STAndardised DIagnostic Assessment for children and adolescents with emotional difficulties (STADIA)
Statistical Analysis Plan

Final Version 2.0
(24 October 2023)

Based on Protocol version 4.1 (dated 01-Aug-2022)

Trial registration: ISRCTN15748675

The following people have reviewed the Statistical Analysis Plan and are in agreement with the contents				
Name	**Job title**	**Trial Role**	**Signature**	**Date**
Grace Holt	Medical Statistician	Trial Statistician (Author)	Grace Holt (Oct 24, 2023 10:26 GMT+1)	Oct 24, 2023
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Abbreviations

Abbreviation	Description
DMC	Data monitoring committee
SAP	Statistical Analysis Plan
TMG	Trial Management Group
TSC	Trial Steering Committee
CAMHS	Child and adolescent mental health services
DAWBA	Development and Well-Being Assessment
MFQ	Mood and Feelings Questionnaire
RCADS	Revised Children's Anxiety and Depression Scale
SDQ	Strengths & Difficulties Questionnaire
PHQ-9	Patient Health Questionnaire
GAD-7	Generalised Anxiety Disorder
CHU9D	Child Health Utility 9 Domains
EQ5DY	EuroQol Quality of Life Questionnaire 5 Domains for Young People
EQ5D5L	EuroQol Quality of Life Questionnaire 5 Domains
CRIES-8	Child Revised Impact of Events Scale

Changes from protocol

The table below details changes to the planned analyses in the SAP compared to the protocol which after discussion with the TMG are not considered to require a protocol amendment.

Protocol version and section	Protocol text	SAP version and section	SAP text	Justification

Amendments to versions

Version	Date	Change/comment	Statistician
1.0	10Aug2023	First version approved	Grace Holt
2.0	24Oct2023 (Post database lock)	Removed the 18-month analysis of index referral acceptance so that the SAP is in line with the protocol v4.1. Added Table 7 to clarify that at 18 months participants can only be categorised as having no diagnostic information if they have no diagnostic information on both the 12- and 18-month forms.	Grace Holt

Additional contributors to the SAP (non-signatory)

Name	Trial role	Job Title	Affiliation

1. INTRODUCTION & PURPOSE

This document details the rules proposed and the presentation that will be followed, as closely as possible, when analysing and reporting the main results from the <insert details of funder and the title of the trial>.

The purpose of the plan is to:

1. Ensure that the analysis is appropriate for the aims of the trial, reflects good statistical practice, and that interpretation of a priori and post hoc analyses respectively is appropriate.

2. Explain in detail how the data will be handled and analysed to enable others to perform or replicate these analyses

Additional exploratory or auxiliary analyses of data not specified in the protocol may be included in this analysis plan.

This analysis plan will be made available if required by journal editors or referees when the main papers are submitted for publication. Additional analyses suggested by reviewers or editors will be performed if considered appropriate. This should be documented in a file note.

Amendments to the statistical analysis plan will be described and justified in the final report of the trial and where appropriate in publications arising from the analysis.

Health economic and qualitative analysis plans are beyond the scope of this document.

2. SYNOPSIS OF STUDY DESIGN AND PROCEDURES

Title	STAndardised DIagnostic Assessment for children and adolescents with emotional difficulties
Acronym	STADIA
Chief Investigator	Kapil Sayal
Objectives	The aim of the study is to evaluate the clinical and cost effectiveness of a standardised diagnostic assessment (SDA) tool as an adjunct to usual clinical care in children and adolescents presenting with emotional difficulties referred to Child and Adolescent Mental Health Services (CAMHS). Additionally, the study will: • Include a detailed qualitative component to address: a) the feasibility of recruitment; b) the acceptability and usability of the interventions and procedure; c) how the intervention is used and how this deployment could be refined. • Seek to optimise the design and delivery of the SDA tool in partnership with young people, parents and CAMHS professionals to enhance acceptability, effectiveness and long-term uptake. • Identify the barriers and facilitators to implementation from the perspective of patients, parents, and CAMHS practitioners, managers and commissioners. • Use the knowledge gained to make evidence-based recommendations for assessment procedures within CAMHS and produce practice guidelines for clinical decision-making around the referral acceptance and assessment processes.
Trial Design	Multi-centre, two-arm, parallel group, randomised controlled trial (RCT).
Setting	Child and Adolescent Mental Health Services (CAMHS)
Sample size estimate	Assuming that 45% of participants randomised to the control arm will have a confirmed diagnosis within 12 months (based on unpublished data obtained from the trial sites), detection of an absolute increase of 10% with 90% power and 5% two-sided alpha, requires 544 participants per arm for analysis. Allowing for up to 10% non-collection of the primary outcome, we aim to randomise a total of 1210 participants.
Eligibility criteria	*Inclusion criteria for the child/young person* • Aged 5 to 17 years. • Referred to outpatient multidisciplinary specialist CAMHS. • Presenting with emotional difficulties. • If aged <16, has an eligible individual with parental responsibility (the parent/carer – see eligibility criteria below) willing and able to participate in the trial. • If aged 16-17, has capacity to provide valid written informed consent. • If aged 16-17 and participating without a parent/carer, able to complete the assessment tool in English. • If aged 16-17 and participating without a parent/carer, access to internet and email or telephone.

	Exclusion criteria for the child/young person • Emergency or urgent referral to outpatient multidisciplinary specialist CAMHS (i.e. requires an expedited assessment) according to local risk assessment procedures. • Child has severe learning disability. • Previously randomised in the STADIA trial. *Inclusion criteria for the parent/carer* • Individual with parental responsibility for the child/young person referred to CAMHS. • Adequate knowledge of the child/young person to be able to complete the assessment tool (i.e., known for at least 6 months). • Has capacity to provide valid written informed consent. • Access to internet and email or telephone. • Able to complete the assessment tool in English. *Exclusion criteria for the parent/carer* Local authority representatives designated to care for the child/young person.
Description of interventions	*Intervention:* The intervention is a standardised diagnostic assessment (SDA) tool as an adjunct to usual clinical care. The SDA tool will be the Development and Well-Being Assessment (DAWBA). The DAWBA will be completed by the parent (and child, if aged 11+) before the referral has been accepted and a summary report will be provided to participants and clinical staff, as an adjunct to usual clinical practice. *Control:* Children and young people randomised to the comparator arm will receive usual care (i.e. referral review as usual). Based on standard information provided with the referral a clinical decision is made about whether the referral is accepted and, if so, a clinician conducts the initial CAMHS assessment as per usual practice in the service.
Randomisation and blinding	Participants will be randomised in a 1:1 ratio to either the intervention arm or the control arm (see Section 7). Allocation will be assigned using a minimisation algorithm balancing on recruiting site, child age (5-10, 11-15, 16-17 years) and sex. It will not be possible to blind participants and all trial staff to treatment allocation, but treatment allocation data will be restricted to those trial staff who require access to facilitate trial conduct.
Outcome measures	*Primary outcome* The primary outcome is a clinician-made diagnosis decision about the presence of an emotional disorder within 12 months of randomisation. *Secondary outcomes* • A clinician-made diagnosis decision about the presence of an emotional disorder within 18 months of randomisation. • Acceptance of index referral • Acceptance of any referral within: a) 12 months and b) within 18 months of randomisation

