Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD) (Review)

McKenna IM, Hunot V, Bailey A, Parker AG, Churchill R

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[Intervention Review]

Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

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ABSTRACT

Background

Social anxiety disorder (SAnD) is a highly prevalent condition, characterised by an intense fear of social or performance situations where individuals worry about being negatively evaluated by others. An up to date systematic review of the effectiveness of cognitive behavioural therapies for SAnD is required to guide practice.

Objectives

To assess the efficacy and acceptability of cognitive behavioural therapy (CBT) compared with treatment as usual/waiting list (TAU/WL) for individuals with SAnD.

Search methods

We searched the Cochrane Depression, Anxiety and Neurosis Group (CCDAN) Controlled Trials Register and conducted supplementary searches of MEDLINE, PsycInfo, EMBASE, and international trial registers (ICTRP; ClinicalTrials.gov) in October 2011 and CINAHL in October 2012. We also searched reference lists of retrieved articles, and contacted trial authors for information on ongoing/completed trials.

Selection criteria

Randomised and quasi-randomised controlled trials undertaken in out-patient settings, involving adults aged 18-75 years with a primary diagnosis of SAnD, assigned either to CBT or TAU/WL.

Data collection and analysis

Data on patients, interventions and outcomes were extracted by two review authors independently, and the Risk of bias in each study was assessed. The primary outcomes were social anxiety reduction (based on relative risk (RR) of clinical response and mean difference in symptom reduction), and treatment acceptability (based on RR of attrition).

Main results

Thirteen studies (715 participants) were included in the review, of which 11 studies (599 participants) contributed data to meta-analyses. Based on four studies, CBT was more effective than TAU/WL in achieving clinical response at post-treatment (RR 3.60, 95% CI 1.35 to 9.57), and on eleven studies (599 participants) it was more effective than TAU/WL in reducing symptoms of social anxiety. No significant difference was found between CBT and TAU/WL for attrition. No significant difference was demonstrated for social anxiety at follow-up and no studies examined follow-up data for clinical response or attrition.

Authors' conclusions

The available evidence suggests that cognitive behavioural therapy might be effective in reducing anxiety symptoms for the short-term treatment of SAnD. However, the body of evidence comparing CBT with TAU/WL is small and heterogeneous.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Cognitive behavioural therapy compared with treatment as usual/waiting list for adults with social anxiety disorder

Patient or population: Adults with social anxiety disorder
Settings: Primary, secondary care or community settings
Intervention: Cognitive behavioural therapy
Comparison: Treatment as usual/Waiting list

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Treatment as usual/ Waiting list	Cognitive behavioural therapy				
Clinical response at post-treatment Loss of social phobia DSM-IV diagnosis using structured diagnostic interview (i.e. the ADIS-IV) *Higher scores indicate improvement (i.e. loss of SAnD diagnosis)*	**Medium risk population**		**RR** 3.60 (1.35 to 9.57)	264 (4 studies)	⊕⊕◯◯◯ **low** [1,2,]	
	112 per 1000	**403 per 1000** (151 to 1072)				
Reduction in social anxiety symptoms Social anxiety symptoms measured on the Social Interaction Anxiety Scale (SIAS). Scale from 0 to 100. (Follow-up: 4 to 12 months) *Lower scores indicate improvement (reduction in social anxiety symptoms)*	The mean social anxiety ranged across control groups from (22.9 to 37.25)	The mean social anxiety in the intervention groups was **16 lower** (-22.44 lower to -9.32 lower) (see comments)		599 (11 studies)	⊕⊕◯◯ **Low**[3,4]	Scores are based on a back-conversation of SMD (-1.18 95%, CI -1.66, -0.69) to BDI-I

Treatment acceptability (attrition), measured by the overall number of people dropping out of post-randomisation and over the course of the trials *Higher scores indicate more attrition*	**Medium risk population**		**RR** 1.09 (0.51 to 2.32)	574 (10 studies)	⊕⊕◯◯ **Low**[3,4]	
	24 per 1000	**26 per 1000** (12.2 to 55.7)				
Reduction in depression symptoms at post-treatment Beck Depression Inventory (BDI-I). Scale from 0 to 63 (Follow-up: 4 to 12 months) *Lower score indicate improvement (reduction in depression symptoms)*	The mean depression symptoms ranged across control groups from (2.57 to 8.39)	The mean depression symptoms in the intervention groups was **7 lower** (10.45 lower to 2.808 lower) (see comments)		382 (7 studies)	⊕⊕◯◯ **Low** [4,5]	Scores are based on a back-conversation of SMD (-0.85, 95% (CI -1.34 to -0.36) to BDI-I

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk Ratio.

[1] Risk of bias issues: high rate of attrition (>20%) and a significant difference in attrition rate among the groups in 1/4 studies
[2] There were small sample sizes (<21 participants) in 2/4 studies
[3] Allocation concealment was not reported for 4/11 studies
[4] There were considerable amounts of statistical heterogeneity indicated
[5] Allocation concealment was not reported for 2/7 studies

BACKGROUND

Description of the condition

Social anxiety disorder (SAnD; or social phobia) is listed in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) (APA 2000) and the International Classification of Diseases 10 (ICD-10) (WHO 1992) alongside other anxiety disorders (e.g. panic disorder). SAnD is characterised by an intense fear of social or performance situations where the individual worries about being negatively evaluated by others (APA 2000). Physical symptoms often accompanying SAnD include sweating, shaking, blushing, palpitations, nausea and diarrhoea, and can develop into a panic attack (APA 2000). According to the DSM-IV-TR APA 2000 symptoms may be generalised (a persistent fear of most social situations) which can lead to increased social isolation, or non-generalised (a fear of specific social contexts; e.g. public speaking). However, recent evidence from the DSM-V Anxiety, Obsessive-Compulsive Spectrum, Posttraumatic, and Dissociative Disorders Work Group among others indicates that there is insufficient support for the current categorical specifier, generalised social anxiety (Aderka 2012; Bögels 2010). The authors conclude that social anxiety exists along a continuum, the larger the number of social fears the greater the severity, without a distinct discrimination point (Aderka 2012; Bögels 2010). Nevertheless, they found evidence indicating that individuals with performance anxiety (e.g. speaking or performing in public) were qualitatively distinct from individuals with SAnD (Bögels 2010). The specifiers of performance SAnD and SAnD are proposed for DSM-V (APA in press) to replace the current DSM-IV-TR generalised and non-generalised SAnD specifiers (Bögels 2010).

SAnD is the third most common psychological disorder (Kessler 2005) after depression and alcohol dependency (Magee 1996). It has a lifetime prevalence of between 3 and 13% (Kessler 2005), more common in women than in men (ratio of 3 to 2) (Fehm 2008; Kessler 2005), and has a typical onset in early adolescence (Wittchen 2003). If left untreated SAnD seems to have an enduring, unremitting prognosis frequently leading to other psychological disorders (e.g. depression) (Stein 2002). Previously viewed as a neglected disorder it has become the focus of increased research over the last 25 years (Liebowitz 1985). SAnD is now understood to be a highly prevalent disorder (Kessler 2003) associated with significant impairments in social and occupational functioning, psychological difficulties, reduced quality of life (Stein 2000) and substantial economic costs (Smits 2006).

Description of the intervention

The efficacy of pharmacological treatments (selective serotonin reuptake inhibitors; SSRIs), (monoamine oxidase inhibitors; MAOIs) and (reversible inhibitors of monamine; RIMAs) for SAnD was demonstrated in a previous Cochrane review (Stein 2004). Treatment guidelines recommend SSRIs and the serotonin-noradrenaline reuptake inhibitor (SNRI) venlafaxine XR as first line pharmacological interventions for SAnD (Swinson 2006), and high potency benzodiazepines such as clonazepam (Davidson 1993) and beta-blockers (Gorman 1987) as second-line pharmacological interventions.

Psychological therapies are an important alternative treatment option for SAnD for two reasons: (1) patients' concerns about the side effects and dependency of pharmacological treatments results in their low adherence rates (Hunot 2007), and (2) research consistently reports patients' preference for psychological interventions compared to antidepressants as a treatment for common mental disorders (Churchill 2000; Riedel-Heller 2005). A wide range of psychological therapies are now used to treat SAnD: (1) cognitive and behavioural therapy approaches (CBT; Beck 1979; Ellis 1962) comprising a number of strategies, in vivo or imaginal exposure to feared social situations (Butler 1985), applied relaxation (Öst 1987), social skills training (Stopa 1993) and cognitive restructuring (Ponniah 2008; Rowa 2005), other techniques include videotape feedback (Smits 2006) and attentional training (McEvoy 2009); clinical practice guidelines recommend CBT as a first-line treatment for SAnD (Swinson 2006); (2) behavioural treatments (Skinner 1953; Watson 1924); (3) psychodynamic treatments (Freud 1949) including brief psychodynamic models (Mann 1973); (4) integrative treatments such as interpersonal therapy (Klerman 1984) and cognitive analytic therapy (Ryle 2002); (5) humanistic treatments, Rogerian person-centred therapy (Rogers 1951) and Gestalt therapy (Perls 1976); and (6) "third-wave" CBT interventions for SAnD acceptance and commitment therapy (Hayes 2004), and mindfulness-based stress cognitive therapy (Segal 2002). However, to date no systematic reviews or meta-analyses are reported for psychodynamic, humanistic, integrative, or third-wave CBT therapies for SAnD; the overwhelming majority of the evidence for psychological interventions used to treat SAnD is for cognitive and behavioural interventions (Acurturk 2009).

How the intervention might work

Behavioural therapy such as exposure therapy is based on learning theory (Rachman 1977). Learning theory proposes that fears (e.g. social anxiety) develop through negative learning experiences and are maintained through the avoidance of the feared social situations (Rachman 1977). Treatment involves repeated and systematic in vivo exposure to a hierarchy of increasingly feared social situations, remaining in each situation until anxiety levels diminish. Cognitive therapy (CT) aims to restructure the individual's unhelpful appraisals of life events through understanding the relationship between thoughts, feelings and behaviour. Clark 1995 argues that SAnD is maintained by increased self-focused attention, utilisation of maladaptive safety behaviours intended to reduce

the probability of negative evaluation from others, and engaging in negatively biased post-event processing. Rapee 1997 purports that SAnD is also maintained through a tendency to make negative predictions about one's anticipated performance in a social situation. A vicious cycle is created whereby dysfunctional beliefs about the self and the expected norms of conduct in social situations, increased self-focus, and the utilisation of safety behaviours paradoxically increases the likelihood of the feared events in social situations (Beck 1985). Cognitive behavioural therapies frequently combine cognitive restructuring with exposure therapy to treat SAnD, and is based on the premise that SAnD arises from the existence of dysfunctional beliefs that an individual holds about themselves, and how they should conduct themselves in social situations (Beck 1985), resulting in negatively biased information processing.The therapist and client co-construct more adaptive ways to perceive social situations, engage in external focused processing, alleviate safety behaviours and test anticipated negative predictions, with the objective of achieving more realistic beliefs about the self and social situations, including an acceptance that negative feared events may sometimes happen in social situations. Third-wave CBT therapy (e.g. acceptance and commitment therapy; Hayes 2004) posits that SAnD results from attempts to control anxiety and an "unwillingness" to tolerate unwanted and distressing thoughts when exposed to difficult social situations (Dalrymple 2007). Therapy aims to increase an individual's "psychological flexibility" via psychological "acceptance", their "willingness" to experience difficult psychological events "mindfully", while also behaving consistently with ones chosen "values" (Hayes 2004). Treatment also utilises traditional behaviour therapy techniques such as role-plays, exposure, and social skills training (Dalrymple 2007).

Why it is important to do this review

Social anxiety disorder is currently recognised as a highly prevalent, disabling disorder with significant economic costs, and the evidence base on interventions for SAnD has expanded considerably. Over the last 15 years the efficacy of psychological interventions (i.e. cognitive and behavioural therapies) for SAnD were assessed in several systematic reviews and meta-analyses (Acurturk 2009; Feske 1995; Taylor 1996). Cognitive behavioural therapies were compared with pharmacological treatments in a number of meta-analyses (Banderlow 2009; Fedoroff 2001; Gould 1997). These reviews indicated that CBT can be effective in the treatment of SAnD, and that it can be as effective as pharmacological treatments (Banderlow 2009; Gould 1997). Importantly, the conclusions of previous reviews and meta-analyses are limited due to a number of clinical and methodological difficulties. All previous reviews involved clinical heterogeneous groups and most do not provide sufficient details about the severity and nature of SAnD symptoms or comorbid Axis-I/Axis-II disorders (Acurturk 2009; Banderlow 2009; Fedoroff 2001; Feske 1995; Gould 1997; Taylor 1996). Moreover, the reviews by Fedoroff 2001 and Feske 1995 included uncontrolled trials in their meta-analysis, thus introducing potential methodological heterogeneity (Higgins 2011) and statistical heterogeneity was not investigated in two of the six reviews (Taylor 1996; Banderlow 2009). The variability across studies included in the above reviews has the potential to shift the estimate of their intervention effect sizes reducing the validity of their findings (Higgins 2011).

To date, there has been no well-conducted high quality Cochrane systematic review of the effects of all cognitive behavioural therapies for SAnD. In view of patients' reported preference for psychological therapies, the lack of pharmacological side-effects associated with these interventions (Churchill 2000; Riedel-Heller 2005), and the clinical, methodological, and statistical heterogeneity issues with previous reviews and meta-analyses, an up to date and comprehensive summary of the evidence of cognitive behavioural therapies for SAnD is required. The findings of this review will guide health care as well as supporting patient/clinician treatment decision-making around the management of this disorder.

OBJECTIVES

To assess the efficacy and acceptability of cognitive behavioural therapy compared with treatment as usual/waiting list for individuals with SAnD.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised trials defined as follows:

1. Randomised controlled trials
2. Quasi-randomised controlled trials, if they utilise treatment assignments such as alternate days of the week
3. Trials that employ a cross-over design, using data from the first active treatment stage only
4. Cluster RCTs were also eligible

No language or publication restrictions were imposed.

Types of participants

Patient characteristics and setting

The review included male and female adults, aged 18 to 75 years, treated in a primary, secondary care or community settings.

Diagnosis

Inclusion criteria

Participants had a primary diagnosis of social anxiety disorder (social phobia), based on DSM-IV, DSM-IV-TR non-generalised/specific social anxiety disorder (excluding performance SAnD see below) and generalised social anxiety disorder criteria respectively (APA 1994; APA 2000), or on ICD criteria (WHO 1992). Diagnosis must have been made by a trained psychiatric assessor using either a standardised interview such as the Anxiety Disorders Interview Schedule for DSM-IV (Di Nardo 1994) or the Structured Clinical Interview for DSM (SCID) (First 1996; First 2002; Spitzer 1990). Comorbid psychological or physical disorders were included if participants had a primary diagnosis of SAnD.

Exclusion criteria

RCTs including more than 80% participants with a primary diagnosis of SAnD were included.

Trials involving participants with the following diagnoses were excluded:

1. Performance SAnD (e.g. public speaking anxiety)
2. Sub-clinical social anxiety (e.g. shyness)
3. Specific social anxieties (e.g. test anxiety)
4. Avoidant personality disorder
5. Comorbid substance related disorder, schizophrenia or psychotic disorder diagnoses

Types of interventions

Experimental interventions

Studies were included in the review if they evaluated a CBT, including the following: cognitive therapy (CT; Beck 1979), rational emotive behavioural therapy (REBT; Ellis 1962), multimodal behaviour therapy (Lazarus 1971), rational behaviour therapy (Maultsby 1984), and stress inoculation training (Meichenbaum 1985), and third-wave CBT interventions, acceptance and commitment therapy (Hayes 2004), and mindfulness-based stress cognitive therapy (Segal 2002).

Modality of therapies

Psychological interventions delivered face to face between the patient and therapist and psychological therapies conducted in either individual or group formats were included. However, psychological therapies comprising couples therapy and family therapy were excluded. Comparisons of dual modality treatments were eligible for inclusion only if the two psychological models compared in the study were prescribed the same pharmacological/placebo interventions. Combination treatments compared against a pharmacological or psychological treatment alone were outside the scope of this review.

Comparators

The comparator was treatment as usual (TAU). This comparator included standard care, usual care, no treatment, and waiting list (WL). In each study, the description of a TAU condition was scrutinised to ensure that it did not involve an active supportive therapy treatment. Studies that allowed participants in the TAU arm to receive appropriate medical care deemed necessary by the clinician during the course of the study (including pharmacotherapy and/or psychological therapy) were included. Additional treatment(s) received by participants in both the control and active comparisons for each included study were carefully documented.

Types of outcome measures

Primary outcomes

The primary outcomes were reduction in social anxiety and treatment acceptability, as follows:

1. Treatment response, comprised the proportion of participants showing absence versus presence of symptoms or clinically significant change, according DSM-IV and DSM-IV-TR (APA 1994; APA 2000) or ICD-10 (WHO 1992) diagnostic criteria for social anxiety disorder/social phobia, or through a defined cut-off on a validated social anxiety measure such as the Liebowitz Social Anxiety Scale (Liebowitz 1987) or a composite of validated measures according to the trialist's definition.
2. Reduction in social anxiety symptoms measured using a validated continuous scale, such as the Liebowitz Social Anxiety Scale (Liebowitz 1987).
3. Treatment acceptability (attrition), measured by the overall number of people dropping out post-randomisation and over the course of the trials.

Secondary outcomes

1. Reduction in depression symptoms, using validated observer-rated scales (e.g. the Hamilton Rating Scale for Depression) (Hamilton 1960) or self-report scales (e.g. the Beck Depression Inventory) (Beck 1987)
2. Clinical Global Impressions - Improvement scale (CGI) (Guy 1976)
3. Quality of life, using validated measures (e.g. SF-36) (Ware 1993)
4. Negative effects of therapy, assessed by collating the number of participants reporting any negative effects of therapy

5. Therapeutic process, perceived strength of therapeutic alliance and perceived therapist empathy, measured using validated scales (e.g. the Relationship Inventory) (Barrett-Lennard 1986)
6. Cost-effectiveness outcomes, calculated as the number of days off work or ability to return to work; number of referrals to primary or secondary care; and use of additional treatments

Timing of outcome assessment

Outcomes were classified as post-treatment, short-term follow-up (up to 6 months post-treatment), medium-term follow-up (7-12 months post-treatment) and long-term (over 12 months).

Search methods for identification of studies

Electronic searches

CCDAN's Specialized Register (CCDANCTR)

We searched the Cochrane Depression, Anxiety and Neurosis Group (CCDAN) CCDANCTR-studies and CCDANCTR-References Registers respectively as well as Cumulative Index to Nursing and Allied Health (CINAHL) and International Trial Registers (ITR) (see Appendix 1 for extended details on the CCDAN Registers, and CCDANCTR-Studies, CCDANCTR-References, and CINAHL search terms).

Searching other resources

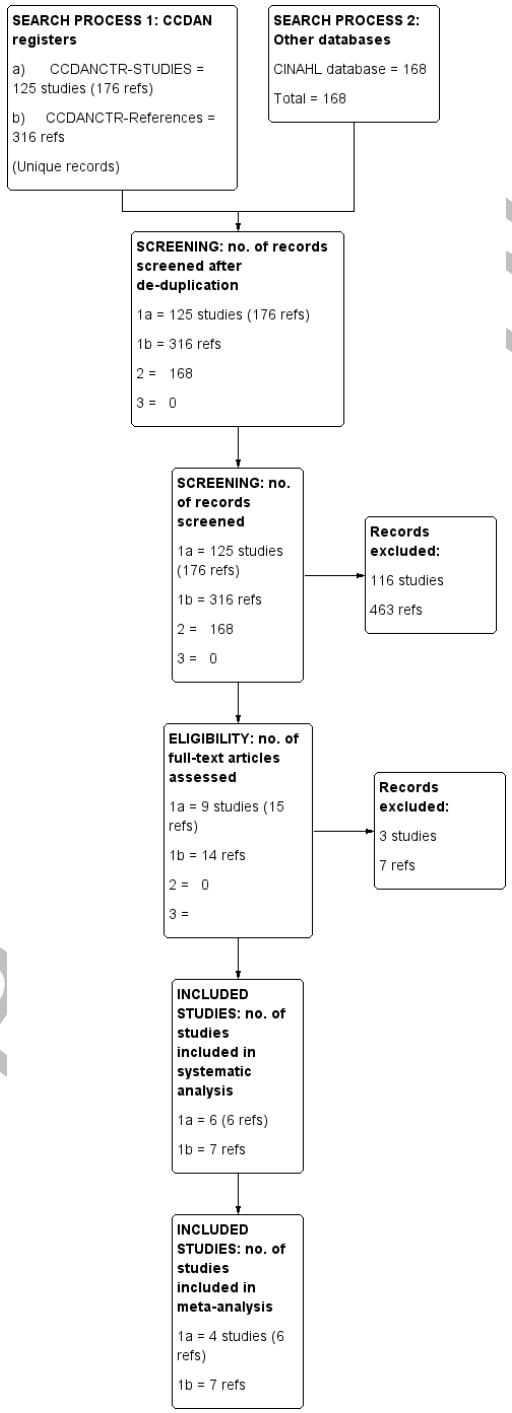
We also searched references lists, cited references and personal communications (see Appendix 2 for extended details).

Data collection and analysis

Selection of studies

The study selection process for each stage of the review is presented in a PRISMA flow diagram (See Figure 1).

