TRIAL PROTOCOL

STAndardised DIagnostic Assessment for children and adolescents with emotional difficulties (STADIA): a multi-centre randomised controlled trial

STADIA Trial

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Protocol Amendments				
The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version				
Amendment number	**Date of amendment**	**Protocol version number**	**Type of amendment**	**Summary of amendment**
N/A	N/A	N/A	N/A	N/A – First approved version
SA01	16-Dec-2019	2.0	Substantial	Confirmation of re-consent procedure for 16 year olds during follow-up. Clarification regarding outcome definitions. Minor corrections and clarifications throughout.
SA03	13-Aug-2020	3.0	Substantial	Additional participant questionnaire (CRIES-8).
SA04	03-Feb-2021	4.0	Substantial	Implementation of SWAT and amendment to arrangements to voucher payments to participants.
MA14	01-Aug-2022	4.1	Non-substantial	Extension of data collection up to 18-months post-randomisation. Minor updates to administrative information and addition of eligible emotional disorder.

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This protocol has been approved by:	
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Protocol Version Number:	Version: 4.1
Protocol Version Date:	01-AUG-2022
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Sponsor approval
Where Nottinghamshire Healthcare NHS Foundation Trust takes on the Sponsor role for oversight of protocol development, signing of the IRAS form by the Sponsor will serve as confirmation of approval of this protocol.

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TRIAL SUMMARY

Title	STAndardised DIagnostic Assessment for children and adolescents with emotional difficulties (STADIA)
Trial Design	Multi-centre, two-arm, parallel group, randomised controlled trial (RCT).
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.

Participant Population and Key Eligibility Criteria	*Population:* Children and young people (age 5-17 years) presenting with emotional difficulties referred to Child and Adolescent Mental Health Services (CAMHS) *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.

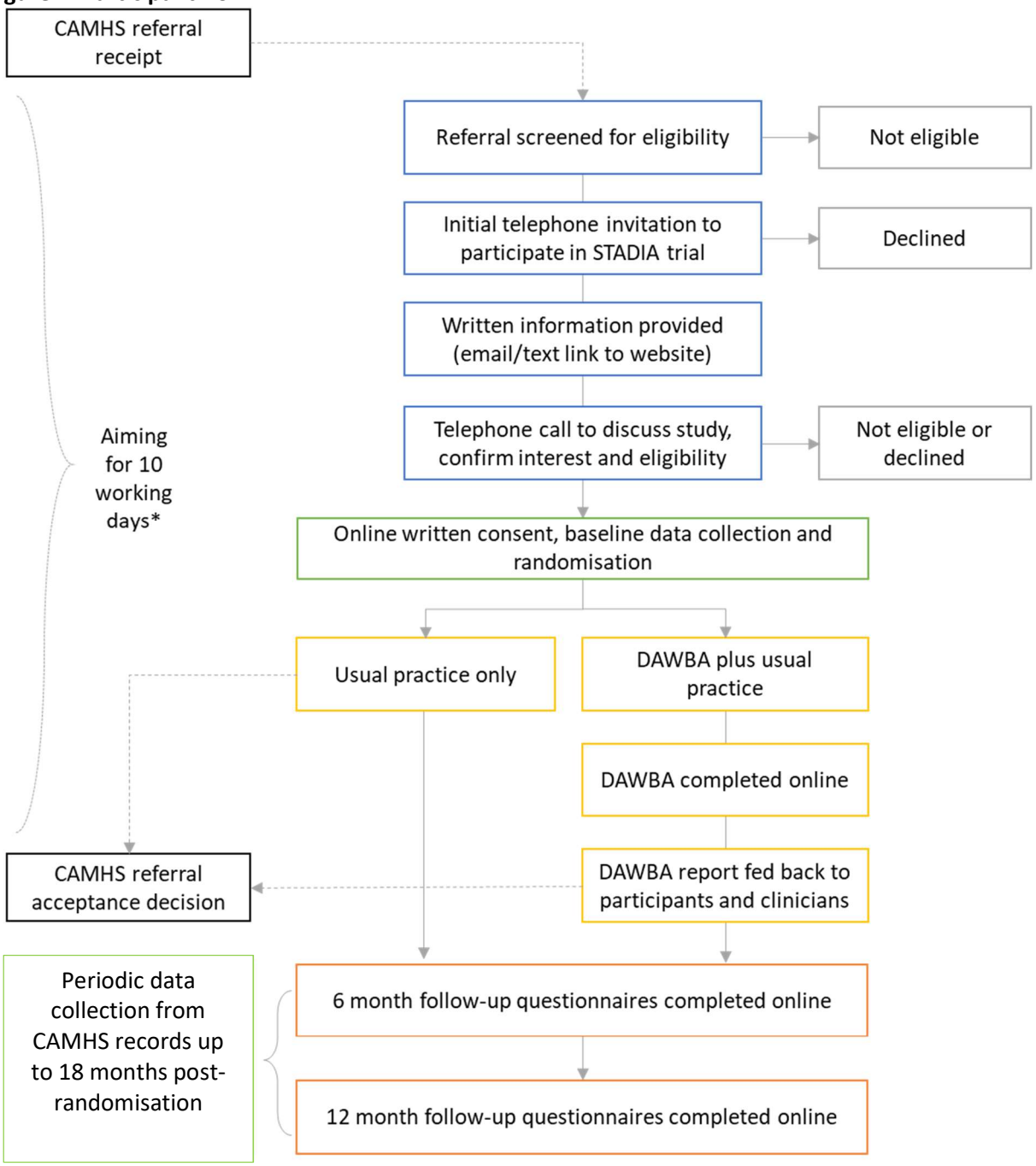
Intervention and control	*Intervention:* The intervention is a standardised diagnostic assessment (SDA) tool as an adjunct to usual clinical care. The SDA tool will be the Development and Well-Being Assessment (DAWBA). The DAWBA will be completed by the parent (and child, if aged 11+) before the referral 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.

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* • Post-traumatic stress disorder symptoms in the child/young person

Sample Size	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.
Health economics	*Health economic outcomes* • Child/young person quality of life • Parent/carer quality of life *Resource Use* Data will be collected on health care resource use, including education and social care. *Analysis* The costs and benefits will be analysed using Marginal Net Benefit approach and Cost Effectiveness planes and cost effectiveness acceptability curves will be determined between the control and the intervention group.
Qualitative study	*Pilot Phase Interview Study* Qualitative interviews will be conducted during the pilot phase 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 for the main trial. Semi-structured interviews will be conducted with up to 25 participants (parents and young people aged 16 and 17), 25 clinicians and 15 service managers and commissioners across the 5 sites. *Main Trial Process Evaluation Study* A process evaluation will aim to identify the barriers and facilitators to implementation of the intervention. Using qualitative approaches, this study will produce evidence on how the intervention is introduced and operationalised in routine practice across the different sites, how it is experienced by different stakeholders, and what contextual factors and causal mechanisms affect outcomes, with the intention of producing learning for future implementation. Semi-structured interviews will be conducted with another 25 participants (parents and young people) and 25 clinicians taking part in the main trial to explore the perceived functioning of the intervention, the organisation of the service and reflective experiences on outcomes. *Analysis* All qualitative interview data will be analysed using interpretative and thematic approaches to coding, and adopt the framework method. NVIVO 12 will be used to manage the qualitative data.

TRIAL FLOW DIAGRAM

Figure 1. Participant flow



** For sites where the waiting time for the CAMHS acceptance decision usually exceeds 10 working days from referral receipt, recruitment activities may start and/or continue beyond 10 working days from referral receipt, providing the intervention period can be completed prior to the CAMHS referral decision.*

CONTENTS

ABBREVIATIONS AND DEFINITIONS

Term	Description
AE	Adverse Event: Any untoward medical occurrence in a clinical trial participant which does not necessarily have a causal relationship with the treatment received.
CAMHS	Child and Adolescent Mental Health Services
CHU9D	Child Health Utility Instrument – 9 domains
CI	Chief Investigator: The research lead for the trial.
CRIES-8	Child Revised Impact of Events Scale
DAWBA	Development and Well-Being Assessment
DMP	Data Management Plan
eAF	Electronic Assent Form
eCRF	Electronic Case Report Form
eICF	Electronic Informed Consent Form
ePIS	Electronic Participant Information Sheet
EQ5D5L	EuroQol Quality of Life Questionnaire 5 Domains, 5 Levels
EQ5DY	EuroQol Quality of Life Questionnaire 5 Domains for Young People
GAD-7	Generalised Anxiety Disorder Questionnaire – 7 items
GCP	Good Clinical Practice
MFQ	Mood and Feelings Questionnaire
NCTU	Nottingham Clinical Trials Unit
pCRF	Paper Case Report Form
PHQ-9	Patient Health Questionnaire – 9 items
PI	Principal Investigator: The research lead at each site.
RCADS	Revised Children's Anxiety and Depression Scale
REC	Research Ethics Committee
SAE	Serious Adverse Event: An untoward occurrence that: • Results in death • Is life-threatening • Requires hospitalisation or prolongation of existing hospitalisation • Results in persistent or significant disability or incapacity • Is a congenital anomaly/birth defect • Or is otherwise considered medically significant by the Investigator
SDA	Standardised Diagnostic Assessment
SDQ	Strengths and Difficulties Questionnaire
Source data	All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial

1. Background and Rationale

1.1. Background

Child and adolescent emotional disorders, such as depression and anxiety disorders, cause considerable distress for affected children and their families, affect day-to-day life and can persist over time with a long-term impact on functioning. Outcomes across a range of domains can be adversely affected including family and peer relationships, quality of life, participation in activities, school attendance, academic attainment and employment opportunities, ultimately affecting life chances.[1-4] Emotional disorders are often comorbid with other disorders (e.g. behavioural disorders, drug and alcohol misuse and physical health problems) and are associated with self-harm and completed suicide. Effective evidence-based interventions are available but require appropriate identification of presenting difficulties to enable timely access to services and earlier recovery.[3]

Children and adolescents with clinically significant emotional difficulties may be referred to outpatient specialist CAMHS for assessment and interventions. A recent report on access to and waiting times for CAMHS highlighted concerns around the high rates of rejected referrals, with the second most common reason for declining referrals being insufficient information.[5] Limited information is currently available to guide optimal approaches to determine which referrals should be accepted contributing to a large variation in acceptance rates.[5] Likewise there is a lack of evidence on how best to conduct assessments for children with emotional difficulties to optimise outcomes. Acceptance criteria and assessment procedures differ across services and there is no single standardised approach.

The multi-disciplinary nature of CAMHS means that children are assessed by practitioners from different professional backgrounds, with variations in training and ethos, who may have different conceptualisations of presenting difficulties. The type and scope of assessments offered by CAMHS practitioners vary. Assessments are often conducted by practitioners without formal diagnostic training.[6] The validity and value of mental health diagnoses have been questioned, possibly reflecting concerns about 'medical' models of care, stigma or labelling.[6-8] This can mean that in routine practice, assessments are often undertaken without the aim of making or recording a diagnosis.

