NIHR | National Institute for Health and Care Research

Health Technology Assessment

Synopsis

Clinical and cost-effectiveness of a standardised diagnostic assessment for children and adolescents with emotional difficulties: the STADIA multi-centre RCT

Kapil Sayal,[1,2*] Laura Wyatt,[3] Louise Thomson,[1,2] Grace Holt,[3] Colleen Ewart,[4] Anupam Bhardwaj,[1,5,6] Bernadka Dubicka,[7,8,9,10] Tamsin Marshall,[11] Julia Gledhill,[12] Alexandra Lang,[13] Kirsty Sprange,[3] Christopher Partlett,[3] Kristina Newman,[2] Sebastian Moody,[3] Helen Bould,[14,15,16] Clare Upton,[3,17] Matthew Keane,[3] Edward Cox,[3] Marilyn James[3] and Alan Montgomery[3]

[1]Unit of Mental Health and Clinical Neurosciences, School of Medicine, University of Nottingham, Nottingham, UK
[2]Institute of Mental Health, Nottinghamshire Healthcare NHS Foundation Trust, Nottingham, UK
[3]Nottingham Clinical Trials Unit, School of Medicine, University of Nottingham, Nottingham, UK
[4]STADIA Patient and Public Involvement Co-Lead, Institute of Mental Health, University of Nottingham, Nottingham, UK
[5]Cambridgeshire and Peterborough Foundation Trust, Brookside CAMHS, Cambridge, UK
[6]School of Medicine, University of Cambridge, Cambridge, UK
[7]Hull and York Medical School, University of York, York, UK
[8]Greater Manchester Mental Health Trust, Manchester, UK
[9]Pennine Care NHS Foundation Trust, Ashton-under-Lyne, UK
[10]Faculty of Biology, Medicine and Health, Manchester Academic Health Sciences, University of Manchester, Manchester, UK
[11]Berkshire Healthcare NHS Foundation Trust, Bracknell, UK
[12]Central and North West London NHS Foundation Trust, Harrow CAMHS, Ash Tree Clinic, Harrow, UK
[13]Human Factors Research Group, Faculty of Engineering, University of Nottingham, Nottingham, UK
[14]Centre for Academic Mental Health, Population Health Sciences, Bristol Medical School, University of Bristol, Bristol, UK
[15]MRC Integrative Epidemiology Unit, Bristol Medical School, University of Bristol, Bristol, UK
[16]Gloucestershire Health and Care NHS Foundation Trust, Gloucestershire, UK
[17]Liverpool Clinical Trials Centre, University of Liverpool, Liverpool, UK

*Corresponding author kapil.sayal@nottingham.ac.uk

Published November 2025
DOI: 10.3310/GJKS0519
Volume 29 • Issue 61

Abstract

Background: Emotional disorders are common in children and young people and can significantly impair their quality of life. Evidence-based treatments require a timely and appropriate diagnosis. The utility of standardised diagnostic assessment tools may aid the detection of emotional disorders, but there is limited evidence of their clinical value.

Objectives: To assess the clinical effectiveness and cost effectiveness of a standardised diagnostic assessment for children and young people with emotional difficulties referred to Child and Adolescent Mental Health Services. A nested qualitative process evaluation aimed to identify the barriers and facilitators to using a standardised diagnostic assessment tool in Child and Adolescent Mental Health Services.

Design: A United Kingdom, multicentre, two-arm, parallel-group randomised controlled trial with a nested qualitative process evaluation.

This synopsis should be referenced as follows:
Sayal K, Wyatt L, Thomson L, Holt G, Ewart C, Bhardwaj A, *et al.* Clinical and cost-effectiveness of a standardised diagnostic assessment for children and adolescents with emotional difficulties: the STADIA multi-centre RCT. *Health Technol Assess* 2025;**29**(61). https://doi.org/10.3310/GJKS0519

Setting: Eight National Health Service Trusts providing multidisciplinary specialist Child and Adolescent Mental Health Services.

Participants: Children and young people aged 5–17 years with emotional difficulties referred to Child and Adolescent Mental Health Services, excluding emergency/urgent referrals that required an expedited assessment. In the qualitative process evaluation, 15 young people aged 16–17 years, 38 parents/carers and 56 healthcare professionals participated in semistructured interviews.

Interventions: Participants were randomly assigned (1 : 1) following referral receipt to intervention (the development and well-being assessment) and usual care, or usual care only.

Main outcome measures: Primary outcome was a clinician-made diagnosis decision about the presence of an emotional disorder within 12 months of randomisation, collected from Child and Adolescent Mental Health Services clinical records. Secondary outcomes collected from clinical records included referral acceptance, time to offer and start treatment/interventions and discharge. Data were also self-reported from participants through online questionnaires at baseline, 6 and 12 months post randomisation, and the cost effectiveness of the intervention was investigated.

