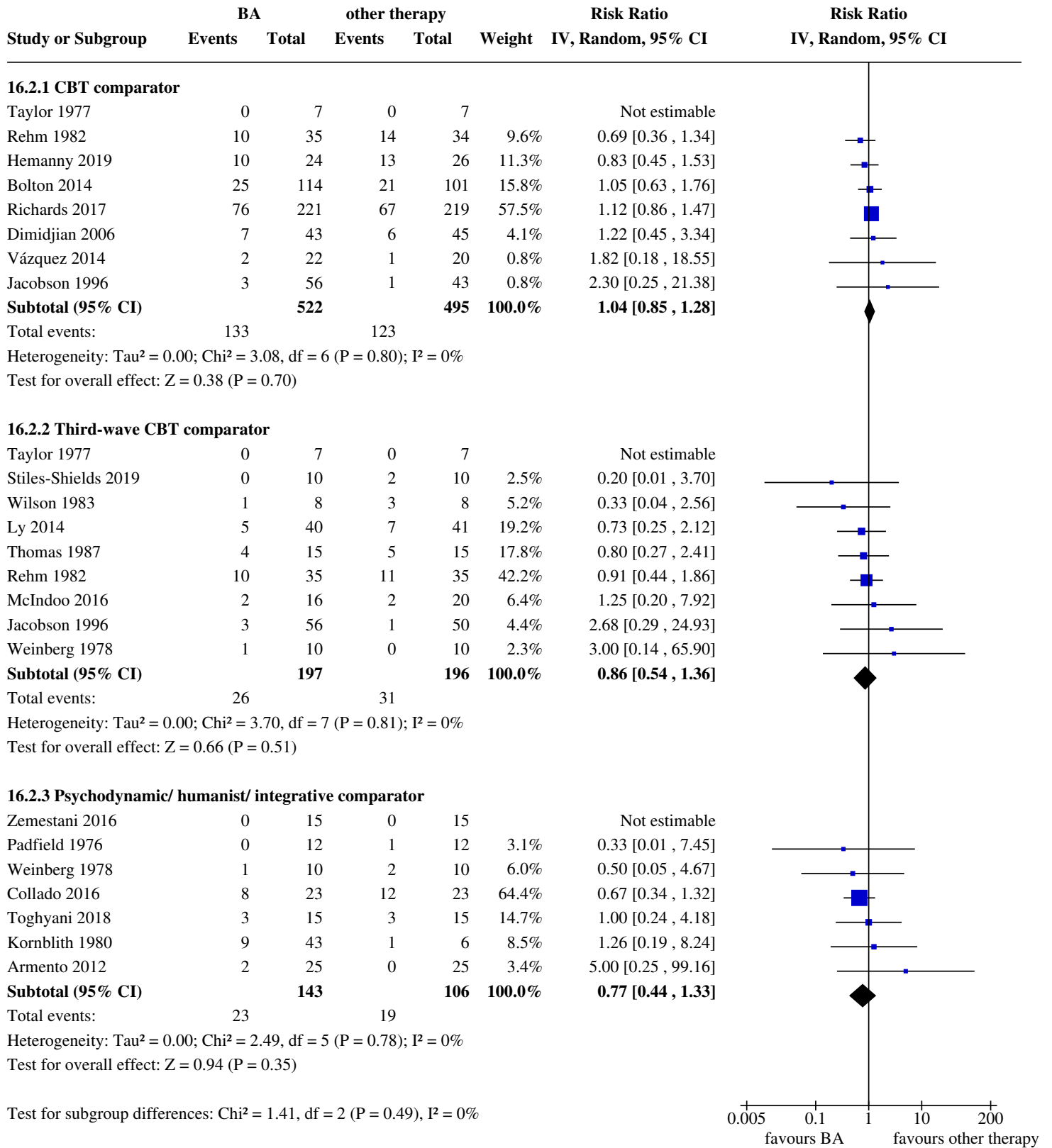
Comparison 16. SUBGROUP 5 THERAPY behavioural activation vs other psychological therapies (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
16.1 treatment efficacy	9		Risk Ratio (IV, Random, 95% CI)	Subtotals only
16.1.1 CBT comparator	5	591	Risk Ratio (IV, Random, 95% CI)	0.99 [0.91, 1.07]
16.1.2 Third-wave CBT comparator	3	118	Risk Ratio (IV, Random, 95% CI)	1.08 [0.91, 1.29]
16.1.3 Psychodynamic/ humanist/ integrative comparator	4	371	Risk Ratio (IV, Random, 95% CI)	1.50 [1.24, 1.81]
16.2 treatment acceptability (dropouts)	20		Risk Ratio (IV, Random, 95% CI)	Subtotals only
16.2.1 CBT comparator	8	1017	Risk Ratio (IV, Random, 95% CI)	1.04 [0.85, 1.28]
16.2.2 Third-wave CBT comparator	9	393	Risk Ratio (IV, Random, 95% CI)	0.86 [0.54, 1.36]
16.2.3 Psychodynamic/ humanist/ integrative comparator	7	249	Risk Ratio (IV, Random, 95% CI)	0.77 [0.44, 1.33]

Analysis 16.1. Comparison 16: SUBGROUP 5 THERAPY behavioural activation vs other psychological therapies (up to 6 months), Outcome 1: treatment efficacy



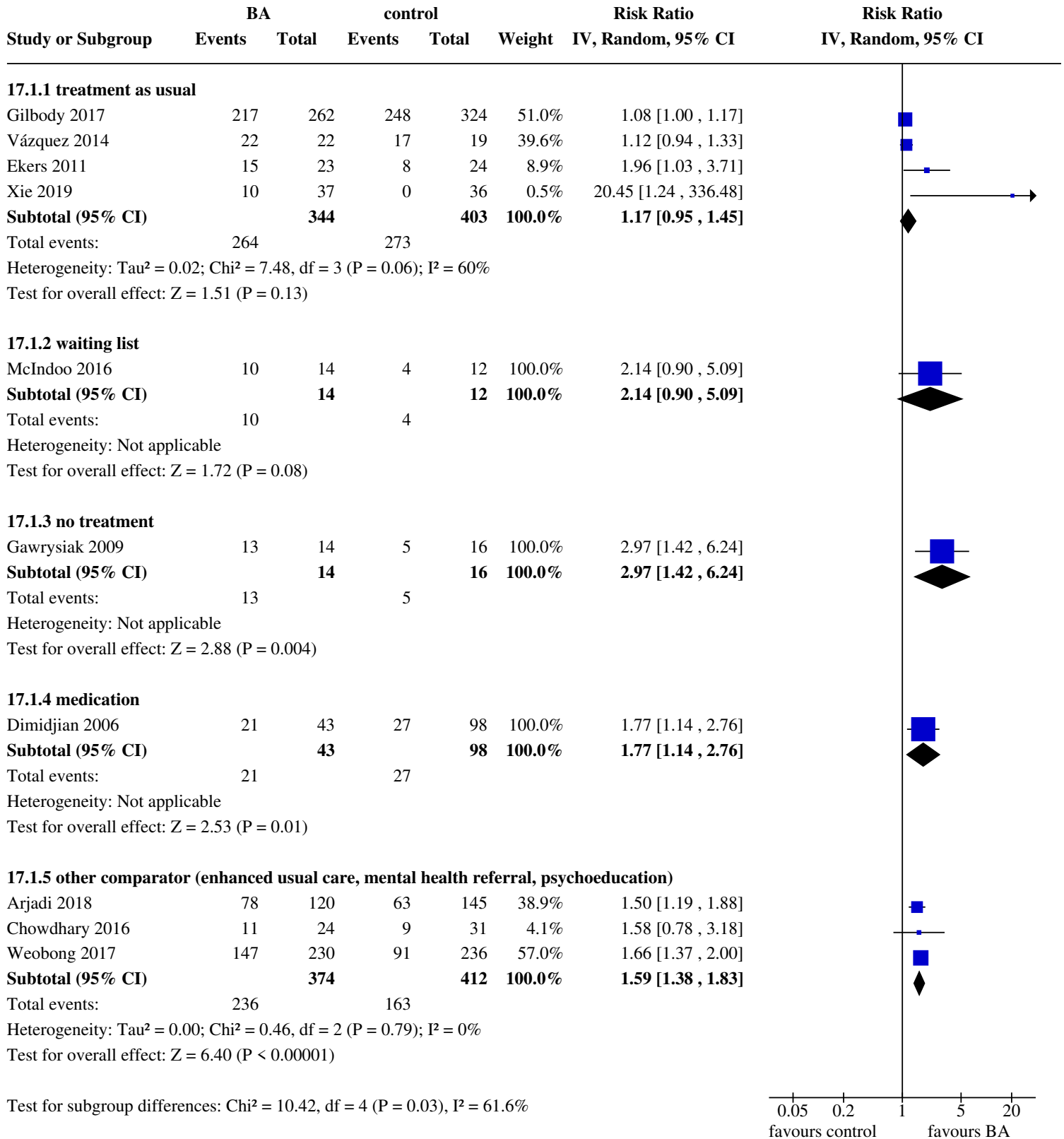
Analysis 16.2. Comparison 16: SUBGROUP 5 THERAPY behavioural activation vs other psychological therapies (up to 6 months), Outcome 2: treatment acceptability (dropouts)



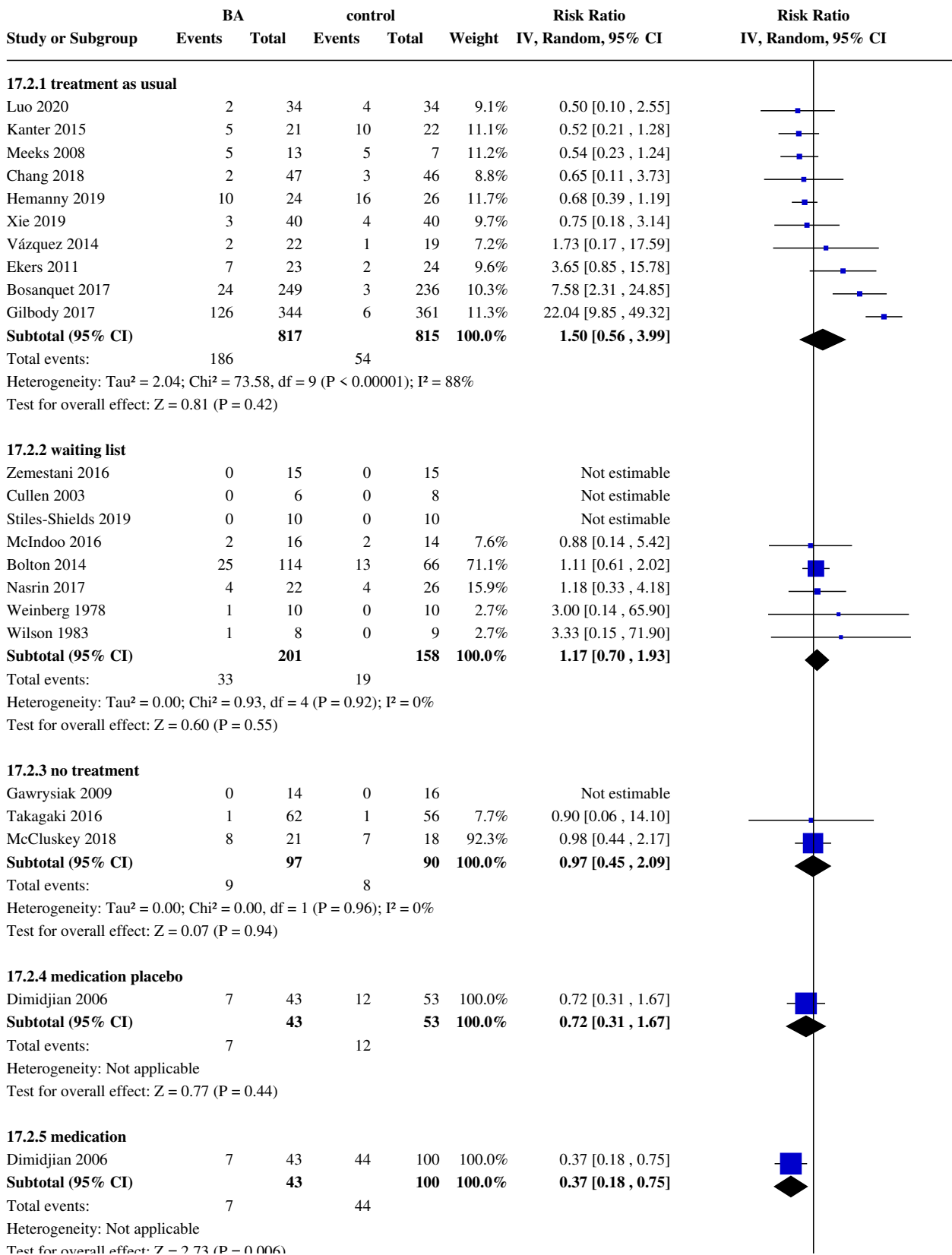
Comparison 17. SUBGROUP 6 CONTROL behavioural activation vs other controls (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
17.1 treatment efficacy	10		Risk Ratio (IV, Random, 95% CI)	Subtotals only
17.1.1 treatment as usual	4	747	Risk Ratio (IV, Random, 95% CI)	1.17 [0.95, 1.45]
17.1.2 waiting list	1	26	Risk Ratio (IV, Random, 95% CI)	2.14 [0.90, 5.09]
17.1.3 no treatment	1	30	Risk Ratio (IV, Random, 95% CI)	2.97 [1.42, 6.24]
17.1.4 medication	1	141	Risk Ratio (IV, Random, 95% CI)	1.77 [1.14, 2.76]
17.1.5 other comparator (enhanced usual care, mental health referral, psychoeducation)	3	786	Risk Ratio (IV, Random, 95% CI)	1.59 [1.38, 1.83]
17.2 treatment acceptability (dropouts)	26		Risk Ratio (IV, Random, 95% CI)	Subtotals only
17.2.1 treatment as usual	10	1632	Risk Ratio (IV, Random, 95% CI)	1.50 [0.56, 3.99]
17.2.2 waiting list	8	359	Risk Ratio (IV, Random, 95% CI)	1.17 [0.70, 1.93]
17.2.3 no treatment	3	187	Risk Ratio (IV, Random, 95% CI)	0.97 [0.45, 2.09]
17.2.4 medication placebo	1	96	Risk Ratio (IV, Random, 95% CI)	0.72 [0.31, 1.67]
17.2.5 medication	1	143	Risk Ratio (IV, Random, 95% CI)	0.37 [0.18, 0.75]
17.2.6 other comparator (enhanced usual care, mental health referral, psychoeducation)	4	886	Risk Ratio (IV, Random, 95% CI)	2.17 [1.04, 4.53]

