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Uphoff E, Ekers D, Dawson S, Richards D, Churchill R.
Behavioural activation therapies for depression in adults.
Cochrane Database of Systematic Reviews 2019, Issue 4. Art. No.: CD013305.
DOI: [10.1002/14651858.CD013305](https://doi.org/10.1002/14651858.CD013305).

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[Intervention Protocol]

Behavioural activation therapies for depression in adults

Eleonora Uphoff^{1,2}, David Ekers^{3,4}, Sarah Dawson^{1,5}, David Richards⁶, Rachel Churchill^{1,2}

¹Cochrane Common Mental Disorders, University of York, York, UK. ²Centre for Reviews and Dissemination, University of York, York, UK.

³Lanchester Road Hospital, Tees, Esk and Wear Valleys NHS Foundation Trust, Durham, UK. ⁴Mental Health and Addiction Research Group, Department of Health Sciences, University of York, York, UK. ⁵Population Health Sciences, Bristol Medical School, University of Bristol, Bristol, UK. ⁶School of Psychology, University of Exeter, Exeter, UK

Contact address: Eleonora Uphoff, Cochrane Common Mental Disorders, University of York, Heslington, York, - None -, YO10 5DD, UK. noortje.uphoff@york.ac.uk.

Editorial group: Cochrane Common Mental Disorders Group

Publication status and date: New, published in Issue 4, 2019.

Citation: Uphoff E, Ekers D, Dawson S, Richards D, Churchill R. Behavioural activation therapies for depression in adults. *Cochrane Database of Systematic Reviews* 2019, Issue 4. Art. No.: CD013305. DOI: [10.1002/14651858.CD013305](https://doi.org/10.1002/14651858.CD013305).

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

1. To examine the effects of behavioural activation compared to all other psychological therapies for acute depression in adults.
2. To examine the effects of behavioural activation compared to all medication for acute depression in adults.
3. To examine the effects of behavioural activation compared to treatment as usual/ waiting list/ attention placebo/ psychological placebo control conditions for acute depression in adults.

BACKGROUND

Description of the condition

Depression, when diagnosed in a clinical setting, most often refers to 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, psychomotor agitation or retardation, 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 ten 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 (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 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 or mild depression, low-intensity psychosocial therapy and psychological therapies are recommended (NICE 2009).

Whilst antidepressants are of proven efficacy for the acute treatment of depression (Arroll 2009; Cipriani 2005; Cipriani 2009a; Cipriani 2009b; Cipriani 2009c; Guaiana 2007), adherence rates remain very low (Hunot 2007; van Geffen 2009), in part because of patients' concerns about side effects and possible dependency (Hunot 2007). Furthermore, surveys consistently demonstrate patients' preference for psychological therapies over treatment with antidepressants (Churchill 2000; McHugh 2013; Riedel-Heller 2005). Therefore, psychological therapies offer an important alternative or adjunctive intervention 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 acquisition and maintenance of behaviours (Nelson-Jones 1990) and, in contrast with psychoanalysis, was developed through experimentally derived principles of learning (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 investigators 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; increasing access to pleasant events, activities, and consequences; activity scheduling and developing social skills self-monitoring links between behaviour and mood; and activity scheduling to promote contact with sources of positive reinforcement from the person's environment. In some cases the use of some form of problem-solving or functional analysis is added to overcome any potential barriers to the scheduling of activities. No attempt is made to directly restructure cognitions, however the exploration of the consequence of rumination in restricting access to positive reinforcement is a common focus of the approach.

Why it is important to do this review

According to the clinical guidelines produced by the National Institute for Health and Clinical Excellence, 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-quality 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 quality 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 recommended for the treatment of depression. Behavioural activation is increasingly receiving attention as a potentially cost-effective intervention for depression, which may be easier to deliver and implement than other psychological therapy models (Richards 2016). Given this resurgence of interest, a comprehensive review of the comparative effectiveness and acceptability of behavioural activation interventions for depression is now timely to inform and update clinical practice and future clinical guideline development.

