

# Social Anxiety Disorder: Review Protocol

## Contents

Social Anxiety Disorder: Review Protocol .....	1
Access and Experience of Care .....	1
Case Identification and Assessment.....	3
Interventions.....	6

Topic	Access and Experience of Care
<b>Review question(s)</b>	<ol style="list-style-type: none"> <li>1) What methods increase the proportion and diversity of people with social anxiety disorder initiating and continuing treatment? RQ1.1</li> <li>2) What dimensions of the experience of care for people with social anxiety disorder require adjustments to the procedures for access to and delivery of interventions for social anxiety disorder over and above those already developed for common mental health conditions RQ1.2</li> </ol>
<b>Sub-question(s)</b>	Do obstacles to access or the effectiveness of interventions differ across subgroups: <ol style="list-style-type: none"> <li>1. Whites versus Black and minority ethnic groups</li> <li>2. Men versus Women</li> <li>3. Children (5 to 12), adolescents (13 to 18), adults (18 to 65), older adults (65+)</li> </ol>
<b>Chapter</b>	Access and Experience of Care
<b>Topic Group</b>	Experience of Care
<b>Objectives</b>	To identify obstacles to access by updating a previous literature review and through expert consensus.
<b>Criteria for considering studies for the review</b>	
<ul style="list-style-type: none"> <li>• Intervention</li> </ul>	Identify methods to overcome obstacles to treatment that are specific to people with social anxiety disorder (i.e. included or in addition to those identified in the <i>Common Mental Health Disorders</i> and <i>Service User Experience in Adult Mental Health</i> NICE guidelines).
<ul style="list-style-type: none"> <li>• Types of participants</li> </ul>	Young people (5 to 18) and adults (18+) with social anxiety disorder or suspected social anxiety disorder. Special consideration will be given to the groups above.
<ul style="list-style-type: none"> <li>• Critical outcomes</li> </ul>	<ol style="list-style-type: none"> <li>1) Initiation of services</li> <li>2) Completion of treatment</li> </ol>
<ul style="list-style-type: none"> <li>• Study design</li> </ul>	<ol style="list-style-type: none"> <li>1) RCTs, quasi-RCTs (in which allocation is determined through a process approximating randomisation like date of birth)</li> </ol>

	<ol style="list-style-type: none"> <li>2) Controlled prospective studies</li> <li>3) Observational studies (e.g. cohort studies and surveys)</li> <li>4) Reviews of qualitative studies</li> </ol>
<ul style="list-style-type: none"> <li>• Include unpublished data?</li> </ul>	Unpublished research may be included, but specific searches for grey literature will not be conducted. Unpublished data will be included if it is accompanied by a report containing sufficient detail to properly assess the conduct of the study, including potential risk of bias.
<ul style="list-style-type: none"> <li>• Minimum sample size</li> </ul>	None.
<ul style="list-style-type: none"> <li>• Study setting</li> </ul>	<ul style="list-style-type: none"> <li>• Primary, secondary, tertiary, health and social care</li> <li>• Children's services and educational settings</li> </ul>
<b>Search strategy</b>	<p><b>General outline:</b></p> <ol style="list-style-type: none"> <li>1) Relevant NICE guidelines (including <i>Common Mental Health Disorders</i> and <i>Service User Experience in Adult Mental Health</i> NICE guidelines) will be searched for recommendations and studies about people with social anxiety disorder</li> <li>2) An electronic database search for qualitative SRs, primary qualitative studies and survey literature to update evidence identified by the relevant NICE guidelines.</li> <li>3) A broad electronic database search for quantitative SRs and RCTs</li> </ol> <p><b>Databases searched:</b>  Qualitative SRs/quantitative SRs/RCTs:  Core databases: Embase, Medline, PreMedline, PsycINFO  Topic specific databases: AEI*, AMED* ASSIA*, BEI*, CDSR*, CENTRAL*, CINAHL*, DARE*, ERIC*, HTA*, IBSS*, Sociological Abstracts, SSA*, SSCI*</p> <p>Primary qualitative studies/survey literature:  Embase, Medline, PreMedline, PsycINFO, CINAHL*</p> <p><b>Date restrictions:</b>  Quantitative SRs - 1997 onwards  RCTs - inception of databases onwards  Qualitative SRs, primary qualitative studies, survey literature - 2010 onwards</p>
<b>Study design filter/limit used</b>	Core databases/topic specific databases: qualitative SR, quantitative SR, RCT <i>[note, no filter/limit used for evidence of qualitative primary studies and survey literature]</i>
<b>Question specific search strategy</b>	Quantitative SRs, RCTs: no, generic Qualitative SRs, primary qualitative studies: yes, focused
<b>Amendments to search strategy/study</b>	None

