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Amendment History		
Version	Date	Summary of changes
2.0	20/03/2018	Changes to reflect decision to not proceed with RCT (phase 2), and bring forward qualitative work with young people and parents and expand to include clinicians and service managers.
1.1	13/06/2017	Addition of patient health questionnaire (PHQ-9) Clarification of time points in Assessment Schedule (Appendix 1)
1.0	20/05/2016	Original



Specific versus generic psychological therapy for children and
young people with social anxiety disorder

Study Protocol

Version 2.0

20th March 2018

Background

Social anxiety disorder (SAD) is characterised by persistent and disproportionate fear of social situations. It is the third most frequent of all mental health disorders, with a lifetime prevalence of up to 13.7% (Kessler et al., 2005) (K. Beesdo et al., 2007). The age of onset is typically during adolescence (median 13 years (Magee, Eaton, Wittchen, McGonagle, & Kessler, 1996; Wittchen & Fehm, 2003)) with most people developing the condition before they reach their twenties. Indeed, studies of the period prevalence of social anxiety disorder that have focused on young people between the ages of 11 and 17 have estimated prevalence between 0.7 and 10.9% (Katja Beesdo, Knappe, & Pine, 2009), with European studies (in Germany and Finland) identifying period prevalence rates between 1.4 and 3.2% (Essau, Conradt, & Petermann, 1998; Ranta, Kaltiala-Heino, Pelkonen, & Marttunen, 2009; Wittchen, Fuetsch, Sonntag, Müller, & Liebowitz, 2000)

Social anxiety disorder is differentiated from normal shyness by the marked disability and interference caused in day to day life. For example, it often impacts negatively on social relationships (e.g. friendships (Whisman, Sheldon, & Goering, 2000), marriages and children (Wittchen et al., 2000)) and is associated with more days off work (Stein, McQuiad, Laffaye, & McCahill, 1999), receipt of state benefits (Patel, Knapp, Henderson, & Baldwin, 2002) and more outpatient medical visits than found in the general population (Katzelnick et al., 2001). SAD is also associated with an increased risk of other mental health problems, including other anxiety and mood disorders, substance abuse and psychosis (Beesdo et al., 2007; Chartier, Walker, & Stein, 2003; Schutters et al., 2011) and has the lowest natural recovery rate of all anxiety disorders (Bruce et al., 2005). Several of the handicaps that result from having the condition in adolescence (for example, missed opportunities for social learning and poor educational achievement) cannot be overcome by treatment when the person reaches adulthood. These factors highlight the need for effective treatment for social anxiety disorder in adolescence.

Currently, the most commonly delivered treatment approach for adolescents with social anxiety disorder is a CBT treatment programme that is used across a range of anxiety disorders.

Unfortunately, in recent studies young people with social anxiety disorder have had significantly poorer outcomes than those with other anxiety disorders (e.g. for 7-17 year olds, remission rates of 40.6% for SAD vs 72% for other anxiety disorders (Ginsburg et al., 2011)). However, adults who receive a focused psychological treatment for social anxiety (Cognitive Therapy (CT)) achieve much higher recovery rates of up to 84% in randomised controlled trials (RCTs) (Clark et al., 2006; Clark et al., 2003; Clark et al., 2012). CT with adults has also shown to be superior to traditional group CBT, exposure therapy, interpersonal psychotherapy, psychodynamic psychotherapy, and medication (SSRIs) (Mayo-Wilson et al., 2014) and is, therefore, the leading NICE recommended treatment.

There is recent evidence that the same psychological maintenance mechanisms apply among adolescents with social anxiety disorder (e.g. (Hodson, McManus, Clark, & Doll, 2008; Parr & Cartwright-Hatton, 2009; Schreiber, Höfling, Stangier, Bohn, & Steil, 2012) as in adults and there is preliminary support for the application of Clark and Wells' CT with children (Melfsen et al., 2011). Therefore, adapting CT for social anxiety disorder so that it is suitable for use with adolescents may significantly enhance treatment efficacy. However adolescents differ from children with anxiety disorders in critical ways, including more severe symptoms, more frequent comorbid mood disorders, less regular school attendance (Waite & Creswell, 2014) and more negative parent-child interactions (Waite & Creswell, Under review). As such, and in line with NICE guidance, the adapted treatment, Cognitive Therapy for Social Anxiety Disorder in Adolescents (CT-SAD-A), will address the need to create treatment supporting environments, by working with parents, teachers and/or peers as appropriate. An individual treatment approach will be used as group CBT is less clinically and cost effective (Pilling et al., 2013).

Work has already begun to adapt CT for use with adolescents and excellent outcomes were achieved in a recent case series (Leigh & Clark, 2015). All adolescents (n=5; 11-17 years) had severe SAD and achieved excellent outcomes after receiving CT-SAD-A; with overall reductions in social anxiety that were greater than the average reductions achieved with adults. Of note, all the adolescents were free of their primary diagnosis of SAD as well as comorbid diagnoses post-treatment. Given this evidence, there is a possibility that CT-SAD-A may improve the treatment outcomes that adolescents with social anxiety disorder can expect to achieve. As social anxiety disorder presents a risk for ongoing mental health problems, impaired educational performance, restricted employment and productivity, and increased medical needs, the ability to extend the findings of the case series (Leigh & Clark, 2015) to routine CAMHS settings where it is administered by CAMHS clinicians will provide

support for its application within standard clinical practice. We are interested in (1) whether we can train CAMHS clinicians to be competent in the therapy and (2) what outcomes can be achieved.

Aims of the study

The study aims to examine the training in and delivery of CT-SAD-A in routine NHS CAMHS, in terms of clinician's ability to delivery CT-SAD-A, young people's outcomes, and the experiences of both participating families (young people and their parents/carers) and the clinicians involved (both clinicians delivering the treatment and their service managers) within a CAMHS setting.