OBJECTIVES

1. To examine the effects of behavioural activation compared to all other psychological therapies for acute depression in adults.
2. To examine the effects of behavioural activation compared to all medication for acute depression in adults.
3. To examine the effects of behavioural activation compared to treatment as usual/ waiting list/ attention placebo/ psychological placebo control conditions for acute 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 in the review (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 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

Trials of men and women aged 18 years and over are eligible for inclusion. We will exclude trials that contain participants under 18 years of age.

Setting

Trials could be conducted in a primary, secondary or community setting. We will exclude trials involving inpatients. We will include trials that focus on specific populations - nurses, care givers, depressed participants at a specific workplace - if all participants meet the criteria for depression. Nursing homes in this review are considered outpatient settings, as they are places of residence.

Diagnosis

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

1. We will include 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). Earlier trials may have used *ICD-Ninth Edition* ((ICD-9); WHO 1978), but ICD-9 is not based on operationalised criteria, so we will exclude trials using ICD-9 from this category.
2. To fully represent the broad spectrum of severity of depressive symptoms encountered by healthcare professionals in primary care, we will include trials that used non-operationalised diag-

nostic criteria or a validated clinician or self-report depression symptom questionnaire, such as the Hamilton Rating Scale for Depression (Hamilton 1960), or the Beck Depression Inventory (Beck 1961), to identify depression cases as based on a recognised threshold.

- Subthreshold depression, also called subsyndromal, subclinical, or minor depression. We will accept any trials that established subthreshold depression based on the above diagnostic criteria or validated depression symptom questionnaires.

When possible, we will use 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-5 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 will exclude from the review trials focusing on chronic depression or treatment-resistant depression (i.e. trials that list these conditions as inclusion criteria). We will also exclude trials in which participants were receiving treatment to prevent relapse after a depressive episode (i.e. where participants were not depressed at trial entry).

If participants meet the criteria for depression or subthreshold depression as stated above, we will include trials of people described as 'at risk of suicide' or with dysthymia or other affective disorders such as panic disorder, but otherwise we will exclude these trials.

We will 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 will include these trials only if the inclusion criteria for the entire trial satisfies our eligibility criteria.

Comorbidity

Trials involving participants with comorbid physical or common mental disorders are eligible for inclusion as long as the comorbidity is not the focus of the trial. For example, we will exclude trials that focus on depression among individuals with Parkinson's disease or after acute myocardial infarction but accept trials that may have included some participants with Parkinson's disease or with acute myocardial infarction.

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 will include 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 will include behavioural therapies in the treatment group as long as they are described using the main elements of behavioural activation. Interventions that contain some elements of behavioural therapy, such as CBT or problem-solving therapy, are not eligible for inclusion.

Format of psychological therapies

Therapies delivered by therapists of all levels are eligible for inclusion. This includes psychologists or psychotherapists accredited by a professional body for psychology or psychotherapy, who completed formal training to deliver psychological therapies, as well as lay counsellors and non-specialist therapists who have been specifically trained to deliver treatment according to a behavioural activation protocol.

We will include computerised and self-help interventions if they were facilitated by a qualified practitioner. This means at least some element of interaction with a qualified facilitator is required.

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

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

Comparators

All comparators are accepted as long as they are not a type of behavioural activation. We categorise psychological therapies as behavioural therapy, social skills training/assertiveness training, relaxation therapy, CBT, third wave CBT, psychodynamic, humanistic and integrative approaches.