	• Discharge from CAMHS within: a) 12 months and b) within 18 months of randomisation • Re-referral to CAMHS within: a) 12 months and b) within 18 months of randomisation • Confirmed diagnosis decision • Time from randomisation to diagnosis of emotional disorder • Diagnoses made over the: a)12 month period and b) 18 month period from randomisation • Treatment offered for diagnosed emotional disorder • Any treatment / interventions given • Time from randomisation to the decision to offer treatment for a diagnosed emotional disorder • Time from randomisation to start of first treatment for a diagnosed emotional disorder • Time from randomisation to the decision to offer any treatment • Time from randomisation to start of any treatment • Participant-reported diagnoses received in the 12 months post-randomisation • Depression symptoms in the child/young person • Anxiety symptoms in the child/young person • Comorbid oppositional defiant / conduct disorder symptoms in the child/young person • Functional Impairment in the child/young person • Self-harm thoughts in the child/young person • Self-harm behaviour in the child/young person • Depression symptoms in the parent/carer • Anxiety symptoms in the parent/carer • Health related quality of life for the child/young person and parent/carer • Time off education, employment or training because of emotional difficulties for the child/young person *Additional data collection* Following the onset of the coronavirus pandemic, additional data collection will be undertaken to ascertain post-traumatic stress disorder symptoms in the child/young person. This measure does not constitute a secondary outcome for the trial, but is intended to contribute to understanding the impact of the pandemic on children and young people and also offer useful context within which to interpret the trial findings.

2.1. Sample size and justification

Assuming that 45% of participants randomised to the control arm will have a diagnosis of an emotional disorder within 12 months, 1088 participants (544 in each arm) are required to detect a 10% increase in diagnoses to 55% in the treatment arm, based on a two-sided test with 5% significance and 90% power.

Allowing for non-collection of the primary outcome in 10% of cases, a total of 1210 participants will be recruited (605 in each arm).

2.2. Blinding and breaking of blind

It will not be possible to blind participants and some trial staff to treatment allocation, but treatment allocation data will be restricted to those trial staff who require access to facilitate trial conduct. The blinding status of individuals involved in the trial is given in Table 4 of the protocol.

There is no foreseeable situation in which blinded staff will need to know the treatment allocation of individual participants at any stage during the trial, therefore it is not necessary to have a blind breaking procedure in place.

2.3. Trial committees

A trial management group (TMG), trial steering committee (TSC) and data monitoring committee (DMC) will be assembled to oversee the trial. The general purpose, responsibilities and structure of the committees are described in the protocol. Further details of the roles and responsibilities of the TSC and DMC can be found in their charters agreed prior to the start of recruitment to the trial.

2.4. Outcome measures

Outcomes can be broadly categorised as being derived from one of three data sources:

- Clinical records
- Child/young person self-report
- Parent/carer report

Table 1 defines the different denominators used for the outcomes based on the data source, unless otherwise specified.

Table 1: Denominators of outcomes based on source of data

Data source	Denominator
Clinical records	All participants randomised
Child/young person self-reported questionnaires	Young people aged 16-17 and children aged 11-15 who assent to participate and whose parents consent to child participating,
Parent/carer reported questionnaires	Children aged 5-15 and young people aged 16-17 with a parent/carer taking part

Outcomes and their derivations are defined in detail in Table 2. For the following outcomes child/young person self-report and parent/carer report will both be obtained where possible (and reported separately):

- Participant reported diagnosis

- Depression symptoms in the child/young person
- Anxiety symptoms in the child/young person
- Comorbid oppositional defiant/conduct disorder symptoms in the child/young person
- Functional Impairment in the child/young person
- Time out of education, employment or training for the child/young person

2.5. Adjudication

Where there is uncertainty around emotional diagnoses and treatments for emotional diagnoses recorded within the clinical records, these diagnoses and treatments will be subject to adjudication, as outlined in the document "STADIA outcome definition and adjudication".

Table 2: Summary of the outcome measures

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Primary outcome								
Clinician-made diagnosis decision about the presence of an emotional disorder	Eligible diagnoses are those that reflect 'emotional' or 'internalizing' disorders in ICD/DSM, listed in Appendix A. The diagnosis must be documented in the clinical record within 12 months of randomisation by a mental health services clinician. Any eligible diagnosis made within 12 months will be included. Pre-specified diagnoses will be captured using a standard proforma. Alternative possible diagnoses identified from the clinical notes will be recorded verbatim on the data capture form and will be subject to adjudication (section 2.5).	Diagnosis of an emotional disorder will be coded as 'yes' if a participant has one of the eligible diagnosis (identified either using the proforma or following adjudication). Diagnosis of an emotional disorder will be coded as 'no' if a complete review of the records was possible, but no eligible diagnoses were identified (including children/young people who have not been seen by CAMHS in the 12-months post-randomisation.) Primary outcome will be missing for participants who died or withdrew consent prior to 12 months post randomisation unless they have a diagnosis prior to these events.	All participants randomised			✓		Risk ratio/ risk difference

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Secondary outcomes collected from records								
Clinician-made diagnosis decision about the presence of an emotional disorder within 18 months of randomisation	Eligible diagnoses are those that reflect 'emotional' or 'internalizing' disorders in ICD/DSM, listed in Appendix A. The diagnosis must be documented in the clinical record within 18 months of randomisation by a mental health services clinician. Any eligible diagnosis made within 18 months will be included. Pre-specified diagnoses will be captured using a standard proforma. Alternative possible diagnoses identified from the clinical notes will be recorded verbatim on the data capture form and will be subject to adjudication (section 2.5).	Diagnosis of an emotional disorder will be coded as 'yes' if a participant has one of the eligible diagnosis (identified either using the proforma or following adjudication). Diagnosis of an emotional disorder will be coded as 'no' if a complete review of the records was possible, but no eligible diagnoses were identified (including children/young people who have not been seen by CAMHS in the 18-months post-randomisation.) This outcome will be missing for participants who died or withdrew consent prior to 18 months post randomisation unless they have a diagnosis prior to these events.	All participants randomised				✓	Risk ratio/ risk difference

