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[Intervention Protocol]

Cognitive behavioural therapy and third wave approaches for anxiety and related disorders in older people

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ABSTRACT

Objectives

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

- To assess the effects of CBT (CT, BT, CBT and third-wave CBT interventions) on severity of anxiety symptoms compared with minimal management for anxiety and related disorders in older adults, aged 55 years or over.
- To assess the effects of CBT (CT, BT, CBT and third-wave CBT interventions) on severity of anxiety symptoms compared with other psychological therapies for anxiety and related disorders in older adults, aged 55 years or over.

BACKGROUND

Description of the condition

Anxiety and related disorders are the most prevalent mental disorders overall across the life span. Epidemiological studies (including, as the most important, panic disorder, agoraphobia, generalised anxiety disorder, social anxiety disorder, specific phobia, obsessive-compulsive disorder, and post-traumatic stress disorder) report a lifetime prevalence rate among the general population ranging from approximately 17% in the European Union (Wittchen 2011) to almost 29% in the USA (Kessler 2005). An age-independent systematic review has found both an intercontinental difference in prevalence and a difference between countries (Baxter 2014). Between East Asia and North Africa, for example, a threefold difference in prevalence was found of 2% and 6% respectively. The parts of the world with the most epidemiological data, i.e. North America and Europe, showed differences between countries of more than 50% (for instance 2% in Israel versus almost 7% in France). The prevalence and burden of disease was also highest in the lower age groups. Nevertheless, despite these difference between studies (probably due to different methodologies), countries and continents, anxiety and related disorders are the most prevalent disorders at a global level and over the course of life.

The estimated prevalence rates of anxiety and related disorders among older adults living in the community varies across several epidemiological studies from 6% to 12%, probably due to methodological issues (Bryant 2008; Byers 2010). A meta-analysis of epidemiological studies (Volkert 2013) on current and lifetime prevalence of anxiety disorders in older age in Western countries revealed the following figures: a current and lifetime prevalence of 0.9% and 2.6% respectively for panic disorder; 0.5% and 1.0% for agoraphobia (with and without panic disorder); 4.5% and 6.7% for specific phobia; 1.3% and 5.1% for social anxiety disorder; and 2.3% and 6.4% for generalised anxiety disorder. These figures correspond with the recently published MentDis_ICF65+ Study, with a current and lifetime prevalence of anxiety disorders of 11.4% and 21.4% respectively in Europe (Andreas 2017). This study also included post-traumatic stress disorder, with a current prevalence of 1.4% and a lifetime prevalence of 2.5%. The prevalence of obsessive compulsive disorder in the elderly is highlighted in other epidemiological studies, with prevalence rates between 1.5% and 2.9% (Klenfeldt 2014; Préville 2010).

These figures show that anxiety and related disorders are also common mental disorders in the elderly, with prevalence rates comparable to the younger-age categories. The diagnostic criteria of these disorders are specified in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; APA 2013), or the International Classification of Diseases and Related Health Problems, 11th revision (ICD-11; WHO 2018). Both international classification systems distinguish three separate sections: namely, 'pure' anxiety disorders, stressor- and trauma-related disorders, and obsessive-compulsive or related disorders. Neither the DSM-5 nor the ICD-11 distinguish between younger and older adults in the diagnostic criteria for these disorders. Although there are no major age-related diagnostic differences, there are a number of characteristics that are specific to the elderly with anxiety and related disorders, and which it is relevant to review briefly.

When these disorders are diagnosed at an older age, they are generally characterised by a relatively young age at onset and a chronic course, with onset above 65 years of age a rare phenomenon (Kessler 2005). Older adults with anxiety and related disorders are at risk of being undiagnosed and untreated. The odds ratios of receiving specialised mental health care were 2.4 to 4.8 greater in the younger adults (Wang 2005). A major feature at the behavioural level between older and younger adults is the difference in helpseeking. The percentage of adults aged 65 and over seeking help is almost 50% lower compared with their younger counterparts (MacKenzie 2012). Negative stereotyping, also known as ageism, of healthcare professionals, older people themselves and their social environment contributes to this phenomenon of underdiagnosing and undertreating, by interpreting specific anxiety symptoms as appropriate for age (e.g. Bodner 2018; Wolitzky-Taylor 2010).

Phenomenological differences can also play an important role in why anxiety and related disorders in the elderly are not recognised. Older adults are more likely to suffer from somatic morbidity, which may be given greater priority in diagnosis and treatment by healthcare professionals, and as a result of which comorbid anxiety disorders may be overlooked. Furthermore, elderly people are more inclined to translate anxiety symptoms into physical complaints, causing the focus to be mainly but mistakenly directed to these symptoms (Wolitzky-Taylor 2010). The presentation of anxiety symptoms seems to be subject to the process of aging. Higher age in general appeared to be accompanied by a decrease in both cognitive and emotional anxiety symptoms, as well as physiological symptoms. Feelings of insecurity and stressful events may therefore be better tolerated in older age (Gould 2010). On the other hand, dysfunctional fear-related cognitions also seem to change in older people with anxiety disorders compared to younger adults. For example, the level of agoraphobic cognitions was less severe in older adults suffering from panic disorder compared to younger adults, whereas both the severity and the nature of agoraphobic avoidance did not differ (Hendriks 2010). It was therefore suggested that in older adults suffering from anxiety disorders focusing on avoidance behaviour and associated limitations in daily functioning may be more appropriate (Grenier 2011; Hendriks 2010). Elderly people with generalised anxiety disorder experienced on average fewer symptoms compared to younger people, although specific symptoms like dizziness, decreased concentration and some physical symptoms (nausea, gastric problems) were more common in older compared to younger people (Miloyan 2014b). Differences were also apparent in worry content. Older people worried about health issues and the well-being of relatives, whereas younger people worried more about work, social life and finances (Miloyan 2014a). In the case of social anxiety disorder no phenomenological differences between the various age groups were found (Miloyan 2014a). Finally, two types of anxiety syndrome are common and specifically related to older age: the first is fear of falling, which may be categorised as a specific phobia. Fear of falling is generally not present in young people and is characterised by changing motor skills during walking (walking more carefully, holding on to yourself, using aids such as a walker) and avoiding physical activities (Parry 2016). The second is fear of dementia, which is mainly characterised by worries about cognitive functioning and developing dementia, and is typically found in the younger elderly (Cutler 2015; Cutler 2017).