Behavioural therapy

If we identify any behavioural therapies that do not contain the main elements of behavioural activation, we will include them 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 collaboratively with patients to understand the link between thoughts, feelings and behaviours, and to identify and modify unhelpful thinking patterns, underlying assumptions and idiosyncratic cognitive schemata 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 conceptualise cognitive thought processes as a form of 'private behaviour' (Hayes 2006; Hofmann 2008). Third wave CBTs target the individual's relationship with cognitions and emotions, focusing primarily on the function of cognitions, such as thought suppression or experiential avoidance (an attempt or desire to suppress unwanted internal experiences, such as emotions, thoughts and bodily sensations (Hofmann 2008)). A range of strategies, including mindfulness exercises, acceptance of unwanted thoughts and feelings and cognitive diffusion (stepping back and seeing thoughts as just thoughts), are used to bring about change in the thinking process. 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 and interpretation, with development of insight and circumscribed character change 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 positive regard (Rogers 1951), are regarded as cornerstones for facilitating client 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 time-limited framework. 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 integratively, according to the theoretical orientation of practitioners (Stiles 2008). Therefore, we will usually include trials of counselling with integrative therapies. However, if the counselling intervention consists of a single discrete psychological therapy approach, we will categorise it as such, even if the intervention is referred to as 'counselling'. If the intervention is manualised, this will 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.

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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.

Excluded interventions

We will exclude 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 will exclude trials of interventions designed to prevent a future episode of depression. Postnatal depression is considered a separate condition with contributing factors distinct from major depressive disorder, and we therefore excluded it.

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 (HAM-D; 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, HAM-D, etc., with some trials defining response using Jacobson's Reliable Change Index; we accepted the trial authors' original definition. If the original authors reported several outcomes corresponding with our definition of response, we calculated and reported the standardised mean difference of all measures used.
2. Treatment acceptability: the number of participants who dropped out of psychological therapy for any reason

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; WHO-QL 1998)
3. Social adjustment and social functioning, including Global Assessment of Function (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.

Search methods for identification of studies

Electronic searches

The Cochrane Common Mental Disorders' Information Specialist will conduct searches on the following bibliographic databases using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource. The search strategies will be 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 will not apply any restrictions on date, language or publication status to the searches.

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

We will rerun all searches close to publication if the initial search date is greater than 12 months. We will also search for any relevant retraction statements and errata.

Searching other resources

Grey literature

We will search the following sources of grey literature (primarily for dissertations and theses):

- 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 will check 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 will contact 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

At least two review authors will examine the abstracts of all publications obtained through the search strategy. We will then obtain full articles of all trials identified by any one of the review authors and two review authors will independently assess full-texts according to the criteria relating to characteristics of the studies, participants, and interventions. We will discuss reasons for disagreement with a third reviewer, and contact external experts or trial authors if necessary in order to reach agreement. We will record reasons for excluding records at this stage. For all included studies, we will link multiple reports from the same study. We will present a PRISMA flow diagram to show the process of study selection (Moher 2009).

Data extraction and management

At least two review authors will independently extract data from each trial. These review authors will discuss any disagreement with an additional review author, and, when necessary, will contact the authors of the trials for further information.

We will extract and enter into a spreadsheet information related to trial population, sample size, interventions, comparators, potential biases in the conduct of the trial, source of funding, outcomes including adverse events, number needed to treat for an additional beneficial outcome (NNTB), follow-up and methods of statistical analysis.

Management of time points

We plan to summarise and categorise post-treatment outcomes and outcomes at each reported follow-up point as follows: short term (up to 6 months post-treatment), medium term (7 to 12 months post-treatment) and long term (longer than 12 months).

Assessment of risk of bias in included studies

We will assess risk of bias for each included trial using the Revised Cochrane Collaboration's 'Risk of bias' tool ((RoB2); Higgins 2016), which considers the following five 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. Missing outcome data
4. Risk of bias in measurement of the outcome, including blinding of outcome assessors
5. Selective outcome reporting

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

In addition, we will systematically appraise the following risks of bias, 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?
4. Other sources of bias: was the trial apparently free of other problems that could put it at high risk of bias?

We will make a judgement on the risk of bias for each domain within and across trials, and categorise this as low, unclear, or high risk of bias.

Two review authors will independently assess the risk of bias in selected trials and discuss any disagreements with a third review author. Where necessary, we will contact trial authors for further information. We will present all 'Risk of bias' data graphically, and narratively in the text. We will use allocation concealment as a marker of trial quality for the purpose of undertaking sensitivity analyses.