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Acceptance of index referral within 12 months	Whether the index referral (i.e., the referral made to CAMHS at the point of recruitment to the STADIA trial) was accepted or declined within 12 months. Acceptance is defined as being offered an appointment within CAMHS, whether or not the initial appointment was attended or subsequent appointments were offered/attended.	Index referral accepted = yes Index referral declined = no This outcome will be missing for participants who died or withdrew consent prior to 12 months post randomisation unless they have an acceptance prior to these events.	All participants randomised			✓		Risk ratio/risk difference
Acceptance of any referral within 12 months	Whether the index referral or any subsequent referral to CAMHS (if made) was accepted or not within 12 months. Acceptance as defined above for index referral.	Any referral accepted = yes No referrals accepted = no This outcome will be missing for participants who died or withdrew consent prior to 12 months post randomisation unless they have an acceptance prior to these events.	All participants randomised			✓		Risk ratio/risk difference
Acceptance of any referral within 18 months	Whether the index referral or any subsequent referral to CAMHS (if made) was accepted or not within 18 months. Acceptance as defined above for index referral.	Any referral accepted = yes No referrals accepted = no This outcome will be missing for participants who died or withdrew consent prior to 18 months post randomisation unless they have an acceptance prior to these events.	All participants randomised				✓	Risk ratio/risk difference

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Discharge from CAMHS within 12 months	Whether the child/young person was discharged from CAMHS (following acceptance of any referral made during the 12-months post-randomisation).	Date of discharge within 12 months recorded in notes = yes No date of discharge or discharge date after 12 months = no This outcome will be missing for participants who died or withdrew consent prior to 12 months post randomisation unless they have a discharge prior to these events. This outcome will only be derived if the participant has had their index or any referral accepted within 12 months.	All participants randomised			✓		Descriptive

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Discharge from CAMHS within 18 months	Whether the child/young person was discharged from CAMHS (following acceptance of any referral made during the 18-months post-randomisation).	Date of discharge within 18 months recorded in notes = yes No date of discharge or discharge date after 18 months = no This outcome will be missing for participants who died or withdrew consent prior to 18 months post randomisation unless they have a discharge prior to these events. This outcome will only be derived if the participant has had their index or any referral accepted within 18 months.	All participants randomised				✓	Descriptive
Re-referral to CAMHS within 12 months	Whether the child/young person was re-referred to CAMHS (for those whose index referral was turned down by CAMHS or those whose index referral was accepted but were subsequently discharged) during the 12-months post-randomisation.	A subsequent referral within 12 months recorded in notes = yes No subsequent referral within 12 months recorded in notes = no This outcome will be missing for participants who died or withdrew consent prior to 12 months post randomisation unless they have a rereferral prior to these events.	All participants randomised			✓		Descriptive

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Re-referral to CAMHS within 18 months	Whether the child/young person was re-referred to CAMHS (for those whose index referral was turned down by CAMHS or those whose index referral was accepted but were subsequently discharged) during the 18-months post-randomisation.	A subsequent referral within 18 months recorded in notes = yes No subsequent referral within 18 months recorded in notes = no This outcome will be missing for participants who died or withdrew consent prior to 18 months post randomisation unless they have a rereferral prior to these events.	All participants randomised				✓	Descriptive

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Confirmed diagnosis decision	Eligible diagnoses are those that reflect 'emotional' or 'internalizing' disorders in ICD/DSM, listed in Appendix A. The diagnosis must be documented in the clinical record within 12 months or 18 months of randomisation by a mental health services clinician. Any eligible diagnosis made within 12 months or 18 months will be included. Pre-specified diagnoses will be captured using a standard proforma. Alternative possible diagnoses identified from the clinical notes will be recorded verbatim on the data capture form and will be subject to adjudication (section 2.5).	Diagnosis of an emotional disorder or confirmed absence of an emotional disorder coded as 'yes' (identified either using the proforma or following adjudication). Confirmed diagnosis decision coded as 'no' if a complete review of the records was possible, but uncertainty around a diagnosis still exists at 12 months or 18 months (including children/young people who have not been seen by CAMHS in the 12-months or 18-months post-randomisation.)	All participants randomised			✓	✓	Risk ratio/risk difference
Time from randomisation to diagnosis of emotional disorder	Date of diagnosis will be the first documented eligible diagnosis. Diagnosis as defined above for primary outcome.	The time (in days) from randomisation to diagnosis will be derived from the randomisation date and date of diagnosis. Participants without a diagnosis will be censored at end of follow-up[1].	All participants randomised			✓	✓	Time to event

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Diagnoses made	The diagnosis must be documented in the clinical record within 12 or 18 months of randomisation by a mental health services clinician. Eligible diagnoses are those that reflect 'emotional' or 'internalizing' disorders in ICD/DSM, listed in Appendix A.	Pre-specified diagnoses will be captured using a standard proforma. Alternative possible diagnoses identified from the clinical notes will be recorded verbatim on the data capture form and will be subject to adjudication (section 2.5). Diagnoses will be reported for 12 and 18 months if the diagnosis date is within 12 and 18 months respectively. All diagnoses reported will be presented regardless of the status at 12 or 18 months. Any diagnoses which are adjudicated and found to not be emotional disorders will not be presented.	All participants randomised			✓	✓	Descriptive

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Treatment offered for diagnosed emotional disorder	Whether treatment was offered for a diagnosed emotional disorder, as defined for primary outcome above. For medications offered will be defined as whether they were prescribed any medications for an emotional disorder. Pre-specified treatments will be captured using a standard proforma. Alternative possible treatments identified from the clinical notes will be recorded verbatim on the data capture form and will be subject to adjudication (section 2.5).	There is a documented diagnosis of an emotional disorder AND a documented treatment plan = yes No documented diagnosis of emotional disorder and / or no documented treatments offered = no	All participants randomised			✓	✓	Risk ratio/risk difference