Figure 1. Study Flow Diagram



Two review authors examined the abstracts of studies obtained from the searches for eligibility and reviewed the full articles of all the identified studies for trials meeting the following criteria:
1. Randomised controlled trial
2. Participants with social anxiety disorder diagnosed by operationalised criteria
3. Any cognitive behavioural therapy versus treatment as usual (waiting list, usual care, placebo and no treatment)
Disagreements between the two authors were discussed with a third review author, until consensus was reached. External subject or methodological experts were consulted as necessary.

Data extraction and management

Data was extracted independently by the two authors. Disagreements were discussed with an additional review author, and the authors of the studies were contacted for further information where necessary. Data were extracted from the original reports (e.g. study population, interventions, randomisation and blinding procedures, sample size, outcome data, follow-up, adverse events and methods of statistical analysis) into specially designed forms and then entered into spreadsheets.

Main comparisons

1. Cognitive behavioural therapy versus treatment as usual

Assessment of risk of bias in included studies

Risk of bias was assessed for each included study using the Cochrane Collaboration 'Risk of bias' tool. The following six domains were considered:
1) Sequence generation: was the allocation sequence adequately generated?
2) Allocation concealment: was allocation adequately concealed?
3) 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?
4) Incomplete outcome data for each main outcome or class of outcomes: were incomplete outcome data adequately addressed?
5) Selective outcome reporting: are reports of the study free of suggestion of selective outcome reporting?
6) Other sources of bias: was the study apparently free of other problems that could put it at a high risk of bias?
A description of what was reported to have happened in each study was provided; a judgement on the Risk of bias was made for each domain within and across studies and recorded on a Risk of bias table, based on the following three categories:
A. Low risk of bias
B. High risk of bias
C. Unclear

A Risk of bias figure was used to present the proportion of studies comprising each judgement ('High', 'Low', 'Unclear') for each risk domain and a summary figure presents all of the judgements in a matrix of study by risk area.
Two independent review authors assessed the risk of bias in selected studies. Any disagreement was discussed with a third review author. Where necessary, the authors of the studies were contacted for further information.

Measures of treatment effect

Continuous outcomes

Where studies compare the same outcome measure, data were combined by calculating the mean difference (MD). If different measures were used to assess the same outcome for comparison, data were combined through calculating the standardised mean difference (SMD), using 95% confidence intervals.

Dichotomous outcomes

These outcomes were examined through calculating a pooled risk ratio (RR) for each comparison, with 95% confidence intervals.

Unit of analysis issues

Cluster-randomised trials

Had there been cluster-randomised (group) trials it would have been necessary to reduce the size of each trial to the 'effective sample size' in order to analyse them in RevMan (Rao 1992) (see Appendix 3 for extended details).

Cross-over trials

If we had obtained cross-over trials, only data from the first treatment periods for the intervention and control groups would have been used.

Studies with multiple treatment groups

Studies with two or more active treatment arms compared with TAU, were analysed as follows:
Continuous data - means, Standard deviations (SDs) and number of participants for each active treatment group were pooled across treatment arms as a function of the number of participants in each arm (Law 2003) to be compared against the control group.

Dichotomous data - active treatment groups were collapsed into a single arm for comparison against the control group.

Dealing with missing data

Wherever possible, request were made to trial authors to obtain missing data. Missing continuous data were either analysed on an endpoint basis, including only participants with a final assessment, or analysed using last observation carried forward to the final assessment (LOCF) if LOCF data were reported by the trial authors. Where SDs were missing, attempts were made to obtain these data through contacting trial authors.

Assessment of heterogeneity

Where there were sufficient trials, clinical heterogeneity was tested through subgroup analysis (see 'Subgroup analysis and investigation of heterogeneity' below).

Statistical heterogeneity was 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 where a small number of participants or trials are included, the p-value was conservatively set at 0.1.

Heterogeneity was also be tested using the I^2 statistic, which calculated the percentage of variability due to heterogeneity rather than chance (see Appendix 4 for extended details).

Assessment of reporting biases

Where sufficient numbers of trials (i.e. 10) allowed a meaningful presentation, funnel plots were constructed and visually inspected to establish the potential influence of reporting biases. However, visual interpretation of funnel plot asymmetry is inherently subjective (Higgins 2011).

Data synthesis

Given the potential variability in the execution of CBT, together with the likelihood of differing secondary comorbid mental disorders in the population of interest, a random-effects model was used in all analyses. A fixed-effect model was also used for the primary outcomes to ensure that the random effects analyses are not being biased by small study effects.

Subgroup analysis and investigation of heterogeneity

Multiple subgroup analyses were performed and interpreted with caution, due to the risk of false positive findings. However, if possible, the following additional subgroup analyses were planned:

1. Group versus individual therapy
2. Control condition (standard care/no treatment versus waiting list)
3. Number of sessions (8 sessions or fewer versus >8 sessions)
4. Age (<65 years or less versus >65 years)
5. Concomitant medical use (<25% use in sample versus >25% or higher use in sample)
6. SAnD diagnosis (<80% generalised SAnD diagnosis sample i.e. mixed non-generalised plus generalised SAnD diagnoses versus >80% generalised SAnD diagnosis sample)
7. Common mental health comorbidity (<50% in the sample versus >50% in the sample)

Where there are sufficient studies, these subgroup analyses were also be used to examine potential sources of clinical heterogeneity.

Sensitivity analysis

Sensitivity analyses were for the purpose of testing the robustness of methodological decisions taken throughout the review process. Sensitivity analyses were planned a priori, limiting studies to those of higher quality as determined by Risk of bias domains, including:

1. Blinding of outcome assessors (removing studies with high and unclear blinding)
2. Use of allocation concealment (removing studies with high and unclear allocation concealment)
3. Dropout rate lower than 20% (removing studies with >20% dropout rate)
4. Use of formal testing of fidelity to psychological therapy manual (removing studies with no use of formal testing)
5. Data synthesis (comparing effects for the primary outcomes using the random-effects and fixed-effects models)

These sensitivity analyses were also be used to examine potential sources of methodological heterogeneity.

Summary of findings table

The main findings of the review are presented in a transparent and simple tabular format in a 'Summary of findings' (SOF) table. (see Appendix 5 for extended details on the SOF key presented elements).

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Results of the search

Electronic databases

A search of CCDANCTR-Studies and -References retrieved 176 references for 125 studies. Based on a review of the abstracts, 109 studies failed to meet the inclusion criteria of the review. Full articles were obtained for 23 studies and screened for eligibility. Eleven published studies were deemed to meet full inclusion criteria (Alden 2011; Clark 2006a; Furmark 2002; Hofmann 2004; Ledley 2009; Mortberg 2006; Mortberg 2007a; Pishyar 2008; Rapee 2007; Robillard 2010; Stangier 2003; Stangier 2011; Wong 2006).

The supplementary search conducted on CINAHL in August 2012 retrieved 168 additional references. No new studies were found to meet inclusion criteria.

Reference checking

Scrutiny of bibliographies of all included and excluded studies did not result in additional trials inclusion in the review.

Personal communication

Through personal contact with experts in the field, one trial that was deemed eligible for the review was found to be still in progress and was excluded.

Included studies

The combined searches resulted in 13 completed studies eligible for inclusion in the review. Descriptive details on each study are given in the Characteristics of included studies Table.

Design

Twelve studies were randomised controlled trials and one was a quasi-randomised control trial (Alden 2011). The duration of trials ranged from three weeks (Mörtberg 2006) to 12 Months (Mörtberg 2007a), with a mean duration of 4 months.

Sample sizes

The mean sample size of included studies was 70, ranging 18 participants (Furmark 2002) to 224 participants (Rapee 2007). Typically psychological therapy was delivered in groups (Alden 2011; Furmark 2002; Hofmann 2004; Mortberg 2006; Pishyar 2008; Rapee 2007; Stangier 2003; Wong 2006), the remaining studies delivered individual therapy (Clark 2006a; Ledley 2009; Robillard 2010; Stangier 2011), or both formats (Mortberg 2007a; Stangier 2003).

Setting

Studies were conducted in the Sweden (n=3), Australia (n=2) Germany (n=2), USA (n=2), Canada (n=1), Hong Kong (n=1), UK (n=1), and one study did not report the setting. Four studies were conducted in university research units/specialist anxiety clinics (Hofmann 2004; Ledley 2009; Rapee 2007; Stangier 2011). Three studies took place in community mental health settings (Mortberg 2006; Mortberg 2007a; Stangier 2003). No details were provided on the settings of the remaining studies.

Participants

Total participants comprised 715. Five studies provided full demographic information on their samples. Seven studies reported a few additional demographic details as well as age and gender, and one study (Hofmann 2004) provided little information on participants. All 13 studies recruited adult participants aged 18 to 75 years. Based on data reported in 11 out of the 13 studies, the mean overall age of participants was 34 years. From the 12 studies reporting figures for gender, 52% of participants were female.

Diagnosis and comorbidity

Participants in all 13 studies had a primary diagnosis of SAnD. Six studies reported on the mean duration of SAnD, ranging from 7.6 years (Wong 2006) to 20 years (Mortberg 2007a). Eight studies reported comorbidity details, with the prevalence of one or more comorbid disorders ranging from 32% (Ledley 2009) to 69% (Alden 2011). In 11 studies, the diagnosis of SAnD was achieved using a structured diagnostic interview in accordance with DSM-IV criteria; the SCID-I was employed in six studies and the ADIS-R used in five studies. For two studies (Pishyar 20088; Wong 2006) a formal diagnosis of SAnD was conducted by the referring clinician, but use of a standardised diagnostic interview was not specified. Therefore, the extent to which bias may have been introduced through the inclusion of these two studies was examined in a sensitivity analysis. Two studies additionally assessed SAnD severity as a diagnostic inclusion criteria.

Interventions

Comparisons

All studies utilised a CBT model of therapy (individual, group, or both) (Alden 2011; Clark 2006a; Furmark 2002; Hofmann 2004; Ledley 2009; Pishyar 2008; Mortberg 2006; Mortberg 2007a; Rapee 2007; Robillard 2010; Stangier 2003; Stangier 2011; Wong 2006).

Treatment manuals and protocols

Eleven studies (85%) utilised CBT manuals (Clark 1995; Stangier 2006; Clark 2006a; Hope 2000; Rapee 1998), one study used a protocol, and another used a client workbook.

Control comparison

In twelve studies the standard care control conditions consisted of waiting list, and one study utilised treatment as usual (TAU; SSRIs) (Mortberg 2007a). Waiting list and TAU conditions ranged from 3 weeks to 1 year.

Treatment provision

Psychological treatments were predominantly conducted by qualified professionals, clinical psychologists (n=42), trainee clinical psychologist (n=1), psychology doctoral students (n=3), psychiatrists (n=5), experienced CBT therapists (n=3), student CBT therapist (n=2) and a nurse therapist (n=1). Treatment fidelity was assessed via review of a random selection of videotapes of therapy sessions by supervisors or therapy experts for treatment compliance against predetermined checklists in six studies (three studies reported a mean interrater reliability score of 0.86).

In seven studies, therapists saw participants in groups (three to nine participants; Alden 2011; Furmark 2002; Hofmann 2004; Mortberg 2006; Pishyar 2008; Rapee 2007; Wong 2006) in four studies therapist conducted individual therapy (Clark 2006a; Ledley 2009; Robillard 2010; Stangier 2011); and in two studies therapists saw patients both individually and in groups (Mortberg 2007a; Stangier 2003). Group treatments ranged from four to sixteen sessions (2-3 hours in duration). Individual interventions spanned fourteen to sixteen sessions (50 minutes to 1.5 hours in duration). Four studies offered booster sessions post initial therapy.

Concomitant Pharmacology

Concomitant prescribing of anti-anxiolytics, antidepressants or other non-reported medication occurred in eight studies, as long at the clients remained on a stable dose for a minimum of 2/3 months prior to and throughout treatment (three studies) or initiated during the course of trials (TAU; one study) (Mortberg 2007a).

Outcomes

The primary outcome clinical response was reported in four studies; Clark 2006a and Rapee 2007 defined clinical response as a loss of SAnD diagnosis on the ADIS-IV, one study defined clinical response as clinically significant reduction in symptom severity from pre- to post-treatment using Jacobson 1991 criteria (Mörtberg 2007a), and one study defined clinical response as a mean reduction of greater than one standard deviation from pre- to post-treatment across seven to nine outcome measures (Furmark, 2002). For the primary outcome social anxiety, all studies used validated measures with the Social Interaction Anxiety Scale used in seven studies (Alden 2011; Clark 2006a; Ledley 2009; Mortberg 2007a; Pishyar 2008; Rapee 2007; Stangier 2003). Twelve studies provided details on the primary outcome attrition (except Robillard 2010). For the secondary outcomes: depression, the Beck Depression Inventory was used in four studies (Clark 2006a; Mortberg 2006; Mortberg 2007a; Stangier 2003); The Clinic Global Impressions - Improvements Scale (CGI-I) two studies (Ledley 2009; Stangier 2011); quality of life, Sheehan Disability Scale two studies (Ledley 2009; Mortberg 2007a); therapeutic process measures, Treatment Credibility and Expectation of Improvement Scales (two studies; Clark 2006a; Stangier 2011). One study measured cost-effectiveness through the number of clients using additional treatments post-intervention (Stangier 2011).

Excluded studies

Fifteen studies were excluded from the review (Butler 1984a; Hope 1995a; Knijnik 2004; Mattick 1989; Mersch 1995; Mortberg 2007b Nelson 2010; Prasko 2006; Price 2011; Taylor 1997a; Salaberria 1998a; Scholing 1993, Scholing 1999; Srinivasan 1984; Stravynski 2000) (see the Characteristics of excluded studies).

Ongoing studies

One study that met inclusion criteria for this review is currently still in progress (Leichsenring 2007).

Studies awaiting assessment

Four studies are awaiting assessment, for which the articles could not be obtained through direct contact with the authors (Antona 2006; Lee 1997; Nagae 2001; Stangier 2001). Four studies are unpublished PhD dissertations awaiting assessment (Bjornsson 2010; Filion-Rosset 2004; McDougall 2000; Schmertz 2011).

Risk of bias in included studies

A graphically representation of the Risk of bias assessment can be seen in Figure 2and Figure 3. Figure 2, Risk of Bias Summary key: low risk of bias (green circle with a "+" symbol), unclear risk of bias (yellow circle with a "?" symbol), and high risk of bias (red circle with a "-" symbol).

Figure 2. Risk of Bias Summary: Review Authors' Judgements about each Risk of Bias Item for each Included Study

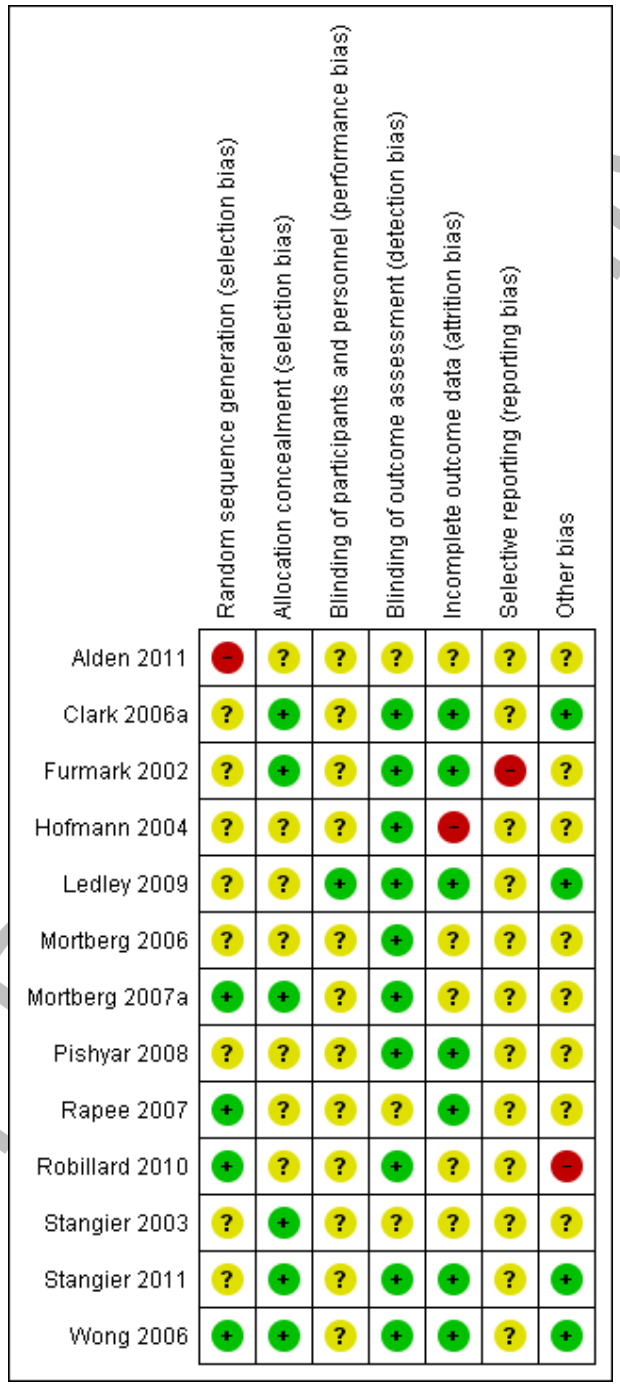
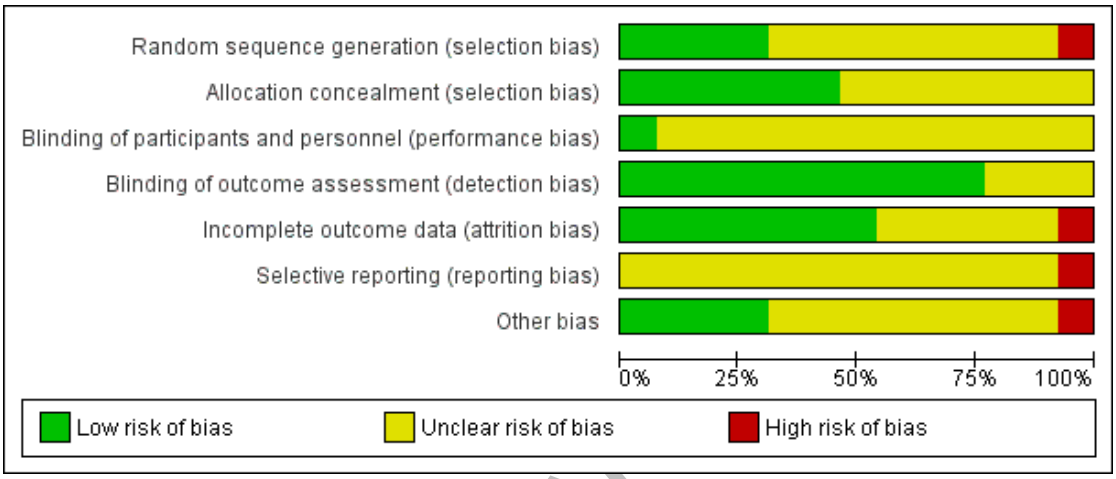


Figure 3. Risk of Bias Graph: Review Authors' Judgements about each Risk of Bias Item Presented as Percentages across all Included Studies



Allocation

Four studies were categorised as low risk (Mortberg 2007a; Rapee 2007; Robillard 2010; Wong 2006). Nine studies were unclear risk (Alden 2011; Clark 2006a; Furmark 2002; Hofmann 2004; Ledley 2009; Mortberg 2006; Pishyar 2008; Stangier 2003; Stangier 2011) which included one study (Alden 2011) where the investigators allocated participants to treatment arms 'in blocks of participants'; therefore, the design of this study was re-categorised as a quasi-randomised trial. It remained eligible for inclusion in the meta-analyses and but its inclusion was tested in sensitivity analyses. Please see the Characteristics of included studies for the full Risk of bias assessment for each study. Allocation concealment was low bias in five studies (Clark 2006a; Furmark 2002; Stangier 2003; Stangier 2011; Wong 2006) and unclear for the remaining eight studies.

Blinding

As is universally the case with studies of psychological treatments, blinding of clinicians/therapists conducting the psychological therapy was not feasible, furthermore clients attending for CBT were encouraged to access reading material on CBT methods.

Five studies (38%) employed assessors who were blind to treatment allocation (Alden 2011; Clark 2006a: Ledley 2009; Mortberg 2007a; Stangier 2011). However, no trials specified whether tests of blinding were conducted. Six studies used only self-report outcome measures (Furmark 2002; Hofmann 2004; Mortberg 2006; Pishyar 2008; Robillard 2010; Wong 2006).

Incomplete outcome data

One waiting list study (Mortberg 2007a) and treatment as usual study (Stangier 2003) had follow-up assessments (12 months and 6 months respectively).

The mean attrition rate from included studies between baseline and post-treatment assessment was 11%. Three studies, all with small sample sizes of <40, reported a 0% attrition rate (Furmark 2002, Pishyar 2008, Wong 2006). Five studies had attrition rates <20% (Alden 2011; Clark 2006a; Mortberg 2006; Stangier 2003; Stangier 2011). In contrast, four studies had attrition rates of over 20% (Hofmann 2004; Ledley 2009; Mortberg 2007a; Rapee 2007). One study did not report attrition (Robillard 2010). Only two studies provided reasons for participants' withdrawal (Mortberg 2006; Mortberg 2007a).

Five studies used intention to treat (ITT) and last observation carried forward (LOCF) analyses for missing data, five studies used data from completers, and two compared ITT and completers data. Six studies were rated as low risk, six as unclear and one as high risk.

Selective reporting

We categorised all included studies as unclear risk because no protocols were available.

Other potential sources of bias

Treatment fidelity was tested in five studies and rated as low in four studies, the remaining eight studies were rated as unclear.