The study will specifically aim to:

- a) Train NHS CAMHS clinicians in delivering the adapted treatment and assess clinician competency and young people's outcomes;
- b) Understand the experience of young people and their parents receiving CT-SAD-A within a CAMHS setting.
- c) Understand the experience of CAMHS clinicians receiving training in and delivering CT-SAD-A and their experience of being part of a research study
- d) Understand the experiences of the CAMHS service managers in relation to supporting the training and delivery of CT-SAD-A and the accompanying research procedures within their services

Design

This project will be conducted in a single phase. This will involve training clinicians to deliver CT-SAD-A and assessing clinician competency. Young people's treatment outcomes will be assessed on the basis of interview and questionnaire measures before and after treatment. Qualitative interviews will explore young people and their parent's experience of receiving the treatment and also clinicians' and service managers' experiences of the training, the treatment, and accompanying research procedures within a CAMHS setting.

Five CAMHS clinicians from Oxford Health and Berkshire NHS Foundation Trusts will complete a training programme comprising an initial 2 day workshop, focussing on the CT-SAD-A model and the key procedures involved in the first stage of therapy. Therapists will then begin 6 months of weekly case supervision. After the first month, a further 1 day workshop will be attended by therapists. This will cover the key procedures used later in the therapy in more detail. A final workshop will take

place at the end of the 6-month period of case supervision that will allow therapists to reflect on things that didn't go so well and the difficulties that they noticed as they went through their practice cases. Further to this, therapists will also have access to various online materials to help them deepen their learning. Clinicians (both supervisors and therapists) will be also required to complete 'clinician's logs' throughout the whole training phase. In these 'ad-hoc' designed forms, supervisors and therapists will record – as applicable - the amount of time spent in training, supervision, preparation and delivery (i.e., contact with client) of the CT-SAD-A treatment. The 'clinician's logs' will provide the necessary information to estimate the mean amount of healthcare resources used (i.e. qualified staff time) per adolescent treated, that the NHS would need if the CT-SAD-A treatment were to be implemented within a CAMHS setting. Assessments will be made of clinician competence in delivering the approach using the Cognitive Therapy Competence Scale for Social Anxiety Disorder (CTCS-SA), incorporating additional items covering features that are specific to CT with adolescents and modifying wording as appropriate. Clinician training will be considered successful if 80% of them pass predetermined competency criteria. Assessments of young people's symptoms and diagnoses will be made by independent assessors prior to and after treatment.

Young people (11-17.5 years) with a current primary diagnosis of SAD will be invited to participate in this study phase. Young people and their parents/carers will complete measures of social anxiety, comorbid anxiety and depression and broader outcomes before and after treatment, and will complete sessional outcomes in line with Children and Young people's Improving Access to psychological Therapies (CYP-IAPT) throughout treatment as well as process measures to guide the progress of treatment. They will also report on the acceptability of the treatment.

Qualitative interviews will be conducted with young people and their parents in order to explore their experiences of CT-SAD-A (n=10-12). Interviews will be conducted by the trial assessors and/or a Research Fellow with particular qualitative expertise (trained and supervised by a specialist in qualitative research). Interviews with young people will be devised to be engaging and sensitive to the interpersonal and communicative preferences of this population.

Qualitative interviews will also be conducted with the therapists (n=10-12) delivering the CT-SAD-A and their line managers (n=3-4). The aim of these interviews is to report on (i) their experience of training in and delivering CT-SAD-A within a CAMHS setting and (ii) their experience of participating in research.

Setting and recruitment

CAMHS clinicians from Oxford Health and Berkshire NHS Foundation Trusts will receive training and case-based supervision in adapted CT for social anxiety disorder in adolescents. These clinicians will

be identified by managers within the Trusts on the basis of meeting the inclusion criteria below. During the training phase, treatment will be delivered to adolescents who have been referred to CAMHS in Oxford Health and Berkshire Healthcare NHS Foundation Trusts through usual routes (e.g. by general practitioners, school nurses, self/carer referral) for treatment of anxiety or mood disorders. Adolescents and their parents will complete the NICE screening questions (Appendix 1) and the Revised Child Anxiety and Depression Scale to identify potential social anxiety disorder within routine CAMHS assessment. Where adolescents 'screen positive', potential participants will be invited to take part in the research. An initial assessment will include a structured diagnostic interview with the young person and carer (ADIS-C/P; (W. Silverman, Albano, & Barlow, 1996) to establish whether the young person meets the study inclusion criteria. Young people who do not meet the study inclusion criteria will be offered usual treatment within their local CAMHS.

Participants

The following inclusion and exclusion criteria will be adopted:

Clinicians

Inclusion criteria

1. Currently in clinical practice within participating CAMHS
2. Willing to be randomly allocated to receive training and supervision in and provide the C.A.T project or CT for social anxiety disorder
3. Have at least 2 years of using CBT as their main treatment approach, receiving regular CBT supervision during this time
4. Minimum 2 years working clinically with children and young people
5. Have treated at least 2 adolescent/adult social anxiety disorder cases and 10 anxiety cases using CBT.

Adolescents

Inclusion criteria:

1. Young people (aged 11-17.5 years at intake) whose primary presenting disorder is a DSM-5 diagnosis of social anxiety disorder.
2. If young people have been prescribed psychotropic medication the dosage must have been stable for two months.

Exclusion criteria:

1. Young people who have previously received CBT for social anxiety will be excluded if they have received more than 4 sessions in which key procedures of CT-SAD-A have been used (i.e. video feedback, attention training, memory work and multiple behavioural experiments).
2. Young people with established autistic spectrum disorders (or suspected on the basis of SCQ; see measures), learning disabilities, suicidal intent or recurrent self-harm (i.e. co-morbid conditions that are likely to interfere with treatment delivery).
3. Young people with a primary presenting disorder other than social anxiety disorder (including a DSM-V diagnosis of selective mutism (SM) or major depressive disorder (MDD)).
4. Young people identified by social services as currently 'at risk' due to child protection concerns.