However, NICE guidelines for management and treatment are often based on diagnostic classification of disorders, so the ability to offer evidence-based interventions requires that the child's difficulties are accurately identified. Although NICE Quality Standards[9] state that children with suspected depression should have the diagnosis confirmed and recorded, this is variable in practice.[6, 10] For example, an audit in one service found that just 18% of children had a diagnosis recorded, despite this being mandatory, [6] and another study found that less than one-third of referred children who met criteria for depression had this diagnosed clinically.[10] Furthermore, we know that emotional difficulties are frequently comorbid with other disorders.[2, 11] However, comorbidity is under-recorded and a training workshop with CAMHS practitioners in one service resulted in little change in diagnostic recording of comorbid disorders. [6]

The use of diagnostic assessments has been recommended so that important problems are detected and appropriate interventions are offered.[3, 8] The NICE guidelines for depression recommend the use of standardised diagnostic assessment (SDA) tools as potential adjuncts in the detection of depression within CAMHS.[12] It has further been recommended that SDA tools should be used as

an adjunct in addition to clinical assessments, potentially at the point of referral receipt, to enable the allocation of cases to the most appropriate professional.[7, 13, 14]

SDA tools include the Development and Well-Being Assessment (DAWBA), a structured package of questionnaires and interviews for parents (and young people, aged 11+) which can be completed online or by telephone and yields algorithm-based diagnostic information.[15] A previous randomised controlled trial (RCT) using the DAWBA highlighted that, for emotional disorders, disclosing DAWBA diagnosis information to clinicians can improve the level of agreement between the DAWBA and clinical diagnoses, suggesting that the DAWBA can aid clinical detection of emotional disorders.[16] The DAWBA information also improved detection of comorbid disorders. A UK trial found higher levels of agreement between DAWBA and clinical diagnoses, following disclosure of DAWBA information, in relation to anxiety disorders.[17] Practitioners acknowledged that parents often want a diagnosis and that additional information could supplement the assessment and aid detection of difficulties.[7] Parents reported finding the DAWBA easy to understand and helpful in feeling more positive about their child.[13]

Logically, it could be expected that the introduction of an SDA tool at the point of referral to CAMHS should enable resources to be better targeted and lead to a more timely conclusion to assessments with a diagnostic decision, increase the probability that an appropriate evidence-based treatment is offered, and lead to improved outcomes (such as greater reduction of symptoms and improvement in functioning) from treatment as well as a better experience of care for the child and their families. However, there is limited evidence on the utility of SDA tools for informing optimal approaches to assessment within routine clinical practice.

There is therefore a need to better evaluate the use of SDA tools and to identify barriers to modifying diagnostic practice. Hence, we propose a multi-centre RCT with a nested qualitative study (pilot phase) and process evaluation (main trial) to evaluate the clinical and cost effectiveness of an SDA tool (the DAWBA), as an adjunct to clinical assessment in CAMHS, for children presenting with emotional difficulties.

2. Aims, Objectives and Outcome Measures

2.1. Aims and Objectives

The aim of the study is to evaluate the clinical and cost effectiveness of a Standardised Diagnostic Assessment (SDA) tool (the Development and Well-Being Assessment; DAWBA), as an adjunct to usual clinical care for children/young people presenting with emotional difficulties referred to Child and Adolescent Mental Health Services (CAMHS).

Specific objectives:

1. To conduct an RCT to determine the effectiveness of an SDA tool as an adjunct to usual clinical care on diagnosis and treatment of emotional disorders, symptoms of emotional difficulties and comorbid disorders and associated functional impairment.

2. To undertake an internal pilot phase of the RCT to assess recruitment and acceptability in all sites, with clear progression criteria to the full trial.

3. To include a detailed qualitative component (see section 15) within the pilot phase to address:
   a) The feasibility of recruitment.
   b) The acceptability and usability of the interventions and procedure.
   c) How the intervention is used and could be refined for the main trial.

4. To conduct a process evaluation (see section 15.4) alongside the main trial which will:
   a) Optimise the design and delivery of the DAWBA SDA tool in partnership with young people, parents and CAMHS professionals to enhance acceptability, effectiveness and long-term uptake.
   b) Identify the barriers and facilitators to implementation of the DAWBA from the perspective of patients, parents, and CAMHS practitioners, managers and commissioners.

5. To estimate cost effectiveness of the use of the DAWBA SDA tool versus usual care (see section 14).

6. To use the knowledge gained, from the perspective of all stakeholders, 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.

2.2. Outcome Measures

2.2.1. Primary outcome

The primary outcome is a clinician-made diagnosis decision about the presence of an emotional disorder within 12 months of randomisation.

2.2.2. 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 12 and 18 months of randomisation
- Discharge from CAMHS within 12 and 18 months
- Re-referral to CAMHS within 12 and 18 months
- Confirmed diagnosis decision
- Time from randomisation to diagnosis of emotional disorder
- Diagnoses made over the 12 and 18 month period from randomisation
- Treatment offered for diagnosed emotional disorder
- Treatments / 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
- Time off education, employment or training because of emotional difficulties for the child/young person

Outcomes are defined further in section 13.1 (Table 6) and section 14.3.

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.

3. Trial Design and Setting

3.1. Trial Design

This is a multi-centre, two-arm, parallel group, randomised controlled trial (RCT). A target sample size of 1210 participants will be recruited and randomised, with equal allocation (1:1), to the SDA tool as an adjunct to usual practice or usual practice only.

Participants will be either:
- Parent/carer and child/young person dyad, or
- Young person only, if aged 16 or 17 and choosing to participate alone

3.2. Trial Setting

Recruitment will take place in at least five sites in the UK that provide outpatient multidisciplinary specialist CAMHS. These sites are geographically dispersed with services covering urban and rural areas, thus are likely to be socio-demographically representative of CAMHS in England, enabling nationally generalisable findings.

Participants will be identified through the usual referral pathways for the participating CAMHS, which may include NHS or local authority managed Single/Central Point of Access referral points or meetings. Participants will be identified from referrals to the participating CAMHS and invited to participate in the trial following referral receipt, but prior to referral acceptance (Figure 1).

3.3. Identification of participants

Consecutive sampling will be employed where (as far as possible) everyone who meets the inclusion criteria will be invited to join the study. Details of all participants screened and approached about the trial will be recorded on the Participant Screening/Enrolment Log. The numbers of potentially eligible children/young people who could not be contacted about the study, those who were approached but were not eligible, and those who were eligible but not recruited (e.g. declined to take part) will be recorded. The reason for non-recruitment will also be recorded including, where given, the reason for declining.

The STADIA researchers (NHS personnel, based within the Single Point of Access (SPA) /triage team to carry out research activities on behalf of the team and authorised to access referral information) at each site will review the referrals received by CAMHS, on a daily basis where possible, to identify 5-17 year olds presenting with emotional difficulties, according to a standard proforma.

The initial invitation to consider participation in the STADIA trial will be made by the STADIA researcher, on behalf of the CAMHS team, and will follow a recommended form of words to ensure an appropriate and consistent approach. Parents of all potentially eligible participants, or the participants themselves if aged 16-17 and contact details are available for the young person (see Table 2), will initially be contacted by telephone to ask if they would like more information about the research. If so an email address and/or contact telephone number(s) will be obtained, so that a link to the STADIA online electronic Participant Information Sheet (ePIS) can be provided. Those that decline will be recorded on the Screening/Enrolment Log and no further contact will be made by the STADIA trial team. Those that agree will be sent an email and/or text with a link to the STADIA ePIS providing full details about the trial, and verbal consent will be sought for the researcher to contact them again to discuss this further and answer any questions.

The researcher will follow-up with a telephone call to the family the next day (at the earliest) to confirm receipt of the information, provide an additional verbal explanation of the trial, answer any questions and, if interested, confirm eligibility.

Potential participants who are interested and confirmed eligible during this follow-up telephone call will be provided with a personal link to the online electronic Informed Consent Form (eICF) and, where applicable the electronic Assent Form (eAF) (see section 5.2), enabling them to review the requirements of the trial and provide written informed consent/assent (as detailed below).

4. Eligibility

4.1. Inclusion criteria for the child/young person

1. Aged 5 to 17 years.
2. Referred to outpatient multidisciplinary specialist CAMHS.
3. Presenting with emotional difficulties.
4. 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.
5. If aged 16-17, has capacity to provide valid written informed consent.
6. If aged 16-17 and participating without a parent/carer, able to complete the assessment tool in English.
7. If aged 16-17 and participating without a parent/carer, access to internet and email or telephone.

4.2. Exclusion criteria for the child/young person

1. Emergency or urgent referral to outpatient multidisciplinary specialist CAMHS (i.e. requires an expedited assessment) according to local risk assessment procedures.
2. Child/young person has severe learning disability.
3. Previously randomised in the STADIA trial.

4.3. Inclusion criteria for the parent/carer

1. Individual with parental responsibility for the child/young person referred to CAMHS (as defined in Table 1).
2. Adequate knowledge of the child/young person to be able to complete the assessment tool (i.e., known for at least 6 months).
3. Has capacity to provide valid written informed consent.
4. Access to internet and email or telephone.
5. Able to complete the assessment tool in English.

4.4. Exclusion criteria for the parent/carer

1. Local authority representatives designated to care for the child/young person.

Table 1: Definition of Parental Responsibility

A person with parental responsibility (the parent/carer) will be required to participate in the trial if the child/young person is aged <16 years and may also participate in the trial alongside young people aged 16-17. The person with parental responsibility will be: • the child's mother or father • the child's legally appointed guardian • a person with a residence order concerning the child

5. Consent

Informed consent for each participant must be obtained and documented (using the online electronic informed consent form) prior to baseline data collection. The potential participant(s) will be given the opportunity to ask questions throughout the consent/assent process. The local site STADIA researcher will provide written and verbal information, answer questions and support the electronic consent/assent process, and will be delegated this responsibility by the Principal Investigator as captured on the Site Delegation Log. It remains the responsibility of the local site Principal Investigator to ensure informed consent/assent is obtained appropriately.

The participation and consent/assent requirements for the trial are shown in Table 2.

5.1. Children <11 years of age

Where the referral to CAMHS is for a child under the age of 11 the parent/carer only will participate in the trial and provide consent for their own participation and on behalf of the child/young person (see **Figure 2**).

The parent/carer is the 'primary' participant and randomisation will take place following documentation of parental consent and completion of parent-reported baseline measures.

5.2. Children/young people aged 11-15

Where the referral to CAMHS is for a child/young person aged 11-15 the parent/carer must participate in the trial and provide consent for their own participation and on behalf of the child/young person. In addition, the child/young person may be invited to provide written assent for their own participation (e.g., completion of the DAWBA and self-report questionnaires) but this is not mandatory (see **Figure 2**).

The child/young person will be provided with age appropriate information about the study and will have the opportunity to discuss this with the researcher if they wish. The parent/carer will be asked to confirm that the child/young person is aware of their participation in the study. In the event of any disagreement between the parent/carer's and child/young person's wishes, the child/young person will not enter the study.

The parent/carer is the 'primary' participant and randomisation will take place following documentation of parental consent and completion of parent-reported baseline measures.

5.3. Young people aged 16-17

Where the referral to CAMHS is for a young person aged 16-17 the young person must participate in the trial and provide consent for their own participation. In addition, the parent/carer may be invited to participate in the trial and provide consent for their own participation (e.g., completion of the DAWBA, parent-report questionnaires and self-report questionnaires) but this is not mandatory (see **Figure 3**).

The parent/carer cannot take part without the agreement of the young person.

In this case the young person is the 'primary' participant and randomisation will take place following documentation of young person consent and completion of the young person's self-reported baseline measures.

5.4. Documentation of consent

An online electronic Participant Information Sheet (ePIS) will be provided to facilitate the consent/assent process. Age appropriate versions of the ePIS will be available. The investigator or delegate will ensure that they adequately explain the aim, trial intervention, anticipated benefits and potential hazards of taking part in the trial to the participant. They will also stress that participation is voluntary and so the potential participant is free to decline participation, and may withdraw from the trial at any time. The potential participant will be given until the next day (at the earliest) to read the ePIS and to discuss their participation with others (e.g. family members, GP or other healthcare professionals outside of the site research team, if they wish).

If the potential participant expresses an interest in participating in the trial they will be asked to provide written consent/assent using electronic signatures on the latest version of the online electronic Informed Consent Form (eICF) or electronic Assent Form (eAF). The Investigator or delegate will also electronically sign and date the form.

A copy of the electronically signed eICF/eAF will be made available to the participant(s), a copy will also be filed in the CAMHS records and the Investigator Site File (ISF). Once the participant is entered into the trial, the participant's unique trial identification number will be entered on the Informed Consent Form maintained in the ISF.

Details of the informed consent discussions will be recorded in the participant's CAMHS records. This will include date of discussion, the name of the trial, summary of discussion, version number of the ePIS given to the participant and version number of eICF/eAF signed and date consent received.

The eICF/eAF will include a full audit trail documenting the date and time of information receipt and provision of written informed consent. It will also be necessary for written consent to be fully documented before the system will permit access to the online baseline data collection system.

