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# Behavioural activation therapy for anxiety disorders in adults (Protocol)

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[Intervention Protocol]

# Behavioural activation therapy for anxiety disorders in adults

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## ABSTRACT

### Objectives

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

1. To study the effects of BA in comparison with other psychological therapies (e.g. mindfulness therapy, CBT, dialectical behavioural therapy) for anxiety disorders in adults
2. To study the effects of BA compared with pharmacotherapy for anxiety disorders in adults
3. To study the effects of BA compared with treatment as usual, waiting list, placebo, and no treatment for anxiety disorders in adults

# BACKGROUND

## Description of the condition

Anxiety disorders are a group of disorders that share features of excessive fear and anxiety and related behavioral disturbances. These disorders include separation anxiety disorder, selective mutism, specific phobia, social anxiety disorder (social phobia), panic disorder, agoraphobia, generalized anxiety disorder, substance/medication-induced anxiety disorder, and anxiety disorder due to another medical condition as classified by the American Psychiatric Association (APA 2013; Robichaud 2019; WHO 2021). Anxiety disorders are the most common mental health problem globally and if severe, they can significantly interfere with daily activities (Baxter 2014). In 2019, 300 million individuals suffered from anxiety disorders. In addition, anxiety disorders contributed to 24.6 million years lived with disability (YLD) in 2015 (GBD 2018; Xiong 2022).

Despite rising prevalence rates, only one-third of people with GAD receive treatment (Waldock 2015). To address this treatment gap, the *Lancet* Commission on global mental health and sustainable development identified scaling-up of psychotherapeutic interventions as a potential approach, pointing to the use of community-based support from non-specialists in mental health as a means of increasing access to care (Patel 2018).

## Description of the intervention

The UK National Institute for Health and Care Excellence (NICE) guidelines for anxiety disorder treatment recommend a stepped-care approach, first offering low-intensity psychological interventions, and secondly offering a choice of a high-intensity psychological intervention or a drug treatment for patients in whom the first intervention fails to achieve the desired response (Kendall 2011, NICE 2014).

Behavioural activation (BA) is a time-efficient, evidence-based psychotherapy for common mental health disorders (Kanter 2012). The primary therapeutic techniques of BA are activity monitoring and scheduling, through which the patient increases active and goal-oriented behaviours (Quigley 2017). The original model of BA, developed by Jacobson, was defined primarily by the elimination of cognitive intervention elements (Dimidjian 2011; Jacobson 2001). On the basis of its original design, components of the BA model 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 problem-solving or functional analysis are added to understand, consider and overcome any potential barriers to the scheduling of activities. In contrast to cognitive behavioural therapy (CBT), no attempt is made to directly change cognitions. However, BA 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 anxiety from meeting up with friends or participating in physical exercise (Chen 2013).

## How the intervention might work

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

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

Treatments are collaborative between the patient and the therapist and are focused on the present time, rather than the past or future. Many schedule-planning 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 (Martell 2011). In doing so, BA therapy helps people to make contact with potentially reinforcing experiences (Jacobson 2001). BA interventions have been commonly used in treating depression (Hopko 2006) and have been shown to be effective in improving depression symptoms and recovery (Cuijpers 2007; Quigley 2017; Richards 2016). There is an overlap between some symptoms of anxiety and depression, and there is evidence that therapies for a given anxiety or depressive disorder may attenuate symptoms associated with not only the target condition, but also improve the 'non-targeted' disorder (Schulberg 1996; Standley 2003). Nevertheless, there are considerable differences in presentation, course and prognosis of these disorders, and therapies may have differential effectiveness in these conditions (Sheard 1999). Evidence for the effectiveness of BA for depression cannot, therefore, be generalised to anxiety disorders.

Using BA to treat anxiety disorder is a relatively new concept (Boswell 2017). Proposed mechanisms for improving anxiety symptoms include reinforcing healthy behaviour and self-monitoring, which have been shown to enhance the person's sense of control and predictability over the environment, and decrease self-focused attention (e.g. ruminative behaviour) (Hopko 2006).