Results: One thousand two hundred and twenty-five (1225) children and young people were randomly assigned (1 : 1) to study groups between 27 August 2019 and 17 October 2021; 615 were assigned to the intervention and 610 were assigned to the control group. Adherence to the intervention (full/partial completion of the development and well-being assessment) was 80% (494/615). At 12 months, 68 (11%) participants in the intervention group received an emotional disorder diagnosis versus 72 (12%) in the control group [adjusted risk ratio 0.94 (95% confidence interval 0.70 to 1.28); $p = 0.71$]. Child and Adolescent Mental Health Services acceptance of the index referral [intervention 277 (45%) vs. control 262 (43%); risk ratio: 1.06 (95% confidence interval: 0.94 to 1.19)] or any referral by 18 months [intervention 374 (61%) vs. control 352 (58%); risk ratio: 1.06 (95% confidence interval: 0.97 to 1.16)] was similar between groups. There was no evidence of any differences between groups for any other secondary outcomes. The qualitative nested process evaluation identified a number of barriers and facilitators to the use of the development and well-being assessment during the trial, particularly at the assessment and diagnosis stages of the Child and Adolescent Mental Health Services pathway.

Limitations: It was not possible to mask participants, clinicians or site researchers collecting source data to treatment allocation.

Conclusions: We found no evidence that completion of the development and well-being assessment aided the detection of emotional disorders in this study. Using the development and well-being assessment in this way cannot be recommended for clinical practice.

Future research: To determine longer-term service use outcomes and to investigate whether receipt of a clinical diagnosis makes a difference to clinical outcomes and care/intervention receipt.

Funding: This synopsis presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number 16/96/09.

A plain language summary of this synopsis is available on the NIHR Journals Library Website https://doi.org/10.3310/GJKS0519.

Introduction

Material within this synopsis has been reproduced with permission from Sayal *et al.*[1] and Thomson *et al.*[2] These are Open Access articles distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The text below includes minor additions and formatting changes to the original text. The full protocol (final version 4.1, 1 August 2022) has been published and is publicly available on the ISRCTN registry.[3] Changes to the protocol after the initial approval are documented in *Appendix 1*, *Table 2*. Protocol deviations are outlined in *Appendix 1*, *Table 3*.

This synopsis details the work undertaken to determine the clinical effectiveness and cost-effectiveness of a standardised diagnostic assessment (SDA) for children and young people (CYP) with emotional difficulties. It was funded through a commissioned research call from the National Institute for Health and Care Research (NIHR) for a randomised controlled trial (RCT) to investigate whether a SDA tool improves the detection of emotional disorders and outcomes in CYP referred to Child and Adolescent Mental Health Services (CAMHS).

Rationale for the STADIA trial and background

Emotional disorders, such as depression and anxiety disorders, cause considerable distress and are common in CYP.[4] They impact quality of life and functioning, including friendships, family relationships, participation in daily activities, school attendance and attainment and educational outcomes.[5–7] If unrecognised and untreated, these difficulties can persist into adulthood and are a risk factor for other mental health conditions, poor physical health, self-harm and suicide. Although evidence-based interventions for emotional disorders are available, access to these requires timely and appropriate identification of difficulties. However, in many countries, service demand exceeds capacity and there are considerable barriers to receiving help. In the UK, for example, these include long waiting lists and rejection of referrals by specialist CAMHS, particularly if insufficient information accompanies the referral. The evidence base to inform which referrals should be accepted is limited.[8]

If accepted for assessment, the process and purpose of assessment can vary considerably within and across services. The multidisciplinary nature of CAMHS in the UK means that assessments are conducted by clinicians from a range of professional backgrounds, often without formal training in making a diagnosis.[4,9] This can lead to heterogeneous conceptualisations of presenting problems. Diagnosis is a controversial topic among mental health clinicians in the UK, reflecting concerns around the validity and value of diagnoses, stigma and labelling.[9–11] In routine care, this often means that assessments do not aim to make, share or record a diagnosis despite recommendations for the use of diagnostic assessments so that appropriate interventions are offered.[11,12] Linked with CAMHS clinician uncertainty around the utility and value of diagnosing child and adolescent mental health disorders in clinical practice, there is also clinician equipoise around the use of SDA tools.

However, National Institute for Health and Care Excellence (NICE) guidelines for the care and treatment of emotional disorders are based on diagnostic classification systems; this implies that, to access appropriate evidence-based interventions, emotional difficulties should be appropriately diagnosed. For depression, for example, NICE quality standards recommend that the diagnosis is confirmed and recorded,[13] but this is often not the case in clinical practice.[9,14] NICE guidelines also recommend the use of SDA tools as an adjunct to usual assessment care in detecting depression.[15] However, there is currently limited evidence about the effectiveness and cost-effectiveness of using SDA tools to support routine CAMHS assessments.

Previous RCTs of SDA tools in CAMHS have tended to be single site and small-scale. RCTs in Switzerland and England found that providing clinicians with diagnostic information from the development and well-being assessment (DAWBA)[16] increased agreement between DAWBA and clinical diagnoses of emotional disorders, suggesting that it could aid diagnostic decision-making.[17,18] A feasibility trial in Denmark suggested that the DAWBA could also act as an adjunct to referral information and improve decision-making around referral acceptance.[8] In terms of the care pathway, therefore, locating SDA tools at the point of referral receipt could potentially optimise decisions about referral acceptance, case allocation to the most appropriate clinician and assessment outcomes.[10,19,20] This could enable a more efficient and timelier conclusion to assessments which reach a diagnostic decision, allow appropriate evidence-based interventions to be offered and result in better clinical outcomes.