In general, people with anxiety disorders have an increased risk of comorbid disorders. Life-time comorbidity in anxiety disorders is estimated at 80% (Brown 2001), with the Netherlands Study of

Depression and Anxiety (NESDA) showing an overall comorbidity of both another anxiety disorder or depression, or both, of 70% (Hofmeijer-Sevink 2012). Moreover, prospective epidemiological studies show that anxiety and related disorders tend to run a chronic course, meaning they are likely to resurface over the life course (Hendriks 2013; Keller 2006; Penninx 2011; Yonkers 2003).

Although the prevalence and the burden of disease in late-life anxiety and related disorders is not as high as in younger adults (Baxter 2014), these disorders are not a minor health problem in older adults. Comorbidity of a second anxiety disorder or depressive disorder or both is common in older age (Hek 2011; Kessler 2005; King-Kallimanis 2009; Lenze 2005; Van Balkom 2000). Secondly, physical diseases or physical complaints, which are more common in older age, are associated with an increased risk of suffering from anxiety in older age (El-Gabalawy 2011). Thirdly, anxiety and related disorders in later life are associated with an increased risk of coronary heart disease (Huffman 2008) and a higher mortality rate (Brenes 2007; Van Hout 2004). In addition, negative stereotyping in both older adults themselves, in their social environment and among healthcare professionals was found to be a general mechanism in older age categories that contributed significantly to reducing both physical and mental health and increasing the burden of disease and healthcare costs (e.g. Levy 2020). Several studies have shown that these factors reduce quality of life in older adults suffering from anxiety and related disorders. Daily functioning decreases, well-being is impaired, healthcare and additional costs increase, and quality of life is more affected by poor mental health compared to physical morbidity (Hohls 2018; Mackenzie 2010; Puvill 2016; Simning 2020)

Description of the intervention

First-line treatments for anxiety disorders which do not improve after education and active monitoring consist of psychological therapy or antidepressant medication or both (NICE guideline 2011). Community studies show that only 5.1% of older adults suffering from anxiety disorders receive psychological therapy, and only 3.8% are prescribed an antidepressant (De Beurs 1999). An epidemiological study has shown that mental health services are still underused for elderly people with anxiety disorders in Europe, and that this has hardly changed during the past 20 years (8.9% in 1999 versus 10.6% in 2017) (Volkert 2017). Both participant and physician characteristics may contribute to this phenomenon. Many older adults resist the use of antidepressants, based on a fear of dependence, prior negative experiences, resistance to viewing their symptoms as a medical illness, and concern that antidepressants will prevent natural feelings (Givens 2006). Instead, they prefer psychotherapy (Luck-Sikorski 2017; Mohlman 2012). This is important, as offering treatment tailored to the patient's preference has a sustained moderate effect in improving the outcome (Lindhiem 2014).

The average time between the onset of anxiety symptom and the first therapy contact has been shown to be between nine and 23 years, suggesting that general practitioners do not easily recognise anxiety disorders (Kroenke 2007; Wang 2005). The referral rate from primary care to a mental health specialist is three times lower for older adults suffering from anxiety disorders (17%) compared to those suffering from depression (55%) (Kessler 2005; Wang 2005). Furthermore, although pharmacological treatment with antidepressants or benzodiazepines is effective in treating late-life anxiety disorders (Pinquart 2007), both drugs are associated with an increased risk of falling and fractures (Coupland 2011; Hartikainen 2007). As most older adults suffering from anxiety disorders are treated in primary care, general practitioners should be aware of increased side-effects in later life, for example the heightened risk of falling and traffic accidents, memory impairment, dependency associated with the use of benzodiazepines (Maree 2016), and the low concentration of sodium in the blood with the use of serotonin reuptake inhibitors (Wright 2008). Also of concern are the adverse effects of drug interactions, such as gastrointestinal bleeding resulting from the concurrent use of serotonin reuptake inhibitors and non-steroidal anti-inflammatory drugs in this age group, known for polypharmacy use (Yuan 2006; Weinrieb 2005). As effective management of anxiety disorders in later life may improve outcomes, it is important that guidelines for therapy become available.

Because cognitive behavioural therapy is the first choice of psychological treatment in the current guidelines for the treatment of anxiety and related disorders in the 18-65 age group, this review focuses on the outcome of CBT in the treatment of anxiety and related disorders in adults aged 65 years and older.

Cognitive-behavioural therapy (CBT) combines principles of both behavioural and cognitive therapy. These principles stem largely from learning and cognitive theories (Bandura 1969; Beck 1995; Yates 1970). Cognitive therapy (CT) assumes that a participant's symptoms (e.g. anxiety) arise from misperceptions and attitudes about the world and themselves. Behavioural therapy (BT) is a directive, active approach involving principles of learning to help the participant to develop new and adaptive ways of behaving. CBT is characterised as a structured, goal-oriented, problem-focused, time-limited intervention (Dobson 2019).

Third-wave CBT was developed some 15 years ago. It was originally designated as an evolution from the existing traditional CBT protocols to a more process oriented cognitive therapy (Dimidjian 2016). It differs from traditional CBT in that it does not focus on syndromes and reducing symptoms. The focus of third wave CBT's is, for example, on context, relationship, emotion, acceptance and the process of therapy, instead of primarily on symptoms and procedures to reduce these symptoms. These third wave CBTs have been used in both the 18-65 age group and the 65+ age-category (Kishita 2017). Examples of evidence-based third-wave CBTs are acceptance and commitment therapy (ACT), dialectical behavioural therapy (DBT), metacognitive therapy (MCT), mindfulness-based cognitive therapy (MBCT) or schema-focused therapy (SFT) (Hayes 2017; Kahl 2012). DBT is characterised by addressing maladaptive emotional regulation and improving tolerance of stress, regulation of emotions and interpersonal coping. ACT is directed at things patients are directly able to influence, such as their own behaviour, rather than trying to control experiences that cannot be directly influenced, such as emotions and thoughts (called experiential avoidance). This implies an accepting attitude towards these emotions and thoughts. MCT is a form of CBT for excessive anxiety. Central to this are dysfunctional thoughts about a patient's own worries. These views are called metacognitions, and are thought to underlie excessive anxiety and dysfunctional behaviours. MCT aims to change these dysfunctional metacognitions into adaptive cognitions. The central goal of MBCT is to be attentive to thoughts, feelings, physical sensations and the physical environment in an acceptable way, without judging

whether something is right or wrong. MBCT helps in recognising automatic, sometimes unhelpful, patterns. Greater awareness of these patterns can lead to more freedom of choice, to breaking through automatic reactions and to learning to react in a more helpful way. SFT is a therapeutic approach in which elements from cognitive, behavioural therapeutic and psychodynamic models, among others, are combined with each other. The therapy aims to identify in patients old dysfunctional coping styles related to events and experiences in the past, and to change them to more adaptive ones; for a concise overview see Kahl 2012. Some of these therapies seem to be particularly suited to older adults with anxiety disorders (Wetherell 2011).