Two studies suggest that BA may be effective in reducing and managing anxiety symptoms (Hopko 2006; Quigley 2017). A Cochrane Review found low-certainty evidence that BA improves anxiety symptoms in people with depression, compared to the outcomes of waiting-list controls, however found no (Uphoff 2020). Several studies have addressed the feasibility and acceptability of BA for GAD and other anxiety disorders (Hopko 2016; Soleimani 2015; Turner 2009). However, it is still unclear whether BA is effective as a treatment for anxiety disorders in any setting (Hopko 2016).

## Why it is important to do this review

There has not yet been a Cochrane Review or other systematic review and meta-analysis examining the effectiveness of BA for treatment of anxiety disorder. According to NICE clinical guidelines, behavioural therapies are one of the recommended treatment options for anxiety disorders (Kendall 2011). However, the evidence for BA in anxiety disorders is currently less clear than for the other recommended therapies.

Evidence indicates that BA therapy is a skill that can be effectively transferred to primary care providers in five-day courses (Moore 2013). Combined with its time-limited nature, this makes BA a potential option to meet the treatment gap for anxiety disorders. To this end, it is important to conduct a synthesis of evidence to know whether BA could be an effective and acceptable treatment to offer to people with anxiety.

BA has increasingly received attention as a potentially cost-effective intervention for anxiety disorders, 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. Given this resurgence of interest, a comprehensive review of the comparative effectiveness and acceptability of BA interventions for anxiety disorders is timely, to inform and update clinical practice and future clinical guideline development.

## OBJECTIVES

1. To study the effects of BA in comparison with other psychological therapies (e.g. mindfulness therapy, CBT, dialectical behavioural therapy) for anxiety disorders in adults
2. To study the effects of BA compared with pharmacotherapy for anxiety disorders in adults
3. To study the effects of BA compared with treatment as usual, waiting list, placebo, and no treatment for anxiety disorders in adults

## METHODS

### Criteria for considering studies for this review

#### Types of studies

All randomised controlled trials (RCTs), irrespective of their reported outcomes, will be eligible for inclusion in this review. Cross-over trials (using data from the first active treatment phase), cluster-RCTs, and quasi-experimental RCTs will also be eligible for inclusion.

Quasi-experimental RCTs, in which treatment assignment is decided through methods such as alternating days of the week, will not be eligible for inclusion. We will include trials that replace dropouts without randomisation only when the proportion of replaced participants is less than 20%.

#### Types of participants

##### *Participants characteristics*

Adults aged 18 years and older and of either sex will be eligible for inclusion. Trials that involve only participants under 18 years of age will be excluded. Trials involving some participants younger and older than 18 years will be eligible for inclusion if the majority of participants are aged 18 or over or if results for those aged 18 and over are reported separately.

##### *Setting*

Trials conducted in primary, secondary, tertiary, clinic or community settings will be included. Trials that involve inpatients and those which focus on specific populations, e.g. nurses, caregivers, or participants at a specific workplace, will be eligible.Trials conducted in any country will be eligible.

##### *Diagnosis of target condition*

1. We will include trials where the diagnosis of anxiety disorder has been made using a validated assessment instrument or diagnosed using the standardized diagnostic criteria in the *International Classification of Disease* (ICD) version 10 (ICD 10) (WHO 1992), ICD version 11 (ICD 11) (WHO 2021), or in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) third edition (DSM-III), fourth edition (DSM-IV) or fifth edition (DSM-5) (APA 2013) .
2. Trials will be included where the diagnosis is either made by a clinician through validated diagnostic interview or using a validated questionnaire, e.g. the Symptom Checklist-90 (Franke 2014), the general health questionnaire (GHQ) (Jackson 2007), the medical outcomes study short form 36 (Ware 1992), the Spielberger state trait anxiety inventory (STAI) (Spielberger 1983), the Beck anxiety inventory (BAI) (Beck 1988) and the hospital anxiety and depression scale-anxiety (HADS) (Stern 2014).

##### *Comorbidity*

Studies in adults with physical or psychiatric comorbidities will be also be included in the review, as long as the comorbidity was not the focus of the trial. For example, we will exclude trials that focus on anxiety among individuals with Parkinson's disease or acute myocardial infarction, but will accept trials that may have included some participants with Parkinson's disease or with acute myocardial infarction. We made this decision to be consistent with the methods of a similar Cochrane Review that evaluated BA for depression in adults (Uphoff 2020).