Effects of interventions

See: **Summary of findings for the main comparison**

Effects of interventions

Thirteen studies were included in the review, of those 11 studies (599 participants) contributed to the meta-analysis. Two studies were excluded from the meta-analysis due to insufficient data for imputation (Hofmann 2004; Mortberg 2006). Statistical heterogeneity was investigated for each outcome, and where indicated to be statistically significant, chi^2 and I^2 figures were reported in the text. The random-effects model was used for all outcomes. Findings from subgroup analyses were reported in the text provided outcome data from a minimum of two studies were reported for each subgroup.

Cognitive behavioural therapies versus waiting list/treatment as usual

Eleven studies contributed to the data (Alden 2011; Clark 2006a; Furmark 2002; Ledley 2009; Mortberg 2007a; Pishyar 2008; Rapee 2007; Robillard 2010; Stangier 2003; Stangier 2011; Wong 2006). Two studies provide follow-up data for primary and secondary measures (Mortberg 2007a; Stangier 2003).

Primary outcome

1) Clinical response

Four studies (264 participants) contributed the outcome. A total of 41% of participants in the CBT group demonstrated clinical response to treatment, compared to 11% in the WL/TAU group. The difference was highly significant in favour of CBT (RR 3.60, 95% CI 1.35 to 9.57) with substantial heterogeneity (I^2 = 56%) (Analysis 1.1).

2) Reduction in social anxiety symptoms

Eleven studies (599 participants) contributed to the outcome. The effect was highly significant in favour of CBT (SMD -1.18, 95% CI -1.66, -0.69) with considerable heterogeneity (I^2 = 85%) (Analysis 1.2). Two studies (159 participants) provided long-term term follow-up data and found a non-significant effect (Analysis 1.7) (SMD -0.27, 95% CI -0.60 to 0.06).

3) Attrition

Ten studies (572 participants) contributed to the outcome. Fifteen percent attrition in the CBT group compared to 14% in WL/TAU, non-significant difference (RR 1.09, 95% CI 0.51 to 2.32) (Analysis 1.3).

Secondary outcomes

1) Reduction in depression symptoms

Seven studies (382 participants) contributed to the outcome. The effect was very highly significant in favour of CBT (SMD -0.85, 95% CI -1.34 to -0.36) with considerable heterogeneity (I^2 = 79%) (Analysis 1.4).Two studies (159 participants) provided long-term term follow-up data and found a highly significant effect in favour of CBT (Analysis 1.8) (SMD -0.51, 95% -0.85 to -0.18) with no heterogeneity.

2) Clinical Global Impression - Improvement Scale

Two studies (110 participants) contributed to the outcome. Sixty-eight percent of participants in the CBT group demonstrated improvements compared to 7% in WL/TAU. The effect was highly significant in favour of CBT (RR 9.61, 95% CI 3.67 to 25.19) with no heterogeneity (Analysis 1.5).

3) Quality of life at post-treatment

Three studies (143 participants) contributed to the outcome. The difference between the CBT and WL/TAU groups was non-significant (SMD 0.32, 95% CI 0.02 to 0.67) (Analysis 1.6). One study (100 participants) provided long-term term follow-up data and found a non-significant (SMD 0.22, 95% CI -0.20 to 0.64) (Analysis 1.9).

Subgroup analyses

a) Individual versus group therapy

No data were reported for the clinical response primary outcome.
For reduction in social anxiety symptoms Analysis 2.1, a highly significant difference was found in favour of CBT for individual treatment (SMD -1.34, 95%, CI -2.01 to -0.67) and group treatment (SMD -1.59, 95% CI -2.40 to -0.77).
For the primary outcome attrition there was a non-significant effect for both individual and group treatments respectively (RR 1.31, 95% CI 0.16, 10.36; RR 1.29, 95% CI 0.67, 2.49) (Analysis 2.2).
The secondary outcome depression symptoms (Analysis 2.3) demonstrated a highly significant effect in favour of CBT for individual treatment (SMD -0.83, 95% CI -1.44 to -0.22) but, not for the group treatment (SMD -1.68, 95%, CI -3.77 to 0.41).

b) Control condition; c) Number of sessions (8 sessions or fewer versus >8 sessions); d) Age (<65 years or less versus >65 years); e) Concomitant medical use (<25% use in sample versus >25% or higher use in sample)

No data were reported to conduct analyses.

f) SAnD diagnosis (samples with 80% or less generalised SAnD diagnoses versus samples with more than 80% generalised SAnD diagnosis)

Two studies had mixed SAnD samples (91 participants) and six studies had generalised SAnD samples (377 participants).
No data were reported for the clinical response primary outcome.
The primary outcome reduction in social anxiety symptoms (Analysis 3.1) reported a significant effect in favour of CBT for the mixed SAnD studies (SMD -1.05, 95% CI -2.03 to -0.06), and a similar effect in favour of CBT for the generalised SAnD studies (SMD -1.19, 95% CI -1.78 to -0.60).
The primary outcome attrition reported a non-significant effect for both individual and group treatments respectively (RR 3.78, 95% CI 0.84, 17.06; RR 0.75, 95% CI 0.39, 1.46) (Analysis 3.2).

g) Comorbidity (50% or less in the sample versus greater than 50%)

No data were reported for clinical response or social anxiety primary outcomes. Three studies had less than 50% comorbidity (202 participants). Four studies had greater than 50% comorbidity (147 participants).
For the primary outcome attrition (Analysis 4.1) a non-significant effect was found for studies with less than 50% comorbidity (RR 0.93, 95% CI 0.39 to 2.24) and greater than 50% comorbidity (RR 2.82, 95% CI 1.01 to 7.87) respectively.

Sensitivity analysis

The results of the sensitivity analysis are presented in Table 1

Blinding of outcome assessor

Only studies with low bias remained in the analysis (341 participants).

Primary outcomes

Clinical response was non-significant (RR 4.03, 95% CI 0.89 to 18.31).
Reduction in social anxiety symptoms remained significant in favour of CBT (SMD -1.12, 95% CI -1.65 to -0.59).
Attrition remained non-significant (RR 0.83, 95% CI 0.24 to 2.95).

Secondary outcomes

Depression symptoms remained significant in favour of CBT (SMD -0.69, 95% CI -1.01 to -0.36).

Use of allocation concealment

Only studies with low bias remained in the analyses (231 participants).

Primary outcomes

Clinical response remained significant in favour of CBT (RR 8.18, 95% CI 1.79, 37.37).
Reduction in social anxiety symptoms remained significant in favour of CBT (SMD -1.05, 95% CI -1.85, -0.24).
Attrition became significant in favour of WL/TAU (RR 4.12, 95% CI 1.09 to 15.60).

Secondary outcomes

Depression symptoms remained significant in favour of CBT significant (SMD -0.62, 95% CI -1.14 to -0.10).
Clinical Global Impression - Improvements remained significant in favour of CBT (RR 8.99, 95% CI 2.95, 27.37).
Quality of life remained non-significant (SMD 0.87, 95% CI -0.34 to 2.08).

Attrition exceeding 20%

Studies with less than 20% attrition remained in the analyses (458 participants).

Primary outcomes

Clinical response remained significant in favour of CBT (RR 8.18, 95% CI 1.79, 37.37).

Reduction in social anxiety symptoms remained significant in favour of CBT (SMD -1.27, 95% CI -1.89 to -0.65).

Attrition became significant in favour of WL/TAU (RR 4.12, 95% CI 1.09 to 15.60).

Secondary outcomes

Depression symptoms remained significant in favour of CBT (SMD -0.94, 95% CI-1.56 to -0.32).

Clinical Global impression - Improvements remained significant in favour of CBT (RR 8.99, 95% CI 2.95 to 27.37).

Quality of life remained non-significant (SMD 0.87, 95% CI -0.34 to 2.08).

Treatment Fidelity

Removal of studies without formal fidelity testing (284 participants).

Primary outcomes

Clinical response remained highly significant in favour of CBT (RR 3.24, 95% CI 1.92 to 5.44).

Reduction in social anxiety symptoms remained highly significant in favour of CBT (SMD -0.84, 95% CI -1.01 to -0.66).

Fixed-effects model

Primary outcomes

Clinical response remained highly significant in favour of CBT (RR 3.24, 95% CI 1.92 to 5.44).

Reduction in social anxiety symptoms remained highly significant in favour of CBT (SMD -0.91, 95% CI -1.39 to -0.43).

Secondary outcomes

Depression symptoms remained highly significant in favour of CBT (SMD -0.59, 95% CI -0.97 to -0.21).

Social anxiety disorder diagnosis from clinician only

Primary outcomes

Reduction in social anxiety symptoms remained highly significant in favour of CBT (SMD -0.91, 95% CI -1.39 to -0.43).

Secondary outcomes

Depression symptoms remained highly significant in favour of CBT (SMD -0.59, 95% CI -0.97 to -0.21).

Exclusion of Alden 2011

Primary outcomes

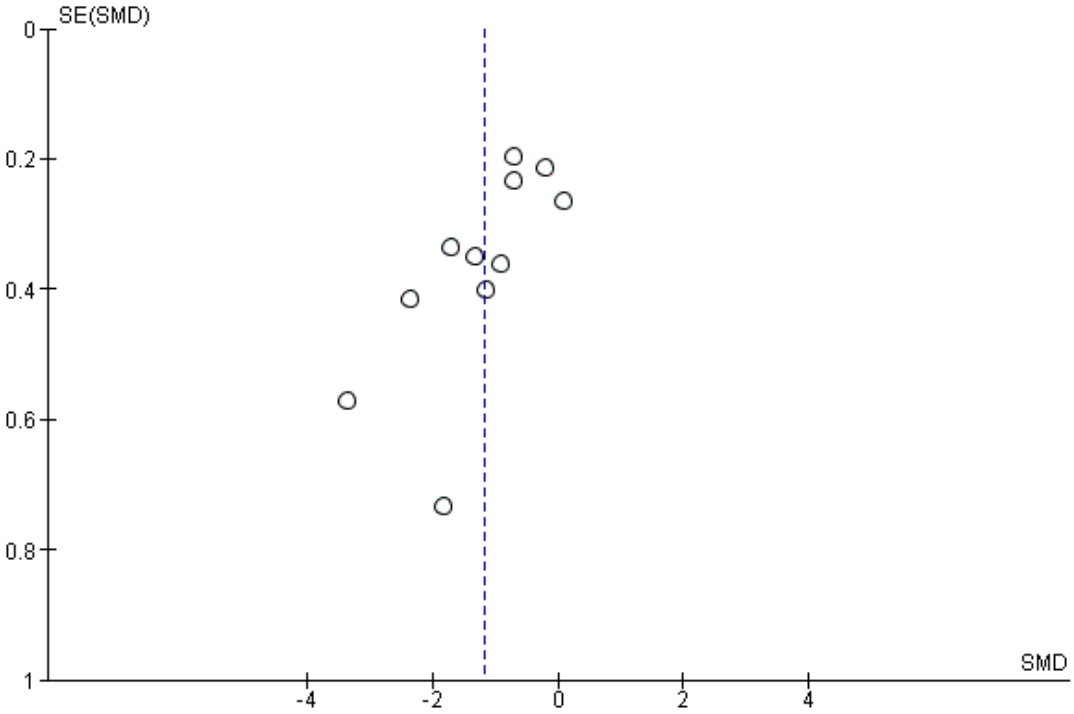
Reduction in social anxiety symptoms became more highly significant in favour of CBT (SMD -1.25, 95% CI -1.80, -0.70).

Attrition was non-significant (RR 1.04, 95% CI 0.44, 2.46).

Consideration of publication bias

A funnel plot was constructed for the primary outcome of social anxiety symptoms (10 studies) (see Figure 4). Visual inspection revealed possible asymmetry, which might suggest that small trials with negative outcomes were not included in the review. However, the small number of studies included in the funnel plot restricts further meaningful interpretations. A funnel plot for clinical response was not completed due to the small number of studies (four studies) for inclusion.

Figure 4. Funnel Plot of comparison: 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List, outcome: 1.2 Reduction in Social Anxiety Symptoms at Post-Treatment.



DISCUSSION

Summary of main results

Cognitive behavioural therapies versus treatment as usual/waiting list

This review provided evidence that patients with social anxiety (SAnD) treated with cognitive behavioural therapy (CBT) had a higher probability of achieving clinical response than patients assigned to treatment as usual/waiting list (TAU/WL). Patients assigned to CBT demonstrated greater reduction in social anxiety symptoms compared to the TAU/WL. No differences in attrition were found for patients who received CBT or TAU/WL. Patients provided with CBT reported greater reduction in depression symptoms relative to the TAU/WL. There was a lack of studies reporting on the long-term effectiveness of CBT for social anxiety symptoms. The negative effects of CBT were not examined in any study. Greater improvements in Clinical Global Impression - Improvements Scale were found for patients who completed CBT relative to the TAU/WL. No differences in quality of life (QOL) were reported between those who engaged in CBT or TAU/WL at post-treatment or follow up.

Summary of additional findings

Individual and group treatments demonstrated positive effects for social anxiety symptoms but only individual therapy showed an effect in favour of CBT for depression symptoms. Mixed and non-mixed SAnD samples showed positive treatment effects for CBT.

Overall completeness and applicability of evidence

Symptom focused outcomes were the main outcome in the studies. Seventeen validated SAnD measures were used across the studies. Nevertheless, 81% of studies used in the meta-analysis utilised the same outcome measure, the Social Phobia Scale (SPS) (Mattick 1989) which has been demonstrated to be a reliable and valid measure of social phobia (Olivares 2001).

Clinical response measures were used in only 31% of studies. Negative effects of treatment, QOL, CGI-I, therapeutic process, and cost-effectiveness measure were underrated in the studies.

Studies included the review were reasonably internationally distributed. Four were conducted in university/specialist anxiety clinics and three in community mental health settings. The remaining six studies did not provide details on settings and may have recruited less symptomatic participants than would present at usual outpatient services. Standardised clinical interview were used in all studies except two (diagnosis by referring clinician). All therapists were qualified and trained. Sixty-two percent of studies allowed for secondary comorbidity, a highly prevalent feature of SAnD, which is likely to have increased the external validity of study findings to clinical practice.

Quality of the evidence

The majority of studies provided good descriptions for specific aspects of methodological quality: treatment, recruitment methods, diagnostic and exclusion criteria, withdrawal information, the outcome measures used, and a number of studies provided a declaration of interest. The aspects of methodological quality that were less well rated for most studies are considered below.

Only 31% of studies adequately described the randomisation method. Thirty-eight percent of studies employed assessors who were reported to be blind to treatment allocation.The studies included in the review were small (Mean n=70). Only two studies reported utilising a power calculation therefore, it seems highly unlikely that any of these studies were adequately powered. Thirty-one percent of studies adequately tested for treatment fidelity. Therefore, it is unclear how treatment fidelity in the other untested studies affected the overall effect estimate (i.e. due to participants receiving potentially substandard CBT or due to receiving other non-CBT therapeutic components). The overall attrition rate in studies was low (11%). However, 30% of studies reported very high attrition rates (>20) and only 15% of studies reported reasons for attrition; it is not known for the remaining studies whether there were systematic differences between dropouts and completers that could have influenced treatment outcomes, leading to an underestimate or overestimate of effects.

Agreements and disagreements with other studies or reviews

Six reviews examined the effectiveness of CBT for SAnD over the last 13 years (Feske 1995; Taylor 1996; Acurturk 2009; Gould 1997; Fedoroff 2001; Banderlow 2009). Only one review conducted a systematic review and meta-analysis in accordance with the statistical methods used by Cochrane (Acurturk 2009), the authors searched for trials in the CCDANCTR register, and employed some of the Cochrane Risk of bias assessments variables (e.g. allocation concealment), and heterogeneity assessments (I^2). However, there were a number of clinical and methodological flaws in the Acurturk 2009 review that limited the validity of its findings. These and the some of the limitations with the other reviews will be discussed.

The included studies in the current review comprised TAU/WL control comparisons whereas most of the previous six reviews comprised studies with TAU/WL, pill placebo/attention placebo. The methodological heterogeneity in previous reviews limits the comparability with this review. In addition, the three previous reviews that compared CBT to pharmacological treatments for SAnD (Gould 1997, Fedoroff 2001; Banderlow 2009) included studies that would not meet the inclusion criteria for dual modality treatments in this review (see the Modality of therapies). This methodological heterogeneity across previous reviews prevents a more in-depth contrast with this review.

There are a number of other important limitations with the previous reviews. Four of the reviews (Taylor 1996; Acurturk 2009; Gould 1997; Banderlow 2009) did not provide details on the nature of participants SAnD diagnoses or explicitly stated "samples were rather heterogeneous with respect to number of participants with specific and generalised social phobia" (Feske 1995). Moreover, all but one review (Gould 1997) failed to provide any or sufficient details on participants Axis-I and Axis-II comorbidity. In addition, three reviews (Feske 1995; Taylor 1996; Fedoroff 2001) included uncontrolled trials in their analyses. Finally, two reviews did not conduct heterogeneity analyses on effect estimates (Taylor 1996; Banderlow 2009). All four factors above introduced clinical heterogeneity into the previous reviews and inhibits the validity and generalisability of their findings, as well as prevents accurate comparisons with this review.

None of the three reviews that examined the effectiveness of CBT versus control conditions for SAnD provided results for clinical response (Feske 1995; Taylor 1996; Acurturk 2009). The current review demonstrated a larger effect size for social anxiety symptom reduction than all three previous reviews (Feske 1995; Taylor 1996; Acurturk 2009). However, the effect estimate was more heterogeneous in the current review compared to Acurturk 2009. Furthermore, it is worth noting the all three previous reviews and this review calculated their effect size estimates in different manners making direct comparisons difficult.

AUTHORS' CONCLUSIONS

Implications for practice

This review provides evidence that psychological therapy using a cognitive behavioural approach is effective in the treatment of social anxiety disorder (SAnD). Forty percent of patients assigned to cognitive behavioural therapy (CBT) demonstrated clinical response at post-treatment, in contrast with 11% in TAU/

WL groups, and social anxiety and depression symptoms were also significantly reduced. There is a lack of evidence for longer-term effectiveness of psychological therapy in treating SAnD.

Whilst the overall attrition rate from psychological therapy using a CBT approach is reasonably low at 15%. Reasons for dropout were under-reported in studies, and may not only have been due to low acceptability or effectiveness of psychological therapy.

Implications for research

Further randomised controlled trials that examine the effectiveness of non-CBT models, and the comparative effectiveness of CBT and non-CBT models for SAnD are needed (see Appendix 6 for further recommendations).