In order to deal with age-associated cognitive impairment, some authors argue for the inclusion of learning and memory aids like homework reminders, troubleshooting calls or weekly review of all concepts and techniques (Mohlman 2003). They also advise the application of a more personalised approach to older people that takes into account, for example, personal context, history, attitudes towards ageing, and available skills (Laidlaw 2015). However, it is questionable whether this is a specific age-appropriate approach or a more general approach which should always be a starting point prior to each treatment. Recent studies on older adults remain inconclusive on whether age-related adaptations of psychotherapeutic techniques are necessary to remain efficacious for anxiety disorders in later life. Some authors argue that CBT is less effective in older people with anxiety disorders than in younger working-age adults (Kishita 2017; Wetherell 2013). Other studies, on the other hand, argue that CBT is no less effective in older adults, and may even be more effective (Chaplin 2015; Hendriks 2014).

How the intervention might work

CBT identifies habitual ways in which participants distort information (e.g. automatic thoughts) and teaches participants to identify and respond to their dysfunctional thoughts and beliefs (e.g. catastrophic misinterpretations), using a variety of techniques to change thinking, mood, and behaviour (Clark 1986).

Behavioural interventions help the participant to develop new and adaptive ways of behaving and consists mainly of exposure-techniques (Marks 1981). Exposure-based therapy uses gradual, systematic, repeated exposure to the feared object or situation to desensitise participants with anxiety disorders to the feared stimulus. The controlled exposures are predictable and the participant is taught a variety of adaptive coping strategies.

CBT-related approaches or the so-called 'third-wave' therapies are represented by a set of different therapies (e.g. mindfulness-based cognitive therapy, acceptance and commitment therapy, compassionate mind training, extended behavioural activation, metacognitive therapy, schema therapy), all originating from the cognitive behavioural approach but compared to which more importance is given to the form, rather than the content, of participants' thoughts. By focusing on the function of cognition, third-wave therapies aim to help participants to develop more adaptive emotional responses to situations. When mindfulness and acceptance are applied to anxiety disorders, the aim is for the individual to be able to observe symptomatic processes without overly identifying with them or without reacting to them in ways that cause further distress (Roemer 2008). In this review CT, BT, CBT and the third-wave CBTs are all referred to as CBT.

Why it is important to do this review

CBT is generally considered the most effective psychological therapy for anxiety disorders, with large effects observed on the severity of anxiety symptoms, comorbid depression, quality of life and functioning (Asnaani 2020). Several authors argue that CBT should be considered the gold standard in psychological treatment (David 2018). The efficacy of CBT for anxiety disorders in young and middle-aged adults is supported by a variety of systematic reviews and meta-analyses (Bakker 1998; Furukawa 2006; Hofmann 2008: Hunot 2007; Loerinc 2015; Mitte 2005a; Mitte 2005b; Van Balkom 1995; Van Dis 2020; Westen 2001), although long-term effects are not consistent across all anxiety disorders (Van Dis 2020). However, whether these results also apply to older adults remains unclear, since most trials exclude participants over the age of 65 years. It can be difficult to generalise findings from studies in young and middle-aged adults to older adults, as older adults often have more chronic disorders which are presumed to be more resistant to successful treatment (Katz 2002). This review therefore aims to provide a comprehensive and up-to-date synthesis of the available evidence on CBT as a therapy for older adults with anxiety and related disorders.

Many of the earlier studies on psychological therapy for anxiety disorders in later life suggest that CBT may be effective, but have been limited to subclinical anxiety and lack rigorous inclusion criteria such as the presence of an anxiety disorder which meets diagnostic guidelines (e.g. Nordhus 2003). Previous reviews have generally concluded that psychological therapy is effective for anxiety and related disorders in older adults, but also state that there is a need for large, rigorous controlled trials for the different anxiety disorders (Goncalves 2012; Hendriks 2008; Pinquart 2007). However, in later life, pure anxiety disorders are rare, as most participants have a comorbid second anxiety disorder or depressive disorder. For the purposes of conducting this review, we will therefore combine generalised anxiety disorder, panic disorder with and without agoraphobia, agoraphobia and social phobia (conditions that often overlap), into a single diagnostic category which we term anxiety disorders. We consider obsessive compulsive disorder and the stress disorders (acute and post-traumatic stress disorder) as separate diagnostic categories.

OBJECTIVES

- To assess the effects of CBT (CT, BT, CBT and third-wave CBT interventions) on severity of anxiety symptoms compared with minimal management for anxiety and related disorders in older adults, aged 55 years or over.
- To assess the effects of CBT (CT, BT, CBT and third-wave CBT interventions) on severity of anxiety symptoms compared with other psychological therapies for anxiety and related disorders in older adults, aged 55 years or over.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) will be eligible for inclusion. In the case of cross-over trials (a rare feature in this field of research), we will include only the first randomisation period in the review. Studies using a quasi-randomised design will not be eligible for inclusion. We will include cluster-RCTs, in which centres

or therapists are randomised to intervention or control groups, provided that the specific aim of the study was to examine the effect of the intervention.

Types of participants

Age

Participants aged 55 or older will be eligible for inclusion.

If a study reports on a mixed group of participants consisting of younger and older adults, we will only include the trial if data are presented separately for adults aged 55 and over and if randomised age blocks were used.

Diagnosis

We will include studies of participants with a primary diagnosis of an anxiety disorder according to DSM-III (APA 1980), DSM-III-R (APA 1987), DSM-IV (APA 1994), (APA 2000), DSM-5 (APA 2013), ICD-9 (ICD-9 1979), or ICD-10 (ICD-10 1999), irrespective of culture and setting. The review will combine generalised anxiety disorder, panic disorder, agoraphobia, specific phobia, and social phobia (conditions that often overlap), into a single category called anxiety disorders.