Intervention

All young people will receive CT-SAD-A. This therapy is based on Clark & Wells' model of the maintenance of the disorder (Clark & Wells, 1995). The treatment programme consists of 14 weekly sessions plus 2 monthly booster sessions and focuses on changing social anxiety related beliefs and behaviours with a particular emphasis on the four maintenance processes specified in the model. These are: (a) increased self-focused attention and observation (self-consciousness) and an associated decrease in observation of other people and their responses, (b) use of internal information (feelings and images) to make excessively negative inferences about how one appears to others, (c) use of overt and covert safety behaviours that prevent patients from discovering that their fears are unrealistic and interfere with the initiation and flow of social interactions, and (d) pre- and post-event processing (e.g. anticipatory worry and rumination).

The components of CT-SAD-A were well received by the adolescents in the case series (Leigh & Clark, 2015). Key elements that have been added to CT-SAD-A are (i) working with peer victimisation (which is likely to involve school liaison) and (ii) working with parents/ carers.

Measures

Primary caregivers and adolescents will be given the choice of completing paper copies of the questionnaires or completing them online through a secure system, using an anonymised unique identifying number. Children will complete the questionnaires (on paper or on a tablet) in the presence of a member of the research team so that they can help if they have any difficulties with

any of the questions. Measures will be completed prior to treatment, within two weeks of the last booster session and at each treatment session.

Screen for social anxiety: The screening questions proposed in the NICE guideline for the identification, assessment and treatment of Social Anxiety Disorder (NICE, 2013) will be used to screen participants for social anxiety in the absence of any validated brief screening measures available. The young person and their parents are asked whether the young person gets scared about doing things with other people, whether they find it difficult to do things when others are watching and whether they ever feel they cannot do these things or try to avoid them (See Appendix 1).

Screen for Autism Spectrum Disorder:

The social communication questionnaire (SCQ) will be used to identify young people with an undiagnosed Autism Spectrum Disorder (ASD). This is a 40 item, parent report measure based on the Autism Diagnostic Interview Revised (ADI-R). It requires a “yes/no” response to 19 items assessing behaviours occurring at any time throughout the young person’s life and 21 items behaviours between the age of 4 and 5 years. The questionnaire consists of three subscales; reciprocal social interaction (13 items), communication (8 items) and repetitive and restrictive behaviours (RRBI; 6 items). A score above the cut off of 15 indicates a possible diagnosis of ASD. Therefore, young people scoring 15 or higher will be excluded from the trial.

Anxiety Disorders Interview Schedule (ADIS) - child and parent report (W. K. Silverman & Nelles, 1988) is a structured diagnostic interview which will be administered to young people and their parents by research assistants (psychology graduates) trained to a high level of inter-rater reliability. If available, a revised version of the ADIS-C/P for DSM-5 will be used in this study. The ADIS-C/P assessment is used to determine whether the young person meets diagnostic criteria for social anxiety disorder and other comorbid anxiety, mood and behavioural disorders and to establish a clinician rating of severity for each disorder (CSR).

The young person self-report version of the **Liebowitz Social Anxiety Scale for Children and Adolescents (LSAS-C/A; (Masia, Klein, & Liebowitz, 1999)** will be administered to assess adolescents’ social anxiety symptoms. The LSAS-C/A includes 24 items, rated on a scale from ‘none’ (0) to ‘severe’ (3), to assess fear and avoidance of social interaction and performance. The LSAS-C/A has well established psychometric properties when administered to children and young people from 7 to 18 years of age (Masia-Warner et al., 2003).

Symptoms of broader anxiety disorders and depression will be assessed using the **Revised Child Anxiety and Depression Scale (RCADS; (Bruce F Chorpita, Yim, Moffitt, Umemoto, & Francis, 2000)** which is routinely collected within CAMHS as part of the CYP IAPT initiative. The RCADS is a 47-item parent and child report scale which assesses symptoms of separation anxiety disorder, social anxiety disorder, generalized anxiety disorder, panic disorder, obsessive compulsive disorder and major depressive disorder. Responders rate how often each item applies on a 0 ('never') to 3 ('always') scale. The RCADS has been shown to have robust psychometric properties in children and young people from 7-18 years of age (B.F. Chorpita, Moffitt, & Gray, 2005).

Concentration in class scale- yp report will be used to measure the level of concentration in class. This is a single item self-report scale in which the young person indicates from 0 ('not at all') to 100 ('totally') how well they have been able to concentrate on what the teacher is saying and what they have been learning in class at school. This scale has been used in the recent pilot work by DC/EL and respondents have found it to be a relevant indicator of change (Leigh & Clark, 2015).

The **Outcome Rating Scales (ORS; Miller & Duncan, 2000)** comprise four simple rating scales in which the young person/parent rates how they (/their son/daughter) have been feeling over the last week (individually, interpersonally, socially, and overall). This scale is routinely used in both participating NHS Trusts as part of the CYP IAPT initiative.

The **CYP IAPT Goals Progress scale** is a simple rating scale in which the young person rates on a 10 point scale the extent to which they have made progress towards their therapy goals. This scale is routinely used in both participating NHS Trusts as part of the CYP IAPT initiative.

Self-focused attention will be measured using the **Social Summary Weekly Rating Scale (SSWRS; Clark et al., 2003)** - adapted for children/adolescents. This measure consists of 6 items focused on the previous week and items assess social anxiety, social avoidance, self-focused versus external attention, anticipatory processing, and post-event rumination. Each item is rated on a scale from 0 to 8. It has good internal consistency in adults (Clark et al., 2003). Language for four of the items has been changed to be more appropriate for children and adolescents on the basis of PPI consultation. Participants will complete this measure weekly at each treatment session.