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Alden 2011

Methods	Allocation: patients were randomised at patient level in blocks - allocation concealment not reported Blinding: assessors blind to condition Trial duration: 12 weeks Follow-up: 6 months
Participants	Setting: not reported Population: Adults recruited through advertisement letters to GPs Sample size: 56 Diagnosis: presence of SAnD symptoms according to DSM-IV, using the ADIS-IV (severity > 4) Comorbidity: 69% met diagnostic criteria for another Axis I anxiety disorder
Interventions	1. Integrated interpersonal group CBT (ICBT) 2. Waitling list Modality: Group Intensity: 12 2-hour sessions over 12 weeks Manualised: Yes Treatment fidelity: Not formally tested
Outcomes	Primary outcomes: 1. Not reported Secondary outcomes - Self-report: 1. Social Phobia Scale 2. Social Interaction Anxiety Scale 3. Brief Fear of Negative Evaluation Scale Clinical rated: 4. ADIS-IV Fear-Avoidance Composite 5. ADIS-IV Severity
Notes	Overall dropout rate (pre-/post-treatment): 11% Analysis: completers

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Participants randomly assigned in blocks of 5-7 to conditions
Allocation concealment (selection bias)	Unclear risk	Not reported

Alden 2011 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Pre and follow-up assessors at were blind to treatment condition. No details provided for post-treatment assessments
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Large discrepancy in the attrition rates between intervention conditions at follow up, and data analysis was based on completers
Selective reporting (reporting bias)	Unclear risk	No published protocol
Other bias	Unclear risk	Treatment fidelity not formally assessed

Clark 2006a

Methods	Allocation: patients were randomised at patient level using stratified randomisation method - allocation concealed Blinding: independent assessors Trial duration: 14 weeks Follow-up: 3 months and 12 months
Participants	Setting: not reported Population: adults referred by GP Sample size: 62 Diagnosis: presence of SAnD symptoms according to DSM-IV, using the social phobia module of the ADIS-IV and the overview and screener modules of the SCID-I Comorbidity: 55% met diagnostic criteria for one or more additional Axis I disorders
Interventions	1. Cognitive behavioural group therapy (CBT) 2. Exposure and applied relaxation 3. Waitling list Modality: individual Intensity: up to 14 1.5-hour sessions over 14 weeks Manualised: yes Treatment fidelity: tested through videotape examination of a randomly selected session for each patient
Outcomes	Primary outcomes - Clinician rated: 1. Loss of social phobia DSM-IV diagnosis using the social phobia module of the ADIS-IV and the overview and screener modules of the SCID-I Self-report: 2. Clinical change on the Liebowitz Social Anxiety Scale (Jacobsen & Traux, 1991) Secondary outcomes - Clinician-rated: 1. The Social Phobia Composite measure comprising the measures 2-7 below: 2. The ADIS (Fear and Avoidance subscales)

	Self-report: 3. Social Phobia Scale 4. Social Interaction Anxiety Scale 5. Social Phobia Weekly Summary Scale 6. Social Phobia Anxiety Inventory Social Phobia subscale 7. Fear of Negative Evaluation 8. Beck Depression Inventory 9. Agnew Relationship Measure - Therapeutic alliance 10. Treatment Credibility and Expectation of Improvement Scales
Notes	Overall dropout rate: 0% Analysis: intention-to-treat, using last observation carried forward for missing data

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	The method of randomisation is not described in the paper
Allocation concealment (selection bias)	Low risk	Independent allocation to treatment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Independent assessors were blind to treatment allocation, and self-report measures were used
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition in all groups and intention-to-treat and last observation carried forward was used to impute missing data
Selective reporting (reporting bias)	Unclear risk	All prescribed outcome measures reported but there is no trial protocol
Other bias	Low risk	Treatment fidelity was assessed and contact between care provider and patient was balanced across the groups

Furmark 2002

Methods	Allocation: patients were randomised by means of sealed envelope to condition - allocation concealed via envelopes Blinding: not reported Trial duration: 9 weeks Follow-up: 12 months
Participants	Setting: not reported Population: adults recruited through newspaper advertisements Sample Size: 18 Diagnosis: presence of SAnD symptoms according to DSM-IV, using the SCID-I and SCID-II Comorbidity: current psychiatric diagnosis other than SAnD was an exclusion criterion
Interventions	1. Cognitive behavioural group therapy (CBGT) 2. Citalopram (SSRI) 3. Waiting list Modality: group Intensity: 8 3-hour sessions over 9 weeks Manualised: yes Treatment fidelity: not tested
Outcomes	Primary outcomes - Self-report: 1. Responders were considered to be patients who improved 1 SD or more from the pretreatment mean value on 7 to 9 outcome measures Secondary outcomes - Self-report: 1. Social Phobia Scale 2. Social Interaction Anxiety Scale 3. Spielberger State Anxiety Inventory (STAI-S) - Global, 4. The Personal Report on Confidence as a Speaker (PRCS) 5. The Social Phobia Screening Questionnaire (SPSQ10) 6. The Global Assessment of Functioning Scale (GAF20)
Notes	Overall dropout rate: 0% Analysis: completers

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Patients were randomised by means of sealed envelope to condition - unclear
Allocation concealment (selection bias)	Low risk	Allocation concealed via envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported

Furmark 2002 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	All self-report measures
Incomplete outcome data (attrition bias) All outcomes	Low risk	No attrition in groups
Selective reporting (reporting bias)	High risk	12-month follow-up data not reported
Other bias	Unclear risk	Treatment not formally assessed

Hofmann 2004

Methods	Allocation: participants were randomly selected from patients who presented at outpatient clinic - allocation not reported Blinding: not reported Trial duration: 12 weeks Follow-up: 6 months
Participants	Setting: university outpatients Population: adult outpatients Sample Size: 90 Diagnosis: presence of SAnD symptoms according to DSM-IV, using the ADIS-IV-Lifetime version Comorbidity: 44% of the sample met criteria for at least one additional DSM-IV diagnosis
Interventions	1. Cognitive behavioural group therapy (CBGT) 2. Exposure group therapy (EGT) 3. Waiting list Modality: group Intensity: not reported Manualised: yes Treatment fidelity: tested through videotape examination of a randomly selected session for each patient
Outcomes	Primary outcomes: 1. not reported Secondary outcomes - Self-report: 1. Social Phobia and Anxiety Inventory (SPAI) 2. Social Cost Questionnaire (SCQ)
Notes	Overall dropout rate: 25% Analysis: completers

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Hofmann 2004 (*Continued*)

Random sequence generation (selection bias)	Unclear risk	Randomisation procedure not described
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-report measures used
Incomplete outcome data (attrition bias) All outcomes	High risk	Participants were added until there were 30 completers in each group
Selective reporting (reporting bias)	Unclear risk	All prescribed outcome measure reported but there is no trial protocol
Other bias	Unclear risk	Not reported

Ledley 2009

Methods	Allocation: participants were randomised to intervention condition - allocation not reported Blinding: not reported Trial duration: 20 weeks Follow-up: 3 months
Participants	Setting: university anxiety clinic Population: adult outpatients Sample Size: 38 Diagnosis: presence of SAnD symptoms according to DSM-IV, using the ADIS-IV and ADIS-IV-L lifetime version Comorbidity: 32% of the sample met criteria for at least one additional DSM-IV diagnosis
Interventions	1. Cognitive behavioural therapy (CBT) 2. Waiting list Modality: individual Intensity: 16 1-hours session over 20 weeks Manualised: yes Treatment fidelity: tested using the Therapist Adherence Scale
Outcomes	Primary outcomes - Clinician rated: 1. Clinician rated; Clinical Global Impression-Improvements (CGI-I) 2. Clinician rated; ADIS - clinicians severity rating CSR 3. Liebowitz Social Anxiety Scale (LSAS)

Ledley 2009 (*Continued*)

	Secondary outcomes- Self-report: 1. The Social Phobia Scale (SPS) 2. Social Interaction Anxiety Scale (SIAS) 3. Brief Fear of Negative Evaluation Scale (BFNE) 4. Quality of Life Inventory (QOLI) 5. Sheehan Disability Scale (SDS)
Notes	Overall dropout rate: 21% Analysis: completers and intention-to-treat analysis

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomisation procedure not described
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors were uninformed about the condition to which clients had been assigned
Incomplete outcome data (attrition bias) All outcomes	Low risk	Completer and intention-to-treat analyses yielded virtually identical findings
Selective reporting (reporting bias)	Unclear risk	Follow-up data not reported
Other bias	Low risk	Intervention fidelity was tested formally

Mortberg 2006

Methods	Allocation: participants were randomised to intervention condition - allocation not reported Blinding: not reported Trial duration: 3 weeks Follow-up: 3, 6 and 12 months
Participants	Setting: community mental health outpatients clinic Population: adult recruited from referrals to an outpatients clinic Sample Size: 26 Diagnosis: presence of SAnD symptoms according to DSM-IV, using the SCID I and SCID II Comorbidity: current major depression, addiction, psychosis were exclusion criteria.

Mortberg 2006 (*Continued*)

	However, 58% had a comorbid avoidant personality disorder DSM-IV diagnosis
Interventions	1. Intensive group CBT (IGCT) 2. Waiting list Modality: group Intensity: 41-hours CBGT over 3 weeks plus 3-hour booster sessions at 3, 6 and 12 months Manualised: yes Treatment fidelity: not reported
Outcomes	Primary outcomes: 1. Not reported Secondary outcomes - Self-report: 1. Liebowitz Social Anxiety Scale (LSAS) 2. The Social Phobia Scale (SPS) 3. Social Interaction Anxiety Scale (SIAS) 3. Fear of Negative Evaluation Scale (FNE) 4. Symptoms Influence on Daily Life Scale (SIDL) 5. Social Behaviors Questionnaire (SBQ) 6. Beck Depression Inventory (BDI)
Notes	Overall dropout rate: 8% Analysis: intention-to-treat analysis

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomisation procedure not described
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-report measures used
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Last observation carried forward and Intention-to-treat analyses
Selective reporting (reporting bias)	Unclear risk	All prescribed outcome measure reported but there was no trial protocol
Other bias	Unclear risk	Intervention fidelity not assessed

Mortberg 2007a

Methods	Allocation: participants were randomised to intervention condition based on an extension of Efron's biased coin design - allocation made by an independent administrator using a random number table Blinding: not reported Trial duration: 12 months Follow-up: 4, 8 and 12 months
Participants	Setting: community mental health outpatients clinic Population: adults recruited through advertisements in a local newspaper Sample Size: 100 Diagnosis: presence of SAnD symptoms according to DSM-IV, using the SCID I Comorbidity: 45% of the sample met criteria for at least one additional DSM-IV diagnosis
Interventions	1. Intensive group cognitive therapy (IGCT); 2. Intensive individual cognitive therapy (ICT); 3. Treatment as usual (TAU) Modality: individual and group Intensity: 41-hours IGCT over 3 weeks plus 3-hour booster sessions at 4, 8 and 12 months; ICT: 2 initial 90-minutes session and 14 60-minute sessions plus booster sessions at 8 and 12 months; TAU 45 minute session - frequency not specified Manualised: yes Treatment fidelity: not formally
Outcomes	Primary outcomes: 1. Loss of DSM-IV SAnD diagnosis on the SCID-I 2. Social Phobia Composite - clinically significant change (Jacobsen & Truax, 1991) defined as a post-treatment score two standard deviations below the pre-treatment score Secondary outcomes - Self-report: 1. Social Phobia Composite (comprised the measures 2 to 7 below) 2. Liebowitz Social Anxiety Scale (LSAS) 3. The Social Phobia Scale (SPS) 4. Social Interaction Anxiety Scale (SIAS) 5. Fear of Negative Evaluation Scale (FNE) 6. The Fear Questionnaire Social Phobia sub-scale (FQ- SOC) 7. The Social Phobia Weekly Summary Scale (SPWSS) 8. Sheehan Disability Scale (SDS) 9. Beck Depression Inventory (BDI)
Notes	Overall dropout rate: 36% Analysis: Last outcome carried forward and intention-to-treat analysis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation based on an extension of Efron's biased coin design

Mortberg 2007a (*Continued*)

Allocation concealment (selection bias)	Low risk	Allocation conducted independently using a random number table
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Clinical-rated measures assess by blind assessors; self-report measure also used
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Last observation carried forward and Intention-to-treat analyses used but there was a large significant difference among the groups
Selective reporting (reporting bias)	Unclear risk	All prescribed outcome measures reported but there is no trial protocol
Other bias	Unclear risk	Intervention fidelity not quantitatively assessed

Pishyar 2008

Methods	Allocation: participants were randomised to intervention condition - allocation details not reported Blinding: not reported Trial duration: 8 weeks Follow-up: none
Participants	Setting: not reported Population: adults recruited through advertisements Sample Size: 32 Diagnosis: presence of SAnD symptoms according to DSM-IV criteria - measure not reported Comorbidity: not reported
Interventions	1. Intensive group cognitive therapy (IGCT) 2. Waiting list Modality: group Intensity: not reported Manualised: yes Treatment fidelity: not assessed
Outcomes	Primary outcomes: 1. Not reported Secondary outcomes: Self-report:

Pishyar 2008 (*Continued*)

	1. The Social Phobia Scale (SPS) 2. Social Interaction Anxiety Scale (SIAS) 3. Fear of Negative Evaluation Scale (FNE) 4. Anxiety Sensitivity Index (ASI) 5. Beck Depression Inventory (BDI II)
Notes	Overall dropout rate: 0% Analysis: completers

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomisation strategy not defined
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-report measures used
Incomplete outcome data (attrition bias) All outcomes	Low risk	no attrition
Selective reporting (reporting bias)	Unclear risk	All prescribed outcome measure reported but there is no trial protocol
Other bias	Unclear risk	not reported

Rapee 2007

Methods	Allocation: participants were randomised using a random number generator - allocation not reported Blinding: not reported Trial duration: 12 weeks Follow-up: 12 weeks
Participants	Setting: university anxiety research unit Population: adult referred from GPs and media sources Sample Size: 224 Diagnosis: presence of SAnD symptoms according to DSM-IV, using the ADIS-IV and the ICD-10 International Personality Disorder Examination - avoidant personality disorder subscale

Rapee 2007 (*Continued*)

	Comorbidity: 43% of the sample met criteria for at least one additional DSM-IV diagnosis
Interventions	1. Cognitive behavioural group therapy (CBGT) 2. 'Pure' self-help CBT (SH) 3. Augmented self-help CBT (SH+CBGT; 5 session group CBT therapist) 3. Waiting list Modality: group, and self-help Intensity: SH+CBGT = 5 2-hour session over 12 weeks; CBGT = 10 2-hour sessions over 12 weeks Manualised: yes Treatment fidelity: Not reported
Outcomes	Primary outcomes: 1. Clinician rated; loss of DSM-IV SAnD diagnoses assessed by the ADIS-IV 2. Self-report; reduction in SAnD symptoms on the composite social phobia symptom measure 3. Reduction in self-rated life interference Secondary outcomes: Self-report: 1. Social Phobia Scale (SPS) 2. The Social Interaction Anxiety Scale (SIAS) 3. The Brief Fear of Negative Evaluation scale (BFNE)
Notes	Overall dropout rate: 22% Analysis: last outcome carried forward and interpolation for missing data

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomisation achieved via a random number generator
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	last outcome carried forward and interpolation for missing data
Selective reporting (reporting bias)	Unclear risk	All prescribed outcome measure reported but there is no trial protocol

Rapee 2007 (*Continued*)

Other bias	Unclear risk	Intervention fidelity not quantitatively assessed

Robillard 2010

Methods	Allocation: participants were randomised to intervention condition using a generator of random numbers - allocation concealment details not reported Blinding: not done Trial duration: 16 weeks Follow-up: not reported
Participants	Setting: not reported Population: adults recruitment details not reported Sample Size: 45 Diagnosis: presence of SAnD symptoms according to DSM-IV, using the SCID I Comorbidity: not reported
Interventions	1. Cognitive behaviour therapy (CBT); 2. Cognitive behaviour therapy with virtual reality exposure CBT-VR); 3. Waiting list Modality: individual Intensity: Not reported Manualised: yes Treatment fidelity: not assessed
Outcomes	Primary outcomes: 1. Not reported Secondary outcomes - Self-report: 1. Liebowitz Social Anxiety Scale (LSAS) 2. The Social Phobia Scale (SPS) 3. Social Interaction Anxiety Scale (SIAS) 4. Fear of Negative Evaluation Scale (FNE) 5. Appraisal of Social Concerns 5. State-trait anxiety inventory (STAI) 6. Beck Depression Inventory (BDI-II)
Notes	Overall dropout rate: Not reported Analysis: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number generator used
Allocation concealment (selection bias)	Unclear risk	Not reported

Robillard 2010 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-report measures used
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	No trial protocol reported
Other bias	High risk	Intervention fidelity not quantitatively assessed

Stangier 2003

Methods	Allocation: participants were randomised using predetermined arbitrary sequence - allocation teams were independent to the assessment teams Blinding: not reported Trial duration: 4 months Follow-up: 10 months
Participants	Setting: Outpatient mental health service Population: adults referred from outpatient mental health services and media advertisements Sample Size: 71 Diagnosis: presence of SAnD symptoms according to DSM-IV, using the German version of SCID I and selected SCID-II Personality disorder subscales Comorbidity: 75% of the sample met criteria for at least one additional DSM-IV diagnosis
Interventions	1. Individual cognitive behavioural therapy (iCGT) 2. Cognitive behavioural group therapy (CBGT) 3. Waiting list Modality: group, and individual Intensity: iCBT, 15 1-hour session over 4 months; CBGT, 6 2-hour sessions over 4months Manualised: yes Treatment fidelity: Not reported
Outcomes	Primary outcomes: 1. Clinician rated; loss of DSM-IV SAnD diagnoses assessed by the SCID I 2. Self-report; clinically significant change in SAnD symptoms on the social phobia measures according to Jacobson and Truax's (1991) criteria Secondary outcomes - Self-report: 1. Social Phobia Scale (SPS) 2. Social Interaction Anxiety Scale (SIAS)

Stangier 2003 (*Continued*)

	3. Social Phobia & Anxiety Inventory (SPAI) 4. Beck Anxiety Inventory (BAI) 5. Beck Depression Inventory (BDI) 6. The Global Symptom Index - Hopkins Symptom Checklist-90-Revisited (SCL-GSI)
Notes	Overall dropout rate: 14% Analysis: intention to treat (pre-treatment scores carried forward for non-completers) and completer data analysis

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomisation procedure not described
Allocation concealment (selection bias)	Low risk	Allocation by independent teams
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Self-report measures used, but blinding of DSM-IV diagnosis assessors not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Intention to treat analysis completed on iCBT versus CBGT, but completer analysis conducted on the waiting list comparisons
Selective reporting (reporting bias)	Unclear risk	All prescribed outcome measures reported, but there no trial protocol reported
Other bias	Unclear risk	Intervention fidelity not quantitatively assessed

Stangier 2011

Methods	Allocation: participants were randomised to intervention condition - allocation was based on a computer-generated list concealed from the investigators Blinding: not reported Trial duration: 20 weeks Follow-up: 12 months
Participants	Setting: two university research centres Population: adults referred from outpatient mental health services and media advertisements Sample Size: 117

	Diagnosis: presence of SAnD symptoms according to DSM-IV, using the SCID I and SCID-II Personality disorder subscales Comorbidity: 54% of the sample met criteria for at least one additional DSM-IV diagnosis
Interventions	1. Cognitive behavioural group therapy 2. Interpersonal psychotherapy (IPT) 3. Waiting list Modality: individual Intensity: 16 50-minutes (approximately) sessions over 20 weeks, plus 1 booster session 2-months post-therapy Manualised: yes Treatment fidelity: Therapists completed checklists of "encouraged" and "prohibited" interventions after each session
Outcomes	Primary outcomes: 1. Clinician rated; treatment response on the Clinical Global Impression Scale (CGI-I scale) - patients rated 1 or 2 were classified as responders Secondary outcomes - Clinical rated: 1. Liebowitz Social Anxiety Scale (LSAS) 2. Hamilton Rating Scale for Depression Self-report: 3. Social Phobia & Anxiety Inventory (SPAI) 4. Treatment Credibility and Expectation of Improvement Scales 5. The Bernese Post-Session Report. 6. Additional treatments sought
Notes	Overall dropout rate: 5% Analysis: last outcome carried forward and intention to treat analysis

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not details about random sequence reported
Allocation concealment (selection bias)	Low risk	Allocation was concealed from the investigators
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Independent assessors were blind to the treatment conditions

Stangier 2011 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	last outcome carried forward and intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	Not all prescribed outcome measures reported in the results
Other bias	Low risk	Fidelity assessed, and contact from therapist was matched between the treatment conditions

Wong 2006

Methods	Allocation: participants were randomised by drawing numbers from a box - allocation - a staff member with no knowledge of the research drew numbers in a box Blinding: not reported Trial duration: 10 weeks Follow-up: none
Participants	Setting: Not reported Population: adults referred from outpatient mental health services and media advertisements Sample Size: 34 Diagnosis: presence of SAnD symptoms according to DSM-IV criteria - measure not reported Comorbidity: Not reported - severe mood disorders were an exclusion criteria
Interventions	1. Cognitive behavioural group therapy 2. Waiting list Modality: group Intensity: 10 2.5-hour sessions over 10 weeks Manualised: yes Treatment fidelity: tested through videotape examination of a selected sessions for each patient
Outcomes	Primary outcomes: 1. Not reported Secondary outcomes - Self-report: 1. Liebowitz Social Anxiety Scale 2. Dysfunctional Attitude scale (DAS)
Notes	Overall dropout rate: 0% Analysis: completers

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Wong 2006 (*Continued*)

Random sequence generation (selection bias)	Low risk	Random numbers drawn from a box
Allocation concealment (selection bias)	Low risk	Staff member with no knowledge of the research drew the numbers
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-reported measures
Incomplete outcome data (attrition bias) All outcomes	Low risk	No attrition
Selective reporting (reporting bias)	Unclear risk	All prescribed outcome measure reported, but there no trial protocol reported
Other bias	Low risk	Fidelity assessed

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Butler 1984a	Did not meet the DSM-IV social anxiety disorder diagnostic cut-off (i.e. DSM-III-R or DSM-III)
Hope 1995a	Did not meet the DSM-IV social anxiety disorder diagnostic cut-off (i.e. was DSM-III-R or DSM-III)
Knijnik 2004	Study was a non-CBT trial
Mattick 1989	Did not meet the DSM-IV social anxiety disorder diagnostic cut-off (i.e. was DSM-III-R or DSM-III)
Mersch 1995	Did not meet the DSM-IV social anxiety disorder diagnostic cut-off (i.e. was DSM-III-R or DSM-III)
Mortberg 2007b	Study examined participants' temperament and character dimensions across treatment
Nelson 2010	Study did not have a waiting list or treatment as usual comparisons
Prasko 2006	Study had an invalid treatment as usual comparison
Price 2011	Study examined performance social anxiety (i.e. public speaking anxiety)
Salaberria 1998a	Did not meet the DSM-IV social anxiety disorder diagnostic cut-off (i.e. was DSM-III-R or DSM-III)

(*Continued*)

Scholing 1993	Study did not have a waiting list or treatment as usual comparisons
Scholing 1999	Study did not have a waiting list or treatment as usual comparisons
Srinivasan 1984	Did not meet the DSM-IV social anxiety disorder diagnostic cut-off (i.e. was DSM-III-R or DSM-III)
Stravynski 2000	Study had an invalid waiting list comparison
Taylor 1997a	Study did not have a waiting list or treatment as usual comparisons

Characteristics of studies awaiting assessment *[ordered by study ID]*

Antona 2006

Methods	Randomised trial
Participants	Eighty-five participants diagnosed with social phobia (DSM-IV)
Interventions	a) exposure and cognitive restructuring components, both integrated in every session (10 sessions), b) exposure block (5 sessions) followed by cognitive restructuring block (5 sessions), and c) a control group that after three months was assigned to the treatment cognitive restructuring block (5 sessions) followed by exposure block (5 sessions)
Outcomes	The Fear of Negative Evaluation scale (FNE; Watson and Friend, 1969) and the Social Avoidance and Distress scale (SAD; Watson and Friend, 1969)
Notes	

Bjornsson 2010

Methods	Randomised trial
Participants	Forty-five college students meeting DSM-IV diagnosis of social anxiety disorder
Interventions	a) group cognitive behavioural therapy (CBGT), and b) non-specific group treatment (NSGT
Outcomes	Not reported
Notes	