Since the introduction of DSM-5 both obsessive-compulsive disorder (OCD) and the stress disorders (acute stress disorder (ASD) and post-traumatic stress disorder (PTSD)) are no longer part of the anxiety disorders section. Instead, these disorders have been divided into two separate categories, i.e. the obsessive-compulsive and related disorders and the trauma and stressor-related disorders. A similar distinction is made by ICD (ICD-9 1979; ICD-10 1999), acknowledging four categories of anxiety disorders, namely: 1) phobic anxiety disorders; 2) other anxiety disorders (together comparable to our category 'anxiety disorders'); 3) obsessive-compulsive disorders; and 4) reaction to severe stress and adjustment disorders. Because the most important disorders from these categories (OCD, ASD and PTSD) were part of the anxiety disorders section in the previous DSM versions, we decided to include them in this review. We will consider OCD, ASD and PTSD separately in subgroup analyses.

Comorbidities

We will exclude studies of anxiety symptoms that are part of the clinical presentation of another primary diagnosis (e.g. substance use disorders, major depression), as well as studies involving participants with a comorbid psychiatric diagnosis of substance-related disorder, schizophrenia or psychotic disorder. However, studies involving participants with comorbid physical illnesses are eligible for inclusion, to increase generalisability, as most older people suffer from physical illnesses.

Types of interventions

Experimental intervention

Cognitive behavioural therapy and 'third wave' approaches:

- **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 (Bennet-Levy 2004). We classify these therapies into six subcategories: cognitive therapy, rational emotive behaviour therapy, problem-solving therapy, self-control therapy, a coping-with-depression course, and other CBTs.

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

Third-wave CBT approaches have been developed more recently and now exist alongside established therapies such as CBT. Rather than focusing on the content 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 suppression 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 classify these therapies into subcategories: acceptance and commitment therapy, metacognitive therapy, mindfulness-based cognitive therapy, dialectical behaviour therapy, and schema focused therapys.

At least six therapy sessions must be delivered, in either an individual or a group format, as this guarantees a solid basis for change. Older people are found to profit from repetition, so at least two sessions are deemed necessary for psycho-education, and the other four are a minimum to practise new behaviours. However, between eight and 15 sessions may not be predictive of greater effectiveness (Wetherell 2005).

Comparator interventions

- Non-CBT psychological therapies
- Minimal management

These interventions are briefly described below:

Non-CBT psychological therapies:

- **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).

- **Psychodynamic therapies**

Grounded in psychoanalytic theory (Freud 1949), psychodynamic therapy (PD) uses the therapeutic relationship to explore and resolve unconscious conflict through transference (projection of feelings on to the therapist) and interpretation, with development of insight and character change (within certain boundaries) as therapeutic goals, and relief of symptoms as an indirect outcome. Brief therapy models have been devised by Malan 1963, Mann

1973 and Strupp 1984. We classify these therapies into four subcategories: drive/structural model (Freud), relational model (Strupp, Luborsky), integrative analytic model (Mann), and other psychodynamic therapies.

- **Humanistic therapies**

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

- **Interpersonal, cognitive analytic and other integrative therapies**

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

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

We also include motivational interviewing and other forms of integrative therapy approaches in this category.

Minimal management:

We consider interventions to represent 'minimal management' (also described in trials as standard care, treatment as usual or waiting list), if they contain elements of clinic attendance, investigation, reassurance, and simple advice, without explicit psychological therapy. Prescribing of medication by the general practitioner is also considered to be usual treatment. Although these interventions are described as minimal, they are very heterogeneous in nature. When describing the studies included and the results, an unambiguous, clear description will be necessary so that it is clear what is meant by minimal.

- **Waiting list/No treatment**

Waiting list refers to: Participants are randomly assigned to the active intervention group or the 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.

No treatment refers to: Trial participants not receiving any treatment for anxiety and related disorders during the course of the trial.

- **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 anxiety and related disorders, most commonly antidepressants; any dose, route of administration, duration, and frequency.

- **Medical placebo**

All types of medical placebos or 'sugar pills'.

- **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 into any of the above categories, for example 'no treatment' or a type of psychological therapy, we categorise it as such.

Excluded interventions

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

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). We also exclude CBT in combination with pharmacological therapy, as its superior effects over single therapies (Bakker 1998; Van Balkom 1997) have been challenged by meta-analyses (Furukawa 2006; Mitte 2005a; Mitte 2005b).

Types of outcome measures

Primary outcomes

Anxiety is the primary outcome in this review, and will be measured as follows:

- Reduction in anxiety severity (continuous), measured by any well-validated, observer-rated instrument such as the Hamilton Rating Scale for Anxiety (Hamilton 1959), or if not available, a validated self-report instrument measuring general anxiety such as the Beck Anxiety Inventory (Beck 1988a), or if not available, subscales of measures of anxiety derived from scales that measure multiple domains of mental health;
- Clinical recovery or improvement (dichotomous), based on diagnostic interview or defined cut-off using validated scales, as specified by trial authors. If the Clinical Global Impression scale (change item) (CGI-C) is used, responders are defined as having a change score of 1 = 'very much' or 2 = 'much' improved (Guy 1976).

Secondary outcomes

We will include the following secondary outcomes in the review:

- Symptoms of worrying, assessed continuously by validated self-report questionnaires, such as the Penn State Worry Questionnaire (Meyer 1990; Van Rijsoort 1999);
- Depression symptoms, assessed continuously by validated self-report questionnaires, such as the Beck Depression Inventory (Beck 1988b);
- Dropout of the study as a surrogate measure of feasibility of the intervention;
- Occurrence of adverse events (e.g. deterioration due to therapy);
- Quality of life, assessed continuously by validated self-report questionnaires, such as the short-form health survey (SF-36) (Ware 1992);
- Long-term outcomes after completion of treatment, if available.

If multiple measures are reported for one outcome in a single study, we will prefer the examples listed above, and the Hamilton Rating Scale for Anxiety to measure reduction in anxiety severity. If multiple measures other than the ones listed above are used, we will prefer the measure we judge to be the most rigorously validated in a population of older adults.

Timing of outcome assessment

We will assess outcomes immediately post-treatment (within two weeks after treatment) and in the medium term (up to six months post-treatment). We will not include longer-term outcomes as high dropout rates may skew results in this population. If multiple time points are reported within the medium-term category, we will include the last time point.