<b>design filter</b>	
<b>Searching other resources</b>	Hand-reference searching of retrieved literature.
<b>Existing reviews</b>	
• <b>Updated</b>	See below (Review strategy).
• <b>Not updated</b>	None.
<b>The review strategy</b>	<p>High order principles from existing NICE guidelines (for example, <i>Common Mental Health Disorders</i> NICE guideline and <i>Service User Experience in Adult Mental Health</i> NICE guideline) will be reviewed by the GDG to determine whether these can be incorporated or adapted for young people and adults with social anxiety disorder.</p> <p>The following sources of information will be used to make this decision:</p> <ol style="list-style-type: none"> <li>1) If we find trials of methods to improve access and experience of care for people with social anxiety disorder, we will synthesise outcomes using meta-analysis if possible. Otherwise, we will present a narrative review of these studies.</li> <li>2) We will use GDG experience to interpret any specific studies, to develop new recommendations, and to incorporate or adapt previous recommendations.</li> </ol>
<p>* AEI (Australian Education Index), AMED (Allied and Complementary Medicine Database), ASSIA (Applied Social Services Index and Abstracts), BEI (British Education Index), CDSR (Cochrane Database of Systematic Reviews), CENTRAL [COCHRANE database of RCTs and other controlled trials), CINAHL, (Cumulative Index to Nursing and Allied Health Literature), DARE (Database of Abstracts of Reviews and Effectiveness), ERIC (Education Resources in Curriculum), HTA (Health Technology Assessment database), IBSS (International Bibliography of Social Science), SSA (Social Services Abstracts), SSCI (Social Sciences Citation Index - Web of Science)</p>	

<b>Topic</b>	<b>Case Identification and Assessment</b>
<b>Review question(s)</b>	<ol style="list-style-type: none"> <li>1) For suspected social anxiety disorder, what identification tools when compared to a gold standard diagnosis (based on DSM or ICD criteria) have adequate clinical utility (i.e. clinically useful with good sensitivity and specificity) and reliability? RQ2.1</li> <li>2) For people with suspected social anxiety disorder, what are the key components of, and the most effective structure for a clinical assessment? RQ2.2</li> </ol>
<b>Chapter</b>	Case Identification and Assessment
<b>Topic Group</b>	Case ID and Assessment
<b>Objectives</b>	<p>For case identification (RQ2.1):</p> <ul style="list-style-type: none"> <li>• To identify brief screening tools to assess need for further assessment of people with a suspected anxiety disorder (as described in the <i>Common Mental Health Disorders</i> NICE guideline).</li> <li>• To assess the diagnostic accuracy of brief screening tools.</li> </ul>