Social functioning will be further examined using an 18 item self-report measure of **social participation and social satisfaction**, developed by Lynn Alden (University British Columbia) for use with adults with social anxiety disorder. Respondents indicate on a 7 point scale how often they have engaged in different social activities and how satisfied they have felt with their relationships with different types of people. This scale has been used in the recent pilot work by DC/EL and young people have found it to be a relevant indicator of change (Leigh & Clark, 2015).

Safety behaviours associated with SAD will be measured using the ***Social Behaviours Questionnaire*** (SBQ; Clark, 2005) - adapted for children/adolescents. The SBQ is a 28 item scale assessing the use of social phobia related safety behaviours when respondents are anxious or in a social situation. Each behaviour is rated on a 4 point scale ranging from, 0 = “Never”, through to 1 = “Sometimes”, 2 = “Other” and 3 = “Always”. The SBQ has good psychometrics properties in adults (Clark, 2005). It has been adapted for use with children and adolescents with the addition of four further questions and changes to wording on four other items to be more developmental appropriate on the basis of consultation with Patient and Public Involvement (PPI) representatives.

Social cognitions and attitudes will be measured using the ***Social Cognitions Questionnaire*** (SCQ; Clark, 2005) and the ***Social Attitudes Questionnaire*** (SAQ; Clark, 2005) – both adapted for children/adolescents. The SCQ is a 22 item questionnaire assessing social phobia related negative automatic thoughts. Each thought is rated twice. First, the respondent rates the frequency with which the thought occurred in the last week when he/she was “nervous or frightened”. The frequency rating scale is: 1 = “thought never occurs”, 2 = “thought rarely occurs”, 3 = “thought occurs during half of the times when I am anxious”, 4 = “thought usually occurs”, 5 = “thought always occurs when I am anxious”. Second, the respondent rates the extent to which the thought was considered to be true. The belief rating scale runs from 0 = “I do not believe this thought” to 100 = “I am completely convinced this thought is true.

The SCQ has high internal consistency and discriminant validity in adults (Clark, 2005). It has been adapted for use with children and adolescents on the basis of PPI consultation, in that wording has been amended to be more developmentally appropriate on seven items and a further seven items have been added. The SAQ is a 50 item scale that assesses beliefs that are thought to make an individual vulnerable to social phobia. The beliefs were intended to fit into three broad categories: “Excessively high performance standards”, “Conditional Beliefs” and “Unconditional Beliefs”.

However, item selection was based more on clinical experience than on an attempt to sample each category in a comprehensive manner. Each item is rated on a scale that ranges from 1 = “Totally agree” through to 2 “Agree very much”, 3 = “Agree slightly”, 4 = “Neutral”, 5 = “Disagree slightly”, 6 = “Disagree very much”, to 7 = “Totally disagree”. Respondents are asked to choose the rating that “Best describes how you think”. The SAQ has high internal consistency and discriminant validity in adults (Clark, 2005). For children and adolescents, two further items have been included and language has been changed to be more developmentally appropriate on the basis of PPI consultation. ***The Children's Global Assessment Scale (CGAS)*** will be administered to assess the young person’s overall functioning. The CGAS is rated by the assessor on a scale from 1 (most impaired) to 100 (most functional). This scale is divided into 10-point sections, in which the relevant

level of functioning is described and examples are given. The CGAS has been found to have good inter-rater and test-retest reliability and is able to demonstrate discriminant and concurrent validity (Shaffer et al., 1983). In the current study a second rater will independent rate the CGAS for all 15 young people in order to establish inter-rater reliability.

Patient Health Questionnaire-9 (PHQ-9) is a nine item measure assessing the presence of the main symptoms of major depression on a four-point scale from 0 (not at all) to 3 (nearly every day) over the last two weeks. This is followed by one item asking young people to rate how difficult these problems have made it for them to work, take care of things at home, or get along with other people on a four-point scale from “not at all difficult” to “extremely difficult”. This measure is widely used and has robust psychometric properties when used with young people (Kroenke, Spitzer, & Williams, 2001)

Changes in global functioning will be assessed using the **Clinical Global Impression Scale - Improvement (CGI-I; (Guy, 1976)**. This asks the clinician to rate how improved the patient is compared to their initial assessment, prior to treatment, on a scale of 1 (very much improved) to 7 (very much worse). Final scores will be dichotomised to represent ‘much or very much improved’ versus other. A second rater will independent rate the CGI-I for all 15 young people in order to establish inter-rater reliability.

Participant Acceptability Rating.

At the end of treatment, participants will rate how acceptable they found the treatment using items used in previous studies of psychological therapies (de Graaf et al., 2009), specifically young people will be asked to report on the extent to which they agree with the statements ‘I was satisfied with the treatment’ and ‘I would recommend the treatment to others’ on a 5 point scale from ‘Completely agree’ to ‘Completely disagree’. They also have the opportunity to complete a free text box to comment on the treatment.

Clinician competency in delivering CT will be assessed using the Cognitive Therapy Competence Scale for Social Phobia (CTCS-SP; (Clark et al., 2006). This scale includes 16 items which are rated on a 7 -point scale from 0-6, assessing how well each component of the treatment is carried out. The final score is calculated as the mean of all 16 items. The CTCS-SP is well validated with good inter-rater (ICC = .81) and test-retest ($r_{tt} = .92$) reliability for mean competency as well as a high internal consistency ($\alpha = .97$) with adults (von Consbruch, Clark, & Stangier, 2012). The scale will be adapted in line with the adaptations made to the treatment to be used with adolescents (i.e. addressing bullying/teasing, working with parents and schools and modifying wording as appropriate). Competency criteria will be set on the basis of prior use of the CTCS-SP with adult populations (i.e.

therapists must achieve an average score of 4 (across sessions) for all items and the overall judgement score). In order to establish inter-rater reliability, therapy sessions will be double rated by DC and EL, and an external, independent assessor who is highly experienced in using the CTCS-SP will rate one randomly selected session for each clinician who receives training.