Measures of treatment effect

Continuous outcomes

Where trials use the same outcome measure for comparison, we will pool data by calculating the mean difference (MD). When trials use different measures to assess the same outcome, we will pool data with standardised mean difference (SMD) and calculate 95% confidence intervals (95% CIs).

A SMD of zero means that the intervention and control groups have equivalent treatment effects. We anticipate that, for most measures, a lower score will indicate greater improvement. For example, a lower score on depression symptom instruments indicates an improvement in symptoms. In these cases, a SMD less than zero indicates that the intervention has a greater effect than the control. An SMD greater than zero indicates that the intervention has a smaller effect than the control. Interpretation of the SMD is reversed in cases where a greater continuous score indicates greater improvement.

To facilitate interpretation of results in terms of their clinical relevance, we will express SMDs for continuous outcomes in terms of units on a commonly used patient-rated outcome (the Beck Depression Inventory (BDI)) and a commonly used clinician-rated instrument (Hamilton Depression Rating Scale (HAM-D)). We will calculate these re-expressed estimates according to guidance in the Cochrane Handbook (Schünemann 2017a).

Dichotomous outcomes

We will analyse dichotomous outcomes by calculating a pooled odds ratio (OR) and 95% CIs for each comparison. Because ORs can be difficult to interpret, we will convert these pooled ORs to risk ratios (RRs) using the formula provided in the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2017a), and we will present them in this form for ease of interpretation.

In addition, we calculated the 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).

If one trial uses both continuous and dichotomous variables for the same outcome we will give preference to the continuous outcome. If different outcomes are used, for example depression score and clinical depression yes/no, we will report both.

Unit of analysis issues

Cluster-randomised trials

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

Cross-over trials

We will include trials employing a cross-over design in the review, but we will only use 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 will manage data in this review as follows.

Multiple experimental intervention groups versus a single control group

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

One or more experimental intervention groups versus multiple control groups

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

Dealing with missing data

We will manage missing dichotomous data through intention-to-treat (ITT) analysis, in which we will assume that participants who dropped out after randomisation had a negative outcome. We also plan to conduct best/worse case scenarios for the clinical response outcome, in which we will assume 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. If a large amount of information is missing, we will give these best/worst case scenarios greater emphasis in the presentation of results.

We will analyse 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 report LOCF data. When SDs are missing, we will at-

tempt to obtain these data by contacting trial authors. When SDs are not available from trial authors, we will calculate them from P values, t-values, CIs or standard errors, if these are reported in the articles (Deeks 1997). If SDs are missing, we will attempt to obtain these data by contacting trial authors.

If a vast majority of SDs are available and only a minority of SDs are unavailable or unobtainable, we plan to use the method devised by Furukawa and colleagues to impute SDs and calculate percentage responders (da Costa 2012; Furukawa 2005; Furukawa 2006). If we use this method, we will interpret data with caution and will take into account the degree of observed heterogeneity. We will also undertake a sensitivity analysis to examine the effect of the decision to use imputed data.

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

Assessment of heterogeneity

We will formally test 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 will conservatively set the P value at 0.1 (Deeks 2017). We will also quantify heterogeneity using the I² statistic, which calculates the percentage of variability due to heterogeneity rather than to chance (Higgins 2003). We consider I² statistic values in the range of 50% to 90% to represent substantial statistical heterogeneity and will explore them further. However, the importance of the observed I² statistic depends on the magnitude and direction of treatment effects and the strength of evidence for heterogeneity. Forest plots generated in Review Manager 5 (RevMan 5) will provide an estimate of tau², the between-trial variance in a random-effects meta-analysis (Deeks 2017; Review Manager 2014). To provide an indication of the spread of true intervention effects, we will also use the tau² estimate to determine an approximate range of intervention effects for the primary outcome using the method outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017).

Assessment of reporting biases

As far as possible, we will minimise 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 will also try to identify outcome reporting bias in trials by recording all trial outcomes, planned and reported, and noting where outcomes are missing. If we find evidence of missing outcomes, we will attempt to obtain any available data directly from the trial authors.

We plan to construct funnel plots to establish the potential influence of reporting biases and small-trial effects (Sterne 2017).