Search methods for identification of studies

We will search a number of sources to identify studies for possible inclusion in this review.

Electronic searches

We will search the following databases using relevant keywords, subject headings (controlled vocabularies) and search syntax, appropriate to each resource:

- Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR) (all years to June 2016; Appendix 1);
- Cochrane Central Register of Controlled Trials (CENTRAL; current year and issue);
- Ovid MEDLINE (2014 onwards; Appendix 2);
- Ovid Embase (2014 onwards);
- Ovid PsycINFO (all years).

We will also search the international trials registries, including ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP), to identify additional ongoing and unpublished studies.

We will apply no restriction by date, language or publication status to the searches.

Searching other resources

Grey literature

We will search the grey literature for dissertations and theses:

- Electronic Theses Online Service (EThOS) - British Library ethos.bl.uk/Home.do;
- DART - Europe e-theses Portal www.dart-europe.eu/basic-search.php;
- Networked Digital Library of Theses and Dissertations (NDLTD) search.ndltd.org/;
- PQDT Open - open access dissertations and theses pqdtopen.proquest.com/search.html;
- Proquest Dissertations & Theses Global search.proquest.com/pqdtglobal/dissertations/.

Correspondence

We will ask experts in this field and principal authors who have published controlled trials in the field of late-life anxiety if they know of any study which meets the inclusion criteria for this review.

Reference lists

We will check the reference lists of identified systematic reviews to identify additional studies missed from the original electronic searches (including unpublished or in-press citations).

Data collection and analysis

Selection of studies

Two review authors (GJH, EU) will independently assess identified studies for inclusion, based on information from the titles and abstracts. We will obtain full-text study reports from online libraries and databases. Where full-text reports cannot be accessed, we will contact study authors. Two review authors (RCOV, GJH) will then independently screen the full-text reports. If the review authors

disagree on the inclusion of a study, they will make the final rating by consensus with the involvement of another review author (RCOV). We will take care to associate multiple publications with the single study to which they relate, and will link these records.

Data extraction and management

We will design spreadsheet forms in Covidence (Covidence 2017), to record descriptive information, summary statistics of the outcome measures, 'Risk of bias' items, and associated commentary. We will pilot the data extraction sheet with three studies prior to starting data extraction. We will export data to Review Manager 5 (Review Manager 2020). Where information is missing, we will contact investigators by email in an attempt to obtain it.

Two review authors (RCOV, GJH) will independently extract the following data from each trial:

- Description of the trials, including primary researcher, date study was conducted (or not reported), year of publication, location of the study, potential conflicts of interest and received funding for study authors;
- Characteristics of participants: gender distribution, mean age, type of anxiety disorder, the duration of primary symptoms,severity of symptoms, comorbid conditions, number of participants randomised to CBT-condition and control groups;
- Characteristics of the interventions: number and length of sessions provided, groups versus individual therapy, face-to-face versus online, type of provider (e.g. trained postgraduate students, licensed psychologists/psychotherapists) and components of the therapy (psycho-education, relaxation training, anxiety management, type(s) of exposure, cognitive techniques, and behavioural experiments), and classification (CT, BT, CBT or third-wave CBT interventions);
- Characteristics of comparisons: number and length of sessions provided, type of comparison (see list above);
- Outcome measures used, and summary continuous (means and standard deviations (SDs)) and dichotomous (number of responders) data. Additional information, such as whether the data reflected the intention-to-treat (ITT), with either last observation carried forward (LOCF)/multiple imputation/mixed effects repeated measures models, or completer/observed cases (OC) sample, and the dropout rates of participants randomised to the experimental and control groups;
- Study type/design: characteristics of trial methodology, including the diagnostic and exclusion criteria employed, the screening instrument used, the inclusion of comorbidities, a minimal severity criterion, and the number of centres involved.

Main comparisons

- The efficacy of CBT interventions for anxiety versus non-CBT psychological therapies.
- The efficacy of CBT interventions for anxiety versus minimal management.

Assessment of risk of bias in included studies

We will assess risks of bias for each included study, using version 1 of the Cochrane 'Risk-of-bias' tool (Higgins 2011). We will address the following six domains:

- Sequence generation: Was the allocation sequence adequately generated?
- Allocation concealment: Was allocation adequately concealed?
- Blinding of participants, personnel and outcome assessors for each main outcome or class of outcomes: Was knowledge of the allocated intervention adequately prevented during the study?
- Incomplete outcome data for each main outcome or class of outcomes: Were incomplete outcome data adequately addressed?
- Selective outcome reporting: Are reports of the study free of suggestion of selective outcome reporting?
- Other sources of bias: Was the study apparently free of other problems (e.g. information concerning treatment fidelity, therapist qualifications/experience and researcher allegiance) that could put it at a high risk of bias?

We will provide a judgement or a quote or both for each domain, with a rating of low, unclear or high risk of bias. For domains relating to blinding and incomplete outcome data, we will consider the risk of bias for different outcomes separately where relevant.

Two review authors (RCOV, GJH) will independently assess the risks of bias in selected studies, discussing any disagreement with a third review author (EU). Where necessary, we will contact the authors of the studies for further information.

Measures of treatment effect

Dichotomous outcomes

We will analyse these outcomes by calculating risk ratios (RRs), with their 95% confidence intervals (95% CIs). In addition, we will calculate the number needed to treat for an additional beneficial outcome (NNTB) when pooled RRs and 95% CIs suggest a beneficial and statistically significant effect of an intervention.

Continuous outcomes

Anticipating different measures across studies, we will calculate the standardised mean difference (SMD) and its 95% CI for continuous outcomes.

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 2020).

Cross-over trials

In cross-over trials we will use only the first part of the trial in analyses, to avoid selection bias (Higgins 2020).

Studies with multiple treatment groups

If studies have two relevant experimental conditions to be compared against a control condition, we will manage the data as follows:

- Continuous data: we will pool means, standard deviations (SDs) and the number of participants for each experimental condition across the two treatment arms as a function of the number of

participants in each arm to be compared against the control arm (Law 2003);

- Dichotomous data: we will collapse active treatment groups into a single arm for comparison against the control group if both treatment groups refer to different forms of CBT (e.g. enhanced CBT and CBT), or we will split the control group equally into two if treatment groups concern CBT versus other non-CBT-therapies.