Clinician Logs

'Clinician's logs' are 'ad-hoc' forms designed to capture the amount of healthcare resources (i.e., qualified staff time) necessary to implement the CT-SAD-A treatment within a CAMHS setting. They will be completed by both supervisors and therapists, who will have to record – as applicable - the amount of time spent in activities related to the CT-SAD-A treatment, including training, supervision, preparation and delivery (ie, contact with client) of the CT-SAD-A treatment.

Data analysis

Analysis of Clinician Competency and Clinical outcomes

Data on the proportion of clinicians achieving specific and overall competency scores will be presented. Changes in the young people and caregiver clinical outcome measures pre and post will be presented using appropriate descriptive statistics and where appropriate differences in repeated measures will be presented as effect sizes with 95% confidence intervals.

Analysis of economic outcomes

Data recorded in the 'clinician's logs' will be used to calculate the total mean amount of qualified staff time used by the NHS per adolescent treated. Results will also be stratified by type of staff time use (i.e., time spent in training, supervision, preparation and delivery of the CT-SAD-A treatment). Results will be reported in terms of mean values with variability around the mean measured by standard deviations. Percentages of missing values will also be reported.

Analysis of qualitative outcomes

Interpretative Phenomenological Analysis (IPA; (Smith, Flowers, & Larkin, 2009), an approach to qualitative research which is used widely in applied psychology, will be used to assess data obtained from the qualitative interviews. This analysis is phenomenological and interpretive in that it is concerned with both understanding how people make sense of their experiences and acknowledging the role of the researcher in identifying patterns of meaning across experiential accounts. IPA has been used extensively to explore people's experiences of psychotherapy and mental health services, including adult social anxiety disorder (McManus, Peerbhoy, Larkin, & Clark, 2010); it has also been used widely to explore families' experiences of mental health issues.

Participants will have the opportunity to withdraw some or all of their interview data prior to data analysis. All interviews approved for data analysis will be transcribed in full and anonymised at point of transcription. Transcription will involve detailed coding (in order to identify the experiences, claims and concerns of each participant), followed by the elaboration of emerging themes for each case. In a multiple perspective design, these themes are generally brought together at the level of each sub-sample group, before any form of between-sample synthesis is attempted.

Credibility of the qualitative analysis will be checked via analytic triangulation on two levels. Firstly, in-depth triangulation will be provided through supervision. This will involve co-analysis of selected transcripts; use of reflexive practices in supervisory discussions; and audit checking for plausibility, coherence and comprehensiveness of analysis at each key stage of the process, with each sub-sample. The aim of this level is to maintain high standards of analysis. Secondly, a broader triangulation exercise will be conducted in order to check the appropriateness of the theme titles, persuasiveness and plausibility of the overarching narrative, and intelligibility of the overall structure. This will involve a presentation of the draft analysis by the research fellow to a small expert reference group which will include the CI, the PPI lead, the interviewing team and representatives from the sub-sample populations. The reference group will be invited to comment upon the presentation, and to provide feedback on the sensitivity to context, rigour, transparency, coherence and utility of the analysis (after (Yardley, 2000)). The aim of this level is to check that the analysis is meaningful, useful and accessible.

Appendix 1

HTA Social anxiety in adolescents: Assessment Schedule

Abbreviations

ADIS-C/P	ADIS for DSM-IV child and parent version
LSAS-C	Liebowitz Social Anxiety Scale- child and parent report
RCADS-c/p	Revised Child Anxiety and Depression Scale- child/parent report
CGAS	Clinical Global Assessment Scale (clinician single rating of functioning; 0-100)
CGI-	Clinical Global Impression- Improvement (1-7)
PHQ-9	Patient Health Questionnaire

Clinician Training and competency assessment

Therapist time in training for CT-SAD-A will be collected using therapist and supervisor logs.

Measure
PRE TREATMENT
Screen for social anxiety*
ADIS-C/P
CGAS
LSAS-C/A
RCADS-c/p
YP age, gender, Parent/child ethnicity, yp history of psychotropic medication, parent relationship status, parent education, parent employment status, yp educational/employment status (parent report)
Concentration in class scale- yp report
Child & Adolescent Social Summary Weekly Rating Scale (includes item on self-focused attention)
Child & Adolescent Social Cognitions Questionnaire – yp report
Child & Adolescent Social Behaviour Questionnaire - yp report
Child & Adolescent Social Attitudes Questionnaire – yp report
Social participation and social satisfaction - yp report
Outcome Rating Scale (ORS)
PHQ-9
Social communication questionnaire (parent report)
SESSION BY SESSION
CYP IAPT Goals Progress scale
Child & Adolescent Social Summary Weekly Rating Scale –yp report
Child & Adolescent Social Cognitions Questionnaire – yp report
LSAS-C/A – yp report
RCADS-social anxiety subscale
Concentration in class scale
Outcome Rating Scale (ORS)
PHQ-9
ADDITIONAL INTERIM MEASURES (session 7)

Child & Adolescent Social Behaviour Questionnaire yp report
Child & Adolescent Social Attitudes Questionnaire – yp report
Social participation and social satisfaction yp report
POST-TREATMENT
ADIS-C/P
CGAS
CGI-I
LSAS-C/A
RCADS-c/p
CYP IAPT Goals Progress scale
Child & Adolescent Social Summary Weekly Rating Scale – yp report
Child & Adolescent Social Cognitions Questionnaire – yp report
Child & Adolescent Social Behaviour Questionnaire - yp report
Child & Adolescent Social Attitudes Questionnaire – – yp report
Social participation and social satisfaction – yp report
Concentration in class scale
Clinician competency with CT
Outcome Rating Scale (ORS)
PHQ-9