#### Types of interventions

##### *Experimental intervention (BA)*

We will include trials that use treatment approaches for anxiety that are either explicitly called 'behavioural activation', or are treatments that are described using the main elements of BA. These main elements include pleasant events and activities scheduling, positive reinforcement from the environment, and positive interaction or re-engagement with the environment. Therapies with only some components of BA, but not its main elements, will not be included.

##### *Comparators*

All comparators will be accepted, as long as they are not a type of BA. Comparators may include the following.

1. Psychological and psychosocial therapies: we will include any psychological intervention including (e.g. counselling, cognitive behaviour therapies, exposure therapies or relaxation therapies and mindfulness based therapies, social skills training, assertiveness training).
2. Pharmacotherapy: benzodiazepines; buspirone; calcium modulators e.g. pregabalin; antidepressants e.g. selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs); and beta blockers.
3. Any other comparator: e.g. treatment as usual (TAU), attention or psychological placebo, waiting list.

###### Format of psychological therapies

Therapies delivered by therapists of all levels will be eligible for inclusion. These therapists include the following.

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.

3. Lay counsellors and non-specialist therapists who have been specifically trained to deliver treatment according to a BA protocol.

We will include 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 will be eligible for inclusion.

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

#### Behavioural therapy

We will not include any behavioural therapies that contain the main elements of BA as comparator.

#### Social skills training

Social skills training/assertiveness training (SST) subsumes assertion and conversational skills, together with more specialised sub-skills 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 will include it in the SST category.

#### Relaxation therapy

Relaxation training is a behavioural stress management technique that induces a relaxation response, helping to switch to the rest/digest 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 .

#### '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 2017). Drawing from psychodynamic and humanistic principles, third-wave CBT approaches place great emphasis on use of the therapeutic relationship. We can categorise 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 (PDs)

Grounded in psychoanalytic theory (Freud 1989). PDs use the therapeutic relationship to explore and resolve unconscious conflict through transference 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 (Malan 1963; Mann 2009; Strupp 1984).

#### 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.

#### 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 1987), and cognitive analytic therapy (CAT) (Ryle 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 2008), drawing in part from attachment theory (Albert 1982), 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. Therefore, we will 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 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 will 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 anxiety, most commonly anti-anxiety medications; any dose, route of administration, duration and frequency.

#### No treatment

Trial participants not receiving any treatment for anxiety 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 will categorise it as such.

### *Excluded interventions*

We will exclude trials of long-term, continuation, or maintenance therapy interventions designed to prevent relapse of anxiety, or to treat chronic anxiety disorders. Similarly, we will exclude trials of interventions designed to prevent a future episode of anxiety.

We will exclude 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, narrative therapy, personal construct therapy, neuro-linguistic programming and brief problem-solving. 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.

## Types of outcome measures

### *Primary outcomes*

1. Reduction in anxiety mean score, measured using any valid scale (continuous outcome); and remission, defined as having anxiety or not having anxiety at the end of the trial (dichotomous outcome)
2. Treatment acceptability, measured as 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. Quality of life, as assessed with the use of any validated measure.
2. Social adjustment and social functioning, including Global Assessment of Function (GAF) scores (Luborsky 1962).
3. Proportion of participants experiencing any adverse events including but not limited to worsening of symptoms or relapses.
4. Improvement in depression symptoms, based on a continuous outcome of group mean scores at the end of treatment using the Beck depression inventory (BDI) (Beck 1996) , the Hamilton depression rating scale (HAM-D) (Hamilton 2012), the Montgomery and Asberg depression rating scale (MADRS) (Montgomery 2012) or any other validated depression scale.

#### Time points for primary and secondary outcomes

We will summarise and categorise 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 post-treatment). If data at multiple time points are available within one of our categories, we will use the latest time point.

## 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:

- Cochrane Common Mental Disorders Controlled Trials Register (CCMD-CTR) (all available years);
- Cochrane Central Register of Controlled Trials (CENTRAL; current issue) in The Cochrane Library;
- Ovid MEDLINE (from 1946 onwards);
- Ovid Embase (from 1974 onwards);
- Ovid PsycINFO (all available years) (Appendix 1).