We will take a similar approach if studies have two relevant control arms (e.g. usual care and a waiting-list control condition) to be compared against one experimental study arm.

Dealing with missing data

Missing continuous data will also be managed through (ITT) analysis using either last observation carried forward to the final assessment (LOCF) if LOCF data are reported by the trial authors or estimates derived from newer imputation methods like multiple imputation or Mixed Effect Model Repeated Measures models. If SDs are missing, attempts will be made to obtain these data through contacting trial authors. If SDs are not available from trial authors, they will be calculated from t-values, confidence intervals or standard errors, where reported in articles (Deeks 1997a; Deeks 1997b). If these additional figures are not available or obtainable, the study data will not be included in the comparison of interest. The robustness of this approach is tested in a sensitivity analysis including only the observed case data (i.e. only participants with a final assessment).

Assessment of heterogeneity

Statistical heterogeneity will be formally tested using the natural approximate Chi^2 test, which provides evidence of variation in effect estimates beyond that of chance. Since the Chi^2 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. We will also assess heterogeneity using the I^2 statistic, which calculates the percentage of variability due to heterogeneity rather than to chance (Deeks 2020). We will apply the following bands of interpretation from the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2020):

- 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.

We will investigate results for which I^2 values or visual examination of forest plots suggest substantial or considerable heterogeneity by checking for data entry errors and exploring the characteristics of included studies and participants. It should be noted that the importance of the observed I^2 statistic depends on the magnitude and direction of treatment effects and the strength of the evidence for heterogeneity. Forest plots generated in Review Manager 5 (Review Manager 2020) will provide an estimate of Tau^2, the between-trial variance in a random-effects meta-analysis (Deeks 2020).

Assessment of reporting biases

If a sufficient number of trials (i.e. more than 10) allow a meaningful presentation, we will produce funnel plots to establish the potential influence of publication bias.

Data synthesis

We will enter data into Review Manager 5 software (Review Manager 2020). We plan to conduct meta-analyses if the availability of data allows for meaningful comparisons between intervention and control groups. In order to obtain a more conservative estimate, we will use a random-effects model in the first instance to combine data. If meta-analyses are not appropriate, we will present results narratively, structured by comparison and outcome.

Subgroup analysis and investigation of heterogeneity

Where possible, we will undertake the following subgroup analyses for the primary outcomes (anxiety severity and clinical recovery or improvement). We will interpret these with caution, due to the risk of false positive conclusions.

- We will create subgroups of different types of anxiety disorder (generalised anxiety disorder, panic disorder, social phobia), OCD, ASD and PTSD to explore potential differences in the efficacy of treatment for different groups of participants. These subgroups are based on the different categories of disorders as described in the DSM-5. OCD is often hypothesised to be part of an obsessive-compulsive symptom spectrum, including body dysmorphic disorder, hypochondriasis, eating disorders, tic disorders and autism (Bartz 2006). Moreover, OCD is more therapy-resistant compared to other anxiety disorders, and pharmacological treatments may differ from the other anxiety disorders, since they include the use of antipsychotics where there is therapy resistance and benzodiazepines are not effective agents (Bandelow 2008; GGZ-Richtlijnen 2003).
- We plan to compare estimates from studies using a waiting list to studies using other minimal-management control groups, as the type of minimal-management control group may create heterogeneity in the results, particularly if other minimal-management control groups consist of a more 'active' treatment than being on a waiting list.
- We will compare other psychological therapy control conditions. These include psychodynamic, interpersonal, and supportive therapies. There are considerable differences in the focus and working mechanisms of these therapies and this may affect results.
- We will compare CT, BT, CBT and third-wave CBT interventions, to explore differences in the effects of different interventions.
- We will create subgroups of group-therapy versus individual-treatment delivery, as the mode of delivery may affect the efficacy of treatment.
- Given the heterogeneity in the population of 'older adults', we will explore differences in the outcomes for participants aged 55 to 79 years and for those aged 80 years and over.

Sensitivity analysis

We plan to undertake sensitivity analyses for the primary outcomes, to assess the degree to which the effect sizes depend on the assumptions made by the review authors.

One sensitivity analysis will only include studies judged to be of higher quality. We will include studies assessed to be at 'low risk of bias' for allocation concealment, with a dropout rate below 20%, formal testing of fidelity to the psychological therapy manual, and use of blinded outcome assessors.

In addition, the following sensitivity analyses will explore how robust estimates are when handling missing data in different ways.

- A best-case scenario for the dichotomous outcome 'Clinical recovery or improvement', in which we assume that dropouts in the treatment group had positive outcomes and those in the control group had negative outcomes.
- A worst-case scenario for the dichotomous outcome 'Clinical recovery or improvement', in which we assume that dropouts in the control group had positive outcomes and those in the treatment group had negative outcomes.
- Available cases for the dichotomous outcome 'Clinical recovery or improvement', in which only the available data are used.
- Available cases for the continuous outcome 'Symptom severity', for which we remove results based on LOCF data.

Summary of findings and assessment of the certainty of the evidence

We will create 'Summary of findings' tables to present the main findings of the review. We will report the outcomes listed below, where available, and will present standardised effect size estimates and 95% CIs. For each comparison, we will include the following outcomes.

- Anxiety severity
- Clinical recovery or improvement
- Symptoms of worrying
- Depression symptoms
- Dropouts from the study
- Occurrence of adverse events
- Quality of life

One review author (GJH) will assess the certainty of the evidence for each outcome using the GRADE approach (Schünemann 2020a), with assessments checked by a second review author. GRADE means Grading of Recommendations Assessment, Development and Evaluation) for assessing certainty (or quality). GRADE is adopted by the Cochrane Collaboration and is used to describe systematically the quality of the included studies in a systematic review. We will use GRADEproGDT (GRADEpro 2015) to create the 'Summary of findings' tables, and will follow the methods for preparing the tables laid out in the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2020b). We will produce the 'Summary of findings' tables before writing the Discussion, Abstract, and conclusions, so that review authors can consider the potential impact of the certainty of the evidence for each outcome on the treatment effects and our confidence in these findings. Our confidence in the findings based on the GRADE assessments will then be reflected in the interpretation of the results, which will inform the Abstract, Plain Language Summary, and Discussion section of the review.