***NICE screen for social anxiety**

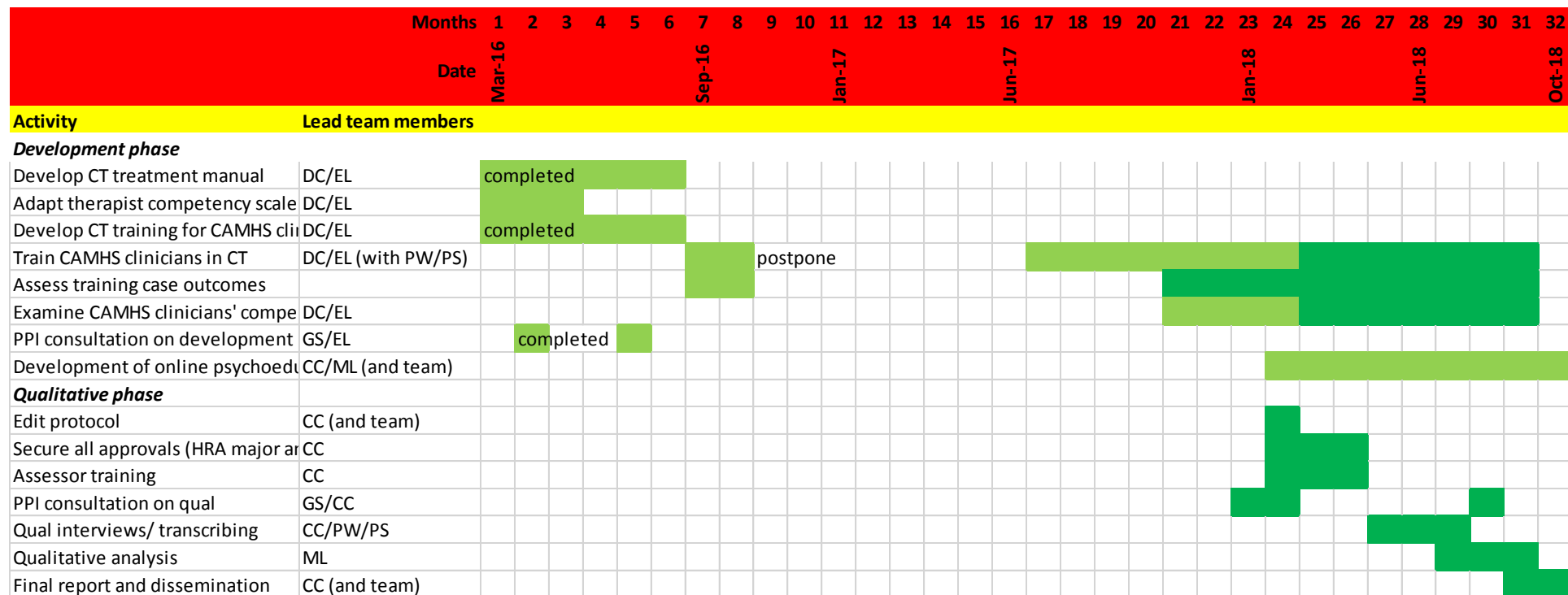
As there is no brief screening measure available for social anxiety (and no data on specificity/sensitivity of subscales from RCADS/SCAS etc) we will use the NICE screening questions as follows:

Sometimes people get very scared when they have to do things with other people, especially people they don't know. They might worry about doing things with other people watching. They might get scared that they will do something silly or that people will make fun of them. They might not want to do these things or, if they have to do them, they might get very upset or cross.	
Do you/does your child get scared about doing things with other people, like talking, eating, going to parties, or other things at school or with friends	YES/NO
Do you/does your child find it difficult to do things when other people are watching, like playing sport, being in plays or concerts, asking or answering questions, reading aloud, or giving talks in class?	YES/NO
Do you/does your child ever feel that you/your child can't do these things or try to get out of them?	YES/NO

If young person and/or parent respond YES to *any* item proceed to ADIS-C/P.

YP and parents will also be administered the RCADS as routine- so any YP that are above clinical cut-offs on the RCADS social anxiety scale who DO NOT screen positive on the above will also proceed to ADIS-C/P.