Analysis 17.1. Comparison 17: SUBGROUP 6 CONTROL behavioural activation vs other controls (up to 6 months), Outcome 1: treatment efficacy



Analysis 17.2. Comparison 17: SUBGROUP 6 CONTROL behavioural activation vs other controls (up to 6 months), Outcome 2: treatment acceptability (dropouts)



Analysis 17.2. (Continued)

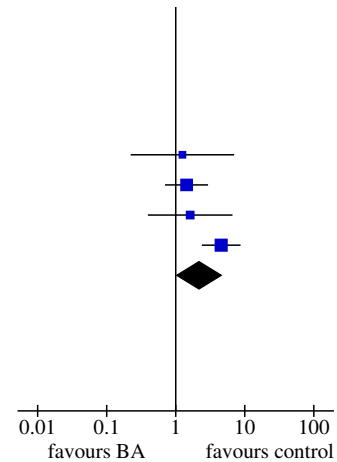
Heterogeneity: Not applicable
Test for overall effect: $Z = 2.73$ ($P = 0.006$)

17.2.6 other comparator (enhanced usual care, mental health referral, psychoeducation)

Raue 2019	2	8	2	10	13.3%	1.25 [0.22 , 7.02]
Weobong 2017	17	245	12	248	33.5%	1.43 [0.70 , 2.94]
Chowdhary 2016	4	28	3	34	17.5%	1.62 [0.39 , 6.64]
Arjadi 2018	47	159	10	154	35.7%	4.55 [2.39 , 8.68]
Subtotal (95% CI)		440		446	100.0%	2.17 [1.04 , 4.53]

Total events: 70 27
Heterogeneity: $\tau^2 = 0.29$; $\chi^2 = 6.59$, $df = 3$ ($P = 0.09$); $I^2 = 54\%$
Test for overall effect: $Z = 2.07$ ($P = 0.04$)

Test for subgroup differences: $\chi^2 = 13.36$, $df = 5$ ($P = 0.02$), $I^2 = 62.6\%$



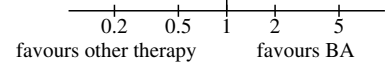
Comparison 18. SENSITIVITY 1 HIGH QUALITY STUDIES behavioural activation versus other psychological therapies (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
18.1 treatment efficacy	5	826	Risk Ratio (IV, Random, 95% CI)	1.20 [0.95, 1.51]
18.2 treatment acceptability (dropouts)	7	1039	Risk Ratio (IV, Random, 95% CI)	1.04 [0.84, 1.29]

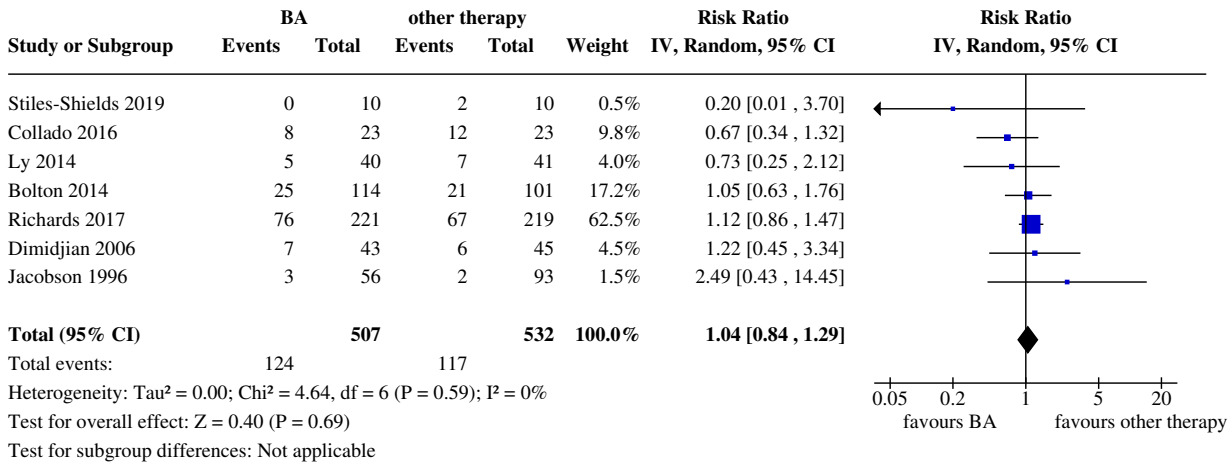
Analysis 18.1. Comparison 18: SENSITIVITY 1 HIGH QUALITY STUDIES behavioural activation versus other psychological therapies (up to 6 months), Outcome 1: treatment efficacy

Study or Subgroup	BA		other therapy		Weight	Risk Ratio IV, Random, 95% CI	Risk Ratio IV, Random, 95% CI
	Events	Total	Events	Total			
Richards 2017	97	185	111	195	26.3%	0.92 [0.77 , 1.11]	
Ly 2014	30	34	26	32	25.1%	1.09 [0.88 , 1.34]	
Dimidjian 2006	21	43	19	45	14.0%	1.16 [0.73 , 1.83]	
Arjadi 2018	78	120	63	145	24.1%	1.50 [1.19 , 1.88]	
Collado 2016	14	15	6	12	10.5%	1.87 [1.04 , 3.34]	
Total (95% CI)		397		429	100.0%	1.20 [0.95 , 1.51]	

Total events: 240 225
Heterogeneity: $\tau^2 = 0.04$; $\chi^2 = 13.62$, $df = 4$ ($P = 0.009$); $I^2 = 71\%$
Test for overall effect: $Z = 1.55$ ($P = 0.12$)
Test for subgroup differences: Not applicable



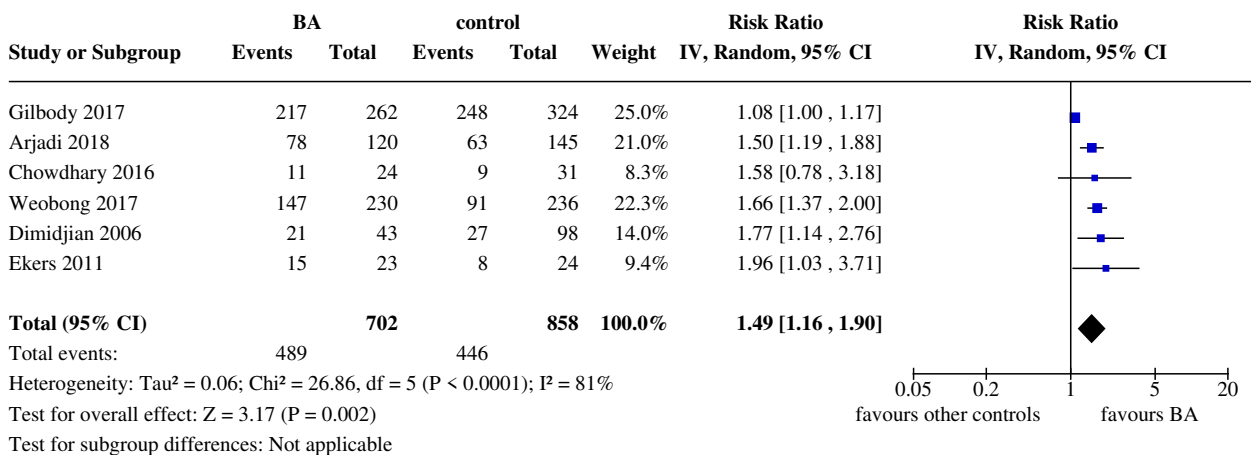
Analysis 18.2. Comparison 18: SENSITIVITY 1 HIGH QUALITY STUDIES behavioural activation versus other psychological therapies (up to 6 months), Outcome 2: treatment acceptability (dropouts)



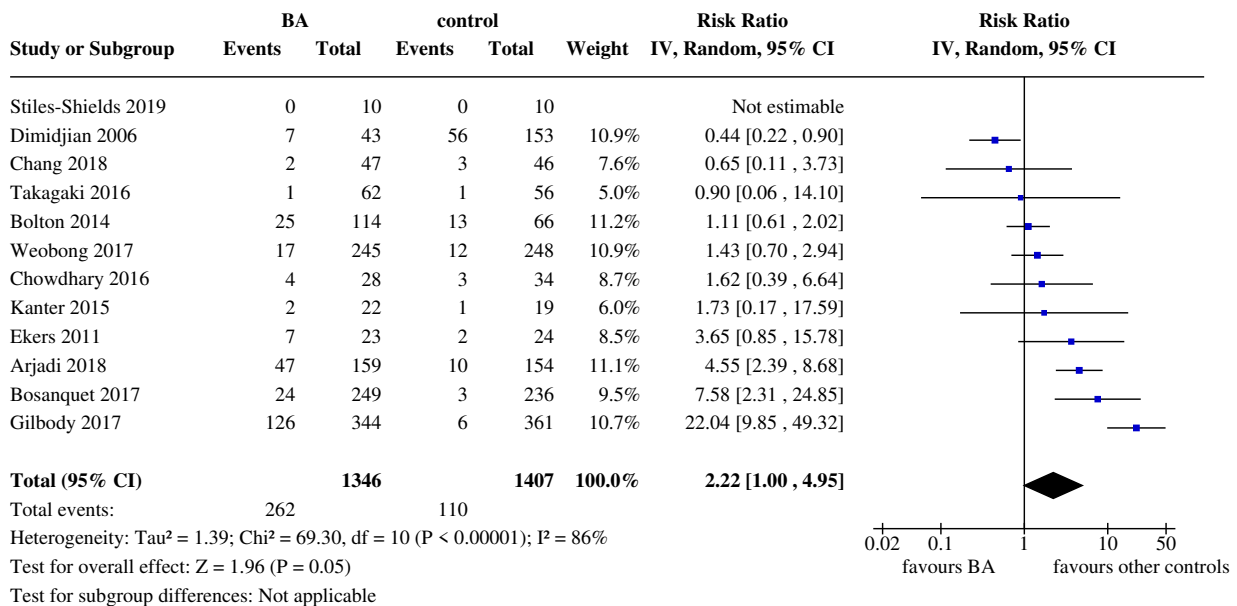
Comparison 19. SENSITIVITY 2 HIGH QUALITY STUDIES behavioural activation versus other controls (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
19.1 treatment efficacy	6	1560	Risk Ratio (IV, Random, 95% CI)	1.49 [1.16, 1.90]
19.2 treatment acceptability (dropouts)	12	2753	Risk Ratio (IV, Random, 95% CI)	2.22 [1.00, 4.95]

Analysis 19.1. Comparison 19: SENSITIVITY 2 HIGH QUALITY STUDIES behavioural activation versus other controls (up to 6 months), Outcome 1: treatment efficacy



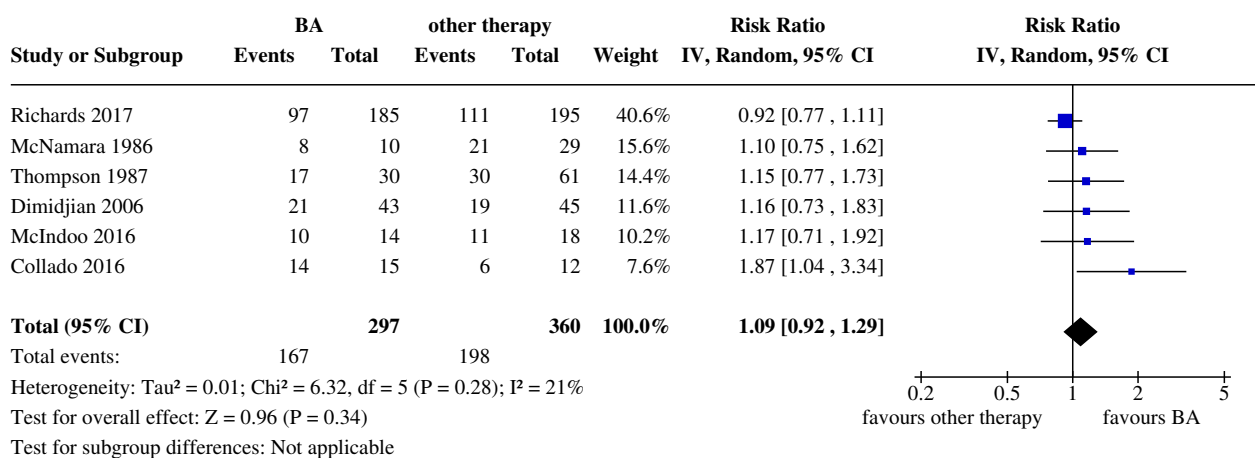
Analysis 19.2. Comparison 19: SENSITIVITY 2 HIGH QUALITY STUDIES behavioural activation versus other controls (up to 6 months), Outcome 2: treatment acceptability (dropouts)