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APPENDICES

Appendix 1. CCMD Controlled Trials Register

The Cochrane Common Mental Disorders (CCMD) maintains two archived clinical trials registers at its editorial base in York, UK: a references register and a studies-based register. The CCMDCTR-References Register contains over 40,000 reports of RCTs in depression, anxiety and neurosis. Approximately 50% of these references have been tagged to individual, coded trials. The coded trials are held in the CCMDCTR-Studies Register and records are linked between the two registers through the use of unique Study ID tags. Coding of trials is based on the EU-Psi coding manual, using a controlled vocabulary; (please contact the CCMD Information Specialists for further details). Reports of trials for inclusion in the Group's registers are collated from routine (weekly), generic searches of MEDLINE (1950 to 2016), Embase (1974 to 2016) and PsycINFO (1967 to 2016); 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 trial registers via the World Health Organization's trials portal (the International Clinical Trials Registry Platform (ICTRP)), pharmaceutical companies, the handsearching of key journals, conference proceedings and other (non-Cochrane) systematic reviews and meta-analyses.

Details of CCMD's generic search strategies (used to identify RCTs) can be found on the Group's website, (cmd.cochrane.org/specialised-register), with an example of the core MEDLINE search (used to inform the register) listed below.

For this review, we will search the CCMDCTR (Studies and References Register) (all years to June 2016), using the following terms:

#1 (anxiety or anxio* or agoraphobi* or *phobi* or panic or OCD or obsessi* or compulsi* or GAD or PTSD or post-trauma* or posttrauma* or “post trauma*” or “acute stress disorder*”):ti,ab,kw,ky,emt,mc,mh
Intervention:
#2 (“cognitive behavi*” or cognitive-behavi* or (cognitive* NEAR3 *therap*) or *CBT*):ti,ab,kw,ky,emt,mc,mh

#3 (attribution* or reattribution* or restructuring or “rational emotiv*” or rational-emotiv* or mindfulness or “problem solv*” or psychoeducat* or “role play*” or schema* or self-control* or “self control*” or (*therap* NEAR (commitment or acceptance))):ti,ab,kw,ky,emt,mc,mh
#4 ((self* or stress*) NEAR3 (control or analysis or direct* or esteem or help or instruct* or manage*)):ti,ab,kw,ky,emt,mc,mh
#5 relaxation
Aged Population:
#6 aged:kw,ky,emt,mc,mh
#7 (elder* or frail or geriatric* or gerontology or seniors or retired or retirement or pensioner* or “late* life” or “old age” or “old* people” or "old* person*" or "old* adult*" or “old* men” or “old* women” or “old* male*” or “old* female*” or “old* patient*” or “old old” or old-old or “very old” or "senior citizen*" or sedentary or "care home*" or "nursing home*" or "middle age*" or middle-age* or midlife or mid-life or young-old or "young old")
#8 ("55 years" or "60 years" or "64 years" or "65 years" or "70 years" or "75 years" or "79 years" or "80 years" or "85 years" or "90 years" or "95 years" or "older than 55" or "older than 60" or "older than 65" or "older than 70" or "older than 75" or "older than 80" or "older than 85" or "older than 90" or "older than 95"):ab
#9 #1 and (#2 or #3 or #4 or #5) and (#6 or #7 or #8)
ti:title; ab:abstract; kw:keywords; emt:EMTREE headings; mc:MeSH checkwords; mh:MeSH Headings

Appendix 2. MEDLINE Search

Search-1: MEDLINE search used to inform the CCMDCTR

A weekly search alert based on condition + RCT filter only
1. *[MeSH Headings]:* eating disorders/ or anorexia nervosa/ or binge-eating disorder/ or bulimia nervosa/ or female athlete triad syndrome/ or pica/ or hyperphagia/ or bulimia/ or self-injurious behavior/ or self mutilation/ or suicide/ or suicidal ideation/ or suicide, attempted/ or mood disorders/ or affective disorders, psychotic/ or bipolar disorder/ or cyclothymic disorder/ or depressive disorder/ or depression, postpartum/ or depressive disorder, major/ or depressive disorder, treatment-resistant/ or dysthymic disorder/ or seasonal affective disorder/ or neurotic disorders/ or depression/ or adjustment disorders/ or exp antidepressive agents/ or anxiety disorders/ or agoraphobia/ or neurocirculatory asthenia/ or obsessive-compulsive disorder/ or obsessive hoarding/ or panic disorder/ or phobic disorders/ or stress disorders, traumatic/ or combat disorders/ or stress disorders, post-traumatic/ or stress disorders, traumatic, acute/ or anxiety/ or anxiety, castration/ or koro/ or anxiety, separation/ or panic/ or exp anti-anxiety agents/ or somatoform disorders/ or body dysmorphic disorders/ or conversion disorder/ or hypochondriasis/ or neurasthenia/ or hysteria/ or munchausen syndrome by proxy/ or munchausen syndrome/ or fatigue syndrome, chronic/ or obsessive behavior/ or compulsive behavior/ or behavior, addictive/ or impulse control disorders/ or firesetting behavior/ or gambling/ or trichotillomania/ or stress, psychological/ or burnout, professional/ or sexual dysfunctions, psychological/ or vaginismus/ or Anhedonia/ or Affective Symptoms/ or *Mental Disorders/
2. *[Title/ Author Keywords]:* (eating disorder* or anorexia nervosa or bulimi* or binge eat* or (self adj (injur* or mutilat*)) or suicide* or suicidal or parasuicid* or mood disorder* or affective disorder* or bipolar i or bipolar ii or (bipolar and (affective or disorder*)) or mania or manic or cyclothymic* or depression or depressive or dysthymi* or neurotic or neurosis or adjustment disorder* or antidepress* or anxiety disorder* or agoraphobia or obsess* or compulsi* or panic or phobi* or ptsd or posttrauma* or post trauma* or combat or somatoform or somati#ation or medical* unexplained or body dysmorphi* or conversion disorder or hypochondria* or neurastheni* or hysteria or munchausen or chronic fatigue* or gambling or trichotillomania or vaginismus or anhedoni* or affective symptoms or mental disorder* or mental health).ti,kf.
3. *[RCT filter]:* (controlled clinical trial.pt. or randomized 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 subsitut* 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 randomized 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 were screened for reports of RCTs within the scope of the Cochrane Common Mental Disorders Group. Secondary reports of RCTs were tagged to the appropriate study record.
Similar weekly search alerts were also conducted on OVID Embase and PsycINFO, using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource.