Filion-Rosset 2004

Methods	Randomised trial
Participants	Eighty-seven participants with a DSM-IV diagnosis of social anxiety disorder
Interventions	a) waiting-list control (W-LC), b) self-administered CBT (SA-CBT), c) group CBT led by either a self-help facilitator (SH-CBGT), and d) a professional therapist (PROF-CBGT)
Outcomes	The Balanced States of Mind scale (BSOM; Schwartz, 1997)
Notes	

Lee 1997

Methods	Randomised trial
Participants	Fifty-one male and female socially anxious adults in Korea
Interventions	a) cognitive behavioral therapy (CBT), b) exposure therapy (ET), and c) waiting list (WL) control
Outcomes	Social Avoidance and Distress scale (SAD; Watson and Friend, 1969)
Notes	

McDougall 2000

Methods	Randomised trial
Participants	Individual with social anxiety disorder
Interventions	a) cognitive behavioural group treatment (CB) b), a cognitive behavioural group treatment plus the addition of training in imagery (CBI) and c), or a wait-list control condition (WLC)
Outcomes	Social Phobia and Anxiety Inventory (SPAI), Brief Social Phobia Scale (BSPS), Social Coping Scale (SCS), Beck Depression Inventory (BDI), Social Interaction Self-Statement Test (SISST), and a behavioural measure of social skills (SSI)
Notes	

Nagae 2001

Methods	Randomised trial
Participants	Twenty Japanese college students with social anxiety
Interventions	a) Constructive cognitive psychotherapy (CCP), b) a rational cognitive psychotherapy (RCP), and c) a waiting list control (WLC)

Nagae 2001 (*Continued*)

Outcomes	Fear of Negative Evaluation Scale (FNE) and the Social Avoidance and Distress Scale (SADS)
Notes	

Schmertz 2011

Methods	Randomised trial
Participants	Ninety-eight individuals with social anxiety disorder
Interventions	a) cognitive behavioral group therapy with virtual reality exposure and b), wait-list control group
Outcomes	Mindful Attention Awareness Scale (MAAS), the Rumination Questionnaire (RQ), the Fear of Negative Evaluations Brief Form (FNE-B), the Liebowitz Social Anxiety Scale (LSAS), and the Personal Report of Communication Apprehension (PRCA)
Notes	

Stangier 2001

Methods	Randomised trial
Participants	Patients with social phobia and avoidant personality disorder
Interventions	Cognitive behavioral therapy
Outcomes	Not reported
Notes	

Characteristics of ongoing studies *[ordered by study ID]*

Leichsenring 2007

Trial name or title	The social phobia psychotherapy research network [ISRCTN53517394]. Controlled-trials.com 2007; Differential efficacy of short-term psychodynamic psychotherapy (STPP) and cognitive behavioral therapy (CBT) in social phobia therapy
Methods	
Participants	Adults with a DSM-IV social phobia diagnosis
Interventions	a) manualized short-term psychodynamic psychotherapy (STPP), b) manualized cognitive behavioral therapy (CBT)

Leichsenring 2007 (*Continued*)

Outcomes	Genetic variation in the serotonin transporter (SERT) gene, Liebowitz Social Anxiety Scale [LSAS], Social Phobia and Anxiety Inventory (SPAI), Beck Depression Inventory (BDI), Interpersonal problems (IIP), Self-image, Quality of life or social functioning (short-form-12 questionnaire SF-12), and Costs and utilities of the treatments
Starting date	Data analysis was completed and preliminary analysis conducted
Contact information	Professor Falk Leichsenring, Univeristy of Geissen Germany Falk.Leichsenring@psycho.med.uni-giessen.de
Notes	

DATA AND ANALYSES

Comparison 1. Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Clinical Response at Post-Treatment	4	264	Risk Ratio (M-H, Random, 95% CI)	3.60 [1.35, 9.57]
2 Reduction in Social Anxiety Symptoms at Post-Treatment	11	599	Std. Mean Difference (IV, Random, 95% CI)	-1.18 [-1.66, -0.69]
3 Attrition at Post-Treatment	10	574	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.51, 2.32]
4 Reduction in Depression Symptoms at Post-Treatment	7	382	Std. Mean Difference (IV, Random, 95% CI)	-0.85 [-1.34, -0.36]
5 Clinical Global Impression Improvement Scale at Post-Treatment	2	110	Risk Ratio (M-H, Random, 95% CI)	9.61 [3.67, 25.19]
6 Quality of Life at Post-Treatment	3	143	Std. Mean Difference (IV, Random, 95% CI)	0.32 [-0.02, 0.67]
7 Reduction in Social Anxiety Symptoms at Follow-Up	2	159	Std. Mean Difference (IV, Random, 95% CI)	-0.27 [-0.60, 0.06]
8 Reduction in Depression Symptoms at Follow-Up	2	159	Std. Mean Difference (IV, Random, 95% CI)	-0.51 [-0.85, -0.18]
9 Quality of Life at Follow-Up	1	100	Std. Mean Difference (IV, Random, 95% CI)	0.22 [-0.20, 0.64]

Comparison 2. Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analyses (Individual versus Group Treatments)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Reduction in Social Anxiety Symptoms at Post-Treatment	9	434	Std. Mean Difference (IV, Random, 95% CI)	-1.45 [-1.93, -0.96]
1.1 Individual Treatment	4	195	Std. Mean Difference (IV, Random, 95% CI)	-1.34 [-2.01, -0.67]
1.2 Group Treatments	5	239	Std. Mean Difference (IV, Random, 95% CI)	-1.59 [-2.40, -0.77]
2 Attrition at Post-Treatment	8	403	Risk Ratio (M-H, Random, 95% CI)	1.31 [0.65, 2.64]
2.1 Individual Treatment	3	158	Risk Ratio (M-H, Random, 95% CI)	1.31 [0.16, 10.36]
2.2 Group Treatment	5	245	Risk Ratio (M-H, Random, 95% CI)	1.29 [0.67, 2.49]
3 Reduction in Depression Symptoms at Post-Treatment	5	217	Std. Mean Difference (IV, Random, 95% CI)	-1.13 [-1.82, -0.43]
3.1 Individual treatment	3	151	Std. Mean Difference (IV, Random, 95% CI)	-0.83 [-1.44, -0.22]
3.2 Group treatment	2	66	Std. Mean Difference (IV, Random, 95% CI)	-1.68 [-3.77, 0.41]

Comparison 3. Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analyses - SAnD Diagnosis (<80% Generalised SAnD versus >80% Generalised SAnD Samples)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Reduction in Social Anxiety Symptoms at Post-Treatment	8		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 <80% Generalised SAnD	2	91	Std. Mean Difference (IV, Random, 95% CI)	-1.05 [-2.03, -0.06]
1.2 >80 Generalised SAnD	6	377	Std. Mean Difference (IV, Random, 95% CI)	-1.19 [-1.78, -0.60]
2 Attrition at Post-Treatment	7	437	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.46, 2.06]
2.1 <80% Generalised SAnD	2	91	Risk Ratio (M-H, Random, 95% CI)	3.78 [0.84, 17.06]
2.2 >80 Generalised SAnD	5	346	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.39, 1.46]

Comparison 4. Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analysis - Common Mental Health Comorbidity (<50% in the Sample versus >50% in the Sample)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Attrition	7		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 <50% Comorbidity	3	149	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.39, 2.24]
1.2 >50% Comorbidity	4	247	Risk Ratio (M-H, Random, 95% CI)	2.82 [1.01, 7.87]

Analysis 1.1. Comparison 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List, Outcome 1 Clinical Response at Post-Treatment.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List

Outcome: 1 Clinical Response at Post-Treatment

Study or subgroup	CBT n/N	WL/TAU n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Clark 2006a	18/21	1/20		16.8 %	17.14 [2.52, 116.73]
Furmark 2002	4/6	1/6		17.2 %	4.00 [0.61, 26.12]
Mortberg 2007a	27/67	8/33		38.5 %	1.66 [0.85, 3.25]
Rapee 2007	13/59	3/52		27.5 %	3.82 [1.15, 12.66]
Total (95% CI)	**153**	**111**		**100.0 %**	**3.60 [1.35, 9.57]**

Total events: 62 (CBT), 13 (WL/TAU)

Heterogeneity: $Tau^2 = 0.53$; $Chi^2 = 6.82$, df = 3 (P = 0.08); I^2 =56%

Test for overall effect: Z = 2.56 (P = 0.010)

Test for subgroup differences: Not applicable

Analysis 1.2. Comparison 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List, Outcome 2 Reduction in Social Anxiety Symptoms at Post-Treatment.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List

Outcome: 2 Reduction in Social Anxiety Symptoms at Post-Treatment

Study or subgroup	CBT N	Mean(SD)	WL/TAU N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Alden 2011	27	34.93 (12.18)	23	54.32 (10)		9.5 %	-1.70 [-2.35, -1.04]
Clark 2006a	21	18.19 (10.01)	20	46.25 (13.23)		8.6 %	-2.35 [-3.17, -1.54]
Furmark 2002	6	13 (10.469)	6	29.67 (5.82)		5.7 %	-1.82 [-3.25, -0.38]
Ledley 2009	14	29.57 (8.26)	16	44.19 (14.84)		8.8 %	-1.16 [-1.95, -0.38]
Mortberg 2007a	67	37.23 (16.09)	33	40.8 (17.6)		10.6 %	-0.21 [-0.63, 0.20]
Pishyar 2008	16	22.9 (8.9)	16	53 (8.6)		7.1 %	-3.35 [-4.47, -2.23]
Rapee 2007	59	44.333 (15.047)	52	54.42 (13.508)		10.7 %	-0.70 [-1.08, -0.31]
Robillard 2010	30	49.036 (20.96)	15	77.93 (22.23)		9.3 %	-1.33 [-2.01, -0.64]
Stangier 2003	44	37.25 (13.54)	21	36 (7.9)		10.1 %	0.10 [-0.42, 0.62]
Stangier 2011	38	51.2 (20.61)	41	69.19 (28.26)		10.4 %	-0.72 [-1.17, -0.26]
Wong 2006	17	50.3 (21.4)	17	68.6 (17.9)		9.2 %	-0.91 [-1.62, -0.20]
Total (95% CI)	**339**		**260**			**100.0 %**	**-1.18 [-1.66, -0.69]**

Heterogeneity: $Tau^2 = 0.53$; $Chi^2 = 65.77$, df = 10 ($P<0.00001$); $I^2 = 85\%$

Test for overall effect: $Z = 4.79$ ($P < 0.00001$)

Test for subgroup differences: Not applicable

Analysis 1.3. Comparison 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List, Outcome 3 Attrition at Post-Treatment.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List

Outcome: 3 Attrition at Post-Treatment

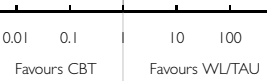
Study or subgroup	CBT n/N	WL/TAU n/N	Risk Ratio M-H,Random,95% CI	Risk Ratio M-H,Random,95% CI
Alden 2011	4/31	2/25		1.61 [0.32, 8.10]
Clark 2006a	0/21	0/20		0.0 [0.0, 0.0]
Furmark 2002	0/6	0/6		0.0 [0.0, 0.0]
Ledley 2009	2/16	6/22		0.46 [0.11, 1.98]
Mortberg 2007a	14/67	15/33		0.46 [0.25, 0.84]
Pishyar 2008	0/16	0/16		0.0 [0.0, 0.0]
Rapee 2007	14/59	10/52		1.23 [0.60, 2.54]
Stangier 2003	6/50	0/21		5.61 [0.33, 95.28]
Stangier 2011	7/38	2/41		3.78 [0.84, 17.06]
Wong 2006	0/17	0/17		0.0 [0.0, 0.0]
Total (95% CI)	**321**	**253**		**1.09 [0.51, 2.32]**

Total events: 47 (CBT), 35 (WL/TAU)

Heterogeneity: $Tau^2 = 0.46$; $Chi^2 = 12.42$, df = 5 (P = 0.03); $I^2 = 60\%$

Test for overall effect: Z = 0.21 (P = 0.83)

Test for subgroup differences: Not applicable



Analysis 1.4. Comparison 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List, Outcome 4 Reduction in Depression Symptoms at Post-Treatment.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List

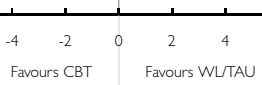
Outcome: 4 Reduction in Depression Symptoms at Post-Treatment

Study or subgroup	CBT N	Mean(SD)	WL/TAU N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Clark 2006a	21	2.57 (3.93)	20	10.25 (6.21)		13.7 %	-1.46 [-2.15, -0.76]
Mortberg 2007a	67	8.394 (8.2172)	33	13 (10.1)		16.6 %	-0.51 [-0.94, -0.09]
Pishyar 2008	16	7.4 (3.8)	16	21.2 (5.7)		10.6 %	-2.78 [-3.78, -1.77]
Robillard 2010	16	7.75 (9.16)	15	16.13 (13.33)		13.3 %	-0.72 [-1.45, 0.01]
Stangier 2003	44	12.4 (9.199)	21	13.3 (7.8)		15.6 %	-0.10 [-0.62, 0.42]
Stangier 2011	38	5.43 (5.74)	41	8.03 (6.13)		16.4 %	-0.43 [-0.88, 0.01]
Wong 2006	17	151.6 (15.9)	17	167.1 (29)		13.8 %	-0.65 [-1.34, 0.04]
Total (95% CI)	**219**		**163**			**100.0 %**	**-0.85 [-1.34, -0.36]**

Heterogeneity: $Tau^2 = 0.33$; $Chi^2 = 28.01$, df = 6 (P = 0.00009); $I^2 = 79\%$

Test for overall effect: Z = 3.40 (P = 0.00067)

Test for subgroup differences: Not applicable



Analysis 1.5. Comparison 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List, Outcome 5 Clinical Global Impression Improvement Scale at Post-Treatment.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List

Outcome: 5 Clinical Global Impression Improvement Scale at Post-Treatment

Study or subgroup	CBT n/N	WL/TAU n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Ledley 2009	11/15	1/16		25.1 %	11.73 [1.72, 80.20]
Stangier 2011	25/38	3/41		74.9 %	8.99 [2.95, 27.37]
Total (95% CI)	**53**	**57**		**100.0 %**	**9.61 [3.67, 25.19]**

Total events: 36 (CBT), 4 (WL/TAU)

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.06$, df = 1 (P = 0.81); $I^2 = 0.0\%$

Test for overall effect: Z = 4.60 (P < 0.00001)

Test for subgroup differences: Not applicable

Analysis 1.6. Comparison 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List, Outcome 6 Quality of Life at Post-Treatment.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List

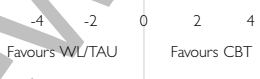
Outcome: 6 Quality of Life at Post-Treatment

Study or subgroup	CBT N	Mean(SD)	WL/TAU N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Furmark 2002	6	82.167 (12.813)	6	70 (13.038)		8.2 %	0.87 [-0.34, 2.08]
Ledley 2009	14	1.14 (1.79)	17	0.43 (2.28)		23.5 %	0.33 [-0.38, 1.05]
Mortberg 2007a	67	-10.42 (7.096)	33	-12.3 (8)		68.3 %	0.25 [-0.17, 0.67]
Total (95% CI)	**87**		**56**			**100.0 %**	**0.32 [-0.02, 0.67]**

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.90$, df = 2 (P = 0.64); $I^2 = 0.0\%$

Test for overall effect: Z = 1.82 (P = 0.068)

Test for subgroup differences: Not applicable



Analysis 1.7. Comparison 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List, Outcome 7 Reduction in Social Anxiety Symptoms at Follow-Up.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List

Outcome: 7 Reduction in Social Anxiety Symptoms at Follow-Up

Study or subgroup	CBT N	Mean(SD)	WL/TAU N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Mortberg 2007a	67	33.45 (16.09)	33	39.4 (19.8)		62.3 %	-0.34 [-0.76, 0.08]
Stangier 2003	39	34.91 (13.51)	20	36.8 (11)		37.7 %	-0.15 [-0.69, 0.39]
Total (95% CI)	**106**		**53**			**100.0 %**	**-0.27 [-0.60, 0.06]**

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.31$, df = 1 (P = 0.58); $I^2 = 0.0\%$

Test for overall effect: Z = 1.58 (P = 0.11)

Test for subgroup differences: Not applicable

Analysis 1.8. Comparison 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List, Outcome 8 Reduction in Depression Symptoms at Follow-Up.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List

Outcome: 8 Reduction in Depression Symptoms at Follow-Up

Study or subgroup	CBT N	Mean(SD)	WL/TAU N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Mortberg 2007a	67	7.511 (8.76)	33	12.7 (10.8)		62.4 %	-0.54 [-0.97, -0.12]
Stangier 2003	39	10.58 (8.44)	20	14.7 (9.5)		37.6 %	-0.46 [-1.01, 0.08]
Total (95% CI)	**106**		**53**			**100.0 %**	**-0.51 [-0.85, -0.18]**

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.05$, df = 1 (P = 0.82); $I^2 = 0.0\%$

Test for overall effect: Z = 3.00 (P = 0.0027)

Test for subgroup differences: Not applicable

Analysis 1.9. Comparison 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List, Outcome 9 Quality of Life at Follow-Up.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 1 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List

Outcome: 9 Quality of Life at Follow-Up

Study or subgroup	CBT N	Mean(SD)	WL/TAU N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Mortberg 2007a	67	-9.06 (7.701)	33	-10.8 (8.3)		100.0 %	0.22 [-0.20, 0.64]
Total (95% CI)	**67**		**33**			**100.0 %**	**0.22 [-0.20, 0.64]**

Heterogeneity: not applicable

Test for overall effect: Z = 1.02 (P = 0.31)

Test for subgroup differences: Not applicable

Analysis 2.1. Comparison 2 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analyses (Individual versus Group Treatments), Outcome 1 Reduction in Social Anxiety Symptoms at Post-Treatment.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 2 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analyses (Individual versus Group Treatments)

Outcome: 1 Reduction in Social Anxiety Symptoms at Post-Treatment

Study or subgroup	CBT N	Mean(SD)	WL/TAU N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Std. Mean Difference IV,Random,95% CI
1 Individual Treatment						
Clark 2006a	21	18.19 (10.01)	20	46.25 (13.23)		-2.35 [-3.17, -1.54]
Furmark 2002	6	13 (10.469)	6	29.67 (5.82)		0.0 [0.0, 0.0]
Ledley 2009	14	29.57 (8.26)	16	44.19 (14.84)		-1.16 [-1.95, -0.38]
Mortberg 2007a	67	37.23 (16.09)	33	40.8 (17.6)		0.0 [0.0, 0.0]
Pishyar 2008	16	22.9 (8.9)	16	53 (8.6)		0.0 [0.0, 0.0]
Rapee 2007	59	44.333 (15.047)	52	54.42 (13.508)		0.0 [0.0, 0.0]
Robillard 2010	30	49.036 (20.96)	15	77.93 (22.23)		-1.33 [-2.01, -0.64]
Stangier 2003	44	37.25 (13.54)	21	36 (7.9)		0.0 [0.0, 0.0]
Stangier 2011	38	51.2 (20.61)	41	69.19 (28.26)		-0.72 [-1.17, -0.26]
Wong 2006	17	50.3 (21.4)	17	68.6 (17.9)		0.0 [0.0, 0.0]
Subtotal (95% CI)	**103**		**92**			**-1.34 [-2.01, -0.67]**
Heterogeneity: Tau^2 = 0.35; Chi^2 = 12.14, df = 3 (P = 0.01); I^2 =75%						
Test for overall effect: Z = 3.92 (P = 0.000089)						
2 Group Treatments						
Alden 2011	27	34.93 (12.18)	23	54.32 (10)		-1.70 [-2.35, -1.04]
Furmark 2002	6	13 (10.469)	6	29.67 (5.82)		-1.82 [-3.25, -0.38]
Pishyar 2008	16	22.9 (8.9)	16	53 (8.6)		-3.35 [-4.47, -2.23]
Rapee 2007	59	44.333 (15.047)	52	54.42 (13.508)		-0.70 [-1.08, -0.31]
Wong 2006	17	50.3 (21.4)	17	68.6 (17.9)		-0.91 [-1.62, -0.20]
Subtotal (95% CI)	**125**		**114**			**-1.59 [-2.40, -0.77]**
Heterogeneity: Tau^2 = 0.67; Chi^2 = 24.19, df = 4 (P = 0.00007); I^2 =83%						
Test for overall effect: Z = 3.81 (P = 0.00014)						
Total (95% CI)	**228**		**206**			**-1.45 [-1.93, -0.96]**
Heterogeneity: Tau^2 = 0.40; Chi^2 = 36.35, df = 8 (P = 0.00002); I^2 =78%						
Test for overall effect: Z = 5.84 (P < 0.00001)						
Test for subgroup differences: Chi^2 = 0.21, df = 1 (P = 0.65), I^2 =0.0%						

Analysis 2.2. Comparison 2 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analyses (Individual versus Group Treatments), Outcome 2 Attrition at Post-Treatment.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 2 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analyses (Individual versus Group Treatments)