Throughout the trial the participant will have the opportunity to ask questions about the trial. Any new information that may be relevant to the participant's continued participation, for example changes to the protocol or study procedures which impact on participants, will be provided through updates to the ePIS which will be notified to participants through text and/or email. Where new information becomes available which may affect the participant's decision to continue, participants will be given time to consider and if happy to continue will be re-consented. Re-consent will be documented through electronic signatures obtained in an updated version of the eICF. This will be requested when follow-up data collection is due. Where relevant new information is available, participants will be asked to re-consent prior to completing follow-up questionnaires. The participant's right to withdraw from the trial will remain.

Young people aged 15 at trial entry, who provided assent at entry to the trial and who turn 16 before their 12-month follow-up will be invited to re-consent using the 16-17 years information sheet and a modified version of the consent form at the next scheduled follow-up visit after their 16th birthday. A link to the relevant participant information and the online consent form will be presented before the follow-up questionnaires, and the young person will be offered the option to discuss the information by telephone with the researcher. If the young person does not complete the consent form then the subsequent questionnaires will not be opened for completion, and data for that time-point will be considered lost to follow-up, but the participant will not be withdrawn from the trial. If applicable the questionnaires due at the next follow-up time-point will still be sent to the participant, along with the request to complete the online re-consent form at this time-point if not completed previously.

Table 2. Consent and participation

WHO WAS REFERRED TO CAMHS?	Young person <11	Young person 11-15		Young person 16-17	
WHO IS INITIALLY CONTACTED?	Parent/carer			Depends on contact details provided with the CAMHS referral*	
WHO CONSENTS?	Parent/carer	Parent/carer	Parent/carer	Parent/carer AND Young person	Young person
WHO ASSENTS?	None	Young person	None	None	None
WHO IS THE PRIMARY PARTICIPANT?**	Parent/carer	Parent/carer	Parent/carer	Young person	Young person
WHO IS INVITED TO COMPLETE THE DAWBA?	Parent/carer	Parent/carer AND Young person	Parent/carer	Parent/carer AND Young person	Young person
WHO IS INVITED TO COMPLETE RESEARCH QUESTIONNAIRES?	Parent/carer report on young person Parent/carer self-report	Parent/carer report on young person Parent/carer self-report Young person self-report	Parent/carer report on young person Parent/carer self-report	Parent/carer report on young person Parent/carer self-report Young person self-report	Young person self-report

For all young people aged <16 the initial contact about the study will be with the parent/carer. The involvement of young people aged 11-15 will be at the discretion of the parent/carer.

* For young people aged 16-17 if the young person's contact details are provided on the CAMHS referral the first contact about the study will be with the young person who can choose to nominate a parent/carer to participate in the trial alongside them or participate alone. If the parent/carer's contact details only are available the first contact will be with the parent/carer and the parent/carer will be asked whether the young person can also be contacted but may choose to refuse this. The parent/carer will not be able to participate in the STADIA trial without the involvement or consent of the young person.

** The primary participant is the person who must provide consent as a minimum requirement in order for randomisation to take place. Assent (of young people aged 11-15) and parental consent (for young people aged 16 and 17) may also be sought but is not mandatory and therefore will not be required prior to randomisation.

Figure 2. Invitation and consent process for young people aged <16

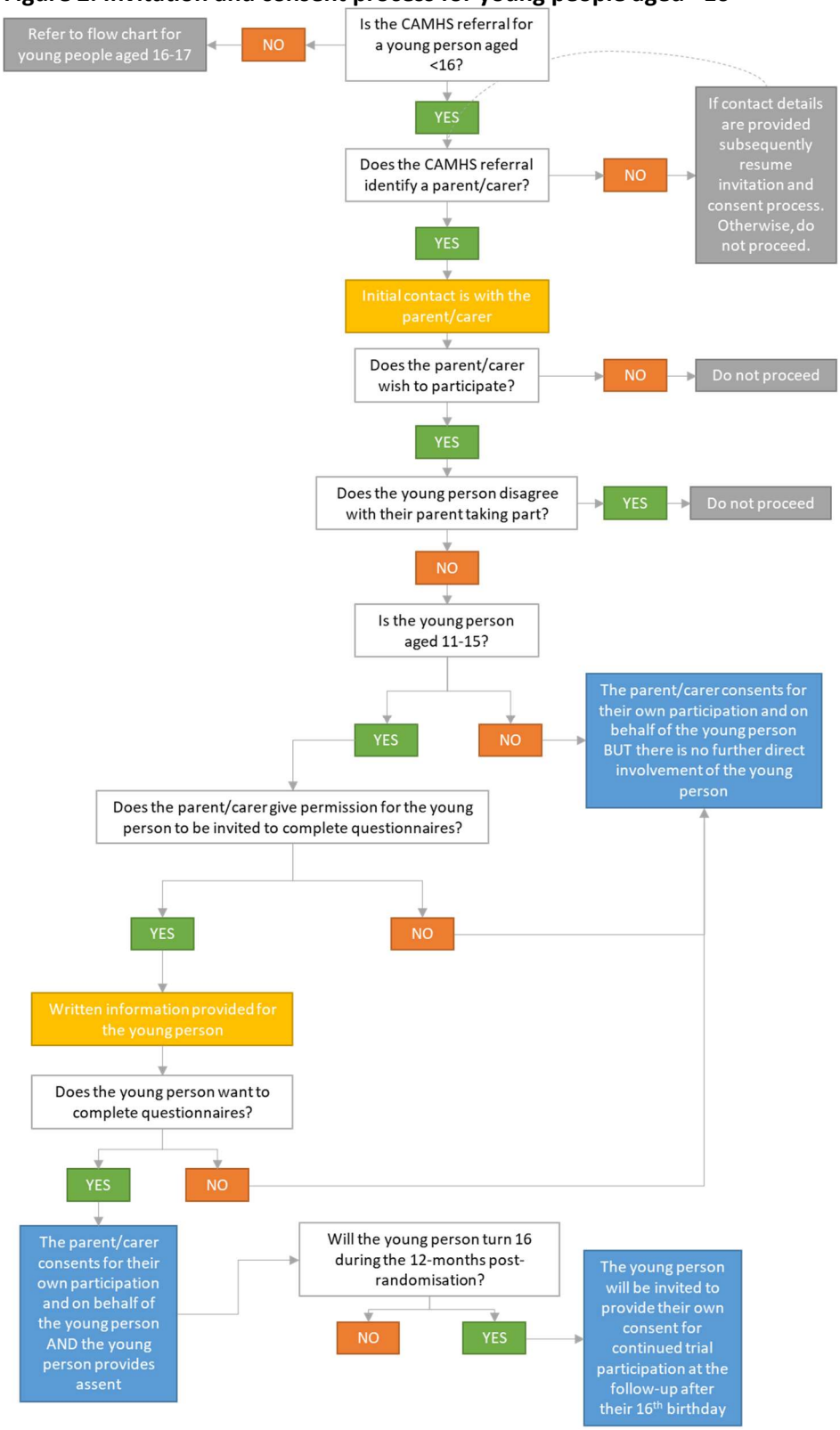
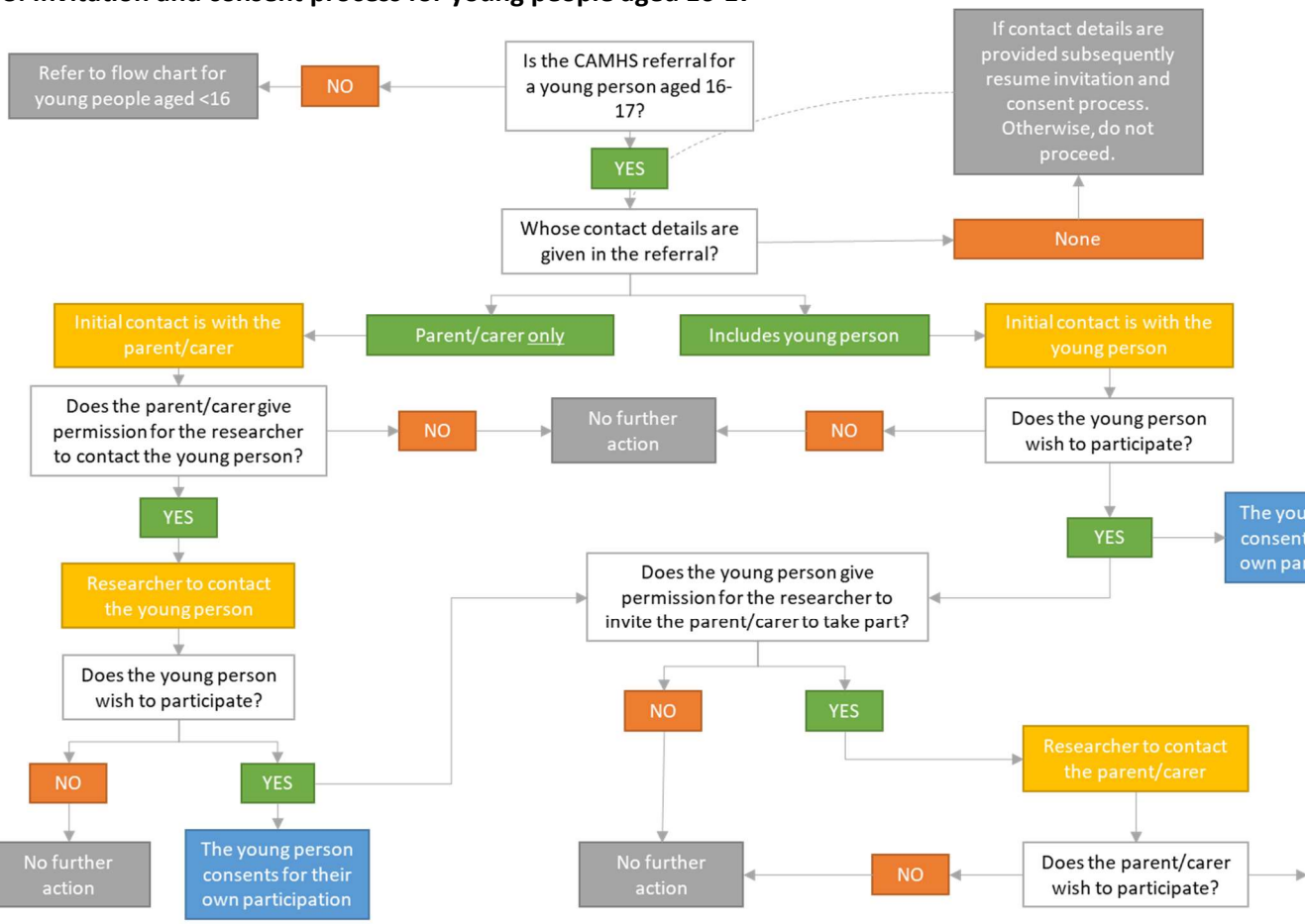


Figure 3. Invitation and consent process for young people aged 16-17



6. Enrolment and Randomisation

6.1. Enrolment/Registration

Participants will be enrolled on the trial database following verbal agreement to participate during the pre-consent telephone call with the researcher. This enrolment will generate a unique eICF, a link to which will be provided to the participant by text or email. Should written consent not be subsequently provided, no further data will be collected but enrolment data obtained with verbal consent will be retained. Contact details collected during enrolment will not be retained if the participant does not subsequently provide consent and will be securely destroyed once the window for consent has passed (i.e., 10 working days post-referral receipt or following identification of potential participant) or if the participant indicates they do not wish to participate.

6.2. Randomisation

Eligible participants will be randomised via a secure online computerised randomisation programme created and maintained by the Nottingham Clinical Trials Unit (NCTU).

Randomisation will be automatically generated following submission and automated verification checks of initial baseline data (as defined in the Data Management Plan) by the primary participant using the online data collection system.

Because participants allocated to the intervention arm will complete the Strengths and Difficulties Questionnaire (SDQ) as part of the DAWBA, the system will ensure this is not duplicated at baseline

for these participants. Allocation will determine whether participants are presented with the SDQ as part of the battery of baseline questionnaires (for participants in the control group), or whether they complete this as part of the DAWBA post-randomisation (for participants in the intervention arm). Allocation will be generated after initial baseline data collection, enabling the system to present the correct baseline test battery (with or without the SDQ) but will not be revealed to participants until after questionnaire completion to reduce risk of bias. Participants randomised to complete the DAWBA will not be presented with the SDQ as part of the baseline data collection, as this will be done as part of the DAWBA, completed as the trial intervention post-randomisation. Data for the baseline SDQ from these participants will be extracted from the DAWBA.