Data synthesis

We plan to conduct a meta-analysis of included trials. Given the potential heterogeneity of behavioural activation approaches for inclusion, together with the likelihood of differing secondary comor-

bid mental disorders in the population of interest, we will use a random-effects model in all analyses.

Subgroup analysis and investigation of heterogeneity

Clinical heterogeneity

We plan to conduct the following subgroup analyses.

1. Patient age: old age in particular can be expected to relate to treatment effect, as older patients are more likely to suffer comorbidities. We plan to conduct subgroup analyses with patients younger than 65 years and those aged 65 years or older.
2. 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 less training, or without a relevant accreditation. We expect that this analysis by level of therapist will also account for potential differences by intervention complexities. We will conduct subgroup analyses with level of therapist classified as:
 - a. accredited/received formal training of several years (specialist); or
 - b. minimal training/lay counsellor (non-specialist)
3. Baseline depression severity: the severity of depression on entry into the trial is expected to have an impact on outcomes. We categorised depression severity as subthreshold depression, mild, moderate, or severe.
4. Length of treatment: we will categorise treatment into those delivered in one to three sessions and treatments of longer duration. We anticipate that the length of treatment could influence effectiveness.
5. 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 will be categorised as psychodynamic, behavioural, humanistic, integrative, or cognitive-behavioural.
6. Type of control comparison: The type of control comparator used is likely to influence the observed effectiveness of the intervention. When possible, comparators will be categorised as waiting list, treatment as usual/usual care, attention placebo, or psychological placebo.

Sensitivity analysis

1. Trial quality: we will exclude low-quality trials in a sensitivity analysis, if we identify a number of higher-quality trials. As a marker of quality, we will use the 'allocation concealment' criteria from the 'Risk of bias' assessment.
2. Mode of delivery: we will exclude therapies delivered through computer-based or electronic guidance without a substantial face-to-face component.
3. Subthreshold depression: we will exclude trials of subthreshold depression to determine whether our decision to include non-clinical levels of depression has had a substantial impact on the results.

4. Group therapy: we will exclude trials of group therapy for behavioural activation as the mode of delivery of psychotherapy could influence effectiveness of the therapy.

'Summary of findings' table

We plan to construct a 'Summary of findings' table to present the main findings of the review. We will report the outcomes listed below and present standardised effect size estimates and 95% confidence intervals. Two reviewers will independently use the GRADE approach to assess the quality of the evidence for each outcome, and agreement will be sought between them, if necessary with help from a third reviewer (Schünemann 2017a). We will use GRADE-proGDT to create our 'Summary of findings' tables (GRADEpro 2015), and follow standard methods as described in the *Cochrane Handbook for Systematic Reviews of Interventions* to prepare our 'Summary of findings' table (Schünemann 2017b). For each of our main comparisons, the following outcomes (measured up to 24 months) will be included:

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 will be created before writing our discussion, abstract, and conclusions, so that the authors can jointly consider the potential impact of the study quality 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 will then be reflected in the interpretation of the results, which informs the abstract, lay summary, and discussion sections of the review.

ACKNOWLEDGEMENTS

The authors and the Cochrane Common Mental Disorders Editorial Team, are grateful to the following peer reviewers for their time and comments: Kerry Dwan, Philip Kerrigan, David Marshall and Laura Pass. They would also like to thank copy editor, Denise Mitchell.

CRG funding acknowledgement: the National Institute for Health Research (NIHR) is the largest single funder of Cochrane Common Mental Disorders.

Disclaimer: the views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR, National Health Service (NHS), or the Department of Health and Social Care.