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Treatments / interventions given	All treatments/interventions offered by CAMHS for any reason within 12 or 18 months of randomisation, whether or not there is a documented diagnosis will be included. Pre-specified treatments will be captured using a standard proforma. Alternative possible treatments identified from the clinical notes will be recorded verbatim on the data capture form and will be subject to adjudication (section 2.5).	Pre-specified treatments will be captured using a standard proforma. Alternative possible treatments identified from the clinical notes will be recorded verbatim on the data capture form and will be subject to adjudication (section 2.5).	All participants randomised			✓	✓	Descriptive
Time from randomisation to the decision to offer treatment for a diagnosed emotional disorder	Date of decision will be the first date that the decision to offer treatment for a diagnosed emotional disorder is documented in the clinical notes. For medications the date of prescription will be used.	The time (in days) from randomisation to the date of the decision to offer treatment for a diagnosed emotional disorder will be derived from the randomisation date and the date of the documented decision. Participants without a decision to offer treatment for a diagnosed emotional disorder will be censored at end of follow-up [1].	All participants randomised			✓	✓	Time to event

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Time from randomisation to start of first treatment for a diagnosed emotional disorder	Date of treatment will be the first date that any treatment offered for a diagnosed emotional disorder is started. Medications will not be included in this analysis as date started medication is not collected. Treatment and diagnosed emotional disorder as defined as above.	The time (in days) from randomisation to start of first treatment for a diagnosed emotional disorder will be derived from the randomisation date and documented start date of first relevant treatment. Participants who have not started treatment for a diagnosed emotional disorder will be censored at end of follow-up[1].	All participants randomised			✓	✓	Time to event
Time from randomisation to the decision to offer any treatment	Date of decision will be the first date that the decision to offer any treatment is documented in the clinical notes. For medications the date of prescription will be used. Treatment as defined as above.	The time (in days) from randomisation to the date of the decision to offer any treatment will be derived from the randomisation date and the date of the documented decision. Participants who are not offered any treatment will be censored at end of follow-up[1].	All participants randomised			✓	✓	Time to event

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Time from randomisation to start of any treatment	Date of treatment will be the first date that any treatment offered is started. Medications will not be included in this analysis as date started medication is not collected. Treatment as defined as above.	The time (in days) from randomisation to start of any treatment will be derived from the randomisation date and documented start date of treatment. Participants have not started any treatment will be censored at end of follow-up[1].	All participants randomised			✓	✓	Time to event
Secondary outcomes collected from questionnaires								
Participant-reported diagnoses	Participants will be asked to report whether or not they received a diagnosis of the child/young person's difficulties from CAMHS in the 12 months post-randomisation and if so, what diagnosis was given and by whom.		Parent/carer report & Child/young person report		✓	✓		Descriptive
Depression symptoms in the child/young person	Mood and Feelings Questionnaire (MFQ)	33-items are answered on a 3-point scale ("not true" = 0, "somewhat true" = 1 point, "true" = 2 points) Scores range from 0 to 66 with higher scores indicating more severe depressive symptoms. A score of 27 or higher may be indicative of depression.	Parent/carer report & Child/young person report	✓	✓	✓		Difference in means

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Anxiety symptoms in the child/young person	Revised Children's Anxiety and Depression Scale (RCADS). An overall anxiety and low mood score is generated, with separate sub-scale scores for separation anxiety, social phobia, generalised anxiety, panic, obsessive compulsive disorder and major depression.	RCADS is a 47-item questionnaire. Each item is rated on a 4-point scale (never = 0, sometimes = 1, often = 2, always = 3). Total anxiety and depression scores range from 0 to 141. We will record scores for each of the 6 sub-scales. For analysis metric, we will use the total anxiety score.	Parent/carer report & Child/young person report	✓	✓	✓		Difference in means
Comorbid oppositional defiant/conduct disorder symptoms in the child/young person	Strengths & Difficulties Questionnaire (SDQ). A 25-item emotional and behavioural screening questionnaire for children and young people.	Each item is rated on a 3 point scale (Mostly "not true" = 0, "somewhat true" = 1 point, "certainly true" = 2 points, with some score in reverse). For each of the 5 scales the score can range from 0 to 10 if all items were completed.	Parent/carer report & Child/young person report	✓	✓	✓		Difference in means
Functional Impairment in the child/young person	SDQ Questionnaire impact supplement.	Impact supplement scores will be used to determine functional impairment. Impact scores range from 0 to 10. When respondents have answered 'no' to the first question on the impact supplement, the impact score is automatically scored zero.	Parent/carer report & Child/young person report	✓	✓	✓		Difference in means

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Self-harm in the child/young person	Frequency of thoughts of self-harm are rated over the last 6 months in the following categories: – Not at all – Once or twice – Three or more times Frequency of self-harm behaviour are rated over the last 6 months in the following categories: – Not at all – Once – Two or more times	Frequency of thoughts of self-harm and frequency of self-harm behaviour are directly asked to participating children and young people aged 11+, who agree to self-report.	Child/young person report **only**	✓	✓	✓		Descriptive
	She/he thought about killing themselves in the past two weeks. – Not true – Sometimes – True	Item 19 of the MFQ (She/he thought about killing themselves) will be used to summarise how the participant had been feeling in the past two weeks. This will be extracted from young person self-report and parent/carer-report of the MFQ.	Parent/carer report & Child/young person report					

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Depression symptoms in the parent/carer	Patient Health Questionnaire (PHQ-9). Total scores range from 0 to 27 with higher scores indicating increased severity of depression.	Each of the nine DSM-IV depression criteria are scored as "0" (not at all) to "3" (nearly every day) depending on the frequency with which they were experienced over the last 2 weeks.	Parent/carer report **only**	✓	✓	✓		Difference in means
Anxiety symptoms in the parent/carer	Generalised Anxiety Disorder (GAD-7). Total scores range from 0 to 21 with higher scores indicating more severe anxiety.	7 items are rated according to the frequency with which they have been experienced over the past 2 weeks (0 = 'not at all', 1 = 'several days', 2 = 'more than half the days', and 3 = 'nearly every day').	Parent/carer report **only**	✓	✓	✓		Difference in means
Time out of education, employment or training for the child/young person	Days missed from education, employment or training (as applicable) for the child/young person due to emotional difficulties		Parent/carer report & Child/young person report		✓	✓		Descriptive
Safety outcomes								
A significant deterioration in depression for the child/young person	MFQ (as above)	A score indicative of depression (27 or above) on the Mood and Feelings Questionnaire (MFQ) completed at follow-up, and an increase of 5 points or more from baseline.	Parent/carer report & Child/young person report		✓	✓		Descriptive