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.

Following completion of all baseline data, participants will be presented with their allocation and further instructions on-screen along with email confirmation. For participants allocated to the intervention group, this will include login details and instructions for DAWBA completion (see Section 7). Email confirmation will also be sent to the Trial Coordinating Centre and the local site research team.

The local CAMHS team will be notified when a participant at their site is allocated to the intervention arm so that they are aware that a DAWBA report will be available. Wherever possible, participating CAMHS teams will wait to receive the DAWBA report before making a decision about acceptance of the referral.

Following randomisation, and with the participant's prior consent, the child/young person's General Practitioner (GP) will also be informed that they are taking part in the trial. The GP will be informed by letter, using the approved template, which will be prepared and sent by the STADIA researcher at each site.

The trial entry procedures from identification of potential participants to randomisation are summarised in Table 3.

Table 3: Trial entry procedures

1. Potential participants will be identified through screening of CAMHS referrals by the STADIA researcher.
2. Potentially eligible participants will be contacted by the STADIA researcher by telephone, provided with a brief description of the trial and invited to consider participating.
3. If the potential participant is interested an email and/or text will be sent with a link to the online electronic Participant Information Sheet (ePIS).
4. The next day (at the earliest), the STADIA researcher will call the potential participant to offer a further explanation, check understanding, answer any questions the participant may have and, if interested, confirm eligibility and seek verbal consent to continue.
5. If the participant provides verbal consent to participate in the trial, brief enrolment data will be collected to enable registration on the trial database and generate a personal link to the online electronic Informed Consent Form (eICF).
6. The STADIA researcher will send an email and/or text containing the participant's personal link to the eICF.
7. Participants will access the eICF, provide written consent, complete initial baseline data and will be automatically randomised.
8. If allocated to the intervention, the randomisation system assigns a unique DAWBA log-in which is provided to the participant (on screen and by email and/or text).
9. Participant's GP and CAMHS triage team informed of trial participation and allocation.

Note: At all times throughout the identification and recruitment of trial participants, the STADIA researcher will liaise with the CAMHS triage/SPA team clinicians to ensure they are aware of the trial related activities and contacts with the potential participants. Contacts with potential participants should also be documented in the CAMHS record in accordance with usual practice.

6.3. Blinding and concealment

The minimisation algorithm will incorporate a probabilistic element to allocation. Allocation will be concealed using an automated web system operated by NCTU.

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.

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.

The risk of contamination between the intervention and control group is considered low. Access to the DAWBA will only be provided to participants in the intervention arm and the DAWBA report will only be generated for these participants. As the DAWBA is not current practice as part of standard care it is unlikely that any control arm patients/parents will be asked to complete the DAWBA or that clinicians will start to conduct this at the point of referral receipt as part of standard care. Therefore, although all participants will have their referral considered by the same triage teams, the DAWBA is not expected to be completed in the control arm and will not be available to control arm participants or triage staff. Data on the potential use of the DAWBA by control arm participants will be obtained from records during outcome data collection.

There is a low risk of participants in the intervention group sharing information about the DAWBA with control group participants (e.g., in the case of siblings presenting to CAMHS where both are randomised individually to separate arms). Access to the DAWBA is restricted by user accounts, and forms will be locked once the DAWBA has been completed and the report generated so the information cannot be modified or re-entered at a later date. The STADIA-specific DAWBA report will only be generated once and provided to participants allocated to the intervention arm so although control arm participants may become aware of the generic structure of the DAWBA, there is no specific DAWBA report available to them.

Table 4. Blinding status

Role	Status	Justification
Participants (parent/carer and child/young person)	Not Blinded	Participants will not be blinded since those randomised to the intervention arm will be asked to complete the DAWBA and will be provided with a report of the findings. Control arm participants will not receive this.
Clinicians	Not Blinded	CAMHS clinicians triaging the referral will be informed of participants' involvement in the trial and their allocation so that: a. for participants in the DAWBA arm they are aware a DAWBA report will be provided to inform their referral review and acceptance decision, and b. for those in the control arm, assessment and decision making should proceed as usual. The DAWBA report will then be shared with the triage clinicians and, through inclusion in the CAMHS records, with clinician(s) allocated to carry out the clinic assessment(s) and further interventions.
Principal Investigator and other trial staff at site	Not blinded	Site staff will not be blinded since they will need to know whether to prepare a DAWBA report and feedback to the participant and clinical teams. The PI will not be routinely unblinded, except where this is necessary to provide specific clinical supervision to the STADIA researcher in relation to the DAWBA.
Researcher completing follow-up data collection from records	Not blinded	Although, wherever possible, the researcher completing follow-up data collection from records will not have prior knowledge of the treatment allocation, they are likely to become unblinded during record searches as the DAWBA will be filed and documented in the notes.
CI	Blinded	Except in the role as PI, noted above, the CI will not have access to any participant data with the potential to unblind until after database lock.

Role	Status	Justification
Specified members of the trial coordinating team	Not blinded	Specified members of the trial coordinating team (as defined in the Data Management Plan) will not be blinded so that they can monitor DAWBA completion and liaise with unblinded site staff.
Other Trial Management staff at NCTU	Blinded	With the exception noted above, the Trial Management team will not have access to any participant data with the potential to unblind until after database lock when this is not required for performance of their role.
Trial Statisticians	Blinded	The trial statisticians will not have access to any participant data with the potential to unblind until after database lock. Provision of any unblinded data, for example for the DMC, will be carried out by an independent statistician.
Other Data Management staff at NCTU	Blinded	Trial Data Management staff will not have access to any participant data with the potential to unblind when this is not required for performance of their role.
IT staff at NCTU	Not Blinded	IT staff will have access to all database information in order to maintain the database and manage queries.
Health Economists	Blinded	The health economists will not have access to any participant data with the potential to unblind until after database lock.
Qualitative researchers	Not Blinded	The researchers undertaking the qualitative study and process evaluation will not be blinded as the interview schedule will include questions about acceptability of the intervention.
Trial Management Group	Blinded	Except in the specified roles, noted above, members of the Trial Management Group will not have access to any participant data with the potential to unblind until after database lock.
Trial Steering Committee	Blinded	Except in the case of a specific recommendation from the Data Monitoring Committee, independent members of the Trial Steering Committee will not have access to any participant data with the potential to unblind until after database lock.
Data Monitoring Committee	Not Blinded	The independent members of the Data Monitoring Committee will be provided with data presented by treatment arm in order to perform their oversight role.

7. Trial intervention

7.1. Intervention

The trial intervention is a standardised diagnostic assessment (SDA) tool, the Development and Well-Being Assessment (DAWBA).[18] The DAWBA consists of a structured package of questionnaires based on diagnostic criteria, which generate computer algorithm-derived diagnostic predictions.[18]

The DAWBA has been widely used, as both a screening and diagnostic tool and outcome measure in previous research in both clinical and community settings [19, 20], in other trials of SDAs[16, 17] and in large scale epidemiological research.[21-23] The DAWBA has been used as an assessment tool within CAMHS for conditions such as hyperkinetic disorder as well as being used outside the UK.[24, 25] The DAWBA has established reliability and validity.[15]

The DAWBA will be completed by:

- The parent/carer of children/young people aged <16
- Children/young people aged 11-15, if participating
- Young people aged 16 and 17
- The parent/carer of young people aged 16 and 17, if participating with the young person

A summary report of the DAWBA results will be sent to participants and CAMHS clinicians, as an adjunct to usual clinical practice (review of the CAMHS referral as usual).

7.2. Comparator

The comparator will be usual clinical practice (review of the CAMHS referral as usual) that does not include the use of SDA tools at the point of referral receipt.

Information from SDA tools do not normally accompany referrals to CAMHS nor are they used at the point of referral receipt (i.e., this is not usual practice and is therefore very unlikely to change during the course of the trial).

7.3. Intervention Delivery

7.3.1. Intervention Access

For the intervention group, the DAWBA will be completed on a secure online platform.[18] Access will be via a unique ID number and password, which will be assigned at the point of randomisation. The unique ID number and password will be provided following completion of baseline data collection. The details will be presented on screen within the online data collection system and additionally will be sent to participants by text and / or email.

If possible (i.e., where permission was granted to collect contact details for all respondents) each DAWBA respondent will be sent their own login details. If this is not possible, the details for all DAWBA respondents will be sent to the primary participant (i.e., the parent/carer for young people aged <16 or the young person themselves if aged 16 or 17 years), and the primary participant will be asked to pass on the relevant DAWBA access details to other respondents.

Participants will also be able to complete the DAWBA in a telephone call with the STADIA researcher if required. In this case, the researcher will access the DAWBA slot for the participant via the unique ID number and password and will record the respondent's responses directly into the online system.

7.3.2. Accountability Procedures

The required number of unique DAWBA 'slots' will be pre-loaded into the online randomisation system and a stock control system will assign slots at the point of randomisation to those participants who are allocated to the intervention group.

The DAWBA is hosted on a standalone online system, provided, hosted and maintained by the DAWBA developer.[18]

The online DAWBA system enables oversight of access and completion to monitor uptake of the intervention. DAWBA completion will be monitored and participants who have not completed the assessment within 2-3 days of randomisation will be contacted by the researcher to support and encourage online completion, or offer telephone completion if required. Wherever possible, the DAWBA should be completed, and the report prepared and sent to the participant(s) and CAMHS clinician, within 10 working days of receipt of the CAMHS referral although up to an additional 3 working days may be offered for DAWBA completion for those participants randomised close to the 10 working day deadline. For sites where the waiting time for the CAMHS acceptance decision usually exceeds 10 working days, additional time for DAWBA completion and report provision may be offered, providing the DAWBA report is available prior to the CAMHS referral decision. DAWBA reports should be generated as soon as practicably possible following DAWBA completion.

All DAWBA records will be locked before generation of the DAWBA report. Participants will be encouraged to use the functionality within the DAWBA system to confirm when they have finished entering data. When this has been indicated, the DAWBA record will be manually locked by trial staff and the DAWBA report will be generated.

If the DAWBA has been fully answered but has not been confirmed as complete by the participant, the STADIA researcher will aim to liaise with the participant to confirm whether they have finished entering data and, if so, the DAWBA record will be manually locked by trial staff and the DAWBA report will be generated.

If the DAWBA report has not been fully answered and has not been confirmed complete by the participant, the STADIA researcher will aim to liaise with the participant to encourage and support completion wherever possible. If the participant confirms that they do not wish to continue completion of the DAWBA, the DAWBA record will be manually locked by trial staff and the DAWBA report will be generated on the basis of the partial responses provided.

If the participant cannot be contacted to confirm completion, the DAWBA record will be manually locked by trial staff and the DAWBA report will be generated on the basis of the responses entered after 10-13 working days from receipt of the CAMHS referral or identification of potential participant.

7.3.3. Intervention Modification

The DAWBA is a modular assessment and only selected modules relevant to emotional difficulties and comorbid disorders will be included.

The DAWBA includes automatic skip rules based on screening questions to maximise relevance to individual participants.

Participants will be asked to complete all sections of the DAWBA presented to them. Should the DAWBA be only partially completed by respondents at the time the DAWBA report is generated the report will be based only on fully answered sections with missing responses identified as such.

Following DAWBA completion, a trial specific DAWBA report will be prepared for each participant, based on a standard template. The computer algorithm-derived DAWBA diagnostic predictions will be used to highlight the probability of a child/young person meeting criteria for an emotional disorder or common comorbid disorders.

We will feedback the results of the DAWBA by making the DAWBA report available to:

1. CAMHS practitioners – the triage team making the decision about the referrals and, if accepted, subsequent assessing / treating clinicians. The DAWBA will also be added to the CAMHS record.
2. The parent/carer and young person – the primary participant (i.e., the parent/carer of children/young people aged <16 or the young person aged 16 and 17) will be sent a copy of the DAWBA report and will also be encouraged to take this along to each CAMHS appointment so that any clinician that they might see is aware of it. The parent/carer of the young person aged 16-17, if they are participating, will also receive a copy of the DAWBA report via the primary participant.