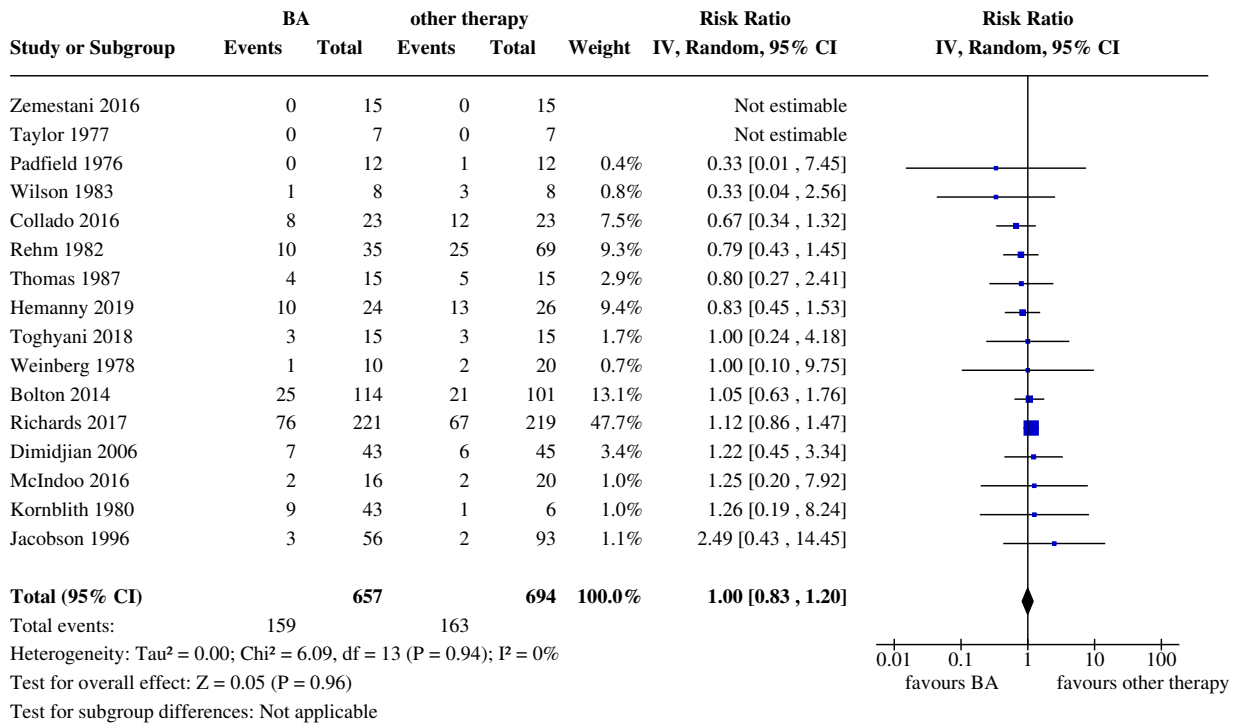
Comparison 20. SENSITIVITY 3 FACE-TO-FACE behavioural activation vs other psychological therapies (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
20.1 treatment efficacy	6	657	Risk Ratio (IV, Random, 95% CI)	1.09 [0.92, 1.29]
20.2 treatment acceptability (dropouts)	16	1351	Risk Ratio (IV, Random, 95% CI)	1.00 [0.83, 1.20]

Analysis 20.1. Comparison 20: SENSITIVITY 3 FACE-TO-FACE behavioural activation vs other psychological therapies (up to 6 months), Outcome 1: treatment efficacy



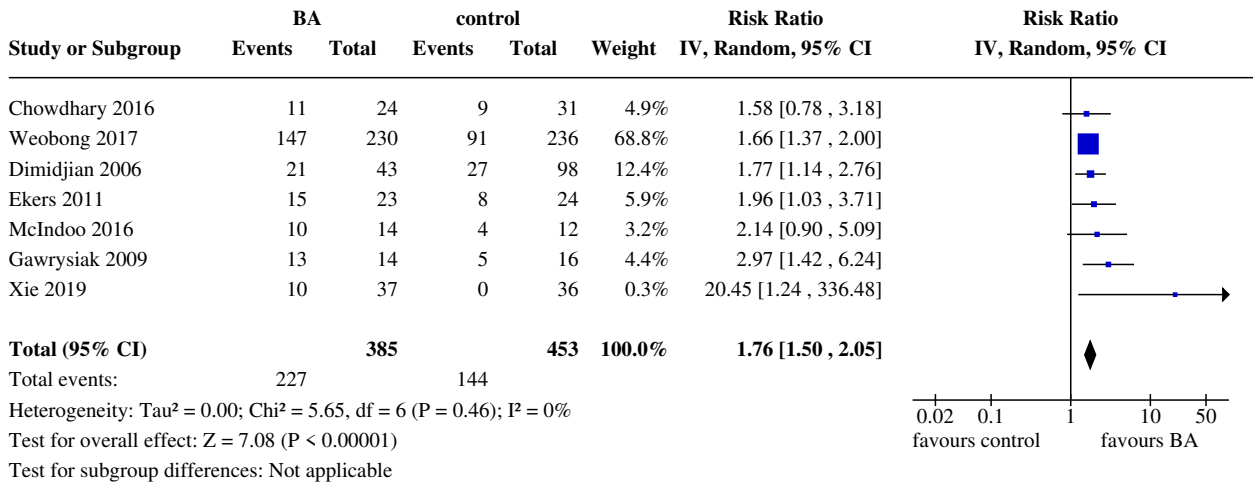
Analysis 20.2. Comparison 20: SENSITIVITY 3 FACE-TO-FACE behavioural activation vs other psychological therapies (up to 6 months), Outcome 2: treatment acceptability (dropouts)



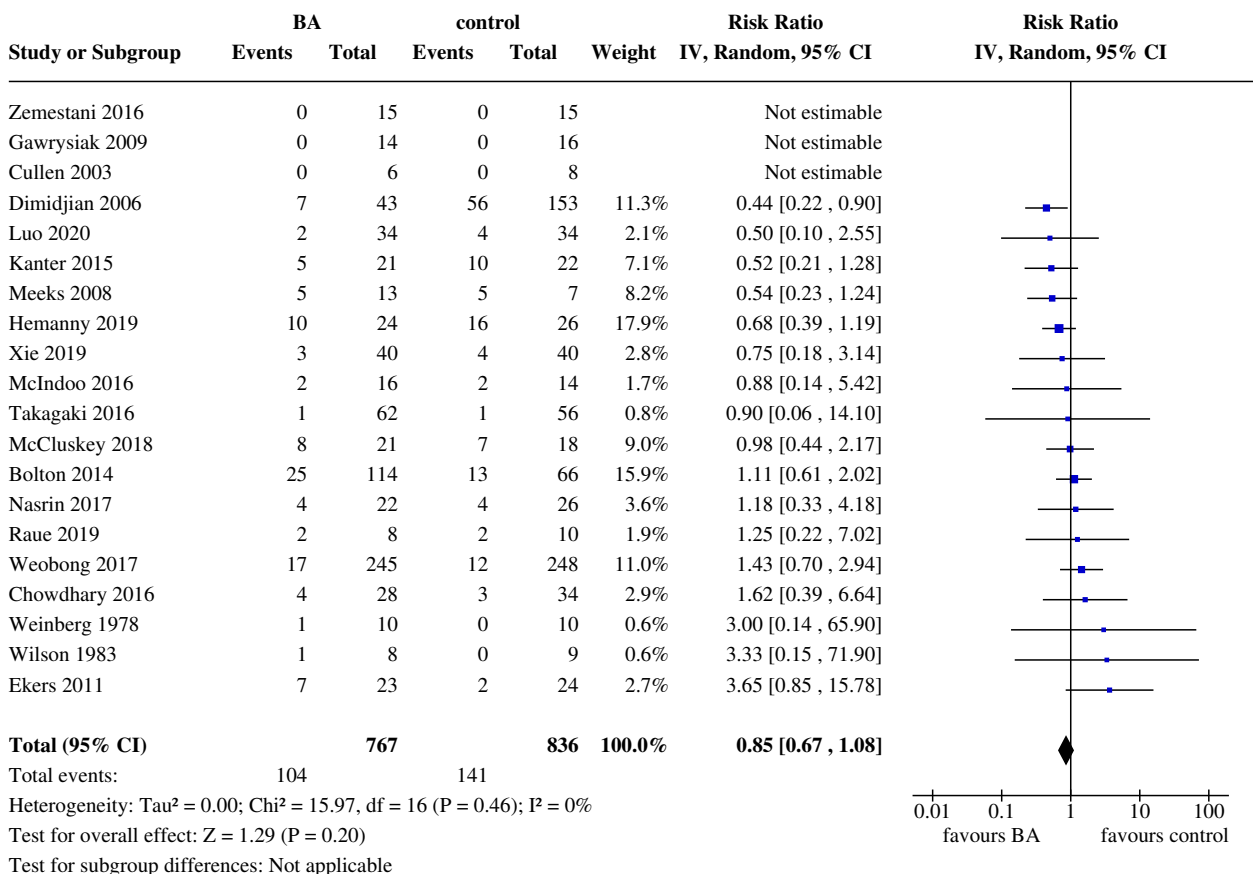
Comparison 21. SENSITIVITY 4 FACE-TO-FACE behavioural activation vs other controls (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
21.1 treatment efficacy	7	838	Risk Ratio (IV, Random, 95% CI)	1.76 [1.50, 2.05]
21.2 treatment acceptability (dropouts)	20	1603	Risk Ratio (IV, Random, 95% CI)	0.85 [0.67, 1.08]

Analysis 21.1. Comparison 21: SENSITIVITY 4 FACE-TO-FACE behavioural activation vs other controls (up to 6 months), Outcome 1: treatment efficacy



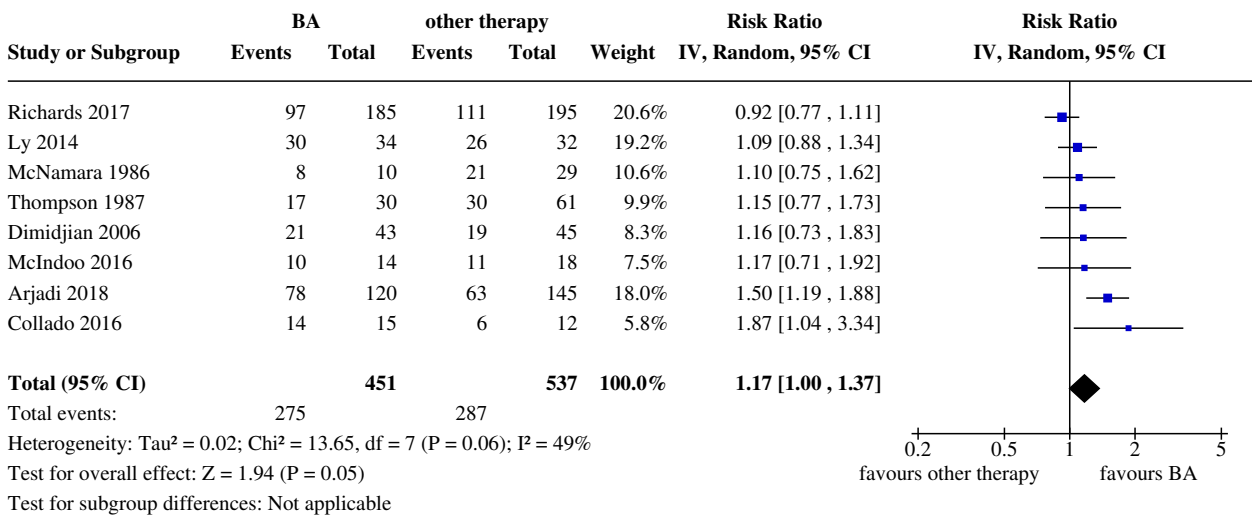
Analysis 21.2. Comparison 21: SENSITIVITY 4 FACE-TO-FACE behavioural activation vs other controls (up to 6 months), Outcome 2: treatment acceptability (dropouts)



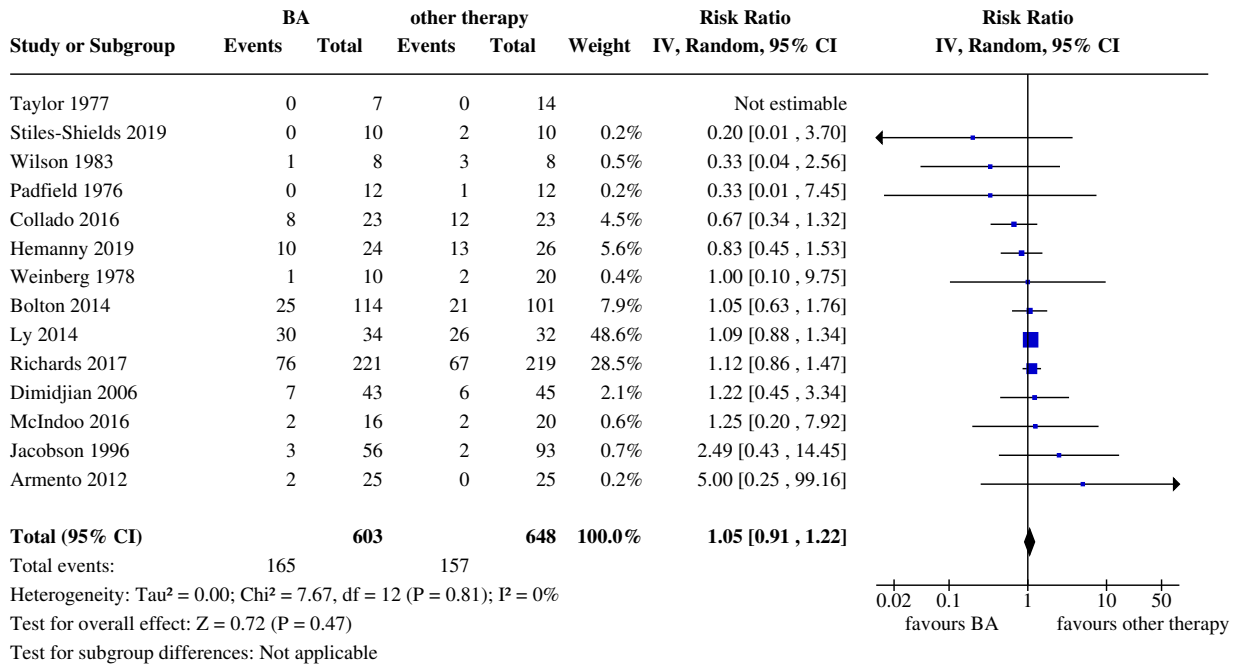
Comparison 22. SENSITIVITY 5 INDIVIDUAL behavioural activation versus other psychological therapies (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
22.1 treatment efficacy	8	988	Risk Ratio (IV, Random, 95% CI)	1.17 [1.00, 1.37]
22.2 treatment acceptability (dropouts)	14	1251	Risk Ratio (IV, Random, 95% CI)	1.05 [0.91, 1.22]

Analysis 22.1. Comparison 22: SENSITIVITY 5 INDIVIDUAL behavioural activation versus other psychological therapies (up to 6 months), Outcome 1: treatment efficacy