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
A significant deterioration in depression for the parent/carer	PHQ-9 (as above)	A score indicative of depression (15 or above) on the Patient Health Questionnaire (PHQ-9) completed at follow-up, and an increase of 5 points or more from baseline.	Parent/carer report **only**		✓	✓		Descriptive
Frequency of self-harm	Self-harm measure (as above)	Frequency self-harm behavior in children/young people based on self-report.	Child/young person report **only**	✓	✓	✓		Descriptive
Hospital admissions	Child/young person **OR** Parent/carer reports that child/young person was admitted to hospital (either physical or mental health-related) due to emotional difficulties as reported in the resource use questionnaire completed at 6- and 12 months post-randomisation.	A response from either the child/young person or the parent/carer indicating hospital admission = 'yes' A response from either source indicating no hospital admission (not contradicted by the other source) = 'no'	All participants randomised		✓	✓		Descriptive
A&E attendances	Child/young person **OR** Parent/carer reports that child/young person attended A&E (either physical or mental health-related) due to emotional difficulties as reported in the resource use questionnaire completed at 6- and 12 months post-randomisation.	A response from either the child/young person or the parent/carer indicating that A&E was used = 'yes' A response from either source indicating that A&E was not used (not contradicted by the other source) = 'no'	All participants randomised		✓	✓		Descriptive

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Deaths	The date of death must be within 12 months of randomisation and recorded either: (i) in the clinical record (ii) on the withdrawal form	Presence of a date of death within 12 months of randomisation on either source = yes No date of death within 12 months of randomisation recorded on either source = no This outcome will be missing for participants who withdrew consent prior to 12 months post randomisation unless they have died prior to this event.	All participants randomised			✓		Descriptive
Deaths	The date of death must be within 18 months of randomisation and recorded either: (iii) in the clinical record on the withdrawal form	Presence of a date of death within 18 months of randomisation on either source = yes No date of death within 18 months of randomisation recorded on either source = no This outcome will be missing for participants who withdrew consent prior to 18 months post randomisation unless they have died prior to this event.	All participants randomised				✓	Descriptive
Additional outcomes								

Outcome measures	Description and source	Derivation	Denominator	Time point (Months)				Analysis metric
				0	6	12	18	
Post-traumatic stress disorder symptoms in the child/young person	The Children's Revised Impact of Event Scale (CRIES-8).	There are 8 items that are scored on a four point scale: Not at all = 0 Rarely = 1 Sometimes = 3 Often = 5 There are two subscales: Intrusion = sum of items 1+3+6+7 Avoidance = sum of items 2+4+5+8 Sub-scale scores range from 0 to 20.	Parent/carer report & Child/young person report	✓	✓	✓		Difference in means

[1]End of follow-up will usually be 12 months from randomisation, but could be curtailed due to death or withdrawal.

3. INTERIM ANALYSIS

There is no planned interim analysis of treatment efficacy. However, an assessment of recruitment and retention will be performed following the internal pilot phase to determine the feasibility of recruitment and acceptability of the intervention according to agreed progression criteria outlined in the protocol.

4. GENERAL ANALYSIS CONSIDERATIONS

4.1. Analysis sets

The primary approach to between-group comparative analyses will be by modified intention-to-treat (i.e. including all participants who have been randomised and without imputation of missing outcome data), however, for partially completed questionnaires we will use questionnaire-specific imputation rules outlined in section 4.5.

4.2. Timing of final analysis

All outcomes will be analysed collectively at the end of the trial.

4.3. Statistical software

All analyses will be performed using Stata version 17 or above.

4.4. Derived variables

Details of how questionnaires are scored is contained within Table 2 and summarised in Appendix B. For details on how missing items will be dealt with refer to section 4.5.

Details of how the primary outcome will be derived are contained in Table 2 with further details in Appendix C.

4.5. Procedures for missing data

Missing baseline data

Missing baseline data is expected to be rare. However any missing baseline data in analyses using the baseline as a covariate will be imputed using the mean score at each centre in order to be able to include these participants in the analysis. These simple imputation methods are superior to more complicated imputation methods when baseline variables are included in an adjusted analysis to improve the precision of the treatment effect [1].

All baseline questionnaires are completed prior to randomisation with the exception of the baseline SDQ, which is completed immediately post-randomisation. However, its close proximity to randomisation (and the fact that it is completed as part of the DAWBA within the intervention arm) means that it is unlikely that responses will be vastly disparate between the randomised groups. For this reason, the same mean imputation methods will be applied for

SDQ at baseline, however, if notable imbalances exist between randomised groups then alternative imputation methods will be employed.

Missing items in questionnaires

Details of how missing items in questionnaires will be handled is outlined in the following table. For questionnaires administered at baseline that are still not scoreable after applying the following rules, will be imputed using the mean imputation as described above.

Table 3: Rules for imputing missing items within questionnaires

Questionnaire	Imputation method
MFQ	Missing scores are imputed pro-rata if no more than two items are missing.
RCADS	Missing data will be handled by prorating the remaining items within a scale if no more than two items within that scale are missing.
SDQ	For the main questionnaire, subscales will be scaled up pro-rata if at least 3 items are completed within each scale. There is no imputation for the impact supplement.
PHQ-9	If one or two values are missing from the score, then they will be substituted with the average score of the non-missing items. Questionnaires with more than two missing values will be disregarded.
GAD-7	If one or two values are missing from the score, then they will be substituted with the average score of the non-missing items. Questionnaires with more than two missing values will be disregarded.
CRIES-8	Missing data will be handled by prorating the remaining items within a scale if no more than one item within that scale are missing.

5. DESCRIPTION OF PARTICIPANT CHARACTERISTICS

5.1. Participant flow

The flow of participants through the trial will be summarised in a CONSORT diagram detailing:

- The number of eligible referrals screened
- The number who were excluded prior to randomisation (and reasons why)
- The number who were randomised into the trial (children/young people and parents/carers separately)
- The number of young people (and parents and carers) randomised to each arm
- The number allocated to the intervention arm that fully or partially completed a DAWBA
- The number of primary participants returning their 6-month questionnaire
- The number of primary and or secondary participants returning their 6-month questionnaire
- The number of primary participants returning their 12-month questionnaire
- The number of primary and or secondary participants returning their 12-month questionnaire

- The number with data collected from records at 12 and 18 months
- The number where primary outcome was not available and the reasons why
- The number where secondary outcome was not available and the reasons why
- The number included in the primary analysis and secondary analysis

5.2. Baseline characteristics

Child/young person

Children or young people will be described by treatment group with respect to baseline demographic and clinical characteristics (including randomisation minimisation variables):