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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 | |

(Continued)

| | | |
|---|----------------|--|
| | | Problem-solving therapy |
| | | Self-control therapy |
| | | Coping with depression course |
| | | 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) |

(Continued)

| | |
|---|---|
| | Relation- al model (Strupp, Luborsky) |
| | Integra- tive analyt- ic model (Mann) |
| | Other psy- chodynamic therapies |
| 5. Humanistic therapies | Person-cen- tered ther- apy (Roger- ian) |
| | Gestalt ther- apy |
| | Experiential therapies |
| | Transaction- al analysis |
| | Existential therapy |
| | Non-direc- tive/support- ive therapies |
| | Other hu- manistic therapies |
| 6. Interpersonal, cognitive analytic and other integrative therapies (integrative therapies) | Interperson- al therapy IPT |
| | Cogni- tive-analytic therapy CAT |
| | Psychody- namic-in- terpersonal therapy |
| | Cogni- tive-behav- ioural analy- sis system of psychother- apy |

(Continued)

Counselling

Motivational
interviewing

Other in-
tegrative
therapy ap-
proaches

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 mutat*)) 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]:

Behavioural activation therapies for depression in adults (Protocol)

(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. MEDLINE search (behavioural activation)

The Ovid MEDLINE databases will be searched (all years to date) using the following terms to identify RCTs of 'behavioural activation', or the main elements of behavioural activation, in participants with clinically diagnosed or subthreshold depression.

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to onwards>

Search Strategy:

-
- 1 ((behavio* adj1 activat*) or BATD).ti,ab,kf.
 - 2 (behavio* adj3 (reinforce* or re-inforce*)).ti,ab,kf.
 - 3 (behavio* adj2 (contracting or modification or modify*)).ti,ab,kf.
 - 4 reinforc*.ti,kf. or (((positive or contingent) adj1 reinforc*) or (reinforc* adj3 (environment* or experience*))).ti,ab,kf.
 - 5 (reinforce or reinforcer or reinforcement or reinforcements or re-inforcement or re-inforcements).ab. /freq=2
 - 6 (activit* adj2 schedul*).ti,ab,kf.
 - 7 ((pleas* or enjoyable or rewarding) adj (activit* or event?)).ti,ab,kf.
 - 8 (operant conditioning or instrumental learning).ti,ab,kf.
 - 9 (positive interaction* or avoidant coping or environmental contingenc* or contingency management).ti,ab,kf.
 - 10 functional analysis.ti,ab,kf.
 - 11 behavio*.mp. and (self adj (evaluat* or monitor*)).ti,ab,kf.
 - 12 ((gain? or reapprais*) adj2 focus*).ti,ab,kf.
 - 13 ((psychoeducat* or psycho-educat*) and (coping behavi* or coping skills or self manag* or (behavi* adj2 chang*))).ti,ab,kf,hw.
 - 14 or/1-13
 - 15 Behavior Therapy/ and depress*.ti,hw.
 - 16 (behavio* therapy adj3 depress*).ti,ab,kf.
 - 17 ((behavio* adj (counsel* or intervention or train* or treatment or therapy or psychotherapy)) and depress*).ti,kf.
 - 18 or/15-17
 - 19 Depression/
 - 20 Depressive Disorder/ or Depressive Disorder, Major/
 - 21 depress*.ti,ab,kf.
 - 22 (mood? or mental health or ((emotion* or psychological) adj (distress or trauma*))).ti,kf.
 - 23 or/19-22
 - 24 (14 and 23) or 18
 - 25 controlled clinical trial.pt.
 - 26 randomized controlled trial.pt.
 - 27 (randomi#ed or randomi#ation or randomi#ing).ti,ab,kf.
 - 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.
 - 29 trial.ab,ti,kf.
 - 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.
 - 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.
 - 32 ((single or double or triple or treble) adj2 (blind* or mask* or dummy*)).ti,ab,kf.
 - 33 double-blind method/ or random allocation/ or single-blind method/
 - 34 exp animals/ not humans.sh.
 - 35 (or/25-33) not 34
 - 36 24 and 35
 - 37 review.pt.
 - 38 case reports.pt.
 - 39 ((child* or adolescent* or infant* or p?ediatr*) not adult?).ti.

40 36 not (or/37-39)

CONTRIBUTIONS OF AUTHORS

RC and DE conceived the idea for this review. All review authors contributed to the writing of the protocol.

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 the author of several publications reporting on trials of behavioural activation.

Sarah Dawson: 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.

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