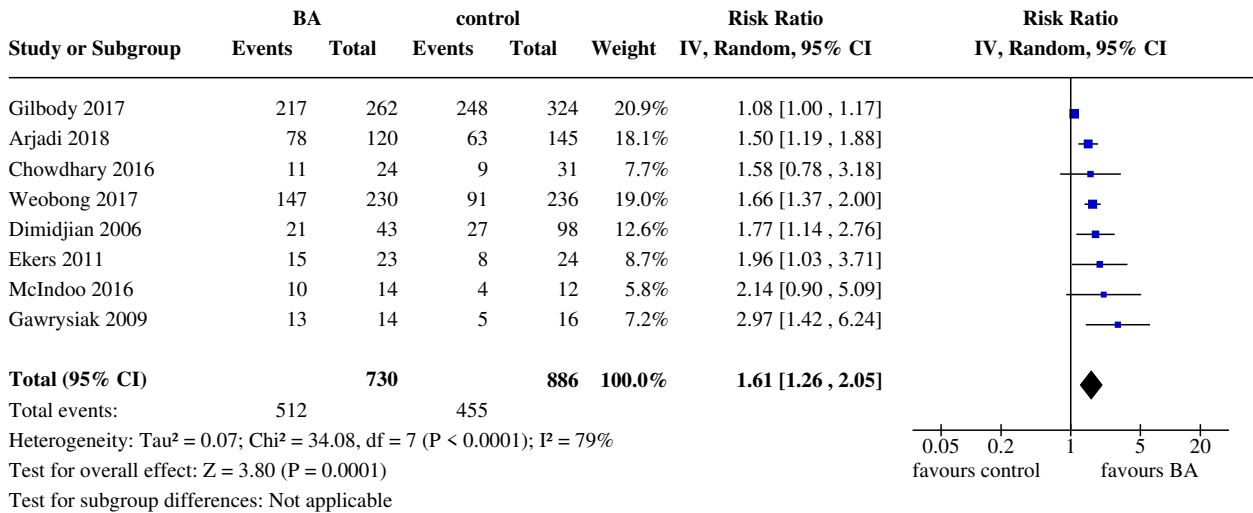
Analysis 22.2. Comparison 22: SENSITIVITY 5 INDIVIDUAL behavioural activation versus other psychological therapies (up to 6 months), Outcome 2: treatment acceptability (dropouts)



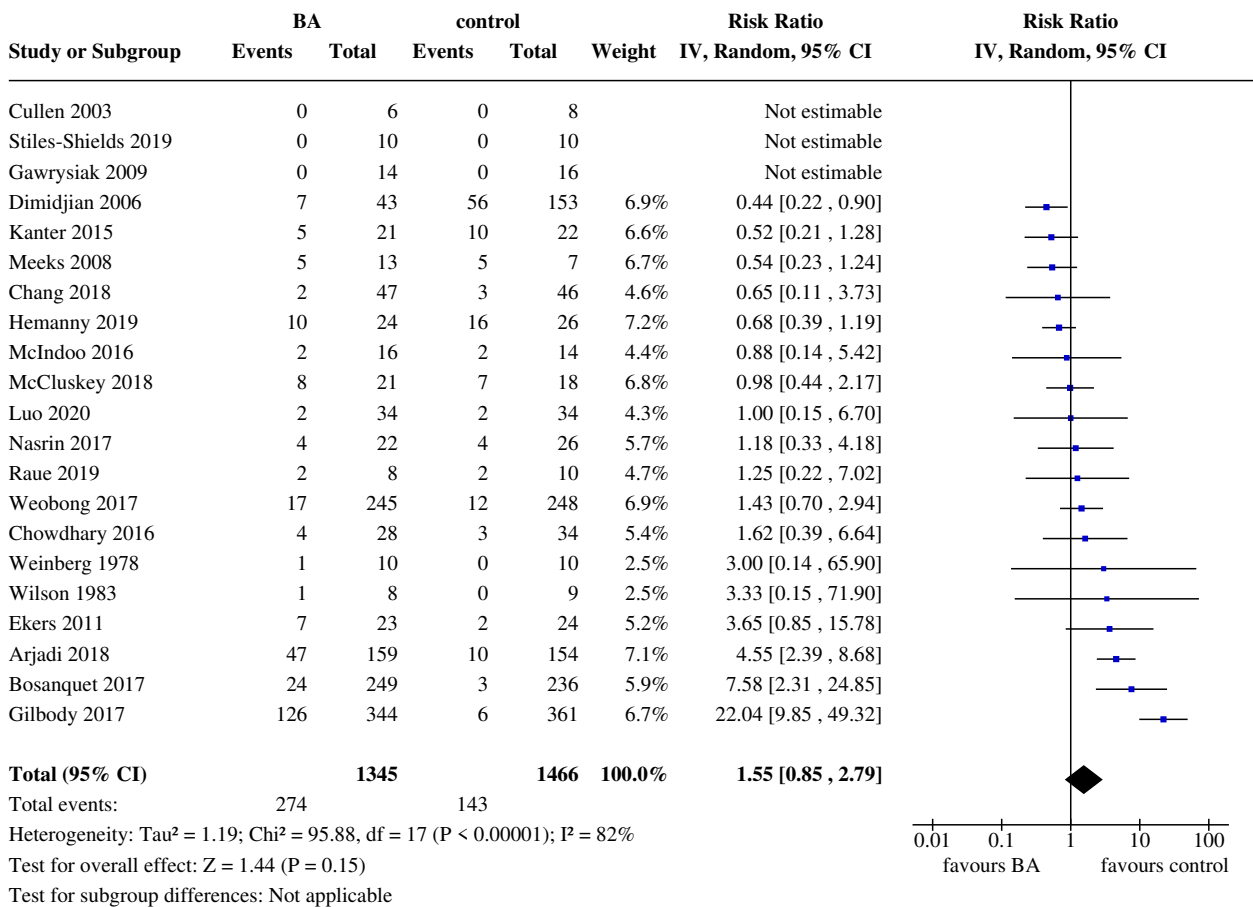
Comparison 23. SENSITIVITY 5 INDIVIDUAL behavioural activation versus other controls (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
23.1 treatment efficacy	8	1616	Risk Ratio (IV, Random, 95% CI)	1.61 [1.26, 2.05]
23.2 treatment acceptability (dropouts)	21	2811	Risk Ratio (IV, Random, 95% CI)	1.55 [0.85, 2.79]

Analysis 23.1. Comparison 23: SENSITIVITY 5 INDIVIDUAL behavioural activation versus other controls (up to 6 months), Outcome 1: treatment efficacy



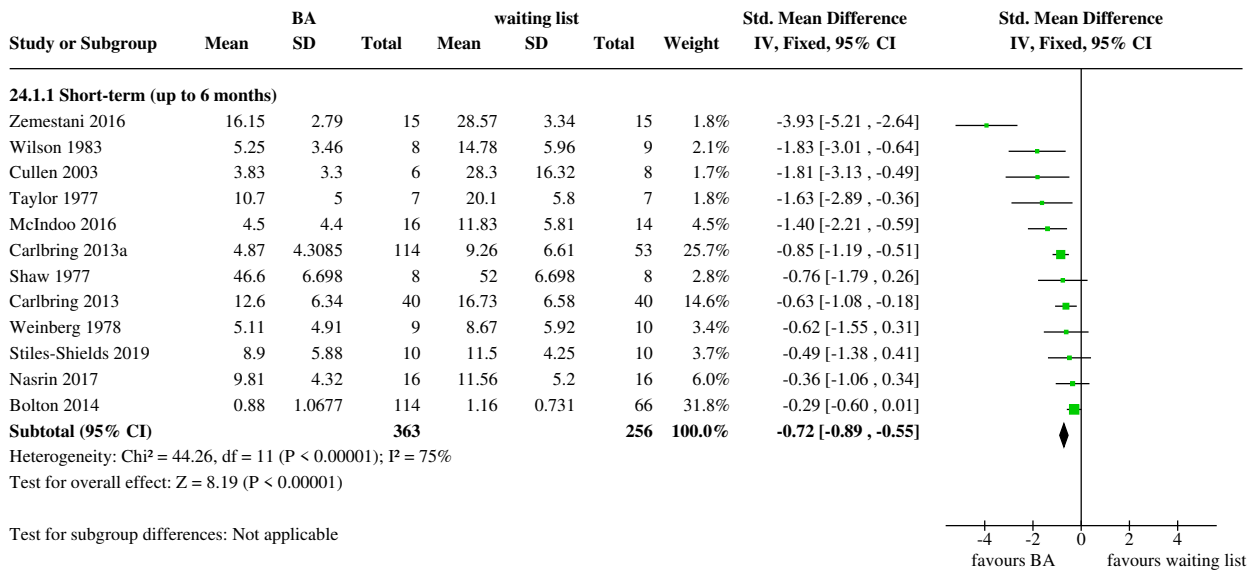
Analysis 23.2. Comparison 23: SENSITIVITY 5 INDIVIDUAL behavioural activation versus other controls (up to 6 months), Outcome 2: treatment acceptability (dropouts)



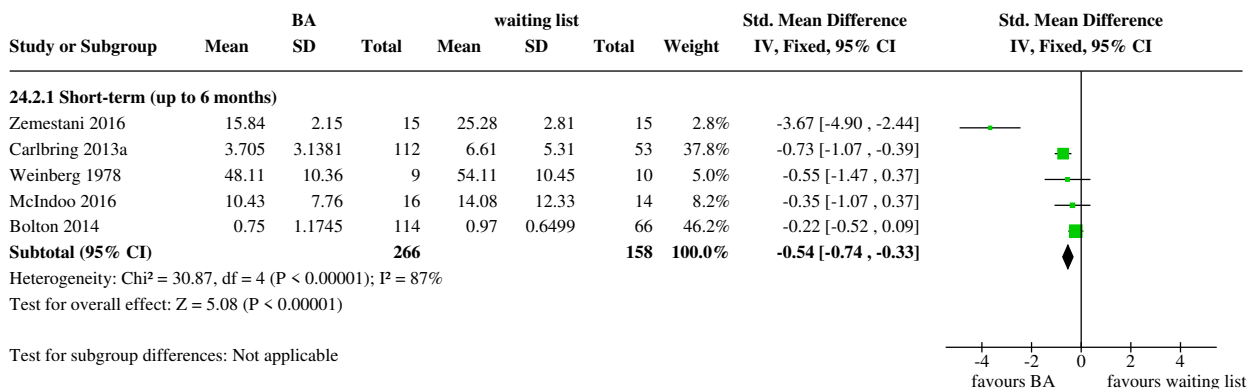
Comparison 24. SENSITIVITY 6 fixed effects BA vs waiting list

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
24.1 depression symptoms	12		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
24.1.1 Short-term (up to 6 months)	12	619	Std. Mean Difference (IV, Fixed, 95% CI)	-0.72 [-0.89, -0.55]
24.2 anxiety symptoms	5		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
24.2.1 Short-term (up to 6 months)	5	424	Std. Mean Difference (IV, Fixed, 95% CI)	-0.54 [-0.74, -0.33]

Analysis 24.1. Comparison 24: SENSITIVITY 6 fixed effects BA vs waiting list, Outcome 1: depression symptoms



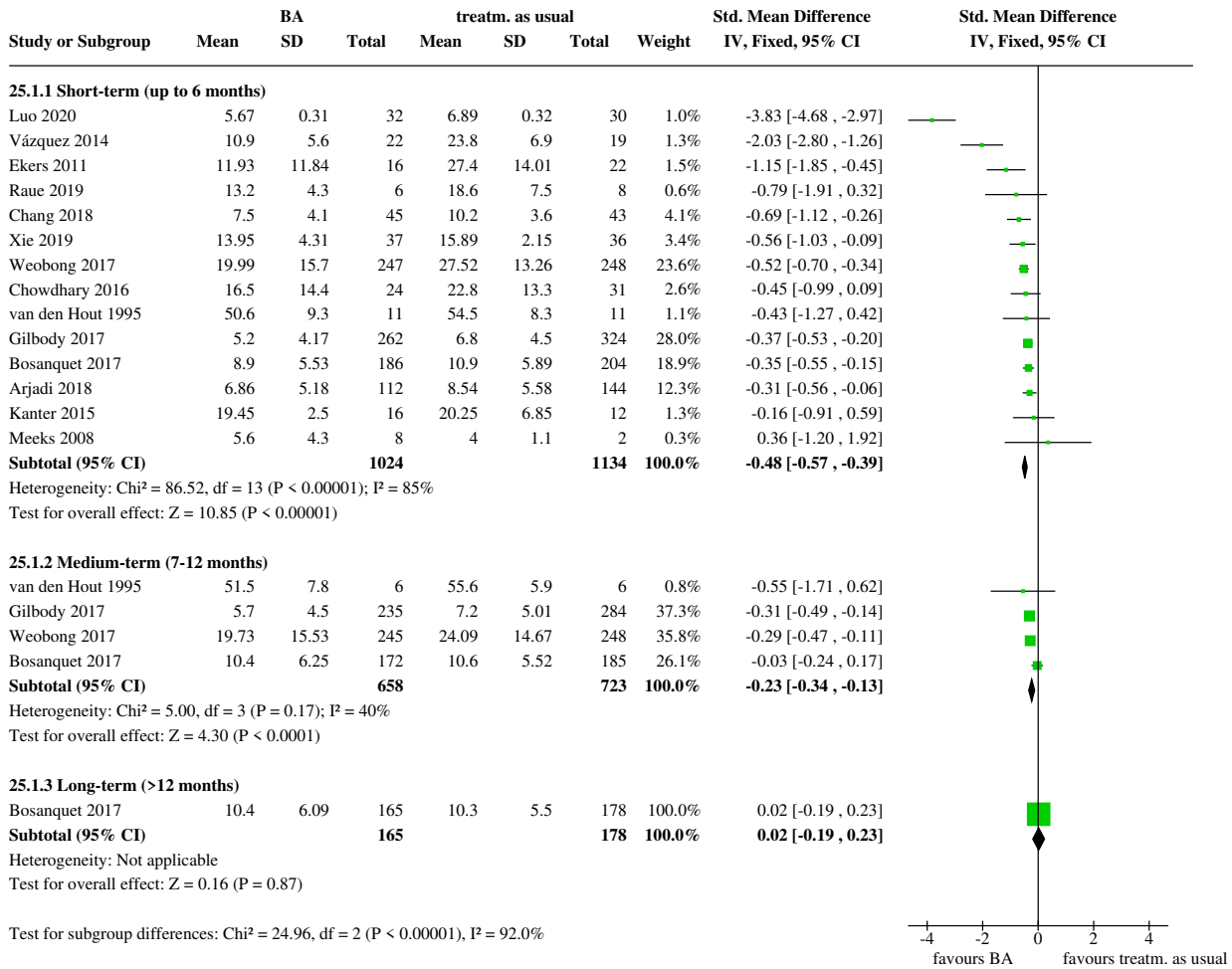
Analysis 24.2. Comparison 24: SENSITIVITY 6 fixed effects BA vs waiting list, Outcome 2: anxiety symptoms