- Age at randomisation
- Sex
- Gender
- Ethnicity
- Education/employment status (including type of school if in education)
- Deprivation index (derived from postcode of child/young person's primary residence)
- Prior CAMHS referral
- Previous or existing diagnoses

The following questionnaire scores for the child/young person will be reported at baseline for both (i) children/young people providing self-report, and (ii) participating parent/carers

- Depression symptoms – Mood and Feelings Questionnaire (MFQ)
- Anxiety symptoms – Revised Children's Anxiety Depression Scale (RCADS)
- Comorbid oppositional defiant/conduct disorder symptoms – Strengths and Difficulties Questionnaire (SDQ)
- Functional Impairment – SDQ impact supplement

The following will be reported at baseline by children/young people providing self-report

- Frequency of thoughts of self-harm are rated over the last 6 months
- Frequency of self-harm behaviour are rated over the last 6 months

Parent/carer

Participating parents and carers will also be described by treatment group with respect to baseline demographic and clinical characteristics:

- Relationship to child/young person
- Age at randomisation
- Gender
- Ethnicity

The following questionnaire scores will be reported at baseline for participating parent/carers

- Patient Health Questionnaire (PHQ-9)
- Generalised Anxiety Disorder (GAD-7)

Continuous data will be summarised in terms of the mean, standard deviation, median, lower & upper quartiles, minimum, maximum and number of observations. Categorical data will be summarised in terms of frequency counts and percentages. No formal statistical comparisons will be made.

6. ASSESSMENT OF STUDY QUALITY

6.1. Randomisation

Randomisation will be carried out using minimisation, including a random component that minimises imbalance with respect to recruiting site and the age and sex of the young person with an 80% chance.

The number of participants randomised to the two treatment groups at each recruiting centre will be tabulated. The other minimisation variables will be tabulated as part of the baseline characteristics.

6.2. Process outcomes

The following process measures

- Time from referral receipt to randomisation
- Time from randomisation to referral decision

will be presented descriptively in each treatment group in terms of the mean, standard deviation, median, lower & upper quartiles, minimum, maximum and number of observations

6.3. Adherence

Adherence is determined in terms of the level of participant completion of the DAWBA. This will be reported using the proportion of participants for whom

- the DAWBA is fully or partially completed by either child/young person or parent/carer
- the DAWBA report is generated
- the DAWBA report is sent to primary participant
- the DAWBA report is uploaded to clinical records

Additionally, for those with a completed DAWBA report the following will also be reported:

- Time from randomisation to the DAWBA report being provided to CAMHS

Additionally, the DAWBA categories will be reported descriptively.

6.4. Follow-up and discontinuations

Participating young people and parents/carers are followed up by a questionnaire at 6 months and 12 months following randomisation. The number and percentage of completed questionnaires will be tabulated in the two groups as well as reasons if the questionnaire has not been completed. Questionnaire completion will be defined as whether the participant

returned their questionnaire or not. The number of weeks to questionnaire completion from randomisation will be summarised using the mean, median, lower & upper quartiles, minimum and maximum.

The following information will be recorded on withdrawals:

- Number and percentage withdrawn consent to either access records or complete questionnaires
- Number and percentage withdrawn consent to access records and whether before or after 12 months post randomisation
- Number and percentage withdrawn from completing questionnaires and whether before or after 12 months post randomisation

6.5. Protocol deviations

A protocol deviation is a divergence or departure from the expected conduct of a study as defined in the protocol. Of particular importance are major deviations which may also be termed violations or non-compliances. These are deviations which may expose participants to increased risk, compromise the integrity of the entire study or affect participant eligibility.

The number of participants with protocol deviations as reported by researchers on the electronic case report form will be summarised by treatment group along with the type of deviation. Protocol deviations will also be listed.

7. ANALYSIS OF EFFECTIVENESS

7.1. Primary analysis

The primary comparative analysis will employ a generalized linear mixed effects regression model, adjusting for minimisation variables. The model will include a random effect for recruiting site, while all other minimisation variables will be adjusted for using fixed effects.

The between group effect will be reported using an adjusted risk difference and adjusted risk ratio along with corresponding 95% confidence intervals for each. A p-value will be reported for the adjusted risk ratio. Point estimates and confidence intervals will be obtained using Stata's Margins command with standard errors computed using the delta method [2].

7.2. Sensitivity analysis of primary outcome

We will repeat the primary analysis additionally adjusting for any variables with marked imbalance at baseline to check that this does not influence the findings.

We expect there to be <10% missing primary outcome data, therefore the primary approach to between-group comparative analyses will be by modified intention-to-treat (i.e. including all participants who have been randomised and without imputation of missing outcome data). However, appropriate imputation methods may be employed as part of a sensitivity analysis depending on the quantity of missing data (e.g. best or worst case imputation).

7.3. Subgroup analysis of primary outcome

Appropriate interaction terms will be included in the primary regression analyses in order to conduct subgroup analyses according to the following subgroups.

Subgroup	Levels
Sex of child/young person	Male Female
Age of child/young person	5-10 years 11-17 years

Between-group treatment effects will be provided for each subgroup as adjusted risk ratios and 95% confidence intervals, but interpretation of any subgroup effects will be based on the treatment-subgroup interaction (odds ratio), 95% confidence interval and p-value, estimated by fitting an appropriate interaction term in the regression models. Since the trial is powered to detect overall differences between the groups rather than interactions of this kind, these subgroup analyses will be regarded as exploratory.

7.4. Secondary analysis of primary outcome

A secondary analysis of the primary outcome will be carried out where the primary outcome will be treated as an ordinal variable which takes into account the fact that a participant cannot have a diagnosis unless they have their referral accepted.

The ordered categories for confirmed diagnosis decision about the presence if an emotional disorder within 12 months of randomisation will be:

1. Referral not accepted (any referral) within 12 months
2. Any referral accepted but no confirmed diagnosis within 12 months
3. Confirmed diagnosis within 12 months

A mixed effects ordered logistic model will be used, adjusting for minimisation variables. Similarly to the primary analysis, a random effect will be used for recruiting site, while all other minimisation variables will be adjusted for using fixed effects.

The between group effect will be reported using an adjusted common odds ratio along with a 95% confidence interval and a p-value.

The ordinal logistic regression model is based on the proportional odds assumption, that is, the effect of the intervention is consistent across the whole composite ordinal primary outcome spectrum. We will test for non-proportionality using a Likelihood Ratio test and if data show significant departures from the proportional odds assumption alternative models will be considered.