8. Trial procedures and assessments

8.1. Summary of assessments

The summary of assessment is detailed in Table 5.

Table 5. Summary of assessments

Time-point	Maximum 10 working days from referral receipt*					6 months post-randomisation	12 months post-randomisation	18 months post-randomisation
Activity	**Screening and invitation**	**Eligibility and enrolment**	**Consent and baseline**	**Randomisation**		**Follow-Up**		
Initial eligibility screen of referral information	X							
Telephone invitation to participate	X							
Verbal agreement to participate		X						
Confirm eligibility		X						
Obtain enrolment data		X						
Participant enrolment		X						
Written informed consent/assent (online)			X		**Intervention**			
Baseline demographics (parent/carer and young person aged 16 & 17)			X		DAWBA in addition to usual practice Or Usual practice only			
MFQ (parent/carer and child/young person aged 11+)			X			X	X	
RCADS (parent/carer and child/young person aged 11+)			X			X	X	
SDQ (parent/carer and child/young person aged 11+)**			X			X	X	
Self-harm measure (child/young person aged 11+ only)			X			X	X	
PHQ-9 (parent/carer only)			X			X	X	
GAD-7 (parent/carer only)			X			X	X	
CHU9D (child/young person self-report if aged 11+ or parent/carer proxy if child aged <11 or 11-15 and not self-reporting)			X			X	X	
EQ5DY (child/young person self-report if aged 11+ or parent/carer proxy if child aged <11 or 11-15 and not self-reporting)			X			X	X	
EQ5D5L (parent/carer only)			X			X	X	

Resource Use Questionnaire (parent/carer and young person aged 16 & 17)			X			X	X	
CRIES-8 (child/young person self-report if aged 11+ or parent/carer proxy if child aged <11 or 11-15 and not self-reporting)			X			X	X	
Data collection from records***			X			X	X	X
* For sites where the waiting time for the CAMHS acceptance decision usually exceeds 10 working days from referral receipt, recruitment activities may start and/or continue beyond 10 working days from referral receipt, providing the intervention period can be completed prior to the CAMHS referral decision. **For participants in the intervention arm, the baseline SDQ will be collected as part of the DAWBA, completed post-randomisation. ***Data collection from records will be completed periodically throughout the 18 month follow-up period.								

8.2. Schedule of Assessments

8.2.1. Invitation and screening

Initial eligibility to approach is confirmed by a review of CAMHS referral information and eligible participants are invited to consider participation. Basic screening information obtained from the CAMHS referral is recorded on the Screening and Enrolment Log, including the child/young person's age and sex.

8.2.2. Eligibility and enrolment

If the participant agrees, enrolment information and contact details are obtained from the participant and the participant is enrolled on the trial database.

8.2.3. Consent and baseline

Informed consent is provided using the online eICF, following which, the following baseline demographic data is obtained from participants:

- Gender (of child/young person and parent/carer)
- Ethnicity (of child/young person and parent/carer)
- Age (of child/young person and parent/carer)
- Parent/carer relationship to child/young person
- Education/employment status including type of school if in education (of child/young person)
- Deprivation index (derived from postcode of child/young person's primary residence)

The following baseline participant questionnaires will be completed online:

- Mood and Feelings Questionnaire (MFQ)
- Revised Children's Anxiety Depression Scale (RCADS)
- Strengths and Difficulties Questionnaire (SDQ); included in baseline questionnaires for control arm participants only, extracted from DAWBA for those in the intervention arm
- Child/young person self-report self-harm measure
- Patient Health Questionnaire (PHQ-9)
- Generalised Anxiety Disorder (GAD-7)
- Child Health Utility Instrument (CHU9D)
- EuroQol Quality of Life Questionnaire 5 Domains for Young People (EQ5DY)
- EuroQol Quality of Life Questionnaire 5 Domains, 5 Levels (EQ5D5L)
- Resource Use Questionnaire
- Child Revised Impact of Events Scale (CRIES-8)

In addition the following data is obtained from CAMHS records:

- Child/young person's date of birth
- Details of current and any previous CAMHS referrals
- Previous or existing diagnoses

8.2.4. Randomisation

Following randomisation, the DAWBA will be completed by participants in the intervention arm and the DAWBA report generated and sent to the participant and CAMHS clinicians.

8.2.5. Follow-up data collection from participants

6 months post-randomisation

The following participant-reported data collection will be completed online*:

- MFQ
- RCADS
- SDQ
- Child/young person self-report self-harm measure
- PHQ-9
- GAD-7
- CHU9D
- EQ5DY
- EQ5D5L
- Resource Use Questionnaire
- Participant self-report diagnoses
- CRIES-8

12 months post-randomisation

The following participant-reported data collection will be completed online*:

- MFQ
- RCADS
- SDQ
- Child/young person self-report self-harm measure
- PHQ-9
- GAD-7
- CHU9D
- EQ5DY
- EQ5D5L
- Resource Use Questionnaire
- Participant self-report diagnoses
- CRIES-8

* Whilst baseline and follow-up questionnaires are intended to be completed online by participants in the first instance, there will be the option for telephone completion, should participants have difficulty accessing or completing the questionnaires online.

8.2.6. Follow-up data collection from records

The following data will be collected from CAMHS records for the 18 month period from randomisation. Periodic searches will be completed over the 18 month reporting period.

- CAMHS referrals and outcome including re-referral
- Documented diagnoses*
- Treatments offered and given
- Deaths

*Site researchers will be allowed to review appointment outcome letters that have been sent up to 3-months after the 12-month and 18-month cut-off, to ascertain information relating to a clinician-made diagnosis decision about the presence of an emotional disorder. The letter must specifically reference the appointment/contact where the appointment/contact is within the 12- or 18-month timeframe. The lag between clinic appointments and appointment outcome letters is variable between Trusts and in some instances can take up to 3 months for the letter to be produced, sent to the patient/GP and uploaded to the clinical records.

8.3. Trial Procedures

The following trial procedures will be developed and documented separately:

- Referral screening guidelines
- Data collection guidelines
- Verification and adjudication of outcome data collection
- Long-term follow-up: either at entry to the trial or during the follow-up period, we will invite parents and young people (aged 16-17 years) to additionally consent to long-term follow-up using routinely collected data through linkage with centrally held NHS and educational records.

8.4. Withdrawal Procedures

Participants are free to withdraw from the trial at any time and for any reason.

Where the parent/carer has consented in their own right and on behalf of the child/young person (<16 years) both parties will cease their involvement in the trial should the parent/carer withdraw this consent.

Where young people aged 16 or 17 have consented for their own involvement they can continue to participate in the trial in the event of the parent/carer's withdrawal, however, the parent/carer involvement would not continue should the young person withdraw consent.

Participants may withdraw from the intervention, follow-up questionnaires and / or data collection from records in any of the following combinations:

- Withdraw from trial intervention but continue to complete follow-up questionnaires in accordance with the trial schedule and continue to permit trial data collection from records for use in the analysis.
- Withdraw from trial intervention and follow-up questionnaires but continue to permit trial data collection from records for use in the analysis.
- Withdraw from the trial intervention and follow-up questionnaires and withdraw consent for any further data collection from records.
- Following completion of the trial intervention, withdraw consent for follow-up questionnaires but continue to permit trial data collection from records for use in the analysis.
- Following completion of the trial intervention, withdraw consent for follow-up questionnaires and withdraw consent for any further data collection from records.
- Following completion of the trial intervention and follow-up questionnaires, withdraw consent for any further data collection from records.

Withdrawn participants will not be replaced. Data collected prior to withdrawal will be retained and used in the analysis.

9. Adverse Event Reporting

The risks of the trial are comparable to that of usual practice. The trial intervention (completion of the DAWBA) is conceptually similar to what might be done as part of usual practice (i.e., children/parents referred to CAMHS may already be sent questionnaires about their difficulties before the referral is accepted). Furthermore, the DAWBA is widely used in research for data collection/outcome measurement therefore, although utilised as an intervention in the STADIA trial, the risks may be regarded as similar to those of an observational/questionnaire study.

The only adverse outcomes that might be plausibly related to the trial procedures are worry or distress for the child/young person and/or parent/carer as a result of the sensitive nature of some questions and increased focus on existing difficulties. However, the trial participants are children and young people referred to CAMHS because of emotional difficulties and symptoms of depression and/or anxiety are likely to be prevalent, therefore these are expected outcomes. Such difficulties may also be observed in the parents/carers of children referred to CAMHS. Measures of depression in both young people and parents/carers are already collected in the trial and will capture any potential deterioration which may be indicative of adverse effects. Data to inform safety oversight will therefore be collected during routine follow-up, from existing outcome measures.

The pre-defined safety outcomes will be:

- Symptoms of depression in child/young people: A significant worsening of symptoms of depression in children/young people, defined as a score indicative of depression (27 or above) on the Mood and Feelings Questionnaire (MFQ) completed at follow-up, where this represents a deterioration from baseline of 5 points or more.
- Parental depression: A significant worsening of parental depression, defined as a score indicative of depression (15 or above) on the Patient Health Questionnaire (PHQ-9) completed at follow-up, where this represents a deterioration from baseline of 5 points or more.
- Self-harm: Frequency of self-harm in children/young people (aged 11+) based on self-report questionnaire completed at 6- and 12-months post-randomisation.
- Hospital admissions: the number of children/young people 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&E attendances: the number of children/young people attending 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.
- Deaths: the number of deaths of children/young people between baseline and 12 and 18 month follow-up.

The number of participants meeting these criteria will be reported on an ongoing basis to the TMG and TSC. Data will be presented by arms to the DMC.

9.1. Reporting Requirements

9.2. Adverse Events

Relevant adverse events (AEs) are outcomes (e.g. symptoms of depression and anxiety) and will be collected during routine follow-up using participant questionnaires. Separate AE reporting will not be required.

9.3. Serious Adverse Events
Relevant serious adverse events (SAEs) are outcomes and will be collected during routine follow-up using participant questionnaires. Separate SAE reporting will not be required.

9.4. Reporting period
The reporting period will be from randomisation to 12-month follow-up. Safety outcomes will be collected during routine follow-up completed at 6- and 12-months post-randomisation.

9.5. Reporting to the Competent Authority and Research Ethics Committee
The Research Ethics Committee (REC) will be notified immediately if a significant safety issue is identified during the course of the trial.

9.6. Investigators
Any safety issue which arises during the course of the trial will be reported to Principal Investigators. A copy of any such correspondence should be filed in the Site File.

9.7. Data Monitoring Committee
The independent Data Monitoring Committee (DMC) will review all safety data.

9.8. Reporting to third parties
There is no requirement for third party reporting in this trial.

10. Data Handling and Record Keeping
10.1. Source Data
In order to allow for the accurate reconstruction of the trial and clinical management of the participant, source data will be accessible, maintained and stored appropriately.

Source documents will be filed at the participating sites and may include, but are not limited to:

- Screening and enrolment logs
- Consent forms
- CAMHS records

For data collected directly from participants using online questionnaires, or via telephone completion if required, the electronic Case Report Form (eCRF) will be considered source data.

All other data collected post-randomisation will obtained from the CAMHS records and the original record will be considered source data.

10.2. Case Report Form Completion
10.2.1. Paper CRF
Data collection from records will be documented in the paper Case Report Form (pCRF).

Where required, data reported on each pCRF will be consistent with the source data and any discrepancies will be explained. Staff delegated to complete pCRFs will be trained to adhere to the study specific pCRF completion guidelines.

The original completed pCRFs will be maintained at the participating site, with copies submitted to NCTU for central adjudication or verification as required.

Entries on pCRFs may be verified by monitoring or inspection by NCTU against the source data. A sample of pCRFs will be checked by central monitoring on a regular basis for verification of all entries made. In addition the subsequent capture of the data on the trial database will be checked. Where corrections are required these will carry a full audit trail and justification.

In all cases it remains the responsibility of the site's Principal Investigator to ensure that the pCRF has been completed correctly and that the data are accurate. Where applicable for the trial this will be evidenced by the signature of the site's Principal Investigator on the pCRF.