There will be no restrictions on date, language or publication status applied to the searches.

We will search for unpublished or ongoing trials via the World Health Organization's International Clinical Trials Registry Platform (ICTRP) (trialsearch.who.int) and the trials registry at the US National Institutes of Health (ClinicalTrials.gov)

### Searching other resources

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

- Open Grey (opengrey.eu);
- ProQuest Dissertations & Theses Global (search.proquest.com/pqdtglobal/dissertations);
- DART-Europe E-theses Portal (dart-europe.eu/basic-search.php);
- Networked Digital Library of Theses and Dissertations (NDLTD) (search.ndltd.org);
- EThOS - the British Libraries e-theses online service;
- Open Access Theses and Dissertations (OATD) (oatd.org).

### *Other*

To help identify further published, unpublished or ongoing research we will scan the reference lists of included studies and any relevant systematic reviews.

We may contact original authors to obtain any missing data or information, as required.

## Data collection and analysis

### Selection of studies

Two review authors will independently examine each title and abstract obtained through the search strategy for relevance. We will then obtain full texts for all of these articles and two independent review authors will assess the full texts according to the criteria relating to characteristics of the studies, participants, and interventions. Disagreements will be discussed and a decision will be made by a third review author if agreement cannot be reached. We will record reasons for excluding studies at this stage. For all included studies, we will link multiple reports from the same study.

### Data extraction and management

Two review authors will independently extract data from each selected study. The data extracted by the review authors will be compared and any discrepancies will be resolved through consensus. A third review author may be requested as needed to resolve discrepancies.

We will extract and enter information for the following categories into Covidence data extraction forms (Covidence): trial design, source of funding, study population, country, interventions and comparators, outcomes, attrition rates, adverse effects, missing data, main findings, missing outcomes (compared with the protocol) and sample size.

### Assessment of risk of bias in included studies

We will assess risk of bias for each included trial using Cochrane's 'Risk of bias 2 ' tool (RoB2) (Cumpston 2019), 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

The overall risk of bias will be defined as the worst risk of bias in any of the domains. However, if we judge a study to have some concerns about risk of bias for more than three domains, we will judge it to be at high risk of bias overall (Sterne 2019).

### Measures of treatment effect

#### *Continuous outcomes*

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

#### *Dichotomous outcomes*

We will analyse dichotomous outcomes by calculating risk ratios (RRs) and 95% CIs for each comparison in RevMan Web (RevMan Web 2020).

### Unit of analysis issues

We will identify the number of included RCTs in which the unit of analysis error occurs and conduct reanalysis where possible for these studies. To assess for unit of analysis error, we will look for whether the study population is truly randomly selected, whether the provider effect and patient-provider interaction effect are accounted for in the analysis, and whether the unit of randomisation and the unit of analysis are the same.

#### *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 2021).

#### *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 pairwise meta-analysis. For trials with more than two eligible arms, we will manage data 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 pairwise 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 BA intervention group (objective 1/2).
2. If studies use multiple control groups including treatment as usual, waiting list, attention placebo, or psychological placebo, we will combine the control groups to compare to the BA intervention group (objective 3).

### Dealing with missing data

We will contact the authors of the original studies to fill in gaps in our data. We will take a pragmatic approach to contacting authors. We will make contact via email or research sharing platforms only and will make two attempts (one week apart) to contact them. If missing information about study design or methods prevents us from assessing the eligibility of a study, we will include it in the review as a study awaiting assessment. Where missing outcomes data cannot be obtained from authors, we will impute the missing data and use statistical methods to account for the uncertainty in our imputed data. We will conduct a sensitivity analysis to assess the impact of data imputation on our study analysis. We will also address the types of missing data and its implications in our 'Discussion' section.