7.5. Secondary outcomes

The following secondary outcomes will be analysed using appropriate mixed effects models depending on the type of outcome variable, adjusting for minimisation variables. The model will include a random effect for recruiting site, while all other minimisation variables will be adjusted for using fixed effects. The between group effect will be reported using an appropriate adjusted effect estimate (See Table 2) along with a corresponding 95% confidence interval. Where an outcome is also measured at multiple time points a mixed model will be fitted with a treatment by time interaction to obtain estimates of treatment effect at each follow-up time.

The analyses of secondary outcomes will be considered supportive to the primary outcome and estimates and confidence intervals, where presented, should be interpreted in this light.

Secondary outcomes from records

Continuous outcome

The clinician-made diagnosis decision about the presence of an emotional disorder within 18 months of randomisation outcome will be analysed using the method used for the primary outcome (described in section 7.1).

Binary outcomes

The following binary outcomes:

- Acceptance of index referral
- Acceptance of any referral within 12 months of randomisation
- Acceptance of any referral within 18 months of randomisation
- Confirmed diagnosis decision within 12 months of randomisation
- Confirmed diagnosis decision within 18 months of randomisation
- Treatment offered for diagnosed emotional disorder within 12 months of randomisation
- Treatment offered for diagnosed emotional disorder within 18 months of randomisation

will be analysed using a mixed effects logistic regression model, adjusting for minimisation variables. The model will include a random effect for recruiting site, while all other minimisation variables will be adjusted for using fixed effects. The between group effect will be reported using an adjusted risk difference and adjusted risk ratio along with corresponding 95% confidence intervals for each. Point estimates and confidence intervals will be obtained using Stata's Margins command with standard errors computed using the delta method [2].

Time to event outcomes

The following time to event outcomes

- Time from randomisation to diagnosis of emotional disorder
- Time from randomisation to the decision to offer treatment for a diagnosed emotional disorder
- Time from randomisation to start of first treatment for a diagnosed emotional disorder
- Time from randomisation to the decision to offer any treatment
- Time from randomisation to start of any treatment

will be compared between groups using a shared-frailty Cox proportional hazards model, adjusting for minimisation variables. The model will be specified so that participants from the same recruitment site have a shared frailty, while all other minimisation variables will be included as fixed effects. Outcomes will be censored at the end of follow-up, which for most participants will be 18 months following randomisation but could be earlier (e.g. due to withdrawal, death etc.)

The between group effect will be reported using an adjusted hazard ratio along with a corresponding 95% confidence interval. Kaplan-Meier curves will be presented for each of the outcomes by trial arm.

Secondary outcomes from participant reported questionnaires

For the following outcomes derived from participant questionnaires,

- Depression symptoms in the child/young person
- Anxiety symptoms in the child/young person
- Comorbid oppositional defiant/conduct disorder symptoms in the child/young person
- Functional Impairment in the child/young person
- Depression symptoms in the parent/carer
- Anxiety symptoms in the parent/carer

which are measured at multiple time points, a linear mixed effects model will be utilised with a treatment by time interaction to obtain estimates of treatment effect at each follow-up time. This longitudinal model permits the inclusion of participants with complete data for at least one timepoint and gives valid inferences when data are assumed missing at random. The model will also include a random effect for recruiting site, while all other minimisation variables will be adjusted for using fixed effects. The model will be fit using an unstructured variance-covariance. If the model fails to converge, a simpler covariance structure will be used.

The between group effect will be reported using an adjusted difference in means along with a corresponding 95% confidence interval.

The comparative statistical analyses described above will be performed for the total questionnaire score while each subscale will be summarised by treatment group in terms of the mean, standard deviation, median, lower & upper quartiles, minimum, maximum and number of observations. A summary of participant reported questionnaires and their subscales is provided in Table 4.

For outcomes that are both (i) self-reported by the child/young person and (ii) reported by the parent/carer these will be reported separately.

Table 4: Participant reported questionnaires and subscales

Trial Outcome	Questionnaire	Subscales
Depression symptoms in the child/young person	MFQ	None (Total score only)
Anxiety symptoms in the child/young person	RCADS	1) separation anxiety disorder, 2) social phobia, 3) generalized anxiety disorder, 4) panic disorder, 5) obsessive compulsive disorder, 6) low mood (major depressive disorder). Total Anxiety Scale (sum of 1-5) Total Internalising Scale (sum of 1-6)
Total symptoms in the child/young person	SDQ	1) Emotional symptoms subscale 2) Conduct problems subscale 3) Hyperactivity/inattention subscale 4) Peer relationships problem subscale 5) Prosocial behaviour Total difficulties (sum of 1-4)
Functional Impairment in the child/young person	SDQ impact supplement	None (Impairment score only)
Depression symptoms in the parent/carer	PHQ-9	None (Total score)
Anxiety symptoms in the parent/carer	GAD-7	None (Total score)
Post-traumatic stress disorder symptoms in the child/young person	CRIES-8	1) Intrusion 2) Avoidance Total score (sum of 1-2)

Sensitivity analysis for participant reported outcomes

A repeat sensitivity analysis will be performed to test the sensitivity of the results to the missing at random assumption. The same longitudinal model (as described in the previous section) with a treatment by time interaction will be used to obtain estimates of treatment effect at each follow-up time, however, missing data will be imputed using multiple imputation using chained equations. 30 imputations will be carried out.

The following baseline variables will be included in the imputation model:

- Site
- Age of young person
- Sex of young person
- Deprivation index quintile

- Questionnaire score at baseline
- PHQ-9 score at baseline

Where applicable, the proxy or self-report equivalent questionnaire score at baseline will also be included in the imputation model.

The following post-randomisation variables will also be included in the imputation model as they are likely to be closely related to the outcome

- Referral acceptance
- Questionnaire score at 6 months

Other secondary outcomes

All other secondary outcomes will be reported descriptively in each group without formal statistical comparisons. Continuous outcomes will be summarised in terms of the mean, standard deviation, median, lower & upper quartiles, minimum, maximum and number of observations. Categorical outcomes will be summarised in terms of frequency counts and percentages.

8. ANALYSIS OF SAFETY

Relevant adverse events (AEs) and serious adverse events (SAEs) are outcomes (e.g. symptoms of depression and anxiety) collected during routine follow-up using participant questionnaires.

Safety outcomes (listed in Table 2) will be reported descriptively by treatment group. Categorical data will be summarised in terms of frequency counts and percentages. No formal statistical comparisons will be made.