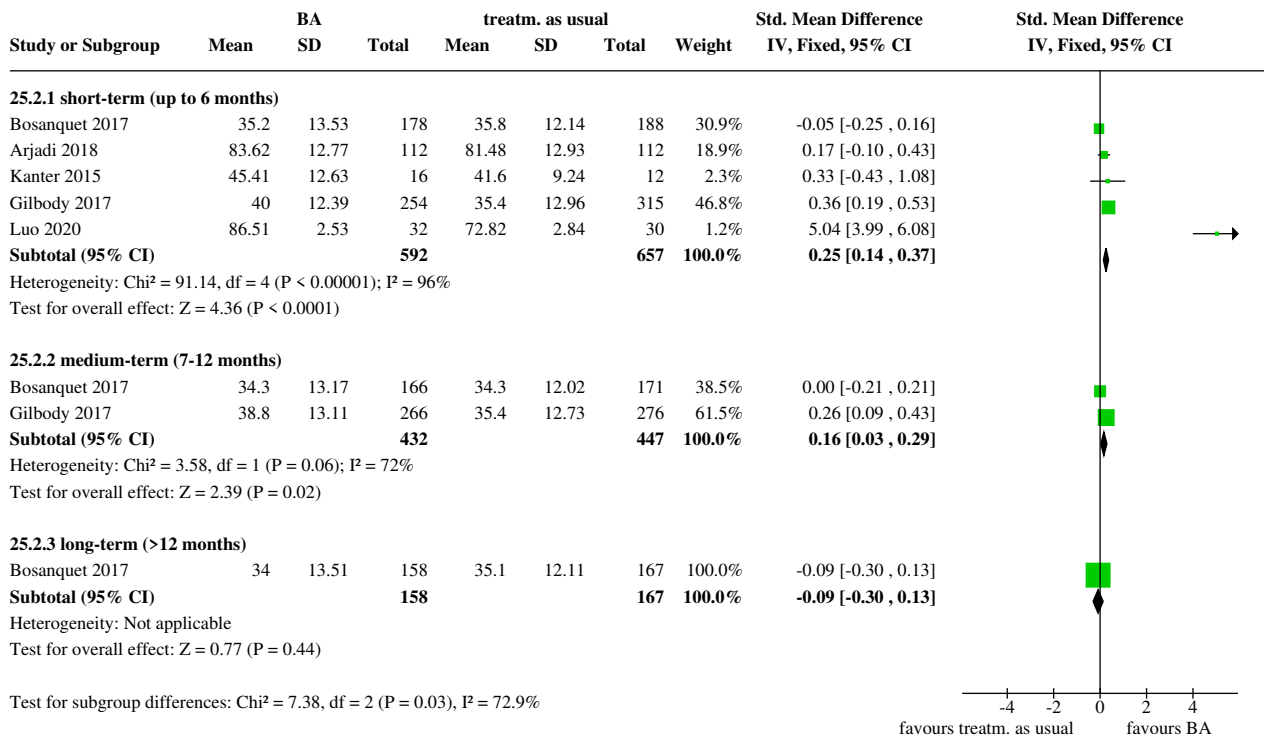
Comparison 25. SENSITIVITY 7 fixed effects BA vs treatment as usual

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
25.1 depression symptoms	14		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
25.1.1 Short-term (up to 6 months)	14	2158	Std. Mean Difference (IV, Fixed, 95% CI)	-0.48 [-0.57, -0.39]
25.1.2 Medium-term (7-12 months)	4	1381	Std. Mean Difference (IV, Fixed, 95% CI)	-0.23 [-0.34, -0.13]
25.1.3 Long-term (>12 months)	1	343	Std. Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.19, 0.23]
25.2 quality of life	5		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
25.2.1 short-term (up to 6 months)	5	1249	Std. Mean Difference (IV, Fixed, 95% CI)	0.25 [0.14, 0.37]
25.2.2 medium-term (7-12 months)	2	879	Std. Mean Difference (IV, Fixed, 95% CI)	0.16 [0.03, 0.29]
25.2.3 long-term (>12 months)	1	325	Std. Mean Difference (IV, Fixed, 95% CI)	-0.09 [-0.30, 0.13]

**Analysis 25.1. Comparison 25: SENSITIVITY 7 fixed effects
BA vs treatment as usual, Outcome 1: depression symptoms**



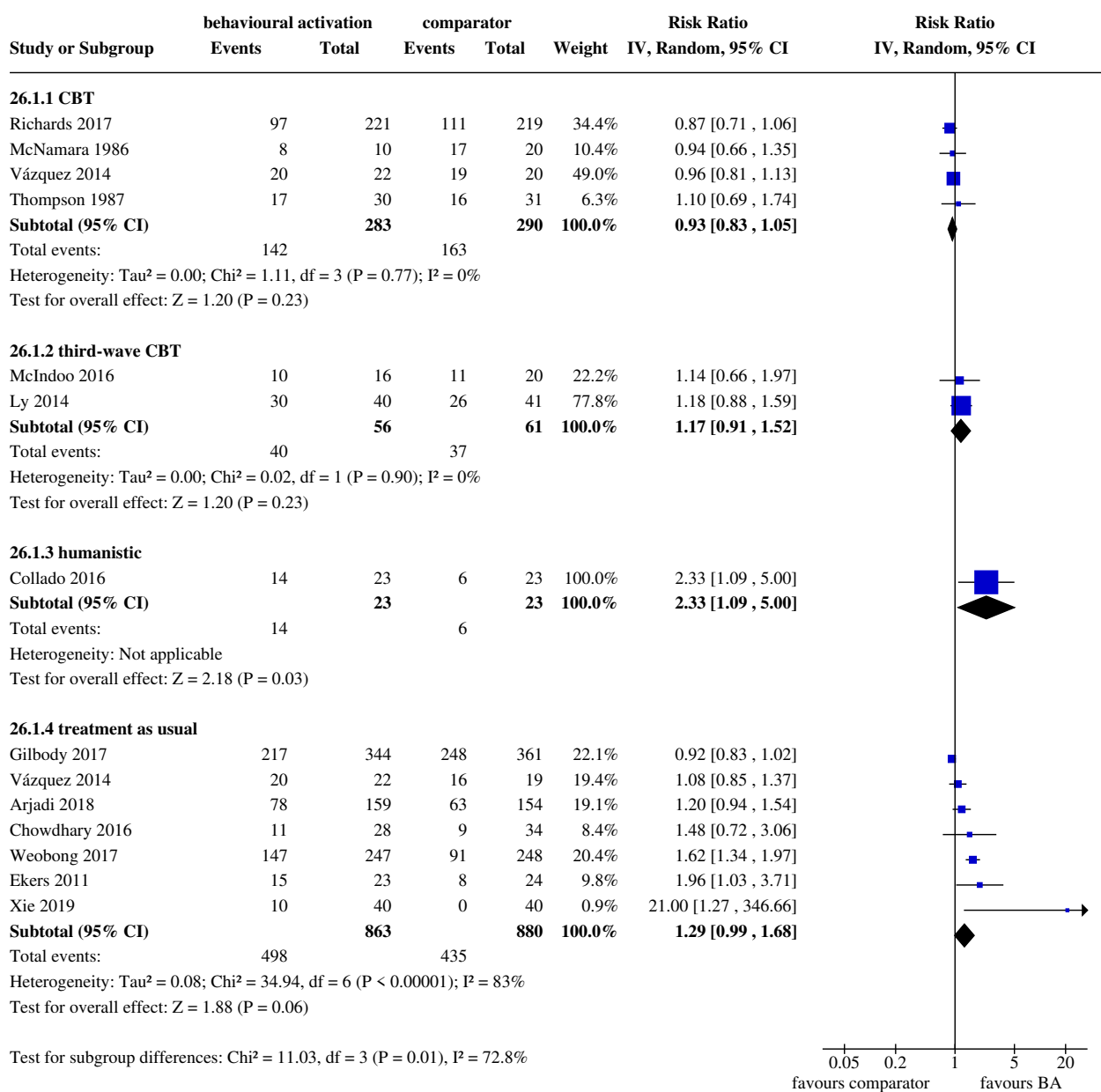
Analysis 25.2. Comparison 25: SENSITIVITY 7 fixed effects BA vs treatment as usual, Outcome 2: quality of life



Comparison 26. MISSING DATA ITT (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
26.1 treatment efficacy	13		Risk Ratio (IV, Random, 95% CI)	Subtotals only
26.1.1 CBT	4	573	Risk Ratio (IV, Random, 95% CI)	0.93 [0.83, 1.05]
26.1.2 third-wave CBT	2	117	Risk Ratio (IV, Random, 95% CI)	1.17 [0.91, 1.52]
26.1.3 humanistic	1	46	Risk Ratio (IV, Random, 95% CI)	2.33 [1.09, 5.00]
26.1.4 treatment as usual	7	1743	Risk Ratio (IV, Random, 95% CI)	1.29 [0.99, 1.68]

Analysis 26.1. Comparison 26: MISSING DATA ITT (up to 6 months), Outcome 1: treatment efficacy



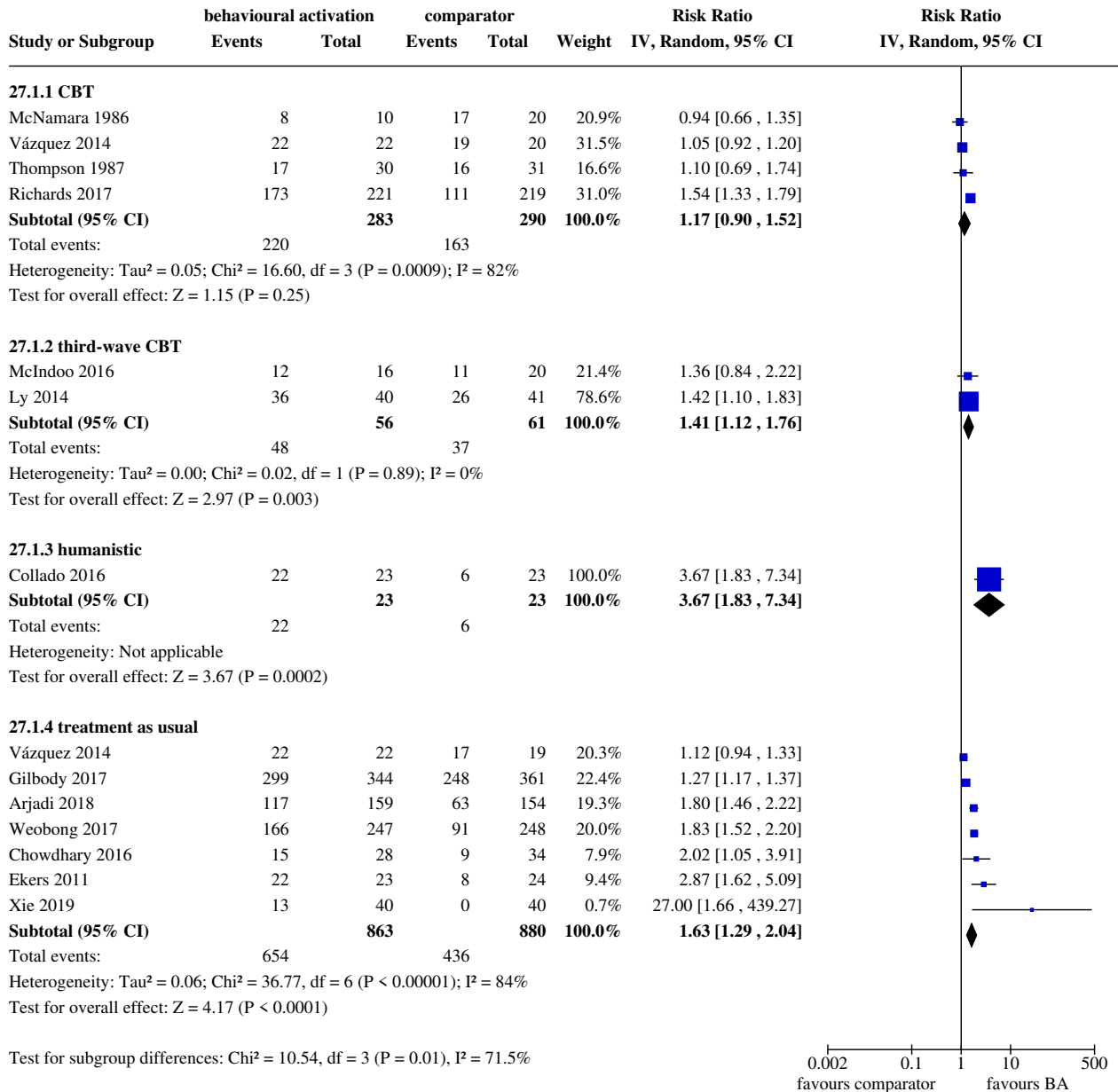
0.05 0.2 1 5 20
favours comparator favours BA

Comparison 27. MISSING DATA BEST CASE (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
27.1 treatment efficacy	13		Risk Ratio (IV, Random, 95% CI)	Subtotals only
27.1.1 CBT	4	573	Risk Ratio (IV, Random, 95% CI)	1.17 [0.90, 1.52]
27.1.2 third-wave CBT	2	117	Risk Ratio (IV, Random, 95% CI)	1.41 [1.12, 1.76]
27.1.3 humanistic	1	46	Risk Ratio (IV, Random, 95% CI)	3.67 [1.83, 7.34]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
27.1.4 treatment as usual	7	1743	Risk Ratio (IV, Random, 95% CI)	1.63 [1.29, 2.04]