Outcome: 2 Attrition at Post-Treatment

Study or subgroup	CBT n/N	WL/TAU n/N	Risk Ratio M-H,Random,95% CI	Risk Ratio M-H,Random,95% CI
1 Individual Treatment				
Alden 2011	4/31	2/25		0.0 [0.0, 0.0]
Clark 2006a	0/21	0/20		0.0 [0.0, 0.0]
Furmark 2002	0/6	0/6		0.0 [0.0, 0.0]
Ledley 2009	2/16	6/22		0.46 [0.11, 1.98]
Mortberg 2007a	14/67	15/33		0.0 [0.0, 0.0]
Pishyar 2008	0/16	0/16		0.0 [0.0, 0.0]
Rapee 2007	14/59	10/52		0.0 [0.0, 0.0]
Stangier 2003	6/50	0/21		0.0 [0.0, 0.0]
Stangier 2011	7/38	2/41		3.78 [0.84, 17.06]
Wong 2006	0/17	0/17		0.0 [0.0, 0.0]
Subtotal (95% CI)	**75**	**83**		**1.31 [0.16, 10.36]**
Total events: 47 (CBT), 35 (WL/TAU)				
Heterogeneity: Tau^2 = 1.66; Chi^2 = 3.88, df = 1 (P = 0.05); I^2 =74%				
Test for overall effect: Z = 0.25 (P = 0.80)				
2 Group Treatment				
Alden 2011	4/31	2/25		1.61 [0.32, 8.10]
Furmark 2002	0/6	0/6		0.0 [0.0, 0.0]
Pishyar 2008	0/16	0/16		0.0 [0.0, 0.0]
Rapee 2007	14/59	10/52		1.23 [0.60, 2.54]
Wong 2006	0/17	0/17		0.0 [0.0, 0.0]
Subtotal (95% CI)	**129**	**116**		**1.29 [0.67, 2.49]**
Total events: 18 (CBT), 12 (WL/TAU)				
Heterogeneity: Tau^2 = 0.0; Chi^2 = 0.09, df = 1 (P = 0.77); I^2 =0.0%				
Test for overall effect: Z = 0.76 (P = 0.45)				
Total (95% CI)	**204**	**199**		**1.31 [0.65, 2.64]**
Total events: 27 (CBT), 20 (WL/TAU)				

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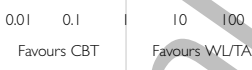
Study or subgroup	CBT n/N	WL/TAU n/N	Risk Ratio M-H,Random,95% CI	Risk Ratio M-H,Random,95% CI
Heterogeneity: Tau^2 = 0.13; Chi^2 = 3.96, df = 3 (P = 0.27); I^2 =24%				
Test for overall effect: Z = 0.74 (P = 0.46)				
Test for subgroup differences: Chi^2 = 0.00, df = 1 (P = 0.99), I^2 =0.0%				



Analysis 2.3. Comparison 2 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analyses (Individual versus Group Treatments), Outcome 3 Reduction in Depression Symptoms at Post-Treatment.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 2 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analyses (Individual versus Group Treatments)

Outcome: 3 Reduction in Depression Symptoms at Post-Treatment

Study or subgroup	CBT N	CBT Mean(SD)	WL/TAU N	WL/TAU Mean(SD)	Std. Mean Difference IV,Random,95% CI	Std. Mean Difference IV,Random,95% CI
1 Individual treatment						
Clark 2006a	21	2.57 (3.93)	20	10.25 (6.21)		-1.46 [-2.15, -0.76]
Mortberg 2007a	67	8.394 (8.2172)	33	13 (10.1)		0.0 [0.0, 0.0]
Pishyar 2008	16	7.4 (3.8)	16	21.2 (5.7)		0.0 [0.0, 0.0]
Robillard 2010	16	7.75 (9.16)	15	16.13 (13.33)		-0.72 [-1.45, 0.01]
Stangier 2003	44	12.4 (9.199)	21	13.3 (7.8)		0.0 [0.0, 0.0]
Stangier 2011	38	5.43 (5.74)	41	8.03 (6.13)		-0.43 [-0.88, 0.01]
Wong 2006	17	151.6 (15.9)	17	167.1 (29)		0.0 [0.0, 0.0]
Subtotal (95% CI)	**75**		**76**			**-0.83 [-1.44, -0.22]**
Heterogeneity: Tau^2 = 0.19; Chi^2 = 5.89, df = 2 (P = 0.05); I^2 =66%						
Test for overall effect: Z = 2.66 (P = 0.0078)						
2 Group treatment						
Pishyar 2008	16	7.4 (3.8)	16	21.2 (5.7)		-2.78 [-3.78, -1.77]

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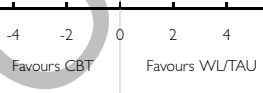
Study or subgroup	CBT N	Mean(SD)	WL/TAU N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Std. Mean Difference IV,Random,95% CI
Wong 2006	17	151.6 (15.9)	17	167.1 (29)		-0.65 [-1.34, 0.04]
Subtotal (95% CI)	**33**		**33**			**-1.68 [-3.77, 0.41]**
Heterogeneity: Tau^2 = 2.07; Chi^2 = 11.72, df = 1 (P = 0.00062); I^2 =91%						
Test for overall effect: Z = 1.58 (P = 0.11)						
Total (95% CI)	**108**		**109**			**-1.13 [-1.82, -0.43]**
Heterogeneity: Tau^2 = 0.49; Chi^2 = 20.82, df = 4 (P = 0.00034); I^2 =81%						
Test for overall effect: Z = 3.19 (P = 0.0014)						
Test for subgroup differences: Chi^2 = 0.59, df = 1 (P = 0.44), I^2 =0.0%						



Analysis 3.1. Comparison 3 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analyses - SAnD Diagnosis (<80% Generalised SAnD versus >80% Generalised SAnD Samples), Outcome 1 Reduction in Social Anxiety Symptoms at Post-Treatment.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 3 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analyses - SAnD Diagnosis (<80% Generalised SAnD versus >80% Generalised SAnD Samples)

Outcome: 1 Reduction in Social Anxiety Symptoms at Post-Treatment

Study or subgroup	CBT N	Mean(SD)	WL/TAU N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Std. Mean Difference IV,Random,95% CI
1 <80% Generalised SAnD						
Clark 2006a	21	18.19 (10.01)	20	46.25 (13.23)		0.0 [0.0, 0.0]
Furmark 2002	6	13 (10.469)	6	29.67 (5.82)		-1.82 [-3.25, -0.38]
Ledley 2009	14	29.57 (8.26)	16	44.19 (14.84)		0.0 [0.0, 0.0]
Pishyar 2008	16	22.9 (8.9)	16	53 (8.6)		0.0 [0.0, 0.0]
Rapee 2007	59	44.333 (15.047)	52	54.42 (13.508)		0.0 [0.0, 0.0]
Robillard 2010	30	49.036 (20.96)	15	77.93 (22.23)		0.0 [0.0, 0.0]
Stangier 2003	44	37.25 (13.54)	21	36 (7.9)		0.0 [0.0, 0.0]
Stangier 2011	38	51.2 (20.61)	41	69.19 (28.26)		-0.72 [-1.17, -0.26]
Wong 2006	17	50.3 (21.4)	17	68.6 (17.9)		0.0 [0.0, 0.0]
Subtotal (95% CI)	**44**		**47**			**-1.05 [-2.03, -0.06]**
Heterogeneity: Tau² = 0.31; Chi² = 2.05, df = 1 (P = 0.15); I² =51%						
Test for overall effect: Z = 2.07 (P = 0.038)						
2 >80 Generalised SAnD						
Alden 2011	27	34.93 (12.18)	23	54.32 (10)		-1.70 [-2.35, -1.04]
Clark 2006a	21	18.19 (10.01)	20	46.25 (13.23)		-2.35 [-3.17, -1.54]
Ledley 2009	14	29.57 (8.26)	16	44.19 (14.84)		-1.16 [-1.95, -0.38]
Mortberg 2007a	67	37.23 (16.09)	33	40.8 (17.6)		-0.21 [-0.63, 0.20]
Rapee 2007	59	44.333 (15.047)	52	54.42 (13.508)		-0.70 [-1.08, -0.31]
Robillard 2010	30	49.036 (20.96)	15	77.93 (22.23)		-1.33 [-2.01, -0.64]
Subtotal (95% CI)	**218**		**159**			**-1.19 [-1.78, -0.60]**
Heterogeneity: Tau² = 0.44; Chi² = 31.33, df = 5 (P<0.00001); I² =84%						
Test for overall effect: Z = 3.94 (P = 0.000082)						
Test for subgroup differences: Chi² = 0.06, df = 1 (P = 0.81), I² =0.0%						

Analysis 3.2. Comparison 3 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analyses - SAnD Diagnosis (<80% Generalised SAnD versus >80% Generalised SAnD Samples), Outcome 2 Attrition at Post-Treatment.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

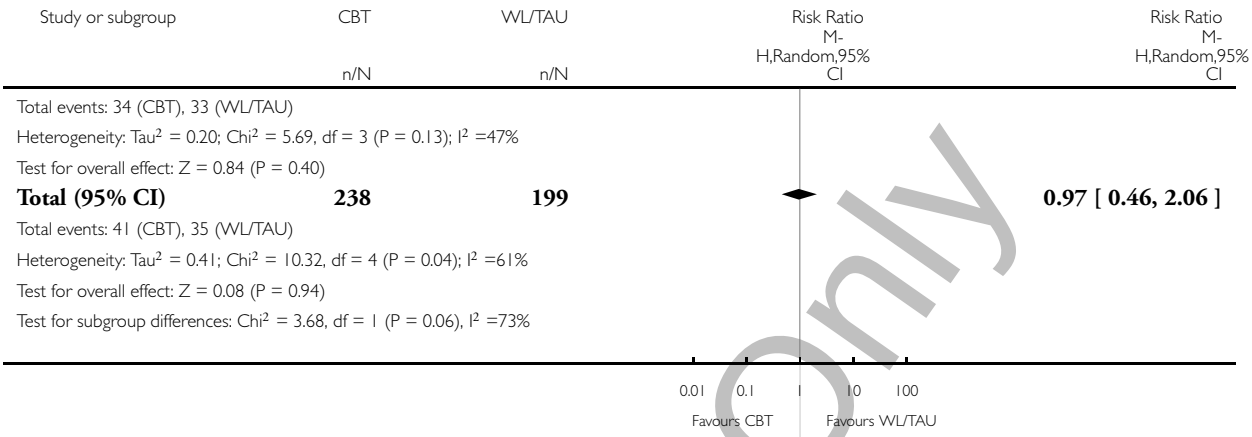
Comparison: 3 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analyses - SAnD Diagnosis (<80% Generalised SAnD versus >80% Generalised SAnD Samples)

Outcome: 2 Attrition at Post-Treatment

Study or subgroup	CBT n/N	WL/TAU n/N	Risk Ratio M-H,Random,95% CI	Risk Ratio M-H,Random,95% CI
1 <80% Generalised SAnD				
Alden 2011	4/31	2/25		0.0 [0.0, 0.0]
Clark 2006a	0/21	0/20		0.0 [0.0, 0.0]
Furmark 2002	0/6	0/6		0.0 [0.0, 0.0]
Ledley 2009	2/16	6/22		0.0 [0.0, 0.0]
Mortberg 2007a	14/67	15/33		0.0 [0.0, 0.0]
Pishyar 2008	0/16	0/16		0.0 [0.0, 0.0]
Rapee 2007	14/59	10/52		0.0 [0.0, 0.0]
Stangier 2003	6/50	0/21		0.0 [0.0, 0.0]
Stangier 2011	7/38	2/41		3.78 [0.84, 17.06]
Wong 2006	0/17	0/17		0.0 [0.0, 0.0]
Subtotal (95% CI)	**44**	**47**		**3.78 [0.84, 17.06]**
Total events: 47 (CBT), 35 (WL/TAU)				
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.0$, df = 0 (P = 1.00); $I^2 = 0.0\%$				
Test for overall effect: Z = 1.73 (P = 0.084)				
2 >80 Generalised SAnD				
Alden 2011	4/31	2/25		1.61 [0.32, 8.10]
Clark 2006a	0/21	0/20		0.0 [0.0, 0.0]
Furmark 2002	0/6	0/6		0.0 [0.0, 0.0]
Ledley 2009	2/16	6/22		0.46 [0.11, 1.98]
Mortberg 2007a	14/67	15/33		0.46 [0.25, 0.84]
Pishyar 2008	0/16	0/16		0.0 [0.0, 0.0]
Rapee 2007	14/59	10/52		1.23 [0.60, 2.54]
Wong 2006	0/17	0/17		0.0 [0.0, 0.0]
Subtotal (95% CI)	**194**	**152**		**0.75 [0.39, 1.46]**

(*Continued . . .*)

(. . . *Continued*)

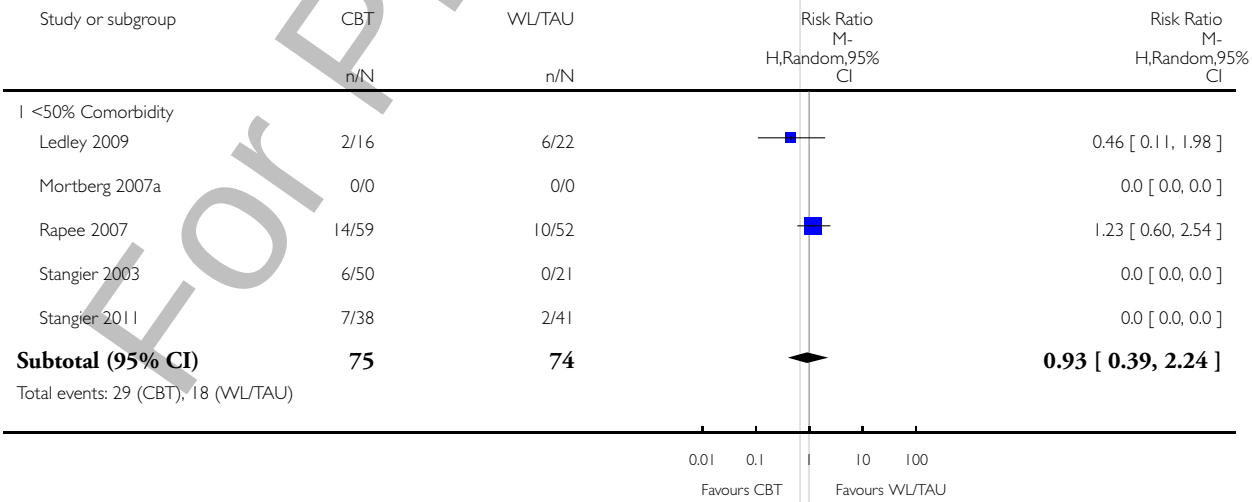


Analysis 4.1. Comparison 4 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analysis - Common Mental Health Comorbidity (<50% in the Sample versus >50% in the Sample), Outcome 1 Attrition.

Review: Cognitive Behavioural Therapies for Social Anxiety Disorder (SAnD)

Comparison: 4 Cognitive Behavioural Therapies versus Treatment as Usual/Waiting List: Subgroup Analysis - Common Mental Health Comorbidity (<50% in the Sample versus >50% in the Sample)

Outcome: 1 Attrition



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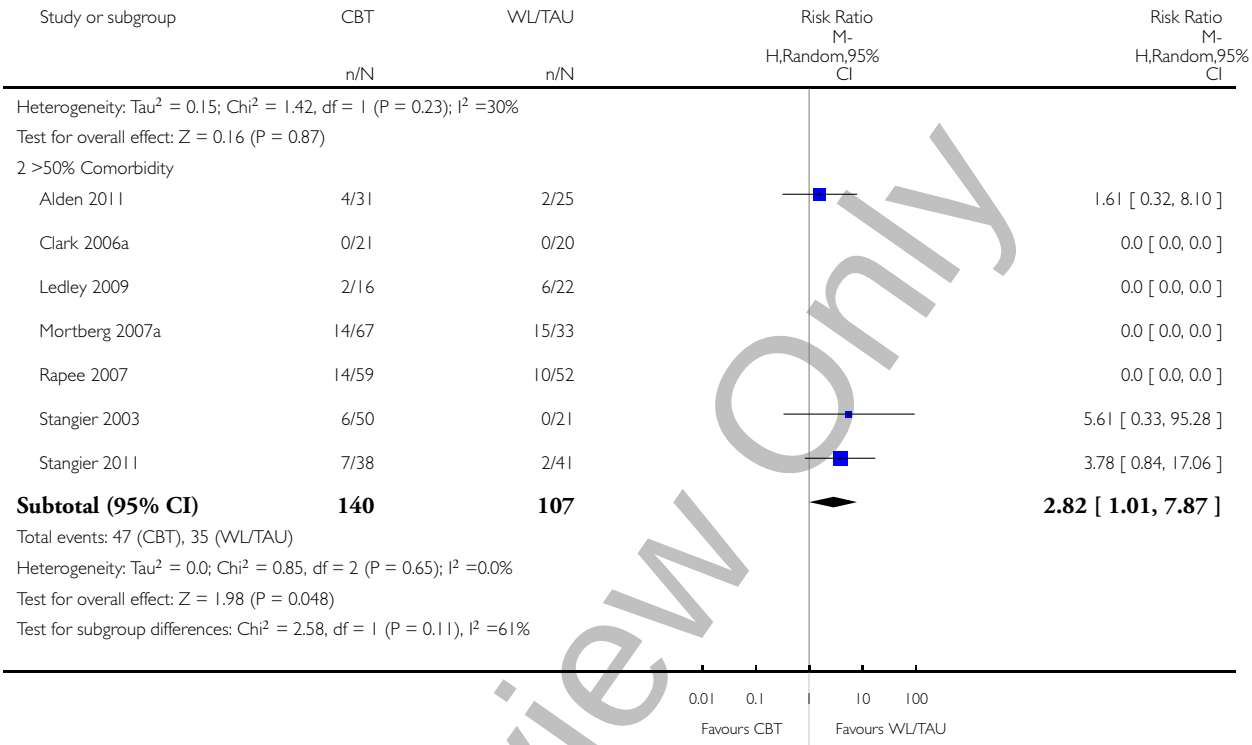

ADDITIONAL TABLES

Table 1. Sensitivity Analyses

Outcome	Blinding	Allocation concealment	Attrition exceeding 20%	Fidelity	Fixed-effects model	Social anxiety disorder diagnosis (non-structured clinical interview)	Exclusion of Alden 2011
Clinical response at post-treatment	RE, RR 4.03 (95% CI 0.89 to 18.31)	RE, RR 8.18 (CI 1.79, 37.37)	RE, RR 8.18 95% (CI 1.79, 37.37)	RE, RR 3.24 95% (CI 1.92 to 5.44)	RE, SMD -0.91 95% (CI -1.39 to -0.43)		
Reduction in social	RR, SMD 1.12 (95% CI -1.65 to -0.59)	RE, SMD -1.05 (CI -1.85, -0.24)	RE, SMD -1.27 95% (CI -1.89 to -0.65)	RE, SMD -0.84, 95% (CI -1.01 to -0.66)	RE, SMD -0.59 95% (CI -0.97 to -0.21)	RE, SMD -0.91 95% (CI -1.39 to -0.43)	RE, SMD -1.25 95% (CI -1.80, -0.70)

Table 1. Sensitivity Analyses (*Continued*)

anxiety symptoms at post-treatment							
Attrition at post-treatment	RE, RR 0.83 (95% CI 0.24 to 2.95)	RE, RR 4.12 95% (CI 1.09 to 15.60)	RR 4.12, 95% (CI 1.09 to 15.60)				RE, RR 1.04 95% (CI 0.44, 2.46)
Reduction in depression symptoms at post-treatment	RE, SMD -0.69 (95% CI -1.01 to -0.36)	RE, SMD -0.62 (95% CI -1.14 to -0.10)	RE, SMD -0.62, 95% (CI -1.14 to -0.10)			RE, SMD -0.59, 95% (CI -0.97 to -0.21)	
Clinical Global Impression Improvement Scale at post-treatment		RE, RR 8.99 (95% CI 2.95, 27.37)	RE, RR 8.99 95% (CI 2.95 to 27.37)				
Quality of life at post-treatment		RE, SMD 0.87 95% (CI -0.34 to 2.08)	RE, SMD 0.87 95% (CI -0.34 to 2.08)				

APPENDICES

Appendix 1. Electronic searches extended details

The Cochrane Depression, Anxiety and Neurosis Group (CCDAN) maintain two clinical trials registers at their editorial base in Bristol, UK, a references register and a studies based register. The CCDANCTR-References Register contains over 30,000 reports of trials in depression, anxiety and neurosis. Approximately 60% of these references have been tagged to individual, coded trials. The coded trials are held in the CCDANCTR-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. Please contact the CCDAN Trials Search Coordinator for further details. Reports of trials for inclusion in the Group's registers are collated from routine (weekly), generic searches of MEDLINE (1950-), EMBASE (1974-) and PsycINFO (1967-); quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL) and review specific searches of additional databases. Reports of trials are also sourced from international trials registers c/o the World Health Organisation's trials portal (ICTRP), ClinicalTrials.gov, drug companies, the hand-searching of key journals, conference proceedings and other (non-Cochrane) systematic reviews and meta-analyses. Details of CCDAN's generic search strategies can be found on the group's website.

1. CCDANCTR-Studies Register

The CCDANCTR-Studies Register was searched using the following terms:
Condition = ("social anxiety" or "social phobia") and Intervention = (*therap* or train* or cousel*)
Additional study records, identified by condition alone, were manually screened for any other non-pharma trials, to ensure no studies have been missed.
No date, language or age group restrictions will be applied (125 studies (176 references) were retrieved).