10.2.2. Electronic CRF

Participant self-reported data collection (e.g., questionnaires) are completed electronically, and responses will be entered directly by participants onto the online data collection system. Participants will be provided with guidance on completion of their online questionnaires which will form the electronic CRF (eCRF).

Data queries will not be raised on participant completed questionnaires.

Participant questionnaires may also be completed with the researcher by telephone, in which case the researcher will access the eCRF to input responses, as reported by participants.

10.3. Data Management

Arrangements for data handling will be specified in the Data Management Plan (DMP). This will include the agreed validation specification which will validate data for consistency and integrity as it is entered. Additional manual and electronic reviews may also be conducted and data queries / clarifications may arise from such reviews.

Data will be held on clinical trial servers. These servers are located within The University of Nottingham data centres, which are managed and monitored 24/7. Security is both physical (secure limited access) and electronic (behind firewalls, access via user accounts (user name and password), restricted access – e.g. site user only have access to their sites data, and by user type/role). All access and data transactions will be logged in a full audit trail.

For qualitative interview data, audio files will be transferred securely for transcription. Transcriptions will be anonymised. Audio files will be destroyed after transcripts have been checked. Anonymised transcriptions will be analysed and stored on password protected computers and the secure University of Nottingham server.

10.4. Archiving

All records created by following trial procedures and all documents listed in guidance relating to the conduct of the trial must be retained and archived. It is the responsibility of the Principal Investigator to ensure all essential trial documentation and source documents (e.g., Investigator Site Files, paper CRFs etc.) at their site are securely retained for at least 10 years.

All trial-specific records held by the site are to be returned to the Sponsor for archiving collectively at the end of the trial. These files should contain study materials only and not include any patient specific medical notes or other clinical documents that are not specific study materials.

Other documents are to be archived following any local procedures. No documents will be destroyed without prior approval from the Sponsor.

Electronic raw datasets will be retained indefinitely. All other electronic data will be retained for at least 10 years.

11. Quality control and quality assurance

11.1. Site Set-up and Initiation

All participating Principal Investigators will be asked to sign the necessary agreements and supply a current CV to the NCTU. All members of the site research team will also be required to sign a site delegation log. Prior to commencing recruitment all sites will undergo a process of initiation and will have completed all required training. Key members of the site research team will be required to complete training covering aspects of the trial design, protocol procedures, safety reporting, collection and reporting of data, and record keeping. Sites will be provided with an Investigator Site File containing essential documentation, instructions, and other documentation required for the conduct of the trial. The NCTU must be informed immediately of any change in the site research team.

11.2. Monitoring

11.2.1. On-site Monitoring

Monitoring will be carried out as required following a risk assessment and as documented in the monitoring plan. Any monitoring activities will be reported to the Sponsor and any issues noted will be followed up to resolution. Additional on-site monitoring visits may be triggered, for example by poor CRF return, poor data quality, excessive number of participant withdrawals or deviations. If a monitoring visit is required the NCTU will contact the site to arrange a date for the proposed visit and will provide the site with written confirmation. Investigators will allow the NCTU staff access to source documents as requested.

11.2.2. Central Monitoring

The NCTU will be in regular contact with the site research team to check on progress and address any queries that they may have. NCTU will check data entered onto the trial database on an ongoing basis for compliance with the protocol, data consistency, missing data and timing. Sites will be asked for missing data or clarification of inconsistencies or discrepancies.

Electronic consent forms will be subject to central review as detailed in the monitoring plan.

11.3. Audit and Inspection

The Principal Investigator will permit trial-related monitoring, quality checks, audits, ethical reviews, and regulatory inspections at their site, providing direct access to source data/documents as required. The Principal Investigator will comply with these visits and any required follow up. Sites are requested to notify NCTU of any audits or inspections.

11.4. Notification of Serious Breaches

The Sponsor is responsible for notifying the REC of any serious breach of the conditions and principles of Good Clinical Practice (GCP) in connection with the trial or the protocol relating to that trial. Sites are therefore requested to notify NCTU of any suspected trial-related serious breach of GCP and/or the trial protocol. Where NCTU is investigating whether or not a serious breach has

occurred, sites are requested to cooperate with NCTU in providing sufficient information to report the breach to the REC where required and in undertaking any corrective and/or preventive action.

Sites may be suspended from further recruitment in the event of serious and persistent non-compliance with the protocol and/or GCP, and/or poor recruitment. Any major problems identified during monitoring may be reported to the Trial Management Group, Trial Steering Committee and the REC. This includes reporting serious breaches of GCP and/or the trial protocol to the REC.

12. End of Trial Definition

The trial includes an 18 month follow-up period; the last data capture will therefore be a minimum of 18 months after randomisation of the last participant. The end of trial will be considered database lock. NCTU will notify the REC within 90 days of end of trial and a summary of the clinical trial report will be provided to the REC within 12 months of the declaration of end of trial.

13. Statistical Considerations

13.1. Definition of Outcome Measures

Outcomes are defined in Table 6.

Table 6. Outcome definition

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
Primary outcome Clinician-made diagnosis decision about the presence of an emotional disorder	Diagnosis of an emotional disorder will be coded as 'yes'; absence or uncertainty (for example, reflecting ongoing assessment / investigation) about the presence of an emotional disorder will be coded as 'no'. 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 by members of the Trial Management Group.	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	Risk ratio/risk difference	Collected from clinical records	Within 12 months of randomisation

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
		• 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) • Trichotillomania The diagnosis must be documented in the clinical record within 12 months of randomisation by a mental health services clinician in an NHS-delivered or NHS-commissioned service. Any eligible diagnosis made within 12 months will be included.			

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
Secondary Outcomes					
Clinician-made diagnosis decision about the presence of an emotional disorder within 18 months of randomisation	Diagnosis of an emotional disorder will be coded as 'yes'; absence or uncertainty (for example, reflecting ongoing assessment / investigation) about the presence of an emotional disorder will be coded as 'no'. 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 by members of the Trial Management Group	Refer to definition of primary outcome above. The diagnosis must be documented in the clinical record within 18 months of randomisation by a mental health services clinician in an NHS-delivered or NHS-commissioned service. Any eligible diagnosis made within 18 months will be included.	Risk ratio/risk difference	Collected from clinical records	Within 18 months of randomisation

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
Acceptance of index referral	Index referral accepted by CAMHS = yes Index referral declined by CAMHS= no	Whether the index referral (i.e., the referral made to CAMHS at the point of recruitment to the STADIA trial) was accepted or declined. Acceptance is defined as being offered an appointment within CAMHS, whether or not the initial appointment was attended or subsequent appointments were offered/attended.	Risk ratio/risk difference	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation
Acceptance of any referral within 12 and 18 months	Any referral accepted by CAMHS = yes No referrals accepted by CAMHS= no	Whether the index referral or any subsequent referral to CAMHS (if made) was accepted or not. Acceptance as defined above for index referral.	Risk ratio/risk difference	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation
Discharge from CAMHS within 12 and 18 months	Date of discharge within 12 or 18 months recorded in notes = yes No date of discharge or discharge date after 18 months = no	Whether the child/young person was discharged from CAMHS (following acceptance of the index referral) during the 12 and 18-months post-randomisation.	Descriptive	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation
Re-referral to CAMHS within 12 18 months	Re-referral documented within 12 or 18 months = yes No re-referral documented within 18 months = no	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 and 18-months post-randomisation.	Descriptive	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
Confirmed diagnosis decision	Diagnosis of an emotional disorder or confirmed absence of an emotional disorder coded as 'yes' vs. uncertainty about the presence of an emotional disorder coded as 'no'	Diagnosis as defined above for primary outcome.	Risk ratio/risk difference	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation
Time from randomisation to diagnosis of emotional disorder	The time (in days) from randomisation to diagnosis will be derived from the randomisation date and date of diagnosis.	Date of diagnosis will be the first documented eligible diagnosis. Diagnosis as defined above for primary outcome.	Time to event	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation
Diagnoses made	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 by	The diagnosis must be documented in the clinical record within 12 and 18 months of randomisation by a mental health services clinician in an NHS-delivered or NHS-commissioned service. All diagnoses made within 12 and 18 months will be included.	Descriptive There will be separate reporting for: 1. Diagnoses of emotional disorders 2. Alternative / cormobid clinical diagnoses	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
	members of the Trial Management Group.				
Treatment offered for diagnosed emotional disorder	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	Whether treatment was offered for a diagnosed emotional disorder, as defined for primary outcome above.	Risk ratio/risk difference	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation
Treatments / interventions given	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 by members of the Trial Management Group.	All treatments/interventions offered by CAMHS for any reason within 12 and 18 months of randomisation, whether or not there is a documented diagnosis will be included.	Descriptive There will be separate reporting for: 1. Treatments offered for emotional difficulties 2. Treatments offered for other difficulties	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
Time from randomisation to the decision to offer treatment for a diagnosed emotional disorder	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.	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.	Time to event	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation
Time from randomisation to start of first treatment for a diagnosed emotional disorder	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.	Date of treatment will be the first date that any treatment offered for a diagnosed emotional disorder is started. Treatment and diagnosed emotional disorder as defined as above.	Time to event	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation
Time from randomisation to the decision to offer any treatment	The time (in days) from randomisation to the date of the decision to offer any treatment will be derived from the randomisation date	Date of decision will be the first date that the decision to offer any treatment is documented in the clinical notes.	Time to event	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
	and the date of the documented decision.				
Time from randomisation to start of any treatment	The time (in days) from randomisation to start of any treatment will be derived from the randomisation date and documented start date of treatment.	Date of treatment will be the first date that any treatment offered is started. Treatment as defined as above.	Time to event	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation
Participant-reported diagnoses	Participant-reported diagnoses received in the 12 months post-randomisation	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.	Descriptive	Self-report by young people aged 11+ AND/OR parent report of child/young person	6 and 12 months post-randomisation
Depression symptoms in the child/young person	Mood and Feelings Questionnaire (MFQ) [26] MFQ is a valid and reliable measure of depression in children and young people.[27, 28] 33-items are answered on a 3-point scale ("not true" = 0,	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.	Mean difference, adjusted for baseline: Child/young person report, adjusted for child/young person reported baseline Parent/carer report, adjusted	Self-report by young people aged 11+ AND/OR parent report of child/young person MFQ will be self-reported by children and young people	Baseline, 6 and 12 months post-randomisation

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
	"somewhat true" = 1 point, "true" = 2 points)		for parent/carer reported baseline	aged 11-17 years old, with an additional version for parent/carer-reports on the child/young person.	
Anxiety symptoms in the child/young person	Revised Children's Anxiety and Depression Scale (RCADS) [29] RCADS is a 47-item questionnaire that measures the reported frequency of various symptoms of anxiety and low mood. 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,	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.	Mean difference, adjusted for baseline: Child/young person report, adjusted for child/young person reported baseline Parent/carer report, adjusted for parent/carer reported baseline	Self-report by young people aged 11+ AND/OR parent report of child/young person RCADS will be self-reported by children and young people aged 11-17 years old, with an additional version for parent/carer-reports on the child/young person.	Baseline, 6 and 12 months post-randomisation

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
	panic, obsessive compulsive disorder and major depression. RCADS demonstrates good psychometric properties.[30]				
Comorbid oppositional defiant / conduct disorder in the child/young person	Strengths & Difficulties Questionnaire (SDQ):[31] A 25-item emotional and behavioural screening questionnaire for children and young people. Each item is rated on a 3-point scale (not true, somewhat true, certainly true). Values of 0, 1 or 2 are assigned to each response. SDQ comprises 5 sub-scales and an impact supplement. The impact supplement asks effect of difficulties on	Scores on the 'conduct problems' subscale will be used in the analysis of this outcome. Sub-scale scores range from 0 to 10.	Mean difference, adjusted for baseline: Child/young person report, adjusted for child/young person reported baseline Parent/carer report, adjusted for parent/carer reported baseline	Self-report by young people aged 11+ AND/OR parent report of child/young person SDQ will be self-reported by children and young people aged 11-17 years old, with an additional version for parent/carer-reports on the child.	Baseline, 6 and 12 months post-randomisation