	<p>For assessment (RQ2.2):</p> <ul style="list-style-type: none"> <li>To identify the key components of a comprehensive assessment</li> </ul>
<b>Criteria for considering studies for the review</b>	
<ul style="list-style-type: none"> <li>Intervention</li> </ul>	For case identification (RQ2.2): Screening questionnaires, Brief screening questionnaires (<12 items), and Ultra-brief screening questionnaires (<3 items)
<ul style="list-style-type: none"> <li>Comparison</li> </ul>	Gold standard: Diagnosis Statistical manual (DSM-IV) or International Classification of Diseases (ICD-10) Other measures of social anxiety
<ul style="list-style-type: none"> <li>Types of participants</li> </ul>	Young people (5 to 18) and adults (18+) with suspected social anxiety disorder. Special consideration will be given to the groups above.
<ul style="list-style-type: none"> <li>Critical outcomes</li> </ul>	<ol style="list-style-type: none"> <li>Sensitivity (percentage of true cases identified)</li> <li>Specificity (percentage of non-cases excluded)</li> </ol>
<ul style="list-style-type: none"> <li>Important, but not critical outcomes</li> </ul>	<ul style="list-style-type: none"> <li>Positive Predictive Value (PPV): the proportion of patients with positive test results who are correctly diagnosed.</li> <li>Negative Predictive Value (NPV): the proportion of patients with negative test results who are correctly diagnosed.</li> <li>Area under the Curve (AUC): are constructed by plotting the true positive rate as a function of the false positive rate for each threshold.</li> </ul>
<ul style="list-style-type: none"> <li>Other outcomes</li> </ul>	<ol style="list-style-type: none"> <li>Reliability (for example, inter-rater, test-retest)</li> <li>Validity (for example, construct, content)</li> </ol>
<ul style="list-style-type: none"> <li>Study design</li> </ul>	RCTs, cross-sectional studies
<ul style="list-style-type: none"> <li>Include unpublished data?</li> </ul>	Unpublished research may be included, but specific searches for grey literature will not be conducted.
<ul style="list-style-type: none"> <li>Restriction by date?</li> </ul>	No
<ul style="list-style-type: none"> <li>Minimum sample size</li> </ul>	No
<ul style="list-style-type: none"> <li>Study setting</li> </ul>	<ul style="list-style-type: none"> <li>Primary, secondary, tertiary, health and social care</li> <li>Children's services and educational settings</li> </ul>
<b>Search strategy</b>	<p><b>General outline:</b> An electronic database search for RCTs and observational studies</p> <p><b>Databases searched:</b> RCTs: Core databases: Embase, Medline, PreMedline, PsycINFO Topic specific databases: AEI*, AMED* ASSIA*, BEI*, CDSR*, CENTRAL*, CINAHL*, DARE*, ERIC*, HTA*, IBSS*,</p>

	<p>Sociological Abstracts, SSA*, SSCI*</p> <p>Observational studies: Core databases: Embase, Medline, PreMedline, PsycINFO</p> <p><b>Date restrictions:</b> None, inception of databases onwards</p>
<b>Study design filter/limit used</b>	RCT, Observational study
<b>Question specific search strategy</b>	RCTs: no, generic Observational studies: yes, focused
<b>Amendments to search strategy/study design filter</b>	None
<b>Searching other resources</b>	Hand-reference searching of retrieved literature.
<b>Existing reviews</b>	
• Updated	None.
• Not updated	See below (Review strategy).
<b>The review strategy</b>	<p>High order principles from existing NICE guidelines (for example, <i>Common Mental Health Disorders</i> NICE guideline and <i>Service User Experience in Adult Mental Health</i> NICE guideline) will be reviewed by the GDG to determine whether these can be incorporated or adapted for young people and adults with social anxiety disorder. In addition:</p> <ol style="list-style-type: none"> <li>1) For case identification (RQ2.1), we will conduct pooled diagnostic accuracy meta-analyses on the sensitivity and specificity of specific case identification instruments for social anxiety disorder (dependent on available data). In the absence of adequate data, a narrative review of case identification instruments will be conducted and guided by a pre-defined list of consensus-based criteria (for example, the clinical utility of the tool, administrative characteristics, and psychometric data evaluating its sensitivity and specificity).</li> <li>2) For assessment (RQ2.2), the GDG will use a consensus-based approach to identify the key components of an effective assessment.</li> </ol>
<p>* AEI (Australian Education Index), AMED (Allied and Complementary Medicine Database), ASSIA (Applied Social Services Index and Abstracts), BEI (British Education Index), CDSR (Cochrane Database of Systematic Reviews), CENTRAL [COCHRANE database of RCTs and other controlled trials), CINAHL, (Cumulative Index to Nursing and Allied Health Literature), DARE (Database of Abstracts of Reviews and Effectiveness), ERIC (Education Resources in Curriculum), HTA (Health Technology Assessment database), IBSS (International Bibliography of Social Science), SSA (Social Services Abstracts), SSCI (Social Sciences Citation Index - Web of Science)</p>	