2. CCDANCTR-References Register

The CCDANCTR-References Register was searched (316 additional references were retrieved) using a more sensitive set of free-text terms to identify additional untagged/uncoded references: ((social* and (phobi* or fear*)) or "social anxi*" or "socially anxious" or "social-evaluative anxiety" or "social inhib*" or "social stress*" or "socially stress*" or heterosocial* or "taijin kyofusho") + CCDAN's psychotherapy search strategy (Table 2 below):

Table 2. CCDANCTR-References Register Search Criteria

1	*Title/Abstract*= therap* or psychotherap*
2	*Keywords* = psychotherapy
3	*Free-Text* = acceptance* or commitment* or "activity scheduling" or adlerian or art or aversion or behavio* or brief or "client cent*" or cognitive or color or colour or compassion-focused or "compassion focus*" or compassionate or conjoint or conversion or conversational or couples or dance or dialectic* or diffusion or distraction or eclectic or (emotion and focus*) or emotion-focus* or existential or experiential or exposure or expressive or family or focus-oriented or "focus oriented" or freudian or gestalt or "group" or humanistic or implosive or insight or integrative or interpersonal or jungian or kleinian or logo or marital or metacognitive or meta-cognitive or milieu or morita or multimodal or multi-modal or music or narrative or nondirective or non-directive or "non directive" or nonspecific or non-specific or "non specific" or "object relations" or "personal construct" or "person cent*" or person-cent* or persuasion or play or ((pleasant or pleasing) and event*) or primal or problem-focused or "problem focused" or problem-solving or "problem solving" or process-experiential or "process experiential" or psychodynamic or "rational emotive" or reality or "reciprocal inhibition" or relationship* or reminiscence or restructuring or rogerian or schema* or self-control* or "self control*" or "short term" or short-term or sex or "social effectiveness" or "social skill*" or socio-environment* or "socio environment*" or "solution focused" or solution-focused or "stress management" or supportive or time-limited or "time limited" or "third wave" or transference or transtheoretical or validation
4	*Free-Text* = abreaction or "acting out" or "age regression" or ((assertive* or autogenic or mind or sensitivity) and train*) or autosuggestion or "balint group" or ((behavior* or behaviour*) and (activation or therap* or treatment or contracting or modification)) or biofeedback or catharsis or cognitive or "mind training" or counsel* or "contingency management" or countertransference or "covert sensitization" or "eye movement desensiti*" or "crisis intervention" or "dream analysis" or "emotional freedom" or "free association" or "functional analys*" or griefwork or "guided imagery" or hypno* or imagery or meditation* or "mental healing" or mindfulness* or psychoanaly* or psychodrama or psychoeducat* or "psychological support*" or "psychosocial support*" or "social support*" or "family support*" or psychotherap* or relaxation or "role play*" or "self analysis" or "self esteem" or "sensitivity training" or (support* and group*) or therapist or "therapeutic technique*" or "transactional analysis"
5	((1 or 2) and 3) or 4

3. Cumulative Index to Nursing and Allied Health (CINAHL)

CINAHL (Cumulative Index to Nursing & Allied Health), was searched (1982 to 2012-08-22), using the following terms:
S1 MH "Social Anxiety Disorders"
S2 (social* N1 anxi*): TI, AB

S3 (social* N2 phobi*): TI, AB
S4 (S1 or S2 or S3)
S5 (MH “Quantitative Studies”)
S6 (MH ”Clinical Trials+“)
S7 (MH ”Random Assignment“)
S8 PT Cinical Trial
S9 TI Trial OR AB Trial
S10 TI ((singl* or doubl* or trebl* or tripl*) and (blind* or dummy or mask))
S11 AB ((singl* or doubl* or trebl* or tripl*) and (blind* or dummy or mask))
S12 TX (randomi?ed)
S13 TX (random* and (allocat* or assign*))
S14 TX (control* N1 trial* or control*N1 stud* or control N1 group*)
S15 (S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14)
S15 (S4 and S14)
(168 studies were received)

4. International Trial Registers

The WHO Trials Portal (ICTRP) and ClinicalTrials.gov was searched for additional unpublished and/or ongoing studies

Appendix 2. Searching other sources extended details

1) Reference lists

The reference lists of reports of all relevant studies will be screened to identify additional research. Relevant review papers will also be checked.

2) Cited reference search

A cited reference search will be conducted on the Web of Science to identify articles citing any of the included studies.

3) Personal communication

Subject experts and authors of all identified RCTs will be contacted to ensure that all known, relevant studies, either published or unpublished, have been considered for inclusion.

Appendix 3. Cluster-randomised trials ’effective sample size’ extended details

The effective sample size of a single intervention cluster in a cluster-randomized trial is the initial sample size divided by an estimate known as the ‘design effect’ (Higgins 2011). The design effect is 1 + (M - 1) ICC, where M is the average cluster size and ICC is the intracluster correlation coefficient (Higgins 2008). A design effect is assumed as similar across intervention clusters. The number of participants and the number experiencing the event will be divided by the same design effect for dichotomous data. This approach may be unsuitable for small trials because the resulting data must be rounded to whole numbers for entry into RevMan. In contrast, only the sample size needs to be reduced for continuous data; means and standard deviations will remain unchanged.

Appendix 4. Heterogeneity extended details

The ranges for interpreting I^2 are:

- 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.

Note that the importance of the observed value of I^2 depends on (1) magnitude and direction of effects and (2) strength of evidence for heterogeneity (e.g. p-value from the chi^2 test, or a confidence interval for I^2.

Appendix 5. Summary of findings table key information

Each SOF table will provide key information concerning the following seven elements:

1. Title and header

The title of each 'Summary of findings' table will outline the clinical question, and specify the population (e.g. individuals with SAnD) and the interventions being compared (e.g. CBT versus TAU). The first rows of each SOF table will describe:

Patients or population:

Further clarity about the population (and sub-populations) of interest and details concerning 'Low', 'Medium' and 'High' risk populations will be provided.

Setting:

The specific characteristics of the settings in which the studies were carried out, which might limit the applicability of the summary of findings to other settings.

Intervention:

The experimental intervention (e.g. CBT).

Comparison:

The control (comparison) intervention (e.g. TAU).

2. Outcomes

The following outcomes will be listed in the summary of findings table:
1. Treatment response, clinically significant change, according DSM-III-R, to DSM-IV-TR (APA 1987; APA 1994; APA 2000) or ICD-10 (WHO 1992).
2. Reduction in social anxiety symptoms measured using a validated continuous scale.
3. Treatment acceptability (attrition), measured by the overall number of people dropping out of post-randomisation and over the course of the trials
4. Reduction in depression symptoms, using validated observer-rated scales for depression such as the Hamilton Rating Scale for Depression (Hamilton 1960) or self-report scales such as the Beck Depression Inventory (Beck 1987).

3 Illustrative comparative risks

Assumed risk:

Up to three typical risks for participants receiving the control intervention will be described. This will be presented as the number of people experiencing the event per 1000 people (natural frequency). A footnote will specify the source or rationale for each control group risk, including the time period to which it corresponds, where appropriate.

Corresponding risk:

The risk for participants receiving the experimental intervention. Absolute risk will be presented for dichotomous outcomes. A difference in means or standardized difference in means will be presented with its confidence interval for continuous outcomes as well as converted to units of the Beck Depression Inventory (Beck 1987) for ease of interpretation.

4 Relative effect (95% confidence interval)

A measure of relative effect, typically risk ratio or odds ratio with its accompanying 95% confidence interval will be presented.

5. Number of participants

The number of participants assessed in the included studies for each outcome and the corresponding number of studies that contributed these participants.

6 Quality of the Evidence (GRADE)

A rating of the overall quality of the evidence for each outcome measure will be reported, 'High', 'Moderate', 'Low', or 'Very Low'. For example, the quality for an outcome measure would be 'High' if the summary is of several randomised trials with low risk of bias. This judgement process operates within a transparent structure using the specific evidence grading system developed by the GRADE collaboration (GRADE Working Group 2004). Judgments other than of 'High' quality will be clarified using footnotes or the Comments column (see below).

7 Comments

This section will provide additional comments to help interpret the information or data identified in the above sections, including important caveats about the results.

Appendix 6. Further recommendations for future studies

Given clinical guidelines in Canada recommend CBT as a first-line treatment for SAnD (Swinson 2006) and the UK Governments directive for an additional 10,000 psychological therapists to be trained in CBT and/or evidence-based therapies (Layard 2004), further research on the effectiveness of non-CBT models, and the comparative effectiveness of CBT and non-CBT treatments for SAnD is imperative. To enhance the internal validity of future studies include the recruitment of larger appropriately powered samples, the use of TAU control conditions rather than WL, adequate allocation concealment, testing of blind for assessors, measurement of treatment adherence and measurement of adverse effects, long-term follow-up assessments, cost-effectiveness outcomes, and process outcomes such as strength of therapeutic alliance.

Appendix 7. Dissemination Plan and Instructions for Authors (Cochrane Handbook; Higgins, & Green, 2011)

Dissemination plan

- The protocol for the current review (i.e. the template for the review; Background and Methods sections) is currently under peer review and, following any necessary revisions, will be published in the Cochrane Library.

- It is hoped that the current review will be published in the Cochrane Library in its current form in the first instance, although there are plans to expand the scope in the future to a review of *All Psychological Therapies for SAnD*.

- If the publication with the Cochrane Library were achieved it is hoped that the findings of this review will help guide health care policy and guideline development as well as supporting patient/clinician treatment decision-making around the management of social anxiety disorder.

A.5 Main text

The text of the review should be succinct and readable. Although there is no formal word limit for Cochrane reviews, review authors should consider 10,000 words an absolute maximum unless there is special reason to write a longer review. Most reviews should be substantially shorter than this. A review should be written so that someone who is not an expert in the area can understand it, in light of the following policy statement, stated in the Cochrane Manual (The Cochrane Collaboration 2007):

"Cochrane reviews should be written so that they are easy to read and understand by someone with a basic sense of the topic who may not necessarily be an expert in the area. Some explanation of terms and concepts is likely to be helpful, and perhaps even essential. However, too much explanation can detract from the readability of a review. Simplicity and clarity are also vital to readability. The readability of Cochrane reviews should be comparable to that of a well written article in a general medical journal."

The text of a Cochrane review contains a number of fixed headings that are embedded in RevMan. Subheadings may be added by the author at any point. Certain specific subheadings are recommended for use by all authors, but are not mandatory and should be avoided if they make individual sections needlessly short. Further subheadings that may or may not be relevant to a particular review are also discussed below.

Some headings are followed by fixed subheadings and therefore have no free text immediately following them: 'Methods', 'Criteria for including studies', 'Results', and 'Authors' conclusions'.

Background

[fixed, level 1 heading]

Well-formulated review questions occur in the context of an already-formed body of knowledge. The background should address this context, help set the rationale for the review, and explain why the questions being asked are important. It should be concise (generally around one page when printed) and be understandable to the users of the methodology under investigation. All sources of information should be cited.

Description of the problem or issue

[recommended, level 2 heading]

The review should begin with a brief description of the methodology being investigated and its significance. It may include information about how common the methodology is in evaluations of health care.

Description of the methods being investigated

[recommended, level 2 heading]

A description of the methods being investigated should place it in the context of any standard, or alternative methods in common use.

How these methods might work

[recommended, level 2 heading]

This section might describe the theoretical reasoning why the methods under review may have an impact in evaluations of health care. Authors may refer to a body of empirical evidence such as similar methods having an impact or identical methods having an impact in other settings. Authors may also refer to a body of literature that justifies the possible impact of the methods.

Why it is important to do this review

[recommended, level 2 heading]

The background should clearly state the rationale for the review and should explain why the questions being asked are important. It might also mention why this review was undertaken and how it might relate to a wider review of a general problem. If this version of the review is an update of an earlier one, it is helpful to state this by writing, for example "This is an update of a Cochrane review first published in YEAR, and previously updated in YEAR". This may be supplemented with a brief description of the main findings of the earlier versions, with a statement of any specific reasons there may be for updating the review.

Objectives

[fixed, level 1 heading]

This should begin with a precise statement of the primary objective of the review, ideally in a single sentence. This might be followed by a series of specific objectives relating to different types of healthcare evaluation or different settings.

Methods

[fixed, level 1 heading]

The Methods section in a protocol should be written in the future tense. Because Cochrane reviews are updated as new evidence accumulates, methods outlined in the protocol should generally be written as if a suitably large number of studies will be identified to allow the objectives to be met (even if it is known this is not the case at the time of writing).

The Methods section in a review should be written in the past tense, and should describe what was done to obtain the *results and conclusions of the current review*. Often a review is unable to implement all of the methods outlined in the protocol, usually because there is insufficient evidence. In such circumstances, it is recommended that the methods that were not implemented be outlined in the section headed 'Differences between protocol and review' (see below), so that it serves as a protocol for future updates of the review.

Criteria for considering studies for this review

[fixed, level 2 heading]

Types of studies

[fixed, level 3 heading]

Eligible study designs should be stated here, along with any thresholds for inclusion based on the conduct of the studies or their risk of bias. For example, 'All randomized controlled comparisons of different methods' or 'All cohorts of clinical trials with prospective registration of the trials'.

Types of data

[fixed, level 3 heading]

The raw material for the methodology studies to be included in the review should be described here, including any restrictions on, for example, the characteristics of the raw material (such as limiting to randomised clinical trials only). Examples of 'Types of data' in Cochrane Methodology reviews are "healthcare trials, including trials of clinical interventions and non-clinical interventions where the effects of the intervention on one or more health outcomes were measured" and "biomedical sciences research studies". Subgroup analyses should not be listed here (see 'Subgroup analysis and investigation of heterogeneity' under 'Methods').

Types of methods

[fixed, level 3 heading]

The methods under investigation should be defined here, under separate subheadings if appropriate. It should be made clear which comparisons are of interest. An example of 'Types of methods' for a Cochrane Methodology review is "randomised trials with adequately versus inadequately concealed allocation". Subgroup analyses should not be listed here (see 'Subgroup analysis and investigation of heterogeneity' under 'Methods').

Types of outcome measures

[fixed, level 3 heading]

Note that outcome measures do not always form part of the criteria for including studies in a review. If they do not, then this should be made clear. Outcome measures of interest should be listed in this section whether or not they form part of the inclusion criteria. Examples of 'Types of outcome measures' in Cochrane Methodology reviews are "the magnitude and direction of estimates of effect (e.g.

relative risk reductions, odds ratios, standardised effect sizes) and imbalances in prognostic factors" and "subsequent full publication of the results described in the abstract and the time interval between presentation at meetings and subsequent publication".

Primary outcomes
[recommended, level 4 heading]
Primary outcomes should be as few as possible. It is normally expected that the review should be able to analyse these outcomes if eligible studies are identified, and that the conclusions of the review will be based in large part on the findings of the review for these outcomes.

Secondary outcomes
[recommended, level 4 heading]
Non-primary outcomes should be listed here. The total number of outcomes addressed should be kept as small as possible.

Search methods for identification of studies
[fixed, level 2 heading]
The methods used to identify studies should be summarized. The following headings are recommended. Before starting to develop this section, authors should contact the Cochrane Methodology Review Group for guidance.
See also
- Search methods are discussed in detail in Chapter 6 (Sections 6.3).

Electronic searches
[recommended, level 3 heading]
The bibliographic databases searched, the dates and periods searched and any constraints, such as language should be stated. The full search strategies for each database should be listed in an appendix to the review. If the Cochrane Methodology Register (CMR) is searched for the review, a standard description of this register can be referred to but information should be included on when and how the CMR was most recently searched for the current version of the review and the search terms used should be listed.
See also
- Search strategies are discussed in detail in Chapter 6 (Section 6.4).

Searching other resources
[recommended, level 3 heading]
List grey literature sources, such as internal reports and conference proceedings. If journals are specifically handsearched for the review, this should be noted but handsearching done by the authors to help build the Cochrane Methodology Register should not be listed because this is covered in the standardized description of the Register. List people (e.g. researchers or topic specialists) and organizations who were contacted. List any other sources used, which may include, for example, reference lists, the World Wide Web or personal collections of articles. The following *optional* headings may be used, either in place of 'Searching other resources' (in which case they would be level 3 headings) or as subheadings (level 4).
Grey literature
Handsearching
Reference lists
Correspondence

See also
- Other search resources are discussed in Chapter 6 (Section 6.2).

Data collection and analysis
[fixed, level 2 heading]
This should describe the methods for data collection and analysis.

Selection of studies
[recommended, level 3 heading]

The method used to apply the selection criteria. Whether they are applied independently by more than one author should be stated, along with how any disagreements are resolved.

See also

- Study selection is discussed in Chapter 7 (Section 7.2).

Data extraction and management

[recommended, level 3 heading]

The method used to extract or obtain data from published reports or from the original researchers (for example, using a data extraction/data collection form). Whether data are extracted independently by more than one author should be stated, along with how any disagreements are resolved. If relevant, methods for processing data in preparation for analysis should be described.

See also

- Data collection is discussed in Chapter 7, including which data to collect (Section 7.3), sources of data (Section 7.4), data collection forms (Section 7.5) and extracting data from reports (Section 7.6)

Assessment of risk of bias in included studies

[recommended, level 3 heading]

The method used to assess risk of bias (or methodological quality). Whether methods are applied independently by more than one author should be stated, along with how any disagreements are resolved. The tool(s) used should be described or referenced, with an indication of how the results are incorporated into the interpretation of the results.

Measures of the effect of methods

[recommended, level 3 heading]

The effect measures of choice should be stated. For example, odds ratio (OR), risk ratio (RR) or risk difference (RD) for dichotomous data; difference in means (MD) or standardized difference in means (SMD) for continuous data. The following *optional* headings may be used, either in place of 'Measures of treatment effect' (in which case they would be level 3 headings) or as subheadings (level 4):

Dichotomous data

Continuous data

Time-to-event data

Unit of analysis issues

[recommended, level 3 heading]

Special issues in the analysis of studies with non-standard designs, such as cross-over trials and cluster-randomized trials, should be described.

See also

- Unit of analysis issues are discussed in Chapter 9 (Section 9.3).
- Methods for cross-over trials, cluster-randomized trials and other non-standard designs are discussed in Chapter 16.

Dealing with missing data

[recommended, level 3 heading]

Strategies for dealing with missing data should be described. This will principally include missing information for methodology studies (for example the loss of trials from cohorts of trials), and missing statistics (such as standard deviations or correlation coefficients).

See also

- Issues relevant to missing data are discussed in Chapter 16 (Section 16.1).

Assessment of heterogeneity

[recommended, level 3 heading]

Approaches to addressing design heterogeneity among the methodology studies should be described, along with how the authors will determine whether a meta-analysis is considered appropriate. Methods for identifying statistical heterogeneity should be stated (for example, visually, using a chi-squared test, or using I^2).

See also

- Assessment of heterogeneity is discussed in Chapter 9 (Section 9.5).

Assessment of reporting biases
[recommended, level 3 heading]
How publication bias, and other reporting biases are addressed (for example, funnel plots, statistical tests, imputation). Authors should remember that asymmetric funnel plots are not necessarily caused by publication bias (and that publication bias does not necessarily cause asymmetry in a funnel plot).
See also
- Reporting biases are discussed in Chapter 10.

Data synthesis
[recommended, level 3 heading]
The choice of meta-analysis method should be stated, including whether a fixed-effect or a random-effects model is used. If meta-analyses are not undertaken, systematic approaches to synthesizing the findings of multiple studies should be described.
See also
- Meta-analysis and data synthesis are discussed in Chapter 9 (Section 9.4).

Subgroup analysis and investigation of heterogeneity
[recommended, level 3 heading]
All planned subgroup analyses should be listed (or independent variables for meta-regression). Any other methods for investigating heterogeneity of effects should be described.
See also
- Investigating heterogeneity is discussed in Chapter 9 (Section 9.6).

Sensitivity analysis
[recommended, level 3 heading]
This should describe analyses aimed at determining whether conclusions are robust to decisions made during the review process, such as inclusion/exclusion of particular studies from a meta-analysis, imputing missing data or choice of a method for analysis.
See also
- Sensitivity analysis is discussed in Chapter 9 (Section 9.7).

The following *optional* (level 3) heading for the Methods section may be helpful:
Methods for future updates

See also
- Issues in updating reviews are discussed in Chapter 3.

Results
[fixed, level 1 heading]
Description of studies
[fixed, level 2 heading]
Results of the search
[recommended, level 3 heading]
The results sections should start with a summary of the results of the search (for example, how many references were retrieved by the electronic searches).
See also
- Presentation of search findings is discussed in Chapter 6. (Section 6.6).

Included studies
[recommended, level 3 heading]

It is essential that the number of included studies is clearly stated. This section should comprise a succinct summary of the information contained in the 'Characteristics of included studies' table. An explicit reference to this table should be included. Key characteristics of the included studies should be described, including the methods, data (e.g. type of clinical trial in methodology study), comparisons and outcome measures in the included studies and any important differences among the studies. Authors should note any other characteristics of the studies that they regard as important for readers of the review to know. The following *optional* (level 4) subheadings may be helpful:

Design
Sample sizes
Setting
Methods
Outcomes

Excluded studies

[recommended, level 3 heading]

This should refer to the information contained in the 'Characteristics of excluded studies' table. An explicit reference to this table should be included. A succinct summary of why studies were excluded from the review should be provided.

The following *optional* (level 3) headings may be used in the 'Description of studies' section:

Ongoing studies
Studies awaiting classification
New studies found at this update

Risk of bias in included studies

[fixed, level 2 heading]

This should summarize the general risk of bias in results of the included studies, its variability across studies and any important flaws in individual studies. The criteria that were used to assess the risk of bias should be described or referenced under 'Methods' and not here. How each study was rated on each criterion should be reported in a 'risk of bias' table and not described in detail in the text, which should be a concise summary.

For large reviews, aspects of the risk of bias assessment may be summarized for the primary outcomes under the following headings.

Allocation

[recommended, level 3 heading]

A summary of how the methods being investigated were assigned in any comparative methodological studies in the review. Judgements concerning the risk of bias that may arise from this assignment should be summarized here.