The Group’s Specialised Register is current to June 2016 only.

The rationale of maintaining a comprehensive specialised register was reviewed when the editorial group moved from the University of Bristol to the University of York in June 2016. At this time, the Group decided to archive the CCMDCTR and return to searching the medical and psychological literature directly, on a review-by-review basis.

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Search-2: MEDLINE search for this review

We will supplement the search of the CCMDCTR with searches of the main biomedical/healthcare databases, with an overlap from 2014 onwards. The MEDLINE search is listed below:

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <2014 to present> Search Strategy:
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1 ANXIETY DISORDERS/ or AGORAPHOBIA/ or ANXIETY, SEPARATION/ or NEUROCIRCULATORY ASTHENIA/ or NEUROTIC DISORDERS/ or PANIC DISORDER/ or PHOBIC DISORDERS/ or PHOBIA, SOCIAL/
2 OBSESSIVE-COMPULSIVE DISORDER/ or HOARDING DISORDER/
3 "TRAUMA and STRESSOR RELATED DISORDERS"/ or ADJUSTMENT DISORDERS/ or STRESS DISORDERS, TRAUMATIC/ or COMBAT DISORDERS/ or PSYCHOLOGICAL TRAUMA/ or STRESS DISORDERS, POST-TRAUMATIC/ or STRESS DISORDERS, TRAUMATIC, ACUTE/
4 (anxiety disorder? or generali#ed anxiety or separation anxiety or GAD or agoraphobi* or panic or phobi*).ti,ab,kf.
5 (obsessi* or compulsive or hoard*).ti,ab,kf.
6 (PTSD or ((posttrauma* or post-trauma* or post trauma*) adj3 (stress* or disorder? or psych* or symptom*)) or acute* stress* or traumatic* stress* or stress disorder? or combat disorder? or war neuros*).ti,ab,kf.
7 anxiety.ti.
8 *anxiety/di, pc, px, th
9 anxiety.ab. /freq=3
10 or/1-9
11 exp COGNITIVE THERAPY/
12 PSYCHOTHERAPY, GROUP/
13 FAMILY THERAPY/ or PSYCHODRAMA/ or ROLE PLAYING/ or SENSITIVITY TRAINING GROUPS/
14 BIBLIOTHERAPY/
15 "EARLY INTERVENTION (Education)"/
16 (CBT or CBGT* or bCBT or b-CBT).ab.
17 ((cogniti* or behavio*) adj3 (counsel* or intervention or therap* or psychotherap* or training or treatment or technique* or restructur* or defusion)).ti,ab,kf.
18 (rational emoti* or (problem* adj2 (focus* or sol*)) or psychoeducat* or role play* or schema* or self-control* or self control*).ti,ab,kf.
19 (((psychotherap* or therap*) adj3 (commitment or acceptance)) or ((self* or stress*) adj3 (control or analysis or direct* or esteem or help or instruct* or manage*))).ti,ab,kf.
20 ((attribution* or reattribution*) adj3 (therap* or psychotherap*)).ti,ab,kf.
21 (mindfulness* or third wave or experiential or (behavio* adj3 (activation or modification)) or (thought* adj3 suppress*) or rumination).ti,ab,kf.
22 ((anxiety adj1 manag*) or confidence building or coping skills or exposure therapy or exposure task* or psychoeducat* or psycho-educat* or relaxation or sensitivity training or self talk or (social adj2 (coach* or skill* or effectiveness))).ti,ab,id,hw.
23 ((controlling or overcoming) adj2 (anxiety or panic or phobi* or agoraphobi*)).ti,ab,kf.
24 ((individually or group or conjoint or family) adj2 (counsel* or intervention* or program* or psychotherap* or therap* or train* or treat*)).ti,ab,kf.
25 *PSYCHOTHERAPY/mt, st, sn, tu
26 or/11-25
27 AGED/ or "AGED, 80 and OVER"/ or FRAIL ELDERLY/
28 AGED/ or HEALTH SERVICES FOR THE AGED/ or HOMES FOR THE AGED/
29 (aging or ageing or elder* or frail or geriatri* or geronto* or psychoger* or geropsych* or seniors or (late* adj (life* or adulthood)) or (old* adj (adult? or age? or people? or person? or citizen? or men or women or male? or female? or patient? or population?)) or old old or very old or senior citizen? or pensioner? or retired or retirement or care home? or nursing home?).ti,ab,kf.
30 (("55" or "60" or "64" or "65" or "69" or "70" or "75" or "79" or "80" or "85" or "90" or "95") adj years).ti,ab.
31 (("55" or "60" or "64" or "65" or "69" or "70" or "75" or "79" or "80" or "85" or "90" or "95") adj2 old*).ti,ab.
32 or/27-31
33 (10 and 26 and 32)
34 controlled clinical trial.pt.
35 randomized controlled trial.pt.
36 (randomi#ed or randomi#ation or randomi#ing).ti,ab,kf.
37 (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 subsitut* or treat*))).ti,ab,kf.
38 (placebo or ((attention or active) adj control*)).ti,ab,kf.
39 trial.ab,ti,kf.
40 ((control* or group* or compar*) adj5 (((care or treatment*) adj2 (usual or standard or routine)) or TAU or CAU)).ab.
41 ((control* or group* or compar*) adj5 (waitlist* or wait* list* or waiting or WLC)).ab.
42 or/34-41
43 (33 and 42)
44 (2014* or 2015* or 2016* or 2017* or 2018* or 2019* or 2020* or 2021*).yr,dc,ed,ez.
45 (43 and 44)
****

WHAT'S NEW

Date	Event	Description
14 January 2021	New citation required and major changes	This protocol has been updated from the earlier version first published in 2009 (Oude Voshaar 2009).

HISTORY

Protocol first published: Issue 1, 2009

CONTRIBUTIONS OF AUTHORS

Dr W van Zelst wrote the first version of the main text of the protocol.
Prof Dr GJ Hendriks revised the first version of the main text and updated references.
Prof Dr RC Oude Voshaar and Prof Dr GJ Hendriks have written the first draft in close collaboration.
Dr G Keijsers and Prof Dr AJLM van Balkom have commented on the draft for important intellectual content.
Dr E Uphoff and Dr L Robertson helped to revise the protocol text.

DECLARATIONS OF INTEREST

GJH: none known.
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