<b>Topic</b>	<b>Interventions</b>
<b>Review question(s)</b>	For adults with social anxiety disorder, what are the relative benefits and harms of psychological and pharmacological interventions? RQ3.1  For children with social anxiety disorder, what are the relative benefits and harms of psychological and pharmacological interventions? RQ3.2
<b>Sub-question(s)</b>	Does the effectiveness of treatment differ across populations:  <ol style="list-style-type: none"> <li>1. Children (5 to 12), adolescents (13 to 18), adults (18 to 64), older adults (65+)</li> <li>2. Generalised social anxiety versus Performance social anxiety</li> <li>3. People with comorbid problems (e.g. substance misuse, other anxiety disorders, depression) versus those with only social anxiety</li> </ol>
<b>Chapter</b>	Interventions
<b>Topic Group</b>	Pharmacological Interventions Psychosocial Interventions Interventions for Children and Young People
<b>Objectives</b>	To estimate the efficacy and cost effectiveness of interventions to treat social anxiety disorder.
<b>Criteria for considering studies for the review</b>	
<ul style="list-style-type: none"> <li>• Intervention</li> </ul>	<ol style="list-style-type: none"> <li>1) Any psychological intervention, for example: <ol style="list-style-type: none"> <li>a. Acceptance and Commitment Therapy (ACT)</li> <li>b. Attention training</li> <li>c. Counselling</li> <li>d. Cognitive Behavioural Therapy (individual, group)</li> <li>e. Cognitive bias modification</li> <li>f. Exposure</li> <li>g. Hypnosis</li> <li>h. Interpersonal psychotherapy</li> <li>i. Mindfulness-based cognitive therapy (MBCT)</li> <li>j. Psychodynamic psychotherapy</li> <li>k. Relaxation (e.g. progressive muscle relaxation)</li> <li>l. Self-help (facilitated and non-facilitated; CBT and other modalities)</li> <li>m. Social skills training</li> <li>n. Support groups</li> </ol> </li> </ol>

	<ul style="list-style-type: none"> <li>o. Supportive therapy</li> <li>2) Additional psychological interventions specifically for children</li> <li>3) Any licensed pharmacological intervention, for example:             <ul style="list-style-type: none"> <li>a. Benzodiazepines</li> <li>b. Beta-blockers</li> <li>c. MAOIs, reversible MAOIs</li> <li>d. SNRIs</li> <li>e. SSRIs</li> <li>f. Tricyclic antidepressants</li> <li>g. Other antidepressants</li> </ul> </li> <li>4) Combined psychological and pharmacological treatment</li> <li>5) Cognitive Enhancers (for example, D-cycloserine)</li> <li>6) Surgical interventions (e.g. for blushing)</li> <li>7) Botulinum toxin injections (e.g. for sweating)</li> </ul>
<ul style="list-style-type: none"> <li>• Comparator</li> </ul>	<ul style="list-style-type: none"> <li>1) Waiting list</li> <li>2) Placebo</li> <li>3) Other interventions</li> </ul>
<ul style="list-style-type: none"> <li>• Types of participants</li> </ul>	<p>Young people (5 to 18) and adults (18+) with social anxiety disorder or avoidant personality disorder. Special consideration will be given to the groups above.</p> <p>If some, but not all, of a study's participants are eligible for our review, we will ask the study authors for disaggregated data.</p>
<ul style="list-style-type: none"> <li>• Outcomes</li> </ul>	<ul style="list-style-type: none"> <li>1) Recovery (no longer meet criteria for diagnosis)</li> <li>2) Symptoms of social anxiety (e.g. Liebowitz Social Anxiety Scale or Social Anxiety Scale for Children)</li> <li>3) Symptoms of depression (e.g Hamilton Rating Scale for Depression)</li> <li>4) Quality of life (e.g. SF-36)</li> <li>5) Disability (e.g. Sheehan Disability Scale)</li> <li>6) Withdrawal</li> <li>7) Side effects (adverse events)</li> </ul>
<ul style="list-style-type: none"> <li>• Time points</li> </ul>	<p>The main analysis will include outcomes at the end of treatment. Additional analyses will be conducted for further follow-up data.</p>
<ul style="list-style-type: none"> <li>• Study design</li> </ul>	<p>Randomised controlled trials (RCTs) and cluster RCTs with a parallel group design. We will exclude quasi-RCTs, such as trials in which allocation is determined by alternation or date of birth.</p>