Blinding

[recommended, level 3 heading]

A brief summary of who was blinded or masked during the conduct and analysis of the methodology studies should be reported here. Judgements concerning the risk of bias associated with blinding should be summarized here.

Follow up and exclusions

[recommended, level 3 heading]

The completeness of data should be summarized briefly here for each of the main outcomes.

Selective reporting

[recommended, level 3 heading]

Concerns over the selective availability of data should be summarized briefly here, including evidence of selective reporting of outcomes, subgroups or analyses.

Other potential sources of bias

[recommended, level 3 heading]

Any other potential concerns should be summarized here.

Effects of methods

[fixed, level 2 heading]

This should be a summary of the main findings on the effects of the methods studied in the review. The section should directly address the objectives of the review rather than list the findings of the included studies in turn. The results of individual studies, and any statistical summary of these, should be included in 'Data and analysis' tables. Outcomes should normally be addressed in the order in which they are listed under 'Types of outcome measures'. Subheadings are encouraged if they make understanding easier (for example, for each different data, comparison or outcome measure if a review addresses more than one). Any sensitivity analyses that were undertaken should be reported. Authors should avoid making inferences in this section.

See also

- Presentation of results is addressed in Chapter 11 (Section 11.7).
- Interpretation of numerical results is discussed in Chapter 12 (Sections 12.4, 12.5 and 12.6).

Discussion

[fixed, level 1 heading]

A structured discussion can aid the consideration of the implications of the review (Docherty 1999).

See also

- Interpretation of results is discussed in Chapter 12.

Summary of main results

[recommended, level 2 heading]

Summarize the main findings (without repeating the 'Effects of methods' section) and outstanding uncertainties, balancing important benefits against important harms. Refer explicitly to any 'Summary of findings' tables.

Overall completeness and applicability of evidence

[recommended, level 2 heading]

Describe the relevance of the evidence to the review question. This should lead to an overall judgement of the external validity of the review. Are the studies identified sufficient to address all of the objectives of the review? Have all relevant types of data, methods and outcomes been investigated? Comments on how the results of the review fit into the context of current practice might be included here, although authors should bear in mind that current practice might vary internationally.

Quality of the evidence

[recommended, level 2 heading]

Does the body of evidence identified allow a robust conclusion regarding the objective(s) of the review? Summarize the amount of evidence that has been included (numbers of studies), state key methodological limitations of the studies, and reiterate the consistency or inconsistency of their results. This should lead to an overall judgement of the internal validity of the results of the review.

Potential biases in the review process

[recommended, level 2 heading]

State the strengths and limitations of the review with regard to preventing bias. These may be factors within, or outside, the control of the review authors. The discussion might include the likelihood that all relevant studies were identified, whether all relevant data could be obtained, or whether the methods used (for example, searching, study selection, data extraction, analysis) could have introduced bias.

Agreements and disagreements with other studies or reviews

[recommended, level 2 heading]

Comments on how the included studies fit into the context of other evidence might be included here, stating clearly whether the other evidence was systematically reviewed.

Authors' conclusions

[fixed, level 1 heading]

The primary purpose of the review should be to present information, rather than to offer advice. Conclusions of the authors are divided into two sections:

Implications for systematic reviews and evaluations of health care
[fixed, level 2 heading]
The implications for systematic reviews and other evaluations of health care should be as practical and unambiguous as possible. They should not go beyond the evidence that was reviewed and be justifiable by the data presented in the review. 'No evidence of effect' should not be confused with 'evidence of no effect'.

Implications for methodological research
[fixed, level 2 heading]
This section of Cochrane Methodology reviews may used by people making decisions about future research, and authors should try to write something that will be useful for this purpose. As with the 'Implications for practice', the content should be based on the available evidence and should avoid the use of information that was not included or discussed within the review. In preparing this section, authors should consider the different aspects of research, perhaps using types of study, data, methods and outcome as a framework. Implications for *how* research might be done and reported should be distinguished from *what* future research should be done. For example, the need for randomized trials rather than other types of study, for better descriptions of studies in the particular topic of the review, or for the routine collection of specific outcomes, should be distinguished from the need for comparisons of specific types of method, or for research in specific settings.

It is important that this section is as clear and explicit as possible. General statements that contain little or no specific information, such as "Future research should be better conducted" or "More research is needed" are of little use to people making decisions, and should be avoided.
See also
- Guidance on formulating conclusions is provided in Chapter 12 (Section 12.7).

Acknowledgements
[fixed, level 1 heading]
This section should be used to acknowledge any people or organizations that the authors wish to acknowledge including people who are not listed among the authors. This would include any previous authors of the Cochrane review or previous sources of support to the review, and might include the contributions of the editorial team of the Cochrane Methodology Review Group. Permission should be obtained from persons acknowledged.

Contributions of authors
[fixed, level 1 heading]
The contributions of the current co-authors should be described in this section. One author should be identified as the guarantor of the review. All authors should discuss and agree on their respective descriptions of contribution before the review is submitted for publication on the *CDSR*. When the review is updated, this section should be checked and revised as necessary to ensure that it is accurate and up to date.

The following potential contributions have been adapted from Yank et al. (Yank 1999). This is a suggested scheme and the section should describe what people did, rather than attempt to identify which of these categories someone's contribution falls within. Ideally, the authors should describe their contribution in their own words:
- Conceiving the review.
- Designing the review.
- Coordinating the review.
- Data collection for the review.

o Designing search strategies.
o Undertaking searches.
o Screening search results.
o Organizing retrieval of papers.
o Screening retrieved papers against inclusion criteria.

- Appraising quality of papers.
- Extracting data from papers.
- Writing to authors of papers for additional information.
- Providing additional data about papers.
- Obtaining and screening data on unpublished studies.
- Data management for the review.
- Entering data into RevMan.
- Analysis of data.
- Interpretation of data.
- Providing a methodological perspective.
- Providing a clinical perspective.
- Providing a policy perspective.
- Providing a consumer perspective.
- Writing the review.
- Providing general advice on the review.
- Securing funding for the review.
- Performing previous work that was the foundation of the current review.

Declarations of interest

[fixed, level 1 heading]

Authors should report any present or past affiliations or other involvement in any organization or entity with an interest in the review that might lead to a real or perceived conflict of interest. Situations that might be perceived by others as being capable of influencing a review author's judgements include personal, political, academic and other possible conflicts, as well as financial conflicts. Authors must state if they have been involved in a study included in the review.

See also

- A summary of the Collaboration's policy on conflicts of interest appears in Chapter 2 (Section 2.6).

Financial conflicts of interest cause the most concern, and should be avoided, but must be reported if there are any. Any secondary interest (such as personal conflicts) that might unduly influence judgements made in a review (concerning, for example, the inclusion or exclusion of studies, assessments of the validity of included studies or the interpretation of results) should be reported.

If there are no known conflicts of interest, this should be stated explicitly, for example, by writing 'None known'.

Differences between protocol and review

[fixed, level 1 heading]

It is sometimes necessary to use different methods from those originally described in the protocol. This could be because:

- methods for dealing with a particular issue had not been specified in the protocol;
- methods in the protocol could not be applied (for example, due to insufficient data or a lack of information required to implement the methods); or
- methods are changed because a preferable alternative is discovered.

Some changes of methods from protocol to review are acceptable, but must be fully described in this section. The section provides a summary of the main changes in methods for the review over time. It should be used for the following.

- Point out any methods that were determined subsequent to the most recent published protocol (e.g. adding or changing outcomes; adding 'Risk of bias' or 'Summary of findings' tables).
- Summarize methods from the protocol that could not be implemented in the current review (e.g. because no studies fell in a particular pre-defined subgroup).
- Explain any changes in methods from the protocol to the review, state when they were made and provide the rationale for the changes. Such changes should not be driven by findings on the effects of the methods under investigation. Consider the potential effect on the review's conclusions of any changes in methods, and consider sensitivity analyses to assess this.

Published notes

[fixed, level 1 heading]

Published notes will appear in the review in the *CDSR*. They may include editorial notes and comments from the Cochrane Methodology Review Group, for example where issues highlighted by editors or referees are believed worthy of publication alongside the review. The author or source of these comments should be specified (e.g. from an editor or a referee).

Published notes must be completed for all withdrawn protocols and reviews, giving the reason for withdrawal. Only basic citation information, sources of support and published notes are published for withdrawn protocols and reviews.

Table 3. Intervention Cochrane Protocol: Checklist for authors

	This checklist is designed to help you (the authors) complete your Cochrane Protocol to an acceptable standard before you submit it for editorial and peer review. **Please complete each item in the checklist before submitting your Cochrane Protocol for editorial review, and email or fax the completed checklist to: Dr. Megan Prictor, Managing Editor at m.prictor@latrobe.edu.au or fax + 61 3 9479 5977.** The editorial team may return your Cochrane Protocol to you if the form is incomplete or not received. There is a 'Notes' section at the end of the form to alert the editorial team to the reason for any incomplete checks	
Cochrane Review title:		
Contact person:		
Date:		
1. General		
1.1	All the authors listed on the Cochrane Protocol have seen and approved this version and take full responsibility for the accuracy of the contents	
1.2	Incorporated any standard text provided by your Cochrane Review Group (CRG). In particular, see recommended text for the Assessment of Risk of Bias, outlined in the Group's Study Quality Guide	

(*Continued*)

1.3	Activated the relevant headings and sub-headings in RevMan and completed each section	
1.4	Completed a validation check in RevMan (File menu > Reports > Validation report), and made corrections where possible	
1.5	Completed a spell check in RevMan (Tools menu > Check spelling)	
1.6	The text is clearly written and all technical and medical terms are explained for non-expert readers	
2. Title and review information (see Cochrane Handbook Section 4.2)		
2.1	Title is the same as the registered title, unless a change has been agreed with the CRG	
2.2	Authors are listed in the correct order and have agreed to the order in which they are listed	
2.3	Names and details of all authors and the contact person appear correctly, or the CRG has been notified of any necessary corrections	
2.4	Completed the 'Date next stage expected' field, estimating when the Cochrane Review will be completed	
3. Background (see Cochrane Handbook Section 4.5)		
3.1	Described the condition or health issue to be addressed, including how it occurs, where it occurs, who is affected (including high risk groups, vulnerable/disadvantaged groups), diagnosis, symptoms and consequences	
3.2	Described the intervention, including for whom it is intended, its context in usual practice, comparison interventions, the treatment regimen or intervention components, and known adverse effects	

(*Continued*)

3.3	Described any likely differences in the use or outcomes of the intervention for specific populations (e.g. children, vulnerable/disadvantaged groups), and have defined those populations where necessary	
3.4	Described how the intervention might work to achieve the desired outcomes	
3.5	Explained why it is important to do this Cochrane Review in the context of the factors described above	
3.6	Supported all facts, figures and statements with references.	
3.7	Cited other Cochrane Reviews relevant to this topic.	
3.8	Avoided the use of plagiarised text	
4. Objectives (see Cochrane Handbook Section 4.5)		
4.1	Where possible, phrased as 'To assess the effects of [intervention or comparison] for [health problem] for/in [types of people, disease or problem and setting if specified]'	
4.2	If relevant, stated explicitly as secondary objectives any specific questions being addressed by the review, such as those relating to particular participant groups, intervention comparisons or outcomes	
4.3	If health economics evidence and/or qualitative research evidence is being reviewed, stated this explicitly in the Objectives	
5. Methods (see Cochrane Handbook Section 4.5)		
5.1.1	Used the future tense and active voice (ie. 'We will conduct searches…' rather than 'Searches will be conducted…')	
Types of studies		

(*Continued*)

5.2.1	Included study designs that are consistent with the objectives of the Cochrane Review, and the CRG has approved these designs. (Note, the inclusion of study designs beyond RCTs must be justified explicitly)	
5.2.2	If studies are excluded on the basis of publication status or language, explained and justified this	
Types of participants		
5.2.3	Stated eligibility criteria for participants, including any criteria around location, setting, diagnosis or definition of condition and demographic factors, and how studies including subsets of relevant participants are handled	
Types of interventions		
5.2.4	Stated eligibility criteria for interventions, including any criteria around delivery, dose, duration, intensity, co-interventions and characteristics of complex interventions	
5.2.5	Listed comparators for the intervention that are consistent with the objectives of the Cochrane Review (e.g. comparison with a placebo addresses a different objective from comparison with an active intervention)	
Types of outcome measures		
5.2.6	Listed the outcomes you plan to report in the Cochrane Review, and it is clear whether any of the outcomes listed are required as part of the eligibility criteria for including studies	
5.2.7	Identified clearly which are primary and which are secondary outcomes	
5.2.8	Included adverse effects among the outcomes to be reported.	

(*Continued*)

5.2.9	Considered including outcomes relevant to special populations (e.g. learning outcomes for children, process outcomes for reaching disadvantaged groups)	
5.2.10	Described appropriate methods of measuring each outcome (e.g. validated tools, meaningful process measures) and appropriate time points for measurement	
5.2.11	Defined in advance how outcome measures will be selected when there are several possible measures (e.g. multiple definitions, assessors or scales)	
5.2.12	Considered the minimally important difference or threshold for appreciable change for each outcome	
5.2.13	Selected a maximum of seven important outcomes, including adverse effects, to be included in the 'Summary of findings' table (s) when the Cochrane Review is complete (see Cochrane Handbook Section 11.5.2).	
5.3.1	Consulted the CRG Trials Search Co-ordinator regarding development of the MEDLINE search strategy	
5.3.2	Search strategy is consistent with the inclusion criteria for the Cochrane Review, including the types of studies to be included	
5.3.3	Search incorporates appropriate sources (e.g. subject-specific databases, trials registers, contact with experts, references and citations, handsearching)	
5.3.4	Search strategy is not limited by year of publication (unless there is justification for this), language or publication type	
5.3.5	If review has specific eligibility criteria to include additional studies such as studies of adverse effects, health economics evidence or qualitative evidence, described search methods for identifying such studies	

(*Continued*)

Selection of studies		
5.4.1	Stated that at least two authors will work independently to select studies for inclusion in the Cochrane Review, and described a strategy for resolving disagreements	
Data extraction and management		
5.4.2	Described methods for extracting and managing data (e.g. using a data collection form which has been piloted; using at least two people working independently to extract study characteristics, and describing a strategy for resolving disagreements)	
5.4.3	Listed the types of information that will be sought from reports of included studies	
5.4.4	Described attempts that will be made to obtain or clarify missing data from individuals or organisations	
Assessment of risk of bias in included studies		
5.4.5	Stated that at least two authors will conduct the assessment of risk of bias, and described a strategy for resolving disagreements	
5.4.6	Methods are consistent with Chapter 8 of the Cochrane Handbook, and the CRG has approved any additional items. Justified any deviations from the 'Risk of Bias' tool	
5.4.7	Described a strategy for using the risk of bias assessment in interpreting the results of the Cochrane Review (e.g. narrative description, stratified analysis, exclusion of high risk trials from analysis)	
Measures of treatment effect		
5.4.8	Described the measures of effect that will be used to measure outcomes (e.g. odds ratio, risk ratio, mean difference) for each type of data (e.g. dichotomous, continuous, other)	

(*Continued*)

Unit of analysis issues		
5.4.9	If the Cochrane Review is likely to identify study designs such as crossover trials and cluster-randomised trials, described analysis of these designs to avoid unit-of-analysis errors	
Dealing with missing data		
5.4.10	Described a strategy for dealing with missing data and following intention-to-treat principles, if appropriate	
Assessment of heterogeneity		
5.4.11	Described a strategy for assessing clinical and statistical heterogeneity, and determining whether meta-analysis is appropriate	
Assessment of reporting biases		
5.4.12	Described a strategy for assessing reporting biases. If funnel plots will be used, it is clear that asymmetric funnel plots are not necessarily caused by publication bias	
Data synthesis		
5.4.13	Described the methods that will be used for meta-analysis, and how results will be synthesised if meta- analysis is not appropriate	
5.4.14	If the Cochrane Review will include non-randomised studies, or non-standard randomised trials, described the analysis of these studies	
5.4.15	If the Cochrane Review will draw on analyses performed outside RevMan, referenced the software and command/macro/program used	
Subgroup analysis and investigation of heterogeneity		

(*Continued*)

5.4.16	Described planned subgroup analyses, including analysis of the effects in vulnerable/disadvantaged populations where possible, and provided a rationale for each	
Sensitivity analysis		
5.4.17	Described planned sensitivity analyses to determine whether conclusions are robust to decisions made during the review process (e.g. choice of meta-analysis method, exclusion of studies from analysis)	
'Summary of findings' table		
5.4.18	Described methods for planned 'Summary of findings' table/s (or for assessing the quality of the body of evidence)	
Ensuring relevance to decisions in health care		
5.4.19	Described methods for ensuring the review's relevance to healthcare decision-making	
6. Acknowledgements (see Cochrane Handbook Section 4.5)		
6.1	Acknowledged those people who contributed to the Cochrane Protocol but are not named as authors, and included the reasons for acknowledging each person	
6.2	Permission has been granted from all the people named to include them in this section	
7. Contributions of authors (see Cochrane Handbook Section 4.5)		
7.1	Described each author's contribution to the design and development of the Cochrane Protocol	
8. Declarations of interest (see Cochrane Handbook Section 4.5)		

(*Continued*)

8.1	Completed for each author, noting present or past affiliations that that may lead to a real or perceived conflict of interest, including whether authors are investigators on studies likely to be included in the review. If no potential conflicts are identified for a particular author, "None known" has been stated	
9. Tables (Additional tables)		
9.1	Each table has a brief and informative heading.	
9.2	Included links to each table from the appropriate part of the main text	
9.3	Included explanations of any abbreviations in footnotes.	
9.4	If footnotes are used, these are referenced in the text using superscript letters (e.g. [a]).	
9.5	Where possible, non-essential tables moved to the 'Appendices'	
10. References		
10.1.1	Checked that a link has been created wherever a reference citation ID appears in the text of the Cochrane Protocol using the 'Find and Mark Links' tool	
10.1.2	Grouped reference citation IDs and links in the text in alphabetical or chronological order, surrounded by round brackets and separated by semi-colons	
References to studies		
10.2.7	None included in the Cochrane Protocol.	
Additional references		
10.2.1	Reference citation IDs are in the correct format (first author or group abbreviation and year of publication, e.g. Smith 1983 or UKPDS 1990)	

(*Continued*)

10.2.2	Included each journal title in full, with no abbreviations.	
10.2.3	Checked how each reference is displayed to remove unnecessary punctuation	
10.2.4	Where applicable, listed the first six authors before using 'et al.'	
10.2.5	Written the page numbers correctly (e.g. 354-7).	
10.2.6	Included the date accessed in any references to web pages.	
Other published versions of this review		
10.2.8	Included references to any previous or derivative published versions of this Cochrane Protocol	
11. Figures (see Cochrane Handbook Section 4.9 **and the RevMan User Guide for specifications on size and resolution)**		
11.1	Permission received to reproduce any figures included in the Cochrane Protocol	
11.2	Each figure has a brief caption describing the purpose of the figure, and acknowledging its source	
11.3	All figures used are scaled so that a reader can see the complete picture within the RevMan window	
11.4	All figures are of a sufficient resolution and quality for publication	
12. Sources of support (see Cochrane Handbook Section 4.10)		
12.1	Listed all sources of funding and in-kind support, including internal sources (e.g. the home institution of any author) and external sources (e.g. grant funding), and specified what they are supporting (eg. Author salary, infrastructure)	

(*Continued*)

13. Appendices (see Cochrane Handbook Section 4.12)		
13.1	The titles of any appendices are clear and informative.	
14. Style		
14.1	Proofread the Cochrane Protocol carefully in accordance with the Cochrane Style Guide Basics.	
14.2	If additional subheadings have been added, the appropriate Heading Style has been selected using the drop- down box on the RevMan toolbar	
14.3	Used either UK or US English consistently throughout the review (e.g. either 'randomised' or 'randomized')	
14.4	Explained all acronyms and abbreviations (e.g. World Health Organization (WHO))	
14.5	Written numbers up to and including nine as words, and numbers 10 or higher as numerals (excluding those at the start of a sentence and numbers appearing in tables or figures)	
14.6	Included a space before and after each unit of measurement or mathematical symbol (e.g. 5 mL, P = 0.03)	
15. **Amended Cochrane Protocols (see Cochrane Handbook** Chapter 3)		
15.	If you are submitting an amendment to an already published Cochrane Protocol, please address these additional criteria:	
15.1	Added an event in the 'What's New' section to describe all relevant changes since the last published version of the Cochrane Protocol	
15.2	In the 'What's New' section, selected whether the new version is an Amendment or New Citation Version, and the selection	

(*Continued*)

	is consistent with Section 3.2 of the Handbook.	
15.3	Updated the methods of the Cochrane Protocol to reflect the latest guidance in the Cochrane Handbook	
15.4	If you received any feedback on your Cochrane Protocol via *The Cochrane Library*, you have included the comments received and your response in the 'Feedback' section	

CONTRIBUTIONS OF AUTHORS

Vivien Hunot, Rachel Churchill, Alec Grant conceived the parent review.

Vivian Hunot, Ian McKenna and Rachel Churchill designed and coordinated the review.

Ian McKenna, Sarah Dawson, Alan Bailey and Alex Parker were responsible for study identification and data collection..

Ian McKenna undertook data management, data analysis, interpretation of data and writing the review.

Rachel Churchill and Vivien Hunot commented on drafts of the review.

DECLARATIONS OF INTEREST

None known

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- University of Bristol, UK.
- University of Brighton, UK.

External sources

- No sources of support supplied