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
	homelife, friendships, education and leisure activities. SDQ has demonstrated reasonable psychometric properties.[32-35]				
Functional Impairment in the child/young person	Questionnaire (SDQ):[31]	Impact supplement scores will be used to determine functional impairment. Impact scores range from 0 to 10.	Mean difference, adjusted for baseline: Child/young person report, adjusted for child/young person reported baseline Parent/carer report, adjusted for parent/carer reported baseline	Self-report by young people aged 11+ AND/OR parent report of child/young person SDQ will be self-reported by children and young people aged 11-17 years old, with an additional version for parent/carer-reports on the child.	Baseline, 6 and 12 months post-randomisation

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
Self-harm thoughts in the child/young person	Young people will be asked to report the frequency of thoughts of self-harm.	Frequency of thoughts of self-harm are rated over the last 6 months in the following categories and scored accordingly: Not at all (0) Once or twice (1) Three or more times (2)	Descriptive	Self-report by young people aged 11+	Baseline, 6 and 12 months post-randomisation
Self-harm behaviours in the child/young person	Young people will be asked to report frequency of instances of self-harm behaviour.	Frequency of self-harm behaviour are rated over the last 6 months in the following categories and scored accordingly: Not at all (0) Once (1) Two or more times (2)	Descriptive	Self-report by young people aged 11+	Baseline, 6 and 12 months post-randomisation
Depression symptoms in the parent/carer	PHQ-9:[36] PHQ-9 is frequently used as a screening tool for depression in general populations. 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.	Mean difference, adjusted for baseline	Parent self-report	Baseline, 6 and 12 months post-randomisation
Anxiety symptoms	GAD-7:[37]	Total scores range from 0 to 21 with higher scores indicating more severe anxiety.	Mean difference,	Parent self-report	Baseline, 6 and 12

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
in the parent/carer	GAD-7 is a measure of the severity of anxiety in general populations. 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').		adjusted for baseline		months post-randomisation
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		Descriptive	Young person self-report for those aged 16 & 17, parent report for those aged <16	Baseline, 6 and 12 months post-randomisation
Safety Outcomes					
A significant deterioration in depression for the	MFQ (as above)	A score indicative of depression (27 or above) on the Mood and Feelings Questionnaire (MFQ) completed at follow-up, where this represents a deterioration from baseline of 5 points or more.	Descriptive	As above	As above

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
child/young person					
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, where this represents a deterioration from baseline of 5 points or more.	Descriptive	As above	As above
Frequency of self-harm	Self-harm measure (as above)	As above	As above	As above	As above
Hospital admissions	Yes/no	The number of children/young people 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.	Descriptive	Parent report only for those aged < 16. Parent report (if participating) AND young person self-report for those aged 16 & 17	Baseline, 6 and 12 months post-randomisation
A&E attendances	Yes/no	The number of children/young people attending 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.	Descriptive	Parent report only for those aged < 16. Parent report (if	

Outcome	Measurement	Definition	Analysis metric	Data collection	Time point
				participating) AND young person self-report for those aged 16 & 17	
Deaths	Yes/no	The number of deaths of participating children/young people from randomisation until 18-month follow-up.	Descriptive	Collected from clinical records	Within a) 12 months and b) 18 months of randomisation
Additional data collection					
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	Scores range from 0 to 40 with higher scores indicating more severe symptoms. 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.	Mean difference, adjusted for baseline: Child/young person report, adjusted for child/young person reported baseline Parent/carer report, adjusted for parent/carer reported baseline	CRIES-8 will be self-reported by children and young people aged 11-17 years old, with an additional version for parent/carer-reports on the child/young person aged <16.	Baseline, 6 and 12 months post-randomisation

13.2. Analysis of Outcome Measures

13.2.1. Description of Analysis Methods

The analysis and presentation of the trial will be in accordance with CONSORT guidelines.[38] A full statistical analysis plan (SAP) will be developed and agreed prior to database lock and un-blinding of the analysing statistician.

Continuous variables will be summarised in terms of the mean, standard deviation, median, lower and upper quartiles, minimum, maximum and number of observations. Categorical variables will be summarised in terms of frequency counts and percentages. Descriptive statistics of demographic and clinical measures will be used to assess balance between the randomised arms at baseline, but no formal statistical comparisons will be made.

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).

The primary comparative analysis will employ generalised linear regression modelling to compare the proportions in each group with a clinician-made diagnosis decision about the presence of an emotional disorder within 12 months of randomisation, adjusted for minimisation variables. The comparison will be presented as both an absolute (risk difference) and relative (risk ratio) effect, along with 95% confidence intervals.

Secondary outcomes will be analysed using appropriate regression models dependent on data type (binary, continuous, survival etc.), and will include factors used in the minimisation and baseline value of the outcome where measured. 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 and estimates and p-values, where presented, should be interpreted in this light.

Presentation of the diagnoses made and the subsequent treatment and interventions given will be descriptive. Frequency counts and percentages of the proportion of participants reporting each will be presented by treatment arms.

Safety outcomes will be presented descriptively according to allocation at randomisation, but no formal statistical comparisons will be made.

13.2.2. Sensitivity Analyses

We will repeat primary analyses 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, but will plan sensitivity analyses using multiple imputation and/or simple methods making different assumptions to investigate the potential impact of missing data. We expect adherence with allocation to be high but will monitor throughout the study and, if appropriate, may consider an analysis to investigate the effects of adherence with the allocated intervention (level of participant completion of the DAWBA) using instrumental variable regression.

13.2.3. Planned Sub Group Analyses

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

- Sex of child (male or female)
- age (5-10 & 11-17 years)

Between-group treatment effects will be provided for each subgroup, but interpretation of any subgroup effects will be based on the treatment-subgroup interaction and 95% confidence interval, 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.

13.2.4. Planned 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 or recruitment and acceptability of the intervention according to agreed progression criteria.

Decision to proceed or stop the trial

A Trial Steering Committee (TSC) meeting will be held shortly after the end of the Internal Pilot. The data on recruitment, retention and engagement will be presented, and the TSC will assess the pre-determined acceptability and recruitment stop/go criteria and decide whether the trial can progress. Criteria will be set as follows for the number of participants randomised by the end of month 9 of recruitment (starting from first participant randomised):

- >90% of cumulative monthly randomisation target - continue the trial.
- 60-90% of cumulative monthly randomisation target - review recruitment/retention procedures to identify underlying problems and put in place strategies to address these, with review in 6 months by the TMG/TSC/DMC.
- 25-59% of cumulative monthly randomisation target - review recruitment/retention procedures to identify underlying problems and put in place strategies to address these. Ongoing review over 6 months by the TMG/TSC/DMC and terminate the trial if the recruitment trajectory does not indicate that full recruitment can occur within an acceptable recruitment period.
- <25% of cumulative monthly randomisation target - terminate the trial.

Retention at 6-month follow-up by the end of the pilot period will also be considered.

13.2.5. Planned Final Analyses

The final analysis will be performed when the recruitment and data collection are finished, data cleaning has been completed, the database is locked and the SAP agreed and signed off by relevant parties.

13.2.6. Power Calculations / sample size calculation

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).

14. Health Economic Analysis

14.1. Aim

The primary economic analysis will take an NHS and personal social services cost perspective in accordance with NICE guidance, and a wider societal perspective to capture the broader effects. The secondary analysis will aim to establish potential broader effects on families and society by establishing time lost from work because of care of children with emotional difficulties and out-of-pocket expenses for the families. The combination of resource use and subsequent calculation of health service and societal cost will be combined with outcome and child/young person and parent/carer quality of life data to provide a measure of the cost effectiveness and cost utility of the use of the SDA tool versus usual care.

14.2. Health care resource use, including education and social care

A purposively designed resource use proforma will collect participant level resource information (see Table 7). This measure will collect data on all aspects of diagnosis, treatment and follow up including medication, inpatient and outpatient hospital visits and primary and community care use as well as societal and education costs. The measure includes sections specifically designed to quantify the effect on time off work for parents/carers (including friends and family) and the implications for productivity. In addition, it will seek to measure effects on time lost from education or training for the child/young person because of emotional difficulties. Ongoing development work will be undertaken during the pilot phase to improve clarity and enhance completion.

Table 7. Resource use data collection

Measurement	Data collection	Time point
A purposely designed resource use collection tool addressing primary, secondary, social care and patient costs.	Parent report only for those aged < 16. Parent report (if participating) AND young person self-report for those aged 16 & 17	Baseline, 6 and 12 months post-randomisation

14.3. Outcome measures

The health economic analyses will utilise the following outcomes as defined in Table 8:

- Child/young person quality of life
- Parent/carer quality of life

Table 8. Health economic outcome measurement

Outcome	Measurement	Definition	Data collection	Time point
Child/young person quality of life	Child Health Utility 9D (CHU9D)[39]	Quality-adjusted life years estimated using the CHU9D	Self-report by young person aged 11+ OR parent/carer report of child/young person aged <11 using CHU9D proxy OR parent/carer report of child/young person aged 11-15 if not self-reported	Baseline, 6 and 12 months post-randomisation
Child/young person quality of life	EuroQol Quality of Life Questionnaire 5 Domains for Young People (EQ5DY)[40]	Quality-adjusted life years estimated using the EQ5DY	Self-report by young person aged 11+ OR parent/carer report of child/young person aged <11 using EQ5DY proxy OR parent/carer report of child/young person aged 11-15 if not self-reported	Baseline, 6 and 12 months post-randomisation
Parent/carer quality of life	EuroQol Quality of Life Questionnaire 5 Domains, 5 Levels (EQ5D5L)[41]	Quality-adjusted life years estimated using the EQ5D5L	Self-report by the parent/carer	Baseline, 6 and 12 months post-randomisation

Health economic outcome data for children/young people will be collected using the EQ5DY and the CHU9D. Use of both measures will enable comparative analysis to be performed of the validity and acceptability of these two measures within the patient group. The two represent the most frequently used preference-based measures in children/young people. Eliciting comparative use of the two measures will provide a valuable resource for researchers going forward, who are seeking to incorporate an outcome-based preference measure into their research. Use of both measures will be evaluated during the pilot phase and if this is considered to impose too great a burden on respondents, the decision will be taken to continue with the collection of one measure only.

14.4. Analysis

The net monetary benefit (NMB) framework will be used and a net benefit regression will be implemented; this allows multivariate analysis to explore baseline and centre-specific effects, which likely influence both clinical effect, cost, and their relationship. Resulting analysis would utilise generalized linear models (GLM), or if a highly skewed distribution of costs is observed a generalized Gamma model could be considered. The NMB framework estimates the extent to which, and the probability that, the SDA tool is cost effective compared to standard care at a range of threshold values (i.e. from £0 to £30,000) for the willingness to pay per QALY. Probabilistic sensitivity analysis (PSA) will be employed to calculate realised values; subsequently generating Cost Effectiveness Acceptability Curves (CEACs), which indicate the probability of being cost effective at the range of threshold values stated before.

Consideration can be given towards examining key cost drivers through sensitivity analysis.

15. Qualitative Study

15.1. Aim

The pilot 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 (e.g. how the DAWBA is summarised and shared with participants and clinicians) for the main trial.

15.2. Methods

Semi-structured interviews will be conducted with up to 25 participants (parents and young people aged 16 and 17, from both the intervention and control arms of the study), 25 staff (including those recruiting participants, triage staff and clinicians) and 15 service managers and commissioners across the 5 sites. Principles of data saturation will be used to guide the final sample size. All interviews and analysis will be conducted by a qualitative researcher, with additional contributions from interested members of our Patient and Public Involvement (PPI) Advisory Group Panels in facilitating interviews and the analysis of emerging themes. The domains of the Consolidated Framework for Implementation will be used to develop the interview questions and as a coding framework for thematic analysis.[42].

Participants for the pilot phase qualitative study will be identified from the main trial, where they will have been asked to consent to being contacted by a qualitative researcher. Those who have consented will be contacted and asked if they want to participate, and if so will be sent a PIS and consent form (by email or post). Interviews will be arranged at a mutually convenient time and location. Where possible interviews will be conducted face-to-face, but where that is not feasible telephone or video call/skype interviews will be conducted. If telephone/video call interviews are conducted, verbal consent procedures will be used to gain participant's informed consent during which the written consent form will be recited by the researcher taking consent, and the participant asked to provide verbal responses. Verbal consent will be recorded as a separate audio file prior to the telephone/video call interview. If requested by the participant, the PIS may be delivered orally by the researcher prior to the telephone/video call interview.