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 will also conduct best case/worst case scenarios for the clinical response outcome. In these scenarios, we will assume that dropouts in the active treatment group had positive outcomes and that those in the control group had negative outcomes (best case scenario). We will assume that dropouts in the active treatment group had negative outcomes and that those in the control group had positive outcomes (worst case scenario). These assumptions provide boundaries for the observed treatment effect. Where there is a large amount of missing data, we will give these best case/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 if trial authors reported these data, by using the last observation carried forward (LOCF) to the final assessment. Where standard deviations (SDs) are missing, we will attempt to obtain these data by contacting trial authors. Where SDs are not available from trial authors, we will calculate them from P values, t values, CIs or standard errors (SEs), if these are reported in the articles (Deeks 2021). If the great majority of SDs are available and only a minority of SDs are unavailable or unobtainable, we will use the method devised by Furukawa and colleagues to impute SDs and calculate percentage responders (Costa 2012; Furukawa 2005). We plan to interpret these data with caution and take into account the degree of observed heterogeneity.

### Assessment of heterogeneity

We will assess our included studies for clinical, statistical and methodological heterogeneity. We will calculate the $I^2$ statistic to calculate the percentage of heterogeneity that is not due to chance alone. In our 'Discussion' section, we will address potential causes for heterogeneity in our included studies. Where $I^2$ values in pooled data suggest substantial or considerable heterogeneity, we will use a random-effects meta-analytic model (Higgins 2021).

We will use the heterogeneity thresholds suggested by the Cochrane handbook (Chapter 10) (Higgins 2021);

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

### Assessment of reporting biases

We will minimise the impact of reporting biases as much as possible by undertaking comprehensive searches of multiple sources (including trials registries) to identify unpublished material. We will include reports published in any language. We will also try to identify outcome reporting bias in trials by recording all trial outcomes, planned and reported, and noting where outcomes were missing. If a study protocol is available, we will compare outcomes in the protocol and the published report. If a study protocol is not available, we will compare outcomes listed in the article's 'methods' section with those actually reported in the article's 'results'. If we find evidence of missing outcomes, we will contact trial authors to try to obtain any available data directly, although it is important to note that such information may be unreliable (Chan 2004).

### Data synthesis

In a narrative synthesis of the results, we will report treatment efficacy (number of participants responding to treatment), treatment acceptability (number of participants who dropped out), improvement in anxiety outcomes as a continuous score, and where available, quality of life. We will present standardized effect size estimates and 95% CIs. We will also present these data in tabular form.

If possible, we will also conduct a meta-analysis of included trials for each primary and secondary outcome. Given the potential heterogeneity of BA approaches for inclusion, together with the likelihood of differing secondary comorbid mental disorders in the population of interest, we will use a random-effects model in all analyses.

### Subgroup analysis and investigation of heterogeneity

We will conduct the following subgroup analyses, based on the availability of sufficient data on outcomes and comparators:

1. Mild versus moderate versus severe GAD groups, based on the psychometric tools used, or clinical assessment using a diagnostic criterion.
2. People with or without severe mental illness (bipolar disorder, major depressive disorder, and schizophrenia).
3. Length of treatment (brief versus long-term interventions) and its effect on recovery/improvement.
4. BA alone versus BA plus other components (e.g. pharmacotherapy, mindfulness-based interventions).

### Sensitivity analysis

1. Low risk of bias studies: we will exclude studies categorised as some concerns and high risk of bias.
2. Sub-threshold anxiety: we will exclude trials of sub-threshold anxiety to determine whether the decision to include the trials of anxiety not meeting clinical thresholds has a substantial impact on the results.
3. Mode of delivery: we will exclude therapies delivered through computer–based electronic guidance without a face-to-face component.
4. Group therapy: we will exclude trials of group therapy for BA as the mode of delivery of psychotherapy can influence its effectiveness.

### Summary of findings and assessment of the certainty of the evidence

We will construct a 'Summary of findings' table to present the findings for the primary and secondary outcomes using GRADE Pro Software (GRADEpro GDT), with the GRADE assesment of the quality of the body of evidence as described in the *Cochrane Handbook* (Schünemann 2021).

For each of our main comparators we will include the following outcomes, measured at six, 12 and 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 anxiety outcomes as a continuous score.

4. Quality of life.
5. Social adjustment/ functioning score.
6. Improvement in depression symptoms as a continuous score.