<ul style="list-style-type: none"> <li>• Include unpublished data?</li> </ul>	Unpublished research may be included.
<ul style="list-style-type: none"> <li>• Restriction by date?</li> </ul>	No limit.
<ul style="list-style-type: none"> <li>• Dosage</li> </ul>	For pharmacological interventions, we will include all interventions within the BNF recommended range. For psychological interventions, we will include all credible interventions; single session treatments will be excluded.
<ul style="list-style-type: none"> <li>• Minimum sample size</li> </ul>	No minimum
<ul style="list-style-type: none"> <li>• Study setting</li> </ul>	<ul style="list-style-type: none"> <li>• Primary, secondary, tertiary, health and social care</li> <li>• Children’s services and educational settings</li> </ul>
<b>Search strategy</b>	<p><b>General outline:</b> An broad electronic database search for quantitative SRs and RCTs</p> <p><b>Databases searched:</b> Core databases: Embase, Medline, PreMedline, PsycINFO Topic specific databases: AEI*, AMED* ASSIA*, BEI*, CDSR*, CENTRAL*, CINAHL*, DARE*, ERIC*, HTA*, IBSS*, Sociological Abstracts, SSA*, SSCI* Grey literature databases: HMIC*, PsycBOOKS, PsycEXTRA</p> <p><b>Date restrictions:</b> Quantitative SRs - 1997 onwards RCTs - inception of databases onwards</p>
<b>Study design filter/limit used</b>	Core databases/topic specific databases: Quantitative SR, RCT Grey literature databases: none
<b>Question specific search strategy</b>	No
<b>Amendments to search strategy/study design filter</b>	None
<b>Searching other resources</b>	We will write to all stakeholders, authors of all included studies, and manufacturers of included drugs to request unpublished studies.
<b>Existing reviews</b>	
<ul style="list-style-type: none"> <li>• Updated</li> </ul>	None.
<ul style="list-style-type: none"> <li>• Not updated</li> </ul>	See below (Review strategy).
<b>The review strategy</b>	<p><b>Data management:</b></p> <p>For each study</p> <ul style="list-style-type: none"> <li>• Year of study</li> <li>• Setting</li> <li>• Total number of study participants in each included group</li> </ul>

- Age (mean)
- Gender (percent female)
- Inclusion and exclusion criteria
- Comorbidities
- Risk of bias

For each intervention or comparison group of interest

- Dose
- Duration
- Frequency
- Co-interventions (if any)

For each outcome of interest

- Time points (i) collected and (ii) reported
- Missing data (exclusion of participants, attrition)

For cross-over trials, we will extract and analyse data from the first period only.

**Data synthesis:**

We plan to compare all eligible interventions for adults using a network meta-analysis of continuous measures of social anxiety assessed at post-treatment. Multiple measures of social anxiety will be averaged to obtain a single effect.

The following will be assessed in pairwise analyses using random effects models:

- Interventions for adults that are not connected to the main network, including studies with no connected intervention and studies of specific populations (e.g. comorbid alcohol misuse).
- Interventions for children and young people.

We will conduct additional pairwise analyses of secondary outcomes and follow-up results for treatment classes using random effects models (e.g. SSRIs, CBT).