Staff, managers and commissioners at each site will be invited to take part in the interview study via the Principal Investigator at that site. The site PI will send potential participants the Letter of Invitation via email, which will request that those interested in taking part in the interview study make direct contact with the qualitative research team. Staff, managers and commissioners who volunteer to take part will be sent a PIS and consent form and the interview will be arranged for a mutually convenient time. Where possible interviews will be conducted face-to-face, but where that is not feasible telephone interviews will be conducted. Interviews will be arranged at a mutually convenient time and location. Group interviews with staff may also be conducted to facilitate the involvement of additional staff participants.

Interviews will be guided by the Interview Schedules and recorded using an encrypted digital recorder where consent is given. Digital audio files will be transferred to the transcription service Dict8 for transcription using secure FTP. Transcriptions will be anonymised. Audio files will be destroyed after transcripts have been checked. Anonymised transcriptions will be analysed and stored on password protected laptops and the secure University of Nottingham server.

15.3. Analysis

NVIVO 12 will be used to manage the qualitative data. All qualitative data will be analysed using interpretative and thematic approaches to coding, and adopt the framework method[43] which can support the involvement of the wider team, including PPI Advisory Group members, in qualitative analysis in multi-disciplinary health research projects. A qualitative analysis workshop will be held to allow the project team and interested PPI Advisory Group members to contribute to the discussion of emerging themes. The analysis will lead to a qualitative appraisal of the intervention and its implementation, and the production of recommendations about the future roll out and scale up in other settings.

15.4. Process evaluation

There will be a process evaluation alongside the main trial with the aim of identifying the barriers and facilitators to implementation. Using qualitative approaches, this study will produce evidence on how the intervention is introduced and operationalised in routine practice across the different sites, how it is experienced by different stakeholders, and what contextual factors and causal mechanisms affect outcomes, with the intention of producing learning for future implementation. The process evaluation will follow the MRC guidance and examine the quality of implementation, role of contextual factors, and mechanisms through which the outcomes occur.[44] A logic model for the process evaluation will be developed using the qualitative data from the internal pilot.[45] Semi-structured interviews will be conducted with another 25 participants (parents and young people aged 16 and 17) and 25 clinicians taking part in the main trial to explore the perceived functioning of the intervention, the organisation of the service and reflective experiences on outcomes.

The methods and analysis will be the same as above, but different interview schedules will be used, which are to be developed following the results of the pilot phase qualitative work.

16. Trial Organisational Structure

16.1. Sponsor

Nottinghamshire Healthcare NHS Foundation Trust will undertake role of Sponsor as defined by the UK Policy Framework for Health and Social Care Research.[46] Delegated responsibilities will be assigned to the Chief Investigator, participating NHS Trusts and Nottingham Clinical Trials Unit.

16.2. Trials Unit

The trial is co-ordinated by the Nottingham Clinical Trials Unit (NCTU).

16.3. Trial Management Group

The full co-applicant team and NCTU staff responsible for the day-to-day management of the trial will form the Trial Management Group (TMG) and have monthly trial meetings via telephone or video conferencing with face-to-face meetings held as required.

16.4. Trial Steering Committee

The role of the Trial Steering Committee (TSC) is to maintain oversight of the trial, monitor progress and provide advice to the research team. The TSC will consist of an independent chair, and other independent members with clinical and research expertise including parent representatives. The Chief Investigator will also be a member of the TSC.

The TSC will operate in accordance with a trial specific charter.

The TSC will meet at least once a year during the trial, including after Month 15 to review the results of the Internal Pilot and decide on trial progression. Additional meetings may be called and the TSC may, at their discretion, request to meet more frequently.

The TSC will consider and act, as appropriate, upon the recommendations of the Data Monitoring Committee (DMC).

16.5. Data Monitoring Committee

The role of the Data Monitoring Committee (DMC) is to give advice on whether the accumulated data from the trial, together with the results from other relevant research, justifies the continuing recruitment of further participants.

Members of the DMC will be independent of the trial and consist of a statistician, a clinician with experience of trials and an academic with experience of trials.

The DMC will operate in accordance with a trial specific charter.

The DMC will meet at least once a year during the trial, including after Month 15 to review the results of the Internal Pilot and make recommendations to the TSC on trial progression. Additional meetings may be called and the DMC may, at their discretion, request to meet more frequently or continue to meet following completion of recruitment. An emergency meeting may also be convened if a safety issue is identified.

The DMC will report directly to the Chair of the Trial Steering Committee (TSC) who will convey the findings of the DMC to the TSC, TMG and Sponsor as applicable.

17. Patient and Public Involvement

17.1. Aims of involvement

The perspectives of young people and parents are central to this research and will help ensure that the outputs are appropriate and meaningful. The aims of active involvement from young people and parents are to:

- Shape the research content so that it maintains its focus throughout on the most important issues for young people and parents.
- Build capacity so that those involved gain knowledge, skills and opportunities throughout the research process.
- Provide support and training that is flexible to the needs of those involved.
- Capture their experiences of and impact from contributing as research partners.
- Collaborate and participate in the range of dissemination and project feedback activities.

17.2. Involvement during the research

PPI will be led by the parent co-applicant and peer researcher with lived experience of caring for a child who has used CAMHS (CE) and co-ordinated by AL.

The project will have a separate Parent Advisory Group Panel and Young Person Advisory Group Panel which will each aim to meet every 3 months throughout the project. Meetings will be co-facilitated by the co-applicant PPI leads (CE, AL) and another of the study researchers. Representatives from the Parent and Young Person panels will also be invited to join and participate in the face-to-face TMG meetings.

Panel members will be reimbursed, with appropriate remuneration and recognition being established for each group as per guidance from NIHR Involve.[47] Participants will have personal experience of CAMHS referrals and/or assessment processes and be able to provide valuable insights into key issues.

The Advisory Panels will actively contribute to all aspects of the research, including:

- Preparation of publicity materials to raise awareness of the study
- Overseeing the wording of Participant Information Sheets
- Advising on the wording of the feedback information from the DAWBA to participants and clinicians
- Developing the health economic proforma
- Designing the qualitative interview schedules
- Facilitating qualitative interviews
- Contributing to qualitative analysis workshops to discuss themes
- Evaluating the findings, and prioritising and disseminating key findings

There will also be a range of flexible opportunities for participating in project feedback and dissemination activities including co-facilitating and presenting at the interactive dissemination workshop / consensus meeting, publication authorship as peer researcher and presenting at conferences to showcase the project findings.

The project PPI will be subject to an evaluation, to provide insight into the effectiveness and impact of PPI within the project.

18. Finance

This trial is funded by the National Institute for Health and Care Research (NIHR), Health Technology Assessment Programme (HTA) (Project Ref. 16/96/09).

18.1. Participant payments and stipends

Participants will not be paid to participate in the trial. However, the parent/carer (if participating in the trial) and young people aged 11 and over will each be provided with a voucher of up to £20, conditional upon completion of the follow up questionnaires, as a thank you for the additional time spent on involvement in the research.

The timing and value of participant vouchers will be tested in a Study Within a Trial (SWAT). Participants recruited into the STADIA trial prior to implementation of the SWAT (February 2021) will be offered a single £20 voucher conditional on completion of the 12-month questionnaires. Following implementation of the SWAT participants will be randomised to receive either:

- A £10 voucher conditional on completion of the 6-month questionnaires plus another £10 voucher conditional on completion of the 12-month questionnaires, or
- A single £20 voucher conditional on completion of the 12-month questionnaires.

Further details are documented in the SWAT protocol (Final v1.0 dated 03-Feb-2021).

19. Ethical Considerations

The trial will be performed in accordance with the recommendations guiding physicians in biomedical research involving human participants, adopted by the 18th World Medical Association General Assembly, Helsinki, Finland, June 1964, amended at the 48th World Medical Association General Assembly, Somerset West, Republic of South Africa, October 1996 (website: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/).

The trial will be conducted in accordance with the UK Policy Framework for Health and Social Care Research, the applicable UK Statutory Instruments, (which include the Data Protection Act 2018) and Guidelines for Good Clinical Practice (GCP). The protocol will be submitted to and approved by the REC prior to circulation.

20. Confidentiality and Data Protection

Personal data recorded on all documents will be regarded as strictly confidential and will be handled and stored in accordance with the Data Protection Act 2018.

Identifiable personal information obtained by consent from participants will be prohibited from disclosure to third parties with the exceptions noted in this protocol.

Only trial staff as listed on the delegation log shall have access to trial documentation, other than the regulatory requirements listed below.

Trial documentation including all source documents, shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

Enrolled participants will be assigned a unique trial identification number. Participants will always be identified using their unique trial identification number on the CRFs/eCRF and in correspondence between NCTU and the participating site. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and date of birth (dd-mmm-yyyy).

At the participating site, the investigator will keep a record (e.g. Participant Identification/Enrolment Log) of the participant's name, date of birth, local Trust/hospital number, NHS number, and participant trial identification number, to permit identification of all participants enrolled in the trial. The Investigator must maintain documents not for submission to NCTU in strict confidence. In the case of specific issues and/or queries from the regulatory authorities, it will be necessary to have access to the complete trial records, provided that participant confidentiality is protected.

Consent will be given for participant contact details to be logged onto a secure trial database based at the NCTU. These details will be used by the coordinating centre and relevant members of the study team in order to send out follow-up questionnaires, and study-related correspondence limited to the duration of the trial unless participants consent for their contact details to be retained beyond the duration of their participation in the trial, in order to be updated about the outcomes of the research, or informed of future research. Participants may also optionally consent to being contacted by a qualitative researcher to be invited to participate in the qualitative interviews.

NCTU will maintain the confidentiality of all participants' data and will not disclose information by which participants may be identified to any third party other than those directly involved in the treatment of the participant and organisations for which the participant has given explicit consent for data transfer (e.g. NHS Digital, competent authority, Sponsor). Representatives of the Nottingham Clinical Trials Unit and Sponsor may be required to have access to participant's notes for quality assurance purposes but participants should be reassured that their confidentiality will be respected at all times.

21. Insurance and Indemnity

Nottinghamshire Healthcare NHS Foundation Trust will act as sponsor for the trial therefore insurance and indemnity for trial participants and NHS trial staff will be covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96) 48. There are no special compensation arrangements, but trial participants may have recourse to the NHS complaints procedure.

The University of Nottingham has appropriate and typical insurance coverage in place (including, but not limited to Clinical Trials, Professional Indemnity, Employer's Liability and Public Liability policies) in relation to the Institution's Legal Liabilities arising from the University's activities and those of its staff, whilst conducting University business and research activity.

22. Publication Policy

Results of this trial will be reported to the funder and published in full in the HTA Journal series and also submitted for publication in a peer reviewed journal. The primary manuscript will be prepared by the Trial Management Group and authorship will be determined by mutual agreement.

Any secondary publications and presentations prepared by Investigators must be reviewed by the Trial Management Group. Manuscripts must be submitted to stadia@nottingham.ac.uk in a timely fashion and in advance of being submitted for publication, to allow time for review and resolution of any outstanding issues. Authors must acknowledge that the trial was performed with the support of Nottinghamshire Healthcare NHS Trust and the Nottingham Clinical Trials Unit and funding provided by the NIHR Health Technology Assessment programme. In the case of publications including results or opinions, the required NIHR disclaimer must also be included.

Approaches to dissemination will include:

- Publications
- Conferences
- Website and Newsletters
- Media
- Interactive dissemination workshop / consensus meeting
- Focussed events for NHS providers, commissioners and training organisations
- CAMHS Clinician Training

22.1. Data sharing statement

Individual participant medical information obtained as a result of this study is considered confidential and disclosure to third parties is prohibited with the exceptions noted in this protocol.

Anonymised trial data may be shared with researchers external to the trial research team in accordance with the NCTU's data sharing procedure.

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