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# APPENDICES

## Appendix 1. PsycINFO Search

APA PsycInfo (Ovid) <1806 to October Week 1 2021>

1 behavioral activation system/ 529
2 ((behavio* adj1 activ*) or BATD).ti,ab,id. 7183
3 (behavio* adj3 (reinforce* or re-inforce*)).ti,ab,id. 5675
4 reinforc*.ti,id. or (((contingent or positive) adj1 reinforc*) or (reinforc* adj3 (environment* or experience*))).ti,ab,id. 30993
5 exp reinforcement/ 53062
6 (reinforce or reinforcer or reinforcement or reinforcements or re-inforcement or re-inforcements).ab. /freq=2 16714
7 (behavio* adj2 (contracting or modification or modify*)).ti,ab,id. 8345
8 behavior contracting/ or behavior modification/ 10864
9 ((activit* or event?) adj2 schedul*).ti,ab,id. 882
10 planned behavior/ 2758
11 ((pleas* or enjoyable or rewarding) adj (activit* or event?)).ti,ab,id. 1073
12 (operant conditioning or instrumental learning).ti,ab,id. 4989
13 exp operant conditioning/ 36365
14 (positive interaction* or avoidant coping or environmental contingenc* or contigency management).ti,ab,id. 3177
15 exp contingency management/ 3176
16 ((gain? or reapprais*) adj2 focus*).ti,ab,id. 149
17 functional analysis.ti,ab,id,sh. 4427
18 (behavio* and (self adj (care or efficacy or evaluat* or monitor*))).ti,id,hw. 11068
19 ((psychoeducat* or psycho-educat*) and (coping behavi* or coping skills or self manag* or (behavi* adj2 chang*))).ti,ab,id,hw. 1050
20 self management/ and behavior change/ 131
21 or/1-20 140597
22 *behavior therapy/ and anxi*.ti,hw,tm. 1016
23 anxiety/ 67191
24 anxiety disorders/ or generalized anxiety disorder/ or panic attack/ or panic disorder/ or exp phobias/ or separation anxiety disorder/ 39313
25 (anxiety disorder* or agoraphobi* or generalized anxiety or generalised anxiety or GAD or (separation adj2 anxiety) or (social adj2 anxi*) or panic or phobi*).ti,ab,id. 70914
26 anxi*.ti,id. or (worry or worries).ti,ab,id. 111614
27 (mood? or mental health or ((emotion* or psychological) adj (distress or trauma*))).ti,id,hw. 205074
28 or/23-27 347029
29 (21 and 28) 7119
30 clinical trials.sh. 11982
31 (randomi#ed or randomi#ation or randomi#ing).ti,ab,id. 96092
32 (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 subsitut* or treat*))).ti,ab,id. 112701
33 ((single or double or triple or treble) adj2 (blind* or mask* or dummy)).ti,ab,id. 27591
34 trial.ti. 33752
35 placebo.ti,ab,id,hw. 42017
36 (control* and (trial or study or group?) and (no-treatment or waitlist* or wait* list* or ((treatment or care) adj2 usual))).ti,ab,id,hw. 14126
37 (((allocat* or assign* or receive*) adj5 ("no-treatment" or waitlist* or wait* list* or ((treatment or care) adj2 usual))) and (control or group?)).ab. 2712
38 empirical study.md. and (("no-treatment" or waitlist* or wait* list* or ((treatment or care) adj2 usual)) adj5 (control or group? or compared or comparison)).ab. 10000
39 (treatment adj5 control).ab. 13494
40 treatment outcome.md. 21904
41 treatment effectiveness evaluation.sh. 26099
42 mental health program evaluation.sh. 2216
43 or/30-42 220940
44 (22 and 43) 297
45 (29 and 43) 829
46 (44 or 45) 1098

# CONTRIBUTIONS OF AUTHORS

Drafting of protocol: GZ, EU, SA, SD, ALB, JVEB, KC, AHE, MI, AJ, KNK, NSM, FNR, SR, RR, TR, NS

Search strategy and search methodology: SD, GZ

## DECLARATIONS OF INTEREST

SA: no conflicts of interest
EU: is a current member of the editorial staff of the Cochrane Common Mental Disorders Review Group. EU was not involved in the editorial process for this protocol.
ALB: no conflicts of interest
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KC: no conflicts of interest
SD: no conflicts of interest
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KNK: no conflicts of interest
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SR: no conflicts of interest
RR: no conflicts of interest
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