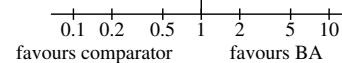
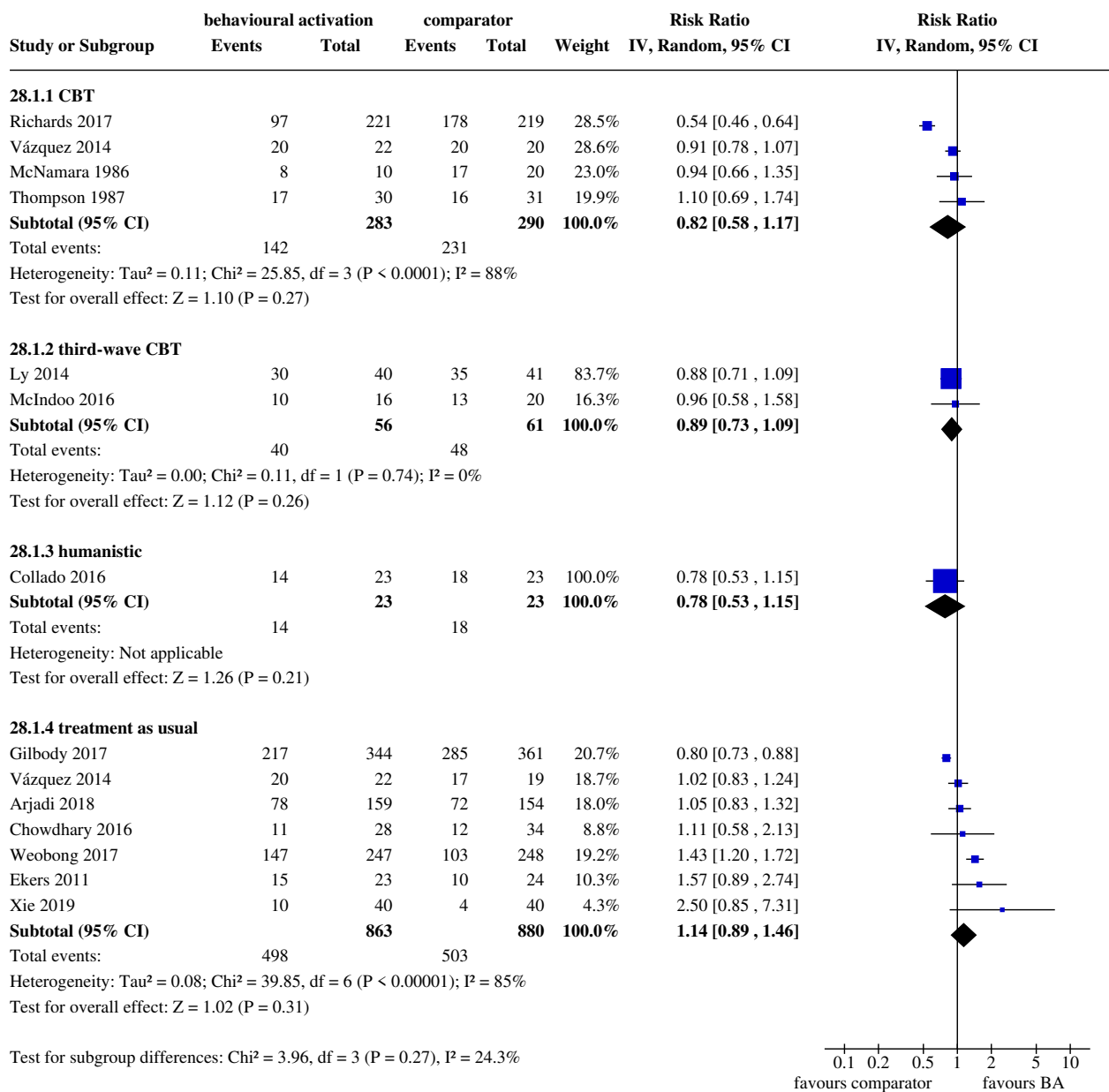
Analysis 27.1. Comparison 27: MISSING DATA BEST CASE (up to 6 months), Outcome 1: treatment efficacy



Comparison 28. MISSING DATA WORST CASE (up to 6 months)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
28.1 treatment efficacy	13		Risk Ratio (IV, Random, 95% CI)	Subtotals only
28.1.1 CBT	4	573	Risk Ratio (IV, Random, 95% CI)	0.82 [0.58, 1.17]
28.1.2 third-wave CBT	2	117	Risk Ratio (IV, Random, 95% CI)	0.89 [0.73, 1.09]
28.1.3 humanistic	1	46	Risk Ratio (IV, Random, 95% CI)	0.78 [0.53, 1.15]
28.1.4 treatment as usual	7	1743	Risk Ratio (IV, Random, 95% CI)	1.14 [0.89, 1.46]

Analysis 28.1. Comparison 28: MISSING DATA WORST CASE (up to 6 months), Outcome 1: treatment efficacy



ADDITIONAL TABLES

Table 1. Adverse events

First author	Year of publication	Comparator group(s)	Description of adverse events (at end of study period)
Bosanquet	2017	Treatment as usual	BA: 47 suspected adverse events. Usual care: 34 suspected adverse events. Elderly sample.

Table 1. Adverse events (Continued)

Dimidjian	2006	CBT, medication, medical placebo	various physical side effects from antidepressant medication and placebo. 1 suicide in antidepressant arm.
Gilbody	2017	Treatment as usual	BA: 37 events; 35 unrelated to intervention and 2 unlikely to be related to intervention. Usual care: 44 events; 40 unrelated and 4 unlikely to be related to intervention. 18 patients died (elderly sample).
Padfield	1976	Interpersonal, cognitive analytic, integrative	2 suicide attempts and 1 case of suicidal thoughts in comparator arm; no adverse events in behavioural activation arm.
Richards	2017	CBT	3 serious adverse events in behavioural activation arm (2 overdose, 1 self-harm) and 8 serious adverse events in comparator arm (7 overdose, 1 self-harm).
Stiles-Shields	2018	CBT and waiting list	No adverse events.
Weobong	2017	Treatment as usual	1 suicide attempt and 18 unplanned hospitalisations in behavioural activation arm. 1 suicide attempt, 26 unplanned hospitalisations, and 2 deaths in comparator arm.

BA: Behavioural activation; **CBT:** cognitive-behavioural therapy;

APPENDICES

Appendix 1. Categories of psychological therapies

Categories	Abbreviation	Subcategories	Abbreviation
1. Behavioural therapies	BT	Behavioural therapy (Lewinsohn)	
		Behavioural activation (original model) (Jacobson)	BA
		Social skills training/assertiveness training	SST/assertion
		Relaxation therapy	
		Other behavioural therapies	
2. Cognitive-behavioural therapies	CBT	Cognitive therapy	
		Rational emotive behaviour therapy	
		Problem-solving therapy	
		Self-control therapy	
		Coping with depression course	

(Continued)

		Other cognitive-behavioural therapies	
3. Mindfulness-based 'third-wave' cognitive and behavioural therapies	Third-wave CBT	Acceptance and commitment therapy	
		Compassionate mind training	
		Functional analytic psychotherapy	
		Extended behavioural activation	eBA
		Metacognitive therapy	
		Mindfulness-based cognitive therapy	
		Dialectical behaviour therapy	
		Other third wave cognitive and behavioural therapies (other third wave CBT)	
4. Psychodynamic therapies		Drive/structural model (Freud)	
		Relational model (Strupp, Luborsky)	
		Integrative analytic model (Mann)	
		Other psychodynamic therapies	
5. Humanistic therapies		Person-centered therapy (Rogerian)	
		Gestalt therapy	
		Experiential therapies	
		Transactional analysis	
		Existential therapy	
		Non-directive/supportive therapies	
		Other humanistic therapies	
6. Interpersonal, cognitive analytic and other integrative therapies (integrative therapies)		Interpersonal therapy	IPT
		Cognitive-analytic therapy	CAT
		Psychodynamic-interpersonal therapy	
		Cognitive-behavioural analysis system of psychotherapy	
		Counselling	
		Motivational interviewing	
		Other integrative therapy approaches	

Appendix 2. Specialised Register: CCMD-CTR

Cochrane Common Mental Disorders Controlled Trials Register (CCMD-CTR)

Cochrane Common Mental Disorders has a specialised register of randomised controlled trials, the CCMD-CTR. This register contains over 40,000 reference records (reports of RCTs) for anxiety disorders, depression, bipolar disorder, eating disorders, self-harm and other mental disorders within the scope of this Group. The CCMD-CTR is a partially studies-based register with more than 50% of reference records tagged to around 12,500 individually PICO-coded study records. Reports of trials for inclusion in the register are collated from (weekly) generic searches of MEDLINE (1950 onwards), Embase (1974 onwards) and PsycINFO (1967 onwards), quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL) and review-specific searches of additional databases. Reports of trials are also sourced from international trials registries, drug companies, the handsearching of key journals, conference proceedings and other (non-Cochrane) systematic reviews and meta-analyses. Details of CCMD's core search strategies (used to identify RCTs) can be found on the Group's website, with an example of the core MEDLINE search displayed below.

The CCMD-CTR will be searched for this review using the following terms:

("behavioral activation" or "behavior therapy" or "behavior modification" or "self-monitoring" or "self-management therapy" or "self-control therapy" or "task assignment"):SIN and (depress*):SCO

N.B. The search of the CCMD-CTR will only retrieve RCTs of 'behavioural activation', or the main elements of behavioural activation in participants with clinically diagnosed depression, hence additional searches of the main bibliographic databases (all years to date) to identify trials which also include participants with subthreshold depression.

The search strategy listed below is the weekly OVID Medline search which was used to inform the Group's specialised register. It is based on a list of terms for all conditions within the scope of the Cochrane Common Mental Disorders Group plus a sensitive RCT filter.

1. [MeSH Headings]: eating disorders/ or anorexia nervosa/ or binge-eating disorder/ or bulimia nervosa/ or female athlete triad syndrome/ or pica/ or hyperphagia/ or bulimia/ or self-injurious behavior/ or self mutilation/ or suicide/ or suicidal ideation/ or suicide, attempted/ or mood disorders/ or affective disorders, psychotic/ or bipolar disorder/ or cyclothymic disorder/ or depressive disorder/ or depression, postpartum/ or depressive disorder, major/ or depressive disorder, treatment-resistant/ or dysthymic disorder/ or seasonal affective disorder/ or neurotic disorders/ or depression/ or adjustment disorders/ or exp antidepressive agents/ or anxiety disorders/ or agoraphobia/ or neurocirculatory asthenia/ or obsessive-compulsive disorder/ or obsessive hoarding/ or panic disorder/ or phobic disorders/ or stress disorders, traumatic/ or combat disorders/ or stress disorders, post-traumatic/ or stress disorders, traumatic, acute/ or anxiety/ or anxiety, castration/ or koro/ or anxiety, separation/ or panic/ or exp anti-anxiety agents/ or somatoform disorders/ or body dysmorphic disorders/ or conversion disorder/ or hypochondriasis/ or neurasthenia/ or hysteria/ or munchausen syndrome by proxy/ or munchausen syndrome/ or fatigue syndrome, chronic/ or obsessive behavior/ or compulsive behavior/ or behavior, addictive/ or impulse control disorders/ or firesetting behavior/ or gambling/ or trichotillomania/ or stress, psychological/ or burnout, professional/ or sexual dysfunctions, psychological/ or vaginismus/ or Anhedonia/ or Affective Symptoms/ or *Mental Disorders/

2. [Title/ Author Keywords]: (eating disorder* or anorexia nervosa or bulimi* or binge eat* or (self adj (injur* or mutilat*)) or suicide* or suicidal or parasuicid* or mood disorder* or affective disorder* or bipolar i or bipolar ii or (bipolar and (affective or disorder*)) or mania or manic or cyclothymic* or depression or depressive or dysthymi* or neurotic or neurosis or adjustment disorder* or antidepress* or anxiety disorder* or agoraphobia or obsess* or compulsi* or panic or phobi* or ptsd or posttrauma* or post trauma* or combat or somatoform or somati#ation or medical* unexplained or body dysmorphi* or conversion disorder or hypochondria* or neurastheni* or hysteria or munchausen or chronic fatigue* or gambling or trichotillomania or vaginismus or anhedoni* or affective symptoms or mental disorder* or mental health).ti,kf.

3. [RCT filter]: (controlled clinical trial.pt. or randomised controlled trial.pt. or (randomi#ed or randomi#ation).ab,ti. or randomly.ab. or (random* adj3 (administ* or allocat* or assign* or class* or control* or determine* or divide* or distribut* or expose* or fashion or number* or place* or recruit* or substitut* or treat*)).ab. or placebo*.ab,ti. or drug therapy.fs. or trial.ab,ti. or groups.ab. or (control* adj3 (trial* or study or studies)).ab,ti. or ((singl* or doubl* or tripl* or trebl*) adj3 (blind* or mask* or dummy*)).mp. or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or randomised controlled trial/ or pragmatic clinical trial/ or (quasi adj (experimental or random*)).ti,ab. or ((waitlist* or wait* list* or treatment as usual or TAU) adj3 (control or group)).ab.)

4. (1 and 2 and 3)

Records are screened for reports of RCTs within the scope of the Cochrane Common Mental Disorders Group. Secondary reports of RCTs are tagged to the appropriate study record.

The CCMD-CTR is current to June 2016 only.

Appendix 3. Other database searches

Date of search: 17-January-2019
 Ovid PsycINFO (Jan, week 2,2019) n = 1694
 CENTRAL (% CRS-Web), (18-Jan-2019), n = 1567
 CCMDCTR-Studies Register (current to June 2016), n = 72
 Ovid Embase, (2019 Week 02), n = 2237
 Ovid MEDLINE all searches to 17-Jan-2019, n = 2036
 Theses databases, n = 139
 Trial Registries, n = 261
 Total = 8006
 Duplicates removed n = 2751
 Total screen, n = 5255

An update search, 17 Jan 2020 retrieved an addition 594 records to screen.