Appendix 3 - Gantt Chart



References

- Alden, L. Interpersonal Outcome Scales. *Unpublished Measure*. University of British Columbia.
- Beesdo, K., Bittner, A., Pine, D. S., Stein, M. B., Höfler, M., Lieb, R., & Wittchen, H. U. (2007). Incidence of social anxiety disorder and the consistent risk for secondary depression in the first three decades of life. *Archives of General Psychiatry*, 64, 903-912.
- Beesdo, K., Knappe, S., & Pine, D. S. (2009). Anxiety and anxiety disorders in children and adolescents: developmental issues and implications for DSM-V. *Psychiatric Clinics of North America*, 32(3), 483-524.
- Borkovec, T. D., & Nau, S. D. (1972). Credibility of analogue therapy rationales. *Journal of Behavior Therapy and Experimental Psychiatry*, 3(4), 257-260.
- Bruce, S. E., Yonkers, K. A., Otto, M. W., Eisen, J. L., Weisberg, R. B., & Pagano, M. (2005). Influence of psychiatric comorbidity on recovery and recurrence in generalized anxiety disorder, social phobia, and panic disorder: A 12-year prospective study. *American Journal of Psychiatry*, 162(6), 1179-1187.
- Chartier, M. J., Walker, J. R., & Stein, M. B. (2003). Considering comorbidity in social phobia. *Social Psychiatry and Psychiatric Epidemiology*, 38(12), 728-734.
- Chorpita, B. F., Moffitt, C. E., & Gray, J. (2005). Psychometric properties of the Revised Child Anxiety and Depression Scale in a clinical sample. *Behaviour research and therapy*, 43(3), 309-322.
- Chorpita, B. F., Yim, L., Moffitt, C., Umemoto, L. A., & Francis, S. E. (2000). Assessment of symptoms of DSM-IV anxiety and depression in children: A revised child anxiety and depression scale. *Behaviour research and therapy*, 38(8), 835-855.
- Clark, D. M. (2005). Three Questionnaires for Measuring Central Constructs in the Cognitive Model of Social Phobia: Preliminary Analysis: Available from Prof. David Clark, Department of Psychiatry, University of Oxford.
- Clark, D. M., Ehlers, A., Hackmann, A., McManus, F., Fennell, M., & Grey, N. (2006). Cognitive therapy versus exposure and applied relaxation in social phobia: A randomized controlled trial. *Journal of consulting and clinical psychology*, 74(3), 568-578.
- Clark, D. M., Ehlers, A., Hackmann, A., McManus, F., Fennell, M., Grey, N., . . . Wild, J. (2006). Cognitive Therapy Versus Exposure and Applied Relaxation in Social Phobia: A Randomized Controlled Trial. *Journal of Consulting & Clinical Psychology*, 74(3), 568-578.
- Clark, D. M., Ehlers, A., McManus, F., Hackmann, A., Fennell, M., & Campbell, H. (2003). Cognitive therapy versus fluoxetine in generalized social phobia: A randomized placebo controlled trial. *Journal of consulting and clinical psychology*, 71(6), 1058-1067.
- Clark, D. M., & Wells, A. (1995). A cognitive model of social phobia. In R. G. Heimberg, M. Liebowitz, D. Hope & F. Schneier (Eds.), *Social phobia: Diagnosis, assessment and treatment* (pp. 69–93). New York: Guilford Press.
- Clark, D. M., Wild, J., Grey, N., Stott, R., Liness, S., & Deale, A. (2012). *Self-study enhances the effects of Cognitive Therapy for social anxiety disorder: A randomized controlled trial. Pre-publication report - registration: ISRCTN11178360. 20122109.*
- Dolan, P., Gudex, C., Kind, P., & Williams, A. (1995). *A social tariff for EuroQol: results from a UK general population survey*: Centre for Health Economics University of York, UK.
- Essau, C. A., Conradt, J., & Petermann, F. (1998). [Frequency and comorbidity of social anxiety and social phobia in adolescents. Results of a Bremen adolescent study]. *Fortschritte der Neurologie-Psychiatrie*, 66(11), 524-530.
- EuroQuol. (2015). European Quality of Life-5 Dimension 5-level: EQ-5D-5L. <http://www.euroquol.org/eq-5d-products/eq-5d-5l.html>.
- Ginsburg, G. S., Kendall, P. C., Sakolsky, D., Compton, S. N., Piacentini, J., Albano, A. M., . . . March, J. (2011). Remission After Acute Treatment in Children and Adolescents With Anxiety Disorders: Findings From the CAMS. *Journal of Consulting & Clinical Psychology*, 79(6), 806-813.

- Guy, W. (1976). *The Clinical Global Impression Scale; ECDEU Assessment Manual for Psychopharmacology*. Rockville, MD.
- Hodson, K. J., McManus, F. V., Clark, D. M., & Doll, H. (2008). Can Clark and Wells' (1995) Cognitive Model of Social Phobia be Applied to Young People? *Behavioural and Cognitive Psychotherapy*, 36(4), 449-461. doi: 10.1017/s1352465808004487
- Katzelnick, D. J., Kobak, K. A., DeLeire, T., Henk, H. J., Greist, J. H., Davidson, J. R., . . . Helstad, C. P. (2001). Impact of generalized social anxiety disorder in managed care. *American Journal of Psychiatry*, 158(12), 1999-2007.
- Kendall, P., & Marrs-Garcia, A. (1999). Psychometric analyses of a therapy-sensitive measure: The Coping Questionnaire (CQ). *Unpublished manuscript, Temple University*.
- Kendall, P. C., Choudhury, M., Hudson, J., & Webb, A. (2002). The CAT project. *Manual For The Cognitive Behavioral Treatment Of Anxious Adolescents*. London: Workbook Publishing.
- Kendall, P. C., Hudson, J. L., Gosch, E., Flannery-Schroeder, E., & Suveg, C. (2008). Cognitive-behavioral therapy for anxiety disorder youth: a randomized clinical trial evaluating child and family modalities. *Journal of consulting and clinical psychology*, 76(2), 282.
- Kessler, R. C., Berglund, P., Demler, O., Jin, R., Merikangas, K. R., & Walters, E. E. (2005). Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the national comorbidity survey replication. *Archives of General Psychiatry*, 62(6), 593-602. doi: 10.1001/archpsyc.62.6.593
- Kroenke, K., Spitzer, R., & Williams, J. (2001). The PHQ-9. Validity of a brief depression severity measure. *Journal of General Internal Medicine*, 16, 606-613.
- Leigh, E., & Clark, D. M. (2015). Cognitive Therapy for Social Anxiety Disorder in Adolescents: A Development Case Series. *Behavioural and cognitive psychotherapy*, 1-17.
- Magee, W. J., Eaton, W. W., Wittchen, H. U., McGonagle, K. A., & Kessler, R. C. (1996). Agoraphobia, simple phobia, and social phobia in the National Comorbidity Survey. *Archives of General Psychiatry*, 53(2), 159-168.
- Masia-Warner, C., Storch, E. A., Pincus, D. B., Klein, R. G., Heimberg, R. G., & Liebowitz, M. R. (2003). The Liebowitz social anxiety scale for children and adolescents: an initial psychometric investigation. *Journal of the American Academy of Child & Adolescent Psychiatry*, 42(9), 1076-1084.
- Masia, C. L., Klein, R. G., & Liebowitz, M. R. (1999). The Liebowitz Social Anxiety Scale for Children and Adolescents (LSAS-CA): available from Carrie Masia-Warner, NYU Child Study Center, 215 Lexington Avenue, 13th floor, New York, NY 10016.
- Mayo-Wilson, E., Dias, S., Mavranouzouli, I., Kew, K., Clark, D. M., Ades, A., & Pilling, S. (2014). Psychological and pharmacological interventions for social anxiety disorder in adults: a systematic review and network meta-analysis. *The Lancet Psychiatry*, 1(5), 368-376.
- McManus, F., Peerbhoy, D., Larkin, M., & Clark, D. M. (2010). Learning to change a way of being: an interpretative phenomenological perspective on cognitive therapy for social phobia. *Journal of anxiety disorders*, 24(6), 581-589.
- Melfsen, S., Kühnemund, M., Schwieger, J., Warnke, A., Stadler, C., Poustka, F., & Stangier, U. (2011). Cognitive behavioral therapy of socially phobic children focusing on cognition: a randomised wait-list control study. *Child and adolescent psychiatry and mental health*, 5(5), 1-12.
- Parr, C. J., & Cartwright-Hatton, S. (2009). Social anxiety in adolescents: The effect of video feedback on anxiety and the self-evaluation of performance. *Clinical Psychology and Psychiatry*, 16, 46-54.
- Patel, A., Knapp, M., Henderson, J., & Baldwin, D. (2002). The economic consequences of social phobia. *Journal of affective disorders*, 68(2), 221-233.
- Pilling, S., Mayo-Wilson, E., Mavranouzouli, I., Kew, K., Taylor, C., Clark, D. M., & Group, G. D. (2013). Recognition, assessment and treatment of social anxiety disorder: summary of NICE guidance. *Bmj*, 346, f2541.