* AEI (Australian Education Index), AMED (Allied and Complementary Medicine Database), ASSIA (Applied Social Services Index and Abstracts), BEI (British Education Index), CDSR (Cochrane Database of Systematic Reviews), CENTRAL [COCHRANE database of RCTs and other controlled trials), CINAHL, (Cumulative Index to Nursing and Allied Health Literature), DARE (Database of Abstracts of Reviews and Effectiveness), ERIC (Education Resources in Curriculum), HMIC (Health Management Information Consortium), HTA (Health Technology Assessment database), IBSS (International Bibliography of Social Science), SSA (Social Services Abstracts), SSCI (Social Sciences Citation Index - Web of Science)	
<b>Topic</b>	<b>Computerised cognitive behavioural therapy for specific phobias</b>
<b>Review question(s)</b>	For adults with specific phobias, what are the relative benefits and harms of computerised cognitive behavioural therapy? RQ4.1
<b>Chapter</b>	Interventions
<b>Topic Group</b>	Psychosocial Interventions
<b>Objectives</b>	To estimate the efficacy and cost effectiveness of computerised cognitive behavioural therapy for specific phobias
<b>Criteria for considering studies for the review</b>	
• Intervention	Computerised cognitive behavioural therapy
• Comparator	1) Waiting list 2) Other interventions
• Types of participants	Adults with a specific phobia.
• Outcomes	1) Recovery (no longer meet criteria for diagnosis) 2) Symptoms of anxiety
• Time points	The main analysis will include outcomes at the end of treatment. Additional analyses will be conducted for follow-up data.
• Study design	Randomised controlled trials (RCTs). We will exclude quasi-RCTs, such as trials in which allocation is determined by alternation or date of birth.
• Include unpublished data?	Unpublished research may be included, but specific searches for grey literature will not be conducted.
• Restriction by date?	No limit.
• Dosage	For psychological interventions, we will include all credible interventions; single session treatments will be excluded.
• Minimum sample size	No minimum
• Study setting	• Primary, secondary, tertiary, health and social care
<b>Search strategy</b>	<b>General outline:</b> An broad electronic database search for quantitative SRs and RCTs  <b>Databases searched:</b>

	<p>Core databases: Embase, Medline, PreMedline, PsycINFO  Topic specific databases: AEI*, AMED* ASSIA*, BEI*, CDSR*, CENTRAL*, CINAHL*, DARE*, ERIC*, HTA*, IBSS*, Sociological Abstracts, SSA*, SSCI*</p> <p><b>Date restrictions:</b>  Quantitative SRs - 1997 onwards  RCTs - inception of databases onwards</p>
<b>Study design filter/limit used</b>	Core databases/topic specific databases: Quantitative SR, RCT
<b>Question specific search strategy</b>	No
<b>Amendments to search strategy/study design filter</b>	None
<b>Searching other resources</b>	None
<b>Existing reviews</b>	
• Updated	Computerised Cognitive Behavioural Therapy
• Not updated	See below (Review strategy).
<b>The review strategy</b>	<p><b>Data management:</b></p> <p>For each study</p> <ul style="list-style-type: none"> <li>• Year of study</li> <li>• Setting</li> <li>• Total number of study participants in each included group</li> <li>• Age (mean)</li> <li>• Gender (percent female)</li> <li>• Inclusion and exclusion criteria</li> <li>• Comorbidities</li> <li>• Risk of bias</li> </ul> <p>For each intervention or comparison group of interest</p> <ul style="list-style-type: none"> <li>• Dose</li> <li>• Duration</li> <li>• Frequency</li> <li>• Co-interventions (if any)</li> </ul>

	<p>For each outcome of interest</p> <ul style="list-style-type: none"> <li>• Time points (i) collected and (ii) reported</li> <li>• Missing data (exclusion of participants, attrition)</li> </ul> <p>For cross-over trials, we will extract and analyse data from the first period only.</p> <p><b>Data synthesis:</b></p> <p>We plan to conduct meta-analyses using random effects models.</p>
<p>* AEI (Australian Education Index), AMED (Allied and Complementary Medicine Database), ASSIA (Applied Social Services Index and Abstracts), BEI (British Education Index), CDSR (Cochrane Database of Systematic Reviews), CENTRAL [COCHRANE database of RCTs and other controlled trials), CINAHL, (Cumulative Index to Nursing and Allied Health Literature), DARE (Database of Abstracts of Reviews and Effectiveness), ERIC (Education Resources in Curriculum), HTA (Health Technology Assessment database), IBSS (International Bibliography of Social Science), SSA (Social Services Abstracts), SSCI (Social Sciences Citation Index - Web of Science)</p>	