Ovid PsycINFO <1806 to January Week 2 2019>

Search Strategy:

- 1 behavioral activation system/ (295)
- 2 ((behavio* adj1 activ*) or BATD).ti,ab,id. (6198)
- 3 (behavio* adj3 (reinforce* or re-inforce*)).ti,ab,id. (5249)
- 4 reforc*.ti,id. or (((contingent or positive) adj1 reforc*) or (reforc* adj3 (environment* or experience*))).ti,ab,id. (29104)
- 5 exp reinforcement/ (46970)
- 6 (reinforce or reinforcer or reinforcement or reinforcements or re-inforcement or re-inforcements).ab. /freq=2 (15569)
- 7 (behavio* adj2 (contracting or modification or modify*)).ti,ab,id. (7960)
- 8 behavior contracting/ or behavior modification/ (10563)
- 9 ((activit* or event?) adj2 schedul*).ti,ab,id. (798)
- 10 planned behavior/ (2518)
- 11 ((pleas* or enjoyable or rewarding) adj (activit* or event?)).ti,ab,id. (909)
- 12 (operant conditioning or instrumental learning).ti,ab,id. (4692)
- 13 exp operant conditioning/ (34771)
- 14 (positive interaction* or avoidant coping or environmental contingenc* or contingency management).ti,ab,id. (2755)
- 15 exp contingency management/ (2898)
- 16 ((gain? or reapprais*) adj2 focus*).ti,ab,id. (120)
- 17 functional analysis.ti,ab,id,sh. (3984)
- 18 (behavio* and (self adj (care or efficacy or evaluat* or monitor*))).ti,id,hw. (9576)
- 19 ((psychoeducat* or psycho-educat*) and (coping behavi* or coping skills or self manag* or (behavi* adj2 chang*))).ti,ab,id,hw. (879)
- 20 self management/ and behavior change/ (111)
- 21 or/1-20 (127748)
- 22 Behavior Therapy/ and depress*.ti,hw,tm. (913)
- 23 (behavio* therapy adj3 depress*).ti,ab,id. (841)
- 24 ((behavio* adj (counsel* or intervention or train* or treatment or therapy or psychotherapy)) and depress*).ti. (1255)
- 25 "depression (emotion)"/ (24732)
- 26 major depression/ or late life depression/ or reactive depression/ (113534)
- 27 emotional states/ or distress/ or emotional trauma/ or grief/ or hopelessness/ or sadness/ (83186)
- 28 depress*.ti,ab,id. (284738)
- 29 (mood? or mental health or ((emotion* or psychological) adj (distress or trauma*))).ti,id. (129767)
- 30 or/25-29 (438086)
- 31 (21 and 30) or 22 or 23 or 24 (9842)
- 32 clinical trials.sh. (11213)
- 33 (randomi#ed or randomi#ation or randomi#ing).ti,ab,id. (77179)
- 34 (RCT or at random or (random* adj3 (administ* or allocat* or assign* or class* or control* or crossover or cross-over or determine* or divide* or division or distribut* or expose* or fashion or number* or place* or recruit* or split or substitut* or treat*))).ti,ab,id. (93213)
- 35 (control* and (trial or study or group) and (placebo or waitlist* or wait* list* or ((treatment or care) adj2 usual))).ti,ab,id,hw. (26859)
- 36 ((allocat* or assign* or receive*) and (placebo or no-treatment or waitlist or wait* list* or ((treatment or care) adj2 usual)) and (control or group)).ab. (12516)
- 37 empirical study.md. and ((placebo or no-treatment or waitlist or wait* list* or ((treatment or care) adj2 usual)) and (control or group or compared or comparison)).ab. (26670)
- 38 ((single or double or triple or treble) adj2 (blind* or mask* or dummy)).ti,ab,id. (24826)
- 39 trial.ti. (27214)
- 40 treatment effectiveness evaluation.sh. (22581)

41 (treatment adj5 control).ab. (11883)
 42 or/32-41 (172828)
 43 31 and 42 (1694)

Cochrane Central Register of Controlled Trials (CENTRAL) % CRS-Web (18-Jan-2019)

#1 ((behavio* adj1 activ*) or BATD): AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET
 #2 (behavio* adj3 (reinforce* or re-inforce*)): AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET
 #3 (((contingent or positive) adj1 reinforc*) or (reinforc* adj3 (environment* or experience*)): AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET
 #4 reinforc*:TO,TI AND CENTRAL:TARGET
 #5 (behavio* adj2 (contracting or modification or modify*)): AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET
 #6 ((activit* or event or events) adj2 schedul*): AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET
 #7 ((pleas* or enjoyable or rewarding) adj (activit* or event or events)): AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET
 #8 (operant conditioning or instrumental learning): AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET
 #9 (positive interaction* or avoidant coping or environmental contingenc* or contingency management): AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET
 #10 functional analysis: AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET
 #11 ((psychoeducat* or psycho-educat*) and (coping behavi* or coping skills or self manag* or (behavi* adj2 chang*)): AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET
 #12 MESH DESCRIPTOR Reinforcement (Psychology) EXPLODE ALL AND CENTRAL:TARGET
 #13 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12)
 #14 depress*: AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET
 #15 (grief or hopelessness or sadness):TI,TO AND CENTRAL:TARGET
 #16 (mood or moods or mental health or emotion* distress* or emotional trauma or psychological distress or psychological trauma): TI,TO AND CENTRAL:TARGET
 #17 (#14 OR #15 OR #16)
 #18 (#13 AND #17)
 #19 MESH DESCRIPTOR Behavior Therapy AND CENTRAL:TARGET
 #20 depress*: EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET
 #21 (#19 AND #20)
 #22 (#18 OR #21), n=1567

CCMDCTR-Sudies Register (current to June 2016)

(("behavioral activation" or "behavior therapy" or "behavior modification" or "self-monitoring" or "self-management therapy" or "self-control therapy" or "task assignment"):SIN and (depress*):SCO)

Ovid-MEDLINE-1 (Initial searches November 2018)

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to November 21, 2018>
 Search Strategy:

 Search-1 (Search for condition initially tailored to retrieve BATD RCTs for clinical depression/MDD)
 1 (behavio* activat* or BATD).ti,ab,kf. (1791)
 2 (behavio* adj3 (reinforce* or re-inforce*)).ti,ab,kf. (2727)
 3 (behavio* adj2 (contracting or modification or modify*)).ti,ab,kf. (6332)
 4 reinforc*.ti,kf. or ((positive adj1 reinforc*) or (reinforc* adj3 (environment* or experience*))).ti,ab,kf. (19953)
 5 (reinforce or reinforcer or reinforcement or reinforcements or re-inforcement or re-inforcements).ab. /freq=2 (10487)
 6 (activit* adj2 schedul*).ti,ab,kf. (509)
 7 (pleas* adj (activit* or event?)).ti,ab,kf. (319)
 8 (operant conditioning or instrumental learning).ti,ab,kf. (2522)
 9 (positive interaction* or avoidant coping or environmental contingenc* or contingency management).ti,ab,kf. (2716)
 10 functional analysis.ti,ab,kf. (21598)
 11 behavio*.mp. and (self adj (evaluat* or monitor*)).ti,ab,kf. (3268)
 12 or/1-11 (64373)
 13 Behavior Therapy/ and depress*.ti,hw. (1382)
 14 ((behavio* adj (counsel* or intervention or train* or treatment or therapy or psychotherapy)) and depress*).ti,kf. (1562)
 15 Depression/ (104912)
 16 Depressive Disorder/ or Depressive Disorder, Major/ (94699)
 17 (depress* adj3 (acute or clinical* or diagnos* or disorder* or major or unipolar or illness or scale* or score* or adult* or patient* or participant* or people or inpatient* or in-patient* or outpatient* or out-patient*)).ab. (135995)

- 18 (depress* and (Beck* or BDI* or DSM* or (Statistical Manual adj2 Mental Disorders) or Hamilton or HAM-D or HAMD or MADRS or (International Classification adj2 Disease?) or ICD-10 or ICD-9)).ab. (39194)
- 19 "with depressi*".ab. (23474)
- 20 (depress* or mood or mental health).ti,kf. (216491)
- 21 or/15-20 (344231)
- 22 13 or 14 or (12 and 21) (4533)
- 23 controlled clinical trial.pt. (92759)
- 24 randomized controlled trial.pt. (471716)
- 25 (randomi#ed or randomi#ation or randomi#ing).ti,ab,kf. (561767)
- 26 (RCT or "at random" or (random* adj3 (administ* or allocat* or assign* or class* or cluster or control* or determine* or divide* or division or distribut* or expose* or fashion or number* or place* or pragmatic or quasi or recruit* or split or substitut* or treat*))).ti,ab,kf. (473029)
- 27 placebo*.ab,ti,kf. (200526)
- 28 trial.ab,ti,kf. (527152)
- 29 (control* and (trial or study or group*) and (placebo or waitlist* or wait* list* or ((treatment or care) adj2 usual))).ti,ab,kf,hw. (182546)
- 30 ((single or double or triple or treble) adj2 (blind* or mask* or dummy)).ti,ab,kf. (161075)
- 31 double-blind method/ or random allocation/ or single-blind method/ (259732)
- 32 exp animals/ not humans.sh. (4517568)
- 33 (or/23-31) not 32 (1139578)
- 34 22 and 33 (1759)
- 35 (abreaction or assertiveness training or autogenic training or aversion therapy or covert sensiti#ation or biofeedback or conversion therapy or distraction therapy or eye movement desensiti#ation or EMDR or exposure therapy or guided imagery or implosive therapy or (problem? adj2 (focus* or solution?)) or psychoeducat* or reciprocal inhibition or (relaxation adj (technique? or training)) or response cost or sensitivity training or sleep phase chronotherapy or social* effective* or (social skills adj2 train*) or systematic desensiti#ation).mp. (29817)
- 36 (relaxation or imagery).ti,kf. (30268)
- 37 21 and 33 and (35 or 36) (1049)
- 38 34 or 37 (2685)
- 39 limit 38 to yr="2014 -Current" (1372)
- 40 review.pt. (2453324)
- 41 case reports.pt. (1909175)
- 42 ((child* or adolescent* or infant* or p?ediater*) not adult?).ti. (1070522)
- 43 39 not (or/40-42) (1132)
- Search-2 (Search for condition amended to retrieve sub-clinical depression. Search terms for intervention also amended by the removal of unwanted terms)
- 44 (behavio* activat* or BATD).ti,ab,kf. (1791)
- 45 (behavio* adj3 (reinforce* or re-inforce*)).ti,ab,kf. (2727)
- 46 (behavio* adj2 (contracting or modification or modify*)).ti,ab,kf. (6332)
- 47 reinforce*.ti,kf. or ((positive adj1 reinforce*) or (reinforc* adj3 (environment* or experience*))).ti,ab,kf. (19953)
- 48 (reinforce or reinforcer or reinforcement or reinforcements or re-inforcement or re-inforcements).ab. /freq=2 (10487)
- 49 (activit* adj2 schedul*).ti,ab,kf. (509)
- 50 (pleas* adj (activit* or event?)).ti,ab,kf. (319)
- 51 (operant conditioning or instrumental learning).ti,ab,kf. (2522)
- 52 (positive interaction* or avoidant coping or environmental contingenc* or contingency management).ti,ab,kf. (2716)
- 53 functional analysis.ti,ab,kf. (21598)
- 54 behavio*.mp. and (self adj (evaluat* or monitor*)).ti,ab,kf. (3268)
- 55 or/44-54 (64373)
- 56 Behavior Therapy/ and depress*.ti,hw. (1382)
- 57 ((behavio* adj (counsel* or intervention or train* or treatment or therapy or psychotherapy)) and depress*).ti,kf. (1562)
- 58 Depression/ (104912)
- 59 Depressive Disorder/ or Depressive Disorder, Major/ (94699)
- 60 depress*.ti,ab,kf. (419064)
- 61 (mood? or mental health).ti,kf. (72990)
- 62 or/58-61 (511522)
- 63 (55 and 62) or 56 or 57 (5331)
- 64 controlled clinical trial.pt. (92759)
- 65 randomized controlled trial.pt. (471716)
- 66 (randomi#ed or randomi#ation or randomi#ing).ti,ab,kf. (561767)
- 67 (RCT or "at random" or (random* adj3 (administ* or allocat* or assign* or class* or cluster or control* or determine* or divide* or division or distribut* or expose* or fashion or number* or place* or pragmatic or quasi or recruit* or split or substitut* or treat*))).ti,ab,kf. (473029)
- 68 placebo*.ab,ti,kf. (200526)
- 69 trial.ab,ti,kf. (527152)
- 70 (control* and (trial or study or group*) and (placebo or waitlist* or wait* list* or ((treatment or care) adj2 usual))).ti,ab,kf,hw. (182546)

71 ((single or double or triple or treble) adj2 (blind* or mask* or dummy)).ti,ab,kf. (161075)
 72 double-blind method/ or random allocation/ or single-blind method/ (259732)
 73 exp animals/ not humans.sh. (4517568)
 74 (or/64-72) not 73 (1139578)
 75 63 and 74 (1857)
 76 review.pt. (2453324)
 77 case reports.pt. (1909175)
 78 ((child* or adolescent* or infant* or p?ediatr*) not adult?).ti. (1070522)
 79 75 not (or/76-78) (1519)
 80 79 not 43 (757)
 81 (43 or 80) (1831)

Ovid-MEDLINE-2 (January 2019)

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to January 17, 2019>

Search Strategy:

1 ((behavio* adj1 activat*) or BATD).ti,ab,kf. (2121)
 2 (behavio* adj3 (reinforce* or re-inforce*)).ti,ab,kf. (2750)
 3 (behavio* adj2 (contracting or modification or modify*)).ti,ab,kf. (6377)
 4 reinforc*.ti,kf. or (((positive or contingent) adj1 reinforc*) or (reinforc* adj3 (environment* or experience*))).ti,ab,kf. (20327)
 5 (reinforce or reinforcer or reinforcement or reinforcements or re-inforcement or re-inforcements).ab. /freq=2 (10583)
 6 (activit* adj2 schedul*).ti,ab,kf. (516)
 7 ((pleas* or enjoyable or rewarding) adj (activit* or event?)).ti,ab,kf. (604)
 8 (operant conditioning or instrumental learning).ti,ab,kf. (2549)
 9 (positive interaction* or avoidant coping or environmental contingenc* or contingency management).ti,ab,kf. (2743)
 10 functional analysis.ti,ab,kf. (21822)
 11 behavio*.mp. and (self adj (evaluat* or monitor*)).ti,ab,kf. (3315)
 12 ((gain? or reapprais*) adj2 focus*).ti,ab,kf. (148)
 13 ((psychoeducat* or psycho-educat*) and (coping behavi* or coping skills or self manag* or (behavi* adj2 chang*))).ti,ab,kf,hw. (409)
 14 or/1-13 (66190)
 15 Behavior Therapy/ and depress*.ti,hw. (1390)
 16 (behavio* therapy adj3 depress*).ti,ab,kf. (623)
 17 ((behavio* adj (counsel* or intervention or train* or treatment or therapy or psychotherapy)) and depress*).ti,kf. (1610)
 18 or/15-17 (3080)
 19 Depression/ (106096)
 20 Depressive Disorder/ or Depressive Disorder, Major/ (95368)
 21 depress*.ti,ab,kf. (423259)
 22 (mood? or mental health or ((emotion* or psychological) adj (distress or trauma*))).ti,kf. (79851)
 23 or/19-22 (519901)
 24 (14 and 23) or 18 (5789)
 25 controlled clinical trial.pt. (92880)
 26 randomized controlled trial.pt. (474938)
 27 (randomi#ed or randomi#ation or randomi#ing).ti,ab,kf. (568726)
 28 (RCT or "at random" or (random* adj3 (administ* or allocat* or assign* or class* or cluster or control* or determine* or divide* or division or distribut* or expose* or fashion or number* or place* or pragmatic or quasi or recruit* or split or substitut* or treat*))).ti,ab,kf. (479458)
 29 trial.ab,ti,kf. (533987)
 30 (control* and (trial or study or group*) and (placebo or waitlist* or wait* list* or ((treatment or care) adj2 usual))).ti,ab,kf,hw. (184046)
 31 ((allocat* or assign* or receive*) and (placebo or no-treatment or waitlist or wait* list* or ((treatment or care) adj2 usual)) and (control or group)).ab. (60576)
 32 ((single or double or triple or treble) adj2 (blind* or mask* or dummy)).ti,ab,kf. (162166)
 33 double-blind method/ or random allocation/ or single-blind method/ (261507)
 34 exp animals/ not humans.sh. (4538357)
 35 (or/25-33) not 34 (1136532)
 36 24 and 35 (2047)
 37 review.pt. (2472450)
 38 case reports.pt. (1917945)
 39 ((child* or adolescent* or infant* or p?ediatr*) not adult?).ti. (1078507)
 40 36 not (or/37-39) (1681)

Ovid Embase <1980 to 2019 Week 02>

Behavioural activation therapy for depression in adults (Review)

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Search Strategy:

1 "behavioral activation"/ (81)
 2 "behavioral activation system"/ (44)
 3 ((behavio* adj1 activat*) or BATD).ti,ab,kw,dq. (2509)
 4 (behavio* adj3 (reinforce* or re-inforce*)).ti,ab,kw. (2831)
 5 reinforc*.ti. or (((contingent or positive) adj1 reinforc*) or (reinforc* adj3 (environment* or experience*))).ti,ab,kw. (16326)
 6 (reinforce or reinforcer or reinforcement or reinforcements or re-inforcement or re-inforcements).ab. /freq=2 (10683)
 7 (behavio* adj2 (contracting or modification or modify*)).ti,ab,kw. (7338)
 8 ((activit* or event?) adj2 schedul*).ti,ab,kw. (969)
 9 ((pleas* or enjoyable or rewarding) adj (activit* or event?)).ti,ab,kw. (775)
 10 (operant conditioning or instrumental learning).ti,ab,kw. (2642)
 11 *Task Performance/ (13223)
 12 (positive interaction* or avoidant coping or environmental contingenc* or contingency management).ti,ab,kw. (3268)
 13 Avoidance Behavior/ (25351)
 14 ((gain? or reapprais*) adj2 focus*).ti,ab,kw. (164)
 15 functional analysis.ti,ab,kw. (26291)
 16 (behavio* therapy and (self adj (care or efficacy or evaluat* or monitor*))).ti,kw,hw. (1845)
 17 ((psychoeducat* or psycho-educat*) and (coping behavi* or coping skills or self manag* or (behavi* adj2 chang*))).ti,ab,kw,hw. (1771)
 18 behavior change/ and (self management/ or self monitoring/) (1049)
 19 or/1-18 (108350)
 20 *Behavior Therapy/ and depress*.ti,hw. (1876)
 21 (behavio* therapy adj3 depress*).ti,ab,kw. (800)
 22 ((behavio* adj (counsel* or intervention or train* or treatment or therapy or psychotherapy)) and depress*).ti. (1424)
 23 or/20-22 (3279)
 24 depression/ or major depression/ or late life depression/ or post-stroke depression/ or reactive depression/ (367710)
 25 minor depression/ or subsyndromal depression/ (316)
 26 *mood disorder/ or minor affective disorder/ (8223)
 27 (depress* adj3 (acute or clinical* or diagnos* or disorder* or major or unipolar or illness or scale* or score* or adult* or patient* or participant* or people or inpatient* or in-patient* or outpatient* or out-patient*)).ab. (193021)
 28 (depressi* adj3 (symptom* or subsyndrom* or "sub syndrom*" or subclinical or "sub clinical" or minor)).ab. (85284)
 29 (depress* and (Beck* or BDI* or DSM* or (Statistical Manual adj2 Mental Disorders) or Hamilton or HAM-D or HAMD or MADRS or (International Classification adj2 Disease?) or ICD-10 or ICD-9)).ab. (61151)
 30 "with depressi*".ab. (33191)
 31 depress*.ti,kw. (201611)
 32 (mood? or mental health or ((emotion* or psychological) adj (distress or trauma*))).ti. (71824)
 33 or/24-32 (526818)
 34 (19 and 33) or 23 (10015)
 35 randomized controlled trial/ (526873)
 36 randomization.de. (80508)
 37 controlled clinical trial/ (459873)
 38 trial.ti. (253670)
 39 (randomi#ed or randomi#ation or randomi#ing).ti,ab,kw. (805315)
 40 (RCT or "at random" or (random* adj3 (administ* or allocat* or assign* or class* or control* or determine* or divide* or division or distribut* or expose* or fashion or number* or place* or recruit* or split or subsitut* or treat*))).ti,ab,kw. (639556)
 41 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj3 (blind\$ or mask\$ or dummy)).mp. (274981)
 42 ((allocat* or assign* or receive*) and (placebo or no-treatment or waitlist or wait* list* or ((treatment or care) adj2 usual)) and (control or group)).ab. (84381)
 43 (group?.ab. or study.ti,ab.) and (placebo or waitlist* or wait* list* or ((treatment or care) adj2 usual)).ti,ab,kw. (257803)
 44 or/35-43 (1495495)
 45 34 and 44 (2572)
 46 limit 45 to (article-in-press status or conference abstract status or embase status or in-process status) (2276)
 47 remove duplicates from 46 (2237)

Open Grey <http://www.opengrey.eu/> (20 Jan 2019)

1. "behavioural activation" and depression (5)
2. "behavioural activation" and depressive (1)
3. "behavioural activation" and depressed (2)
4. "behavioral activation" and depression (0)
5. "behavioral activation" and depressive (0)
6. "behavioral activation" and depressed (0)

7. or/1-6 (6)

ProQuest Dissertations & Theses Global (20 Jan 2019)

noft("behavioural activation" OR "behavioral activation") AND noft(depression OR depressive OR depressed) n=104

DART-Europe E-theses Portal (www.dart-europe.eu/)

1. "behavioural activation" and depression (6)
2. "behavioural activation" and depressive (5)
3. "behavioural activation" and depressed (3)
4. "behavioral activation" and depression (6)
5. "behavioral activation" and depressive (3)
6. "behavioral activation" and depressed (3)
7. or/1-6 (14)

British Library eTheses Online (ETHOS) (20 Jan 2019)

1. "behavioural activation" and depression (23)
 2. "behavioural activation" and depressive (23)
 3. "behavioural activation" and depressed (23)
 4. "behavioral activation" and depression (0)
 5. "behavioral activation" and depressive (0)
 6. "behavioral activation" and depressed (0)
 7. or/1-6 (23)
- (n=27)

Open Acces Theses and Dissertations (oatd.org).

Advanced search:

Exact phrase: behavioural activation

AND

Any of these words: depression depressive depressed

Any Language, Any Country

n=89 [62 (unique refs)]

[Note. Variant spelling "behavioral activation" automatically searched]

Trial Registers

ClinicalTrials.gov (20-Jan-2019)

Advanced search-1 (n=157) (n=184 (18-Jan-2019))

Condition or Disease: depression OR depressive OR depressed

Other terms: "behavioral activation"

Applied Filters: Interventional Adult (18–64) Older Adult (65+)

[Synonyms automatically searched: Depressivity, low mood, melancholic automatically searched]

ClinicalTrials.gov (20-Jan-2019)

Advanced Search-2 (n=30) (n=43 (18-Jan-2019))

Condition or Disease: depression OR depressive OR depressed

Other terms: "behavioural activation"

Applied Filters: Interventional Adult (18–64) Older Adult (65+)

[Synonyms automatically searched: Depressivity, low mood, melancholic automatically searched]

Records deduplicated in EndNote: Search-1 OR Search-2 = 175 trial records

WHO International Clinical Trials Registry Platform (ICTRP) (20-Jan-2019) n=101

behavioural activation and depression and randomized or behavioural activation and depressive and randomized or behavioural activation and depressed and randomized

or

behavioral activation and depression and randomized or behavioral activation and depressive and randomized or behavioral activation and depressed and randomized

or

behavioural activation and depression and randomised or behavioural activation and depressive and randomised or behavioural activation and depressed and randomised

or

behavioral activation and depression and randomised or behavioral activation and depressive and randomised or behavioral activation and depressed and randomised

or

Behavioural activation therapy for depression in adults (Review)

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behavioural activation and depression and RCT or behavioural activation and depressive and RCT or behavioural activation and depressed and RCT

or

behavioral activation and depression and RCT or behavioral activation and depressive and RCT or behavioral activation and depressed and RCT

[Synonyms automatically searched: Feeling blue, Feeling down, Low mood, Morose mood, Melancholy, Random]

Trials de-duplicated (n=175 (CT_gov) + ICTRP (101)) =261

WHAT'S NEW

Date	Event	Description
16 July 2020	Amended	Minor typographical error corrected in the abstract

HISTORY

Protocol first published: Issue 4, 2019

Review first published: Issue 7, 2020

CONTRIBUTIONS OF AUTHORS

RC and DE conceived the idea for this review. All review authors contributed to the writing of the protocol. SD performed the literature searches and contributed to screening of studies. EU, LR, ESa, and ESo performed the data extraction and 'Risk of bias' assessments. DE, DR, and RC were available to discuss disagreements in data extraction and 'Risk of bias' assessments. NM supervised statistical analyses conducted by EU. EU, NM, and LR contributed to GRADE assessments and constructed 'Summary of findings' tables.

DECLARATIONS OF INTEREST

Eleonora Uphoff: no conflicts of interest

David Ekers, in his role of Chief Investigator, is responsible for the conduct of the ongoing CHEMIST and MODS trials in which behavioural activation therapies are evaluated. He is a Co-Investigator of the included CASPER trial and the author of several publications reporting on trials of behavioural activation.

Lindsay Robertson: no conflicts of interest

Sarah Dawson: no conflicts of interest

Emily Sanger: no conflicts of interest

Emily South: no conflicts of interest

Zainab Samaan: no conflicts of interest

David Richards has been involved in several trials of behavioural activation, including in his role as Chief Investigator of the UK National Institute for Health Research funded COBRA and CADET trials. He has published extensively on the subject of behavioural activation in peer reviewed journals and clinical text books.

Nicholas Meader: no conflicts of interest

Rachel Churchill leads and has responsibility for Cochrane Common Mental Disorders, which has supported parts of the review process and is largely funded by a grant from the National Institute of Health and Research (NIHR) in the UK.

SOURCES OF SUPPORT

Internal sources

- Tees, Esk and Wear Valleys NHS Foundation Trust (TEWV), UK
- University of York, UK
- University of Exeter, UK

External sources

- National Institute for Health Research (NIHR), UK

Cochrane Infrastructure funding to the Common Mental Disorders Cochrane Review Group

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The protocol stated that any online therapy with an element of interaction with a qualified therapist would be included. However, as our review comprises interventions delivered by specialists as well as non-specialists, this was changed to the requirement for interaction with a therapist, regardless of the therapist qualifications.

During data extraction, we found it difficult in some cases to distinguish between a specialist and a non-specialist therapist. A third category of 'specialist in training' was added for those with substantial training of more than a year who were not yet qualified.

We planned to use the revised Cochrane 'Risk of bias' tool, but this was not deemed practical. The new tool had not been integrated in Covidence yet, the review authors performing the 'Risk of bias' assessments were not trained in using it, and the roll-out of the new tool across Cochrane groups was ongoing. We used the original Cochrane 'Risk of bias' tool instead.

In addition to the domains which form part of the Cochrane 'Risk of bias' tool, the Cochrane Common Mental Disorders group has previously used three domains with particular relevance to psychotherapy trials: assessment of treatment fidelity, therapist conflict of interest, and researcher conflict of interest. Following advice from Associate Editor Nuala Livingstone, we decided to consider these items within the 'Other bias' domain, rather than using separate domains that deviate from the standard Cochrane 'Risk of bias' tool. As we excluded any data from the second phase of cross-over trials, we assessed risk of bias for these trials with the standard Cochrane 'Risk of bias' tool, rather than considering additional domains.

Several studies reported multiple measures of our primary outcome, treatment efficacy. We prioritised remission over clinically significant improvement, and recovery or remission over response. If multiple components of quality of life were reported in the same trial we included the physical domain (for example, Short Form 36 physical functioning), as this addresses an outcome relevant to mental health while being clearly distinct from other included outcomes. If multiple measures of social adjustment and functioning were reported, we combined these data.

We planned to conduct a subgroup analysis of depression severity, according to three categories: subthreshold or mild depression, moderate depression, and severe depression. Upon examination of the primary data, it became clear that the distinction between moderate and severe depression was difficult to make. Instead, we performed sensitivity analyses using the categories subthreshold/mild depression and moderate to severe depression.

Upon examination of the data, we decided to conduct several unplanned sensitivity analyses: we removed one study from Analysis 1.1 as this was a small study with a large weight in the analysis; we removed one outlier from Analyses 10.3 and 10.4, and we conducted fixed-effect rather than random-effects analyses to investigate the impact of small studies on the results (Analyses 6.3, 6.5, 10.3, and 10.4).

Because the review was not finished a year after the literature was first searched, we performed an update search in January 2020 to identify newly published studies. Two additional studies were included in the review as a result.