- Ranta, K., Kaltiala-Heino, R., Pelkonen, M., & Marttunen, M. (2009). Associations between peer victimization, self-reported depression and social phobia among adolescents: the role of comorbidity. *Journal of Adolescence*, 32(1), 77-93.
- Ratcliffe, J., Stevens, K., Flynn, T., Brazier, J., & Sawyer, M. (2012). An assessment of the construct validity of the CHU9D in the Australian adolescent general population. *Quality of life research*, 21(4), 717-725.
- Ronan, K. R., Kendall, P. C., & Rowe, M. (1994). Negative affectivity in children: Development and validation of a self-statement questionnaire. *Cognitive Therapy and Research*, 18(6), 509-528.
- Schreiber, F., Höfling, V., Stangier, U., Bohn, C., & Steil, R. (2012). A cognitive model of social phobia: Applicability in a large adolescent sample. *International Journal of Cognitive Therapy*, 5(3), 341-358.
- Schutters, S. I. J., Dominguez, M. d. G., Knappe, S., Lieb, R., van Os, J., Schruers, K. R. J., & Wittchen, H. U. (2011). The association between social phobia, social anxiety cognitions and paranoid symptoms. *Acta Psychiatrica Scandinavica*, 125, 213-227.
- Shaffer, D., Gould, M. S., Brasic, J., Ambrosini, P., Fisher, P., Bird, H., & Aluwahlia, S. (1983). A children's global assessment scale (CGAS). *Archives of General Psychiatry*, 40(11), 1228-1231. doi: 10.1001/archpsyc.1983.01790100074010
- Silverman, W., Albano, A., & Barlow, D. (1996). Manual for the ADIS-IV-C/P. New York: Psychological Corporation.
- Silverman, W. K., & Nelles, W. B. (1988). The anxiety disorders interview schedule for children. *Journal of the American Academy of Child & Adolescent Psychiatry*, 27(6), 772-778.
- Smith, J., Flowers, P., & Larkin, M. (2009). Interpretative Phenomenological Analysis: theory, method and research: London: SAGE Publications.
- Stein, M. B., McQuaid, J. R., Laffaye, C., & McCahill, M. E. (1999). Social phobia in the primary care medical setting. *Journal of Family Practice*, 48(7), 514-514.
- Stevens, K., & Ratcliffe, J. (2012). Measuring and valuing health benefits for economic evaluation in adolescence: an assessment of the practicality and validity of the Child Health Utility 9D in the Australian adolescent population. *Value in Health*, 15(8), 1092-1099.
- von Consbruch, K., Clark, D. M., & Stangier, U. (2012). Assessing Therapeutic Competence in Cognitive Therapy for Social Phobia: Psychometric Properties of the Cognitive Therapy Competence Scale for Social Phobia (CTCS-SP). *Behavioural and Cognitive Psychotherapy*, 40(2), 149-161. doi: 10.1017/s1352465811000622
- Waite, P., & Creswell, C. (2014). Children and adolescents referred for treatment of anxiety disorders: Differences in clinical characteristics. *Journal of affective disorders*, 167(0), 326-332. doi: <http://dx.doi.org/10.1016/j.jad.2014.06.028>
- Waite, P., & Creswell, C. (Under review). Observing parent-child interactions in children and adolescents: The effects of anxiety disorder and age.
- Whisman, M. A., Sheldon, C., & Goering, P. (2000). Psychiatric disorders and dissatisfaction with social relationships: Does type of relationship matter? *Journal of abnormal psychology*, 109(4), 803.
- Wittchen, H.-U., Fuetsch, M., Sonntag, H., Müller, N., & Liebowitz, M. (2000). Disability and quality of life in pure and comorbid social phobia. Findings from a controlled study. *European Psychiatry*, 15(1), 46-58.
- Wittchen, H. U., & Fehm, L. (2003). Epidemiology and natural course of social fears and social phobia. *Acta Psychiatrica Scandinavica Supplementum*, 108(417), 4-18.
- Yardley, L. (2000). Dilemmas in qualitative health research. *Psychology and health*, 15(2), 215-228.