9. EXPLORATORY ANALYSIS

Exploratory analysis – impact of COVID-19

Temporal changes in baseline demographic and clinical measures will assessed using descriptive statistics. For participants that have completed the Children's Revised Impact of Event Scale (CRIES-8), either self-reported or proxy, a supplementary longitudinal study will analyse changes in PTSD symptoms over the subsequent recruitment period, adjusting for randomised trial arm. Further details of this analysis will be described in a separate analysis plan.

10. REFERENCES

10.1. Internal references

Document	Version	Date
STADIA Protocol	4.1	01 August 2022
STADIA Dummy Tables	2.0	10 August 2023
STADIA SWAT Dummy Tables	1.0	10 August 2023
STADIA outcome definition and adjudication	1.0	25 Feb 2020

10.2. External references

1. Sullivan, T.R., et al., *Should multiple imputation be the method of choice for handling missing data in randomized trials?* Statistical Methods in Medical Research, 2016. **27**(9): p. 2610-2626.
2. Norton, E.C., M.M. Miller, and L.C. Kleinman, *Computing adjusted risk ratios and risk differences in Stata.* Stata Journal, 2013. **13**(3): p. 492-509.

A. Appendix: Eligible diagnoses

Eligible diagnoses are those that reflect 'emotional' or 'internalizing' disorders in ICD/DSM, to include:

- Anxiety disorder
- Separation anxiety disorder
- Specific phobia (any)
- Social phobia or Social anxiety disorder
- Agoraphobia
- Panic disorder (DSM5 additionally has Panic Attack with a specifier)
- Phobic anxiety disorder (unspecified)
- Selective mutism
- Generalized anxiety disorder
- Obsessive compulsive disorder
- Body dysmorphic disorder
- Acute stress reaction
- Post-traumatic stress disorder
- Adjustment Disorder
- Other anxiety disorder
- Mixed anxiety and depressive disorder

- Depression
- Depressive episode (any / mild / moderate / severe)
- Depressive disorder
- Recurrent depressive disorder (any / mild / moderate / severe)
- Major Depressive disorder
- Persistent Depressive disorder
- Other depressive episode
- Persistent mood (affective) disorder (including cyclothymic disorder / dysthymic disorder)
- Other / Unspecified mood (affective) disorder

- Bipolar disorder
- Bipolar affective disorder
- Manic episode

- Childhood emotional disorder unspecified (F93.9)

B. Appendix: Deriving questionnaire scores

Table 5: Deriving questionnaire scores

Questionnaire	Score derivation
MFQ	33-items are answered on a 3-point scale ("not true" = 0, "somewhat true" = 1 point, "true" = 2 points) Scores range from 0 to 66 with higher scores indicating more severe depressive symptoms. A score of 27 or higher may be indicative of depression.
RCADS	RCADS is a 47-item questionnaire. Each item is rated on a 4-point scale (never = 0, sometimes = 1, often = 2, always = 3). An overall anxiety and low mood score is generated, with separate sub-scale scores for separation anxiety, social phobia, generalised anxiety, panic, obsessive compulsive disorder and major depression.
SDQ	The 25 items in the SDQ comprise 5 scales of 5 items each. Each item is rated on a 3 point scale (Mostly "not true" = 0, "somewhat true" = 1 point, "certainly true" = 2 points, with some score in reverse). For each of the 5 scales the score can range from 0 to 10 if all items were completed. Impact supplement scores will be used to determine functional impairment. Impact scores range from 0 to 10. When respondents have answered 'no' to the first question on the impact supplement (i.e. when they do not perceive themselves as having any emotional or behavioural difficulties), they are not asked to complete the questions on resultant distress or impairment; the impact score is automatically scored zero in these circumstances.
PHQ-9	Each of the nine DSM-IV depression criteria are scored as "0" (not at all) to "3" (nearly every day) depending on the frequency with which they were experienced over the last 2 weeks. Total scores range from 0 to 27 with higher scores indicating increased severity of depression.
GAD-7	7 items are rated according to the frequency with which they have been experienced over the past 2 weeks (0 = 'not at all', 1 = 'several days', 2 = 'more than half the days', and 3 = 'nearly every day'). Total scores range from 0 to 21 with higher scores indicating more severe anxiety.
CRIES-8	There are 8 items that are scored on a four point scale (Not at all = 0, Rarely = 1, Sometimes = 3, Often = 5 There are two subscales (scores range from 0 to 20 each): Intrusion = sum of items 1+3+6+7 Avoidance = sum of items 2+4+5+8

C. Appendix: Deriving primary outcome

A categorical variable will be derived to describe participants diagnoses within 12 and 18 months:

1) Emotional disorder diagnosis documented in notes
2) Having a clearly documented absence of an emotional disorder
3) Uncertainty about the presence of an emotional disorder
4) No diagnostic information

Missing

This is used to determine both the primary outcome (Confirmed emotional disorder diagnosis – category 1 versus 2, 3 & 4) and confirmed diagnosis decision (1 & 2 versus 3 & 4).

Participants will be categorised as missing if they have either:

- Died within 12- or 18-months post randomisation
- Withdrawn consent to access records within 12- or 18-months post randomisation

unless they have had an emotional disorder diagnosis prior to any of these events.

To categorise participants at both 12 and 18 months post randomisation, both data from records and adjudication data will be used. Table 6 shows how the outcome will be derived based on the data obtained from records and adjudication.

Table 6: Diagnosis categorisation outcome dependent on data from records and adjudication

		Adjudication			
		1 Confirmed presence of emotional disorder	**2** Confirmed absence	**3** Uncertainty	**4** No diagnostic information
Data collection form records	**1** Confirmed presence of emotional disorder	**1**	**1**	**1**	**1**
	2 Confirmed absence	**1**	**2**	**2**	**2**
	3 Uncertainty	**1**	**2**	**3**	**3**
	4 No diagnostic information	**1**	**2**	**3**	**4**

The number within the table refers to the resulting categorical variable.

Data from records are being collected at both 12 and 18 months post randomisation. Table 7 shows how to derive the categorical outcome at 18 months. This includes both data from records and adjudication datasets.

Table 7: Derivation of categorical diagnosis outcome at 18 months

	18 Month – based on records and adjudication				
12 Month Outcome – based on records and adjudication		Diagnosis	Absence	Uncertainty	No diagnostic information
	Diagnosis	Diagnosis	Diagnosis	Diagnosis	Diagnosis
	Absence	Diagnosis	Absence	Uncertainty	Absence
	Uncertainty	Diagnosis	Absence	Uncertainty	Uncertainty
	No diagnostic information	Diagnosis	Absence	Uncertainty	No diagnostic information