In the multicentre standardised diagnostic assessment for children and adolescents with emotional difficulties (STADIA) RCT, we aimed to investigate the clinical effectiveness and cost-effectiveness of a SDA tool for CYP with emotional difficulties referred to CAMHS.

Objectives

The objectives were to evaluate the clinical effectiveness and cost-effectiveness of a SDA tool (the DAWBA), as an adjunct to usual clinical care for CYP presenting with emotional difficulties (following review of the referral according to a standard proforma (*Report Supplementary Material 1*: STADIA Screening Form) referred to CAMHS.

Specific objectives were to:

1. conduct an RCT to determine the clinical effectiveness and cost-effectiveness of the DAWBA as an adjunct to usual clinical care on diagnosis (see *Outcomes* section for primary outcome) and treatment of emotional disorders, symptoms of emotional difficulties and comorbid disorders and associated functional impairment
2. carry out a detailed qualitative study to address: (1) the feasibility of recruitment; (2) the acceptability and usability of the interventions and procedure and (3) how the intervention is used and how this deployment could be refined
3. 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
4. identify the barriers and facilitators to implementation from the perspectives of young people, parents/carers and CAMHS practitioners, managers and commissioners.

This synopsis should be referenced as follows:
Sayal K, Wyatt L, Thomson L, Holt G, Ewart C, Bhardwaj A, *et al.* Clinical and cost-effectiveness of a standardised diagnostic assessment for children and adolescents with emotional difficulties: the STADIA multi-centre RCT. *Health Technol Assess* 2025;**29**(61). https://doi.org/10.3310/GJKS0519

Methods for data collection and analysis

Study design and setting

We conducted a pragmatic multicentre, two-arm parallel-group RCT in community-based multidisciplinary CAMHS in eight dispersed NHS Trusts covering urban and rural areas in England. A list of recruiting sites is provided in *Appendix 1*, *Table 1*.

Participants and eligibility

Eligible participants were CYP with emotional difficulties referred to CAMHS and their parents/carers.

Inclusion criteria for the child and young person

The inclusion criteria for CYP were as follows:

- aged 5–17 years
- referred to outpatient multidisciplinary specialist CAMHS
- presenting with emotional difficulties according to a standard proforma (*Report Supplementary Material 1*)
- if aged < 16 years, has an eligible individual with parental responsibility willing and able to participate in the trial
- if aged 16–17 years:
    - has capacity to provide valid written informed consent
    - and if participating without a parent/carer, able to complete the assessment tool in English and has access to internet and e-mail or telephone.

Exclusion criteria for the child and young person

The exclusion criteria for CYP were as follows:

- emergency or urgent referral to outpatient multidisciplinary specialist CAMHS, requiring an expedited assessment
- severe learning disability
- previously randomised in the STADIA trial.

Inclusion criteria for the parent/carer

The inclusion criteria for parent/carer were as follows:

- individual with parental responsibility for the CYP referred to CAMHS
- adequate knowledge of the CYP 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 the internet and e-mail or telephone
- able to complete the assessment tool in English.

Exclusion criteria for the parent/carer

The exclusion criterion for parent/carer was as follows:

- local authority representatives designated to care for the CYP.

Participants were identified through the usual CAMHS referral pathways via single/central point of access triage teams. Referrals were screened by STADIA researchers (*Report Supplementary Material 1*), and potentially eligible participants were invited to participate in the trial and written information provided. Eligibility and verbal consent were confirmed during a telephone call, and participants were provided with an e-link to the online electronic informed consent/assent form to give written informed consent/assent. Participant flow is described in *Figure 1*. The summary of assessments is provided in *Appendix 1*, *Table 4*.

For CYP aged 5–15 years, parents/carers with parental responsibility provided informed consent and data (primary participant), with an option for 11- to 15-year-olds (secondary participant) to provide assent and data. Young people aged 16–17 years (primary participant) provided informed consent and data, and with their permission, their parent/carer (secondary participant) could also participate (*Report Supplementary Material 2*). As all study procedures were completed electronically, participants needed access to the internet and e-mail.

Randomisation and masking

Participants were randomised (1 : 1) to either the DAWBA plus assessment as usual (intervention) or assessment as usual only (control). Allocation was assigned using a minimisation algorithm balanced by recruiting site, CYP age (5–10, 11–15 and 16–17 years) and sex, minimising imbalance with 80% probability. The allocation algorithm was created and concealed using a secure, automated web system operated by the Nottingham Clinical Trials Unit (NCTU).

Participants were randomised after submitting their baseline data and were informed of their allocation. An e-mail also confirmed allocation, and instructions for DAWBA completion were included for the intervention group. Data were collected from clinical records (source data) using the case report forms (CRFs), by site researchers at 12 and 18 months post randomisation.

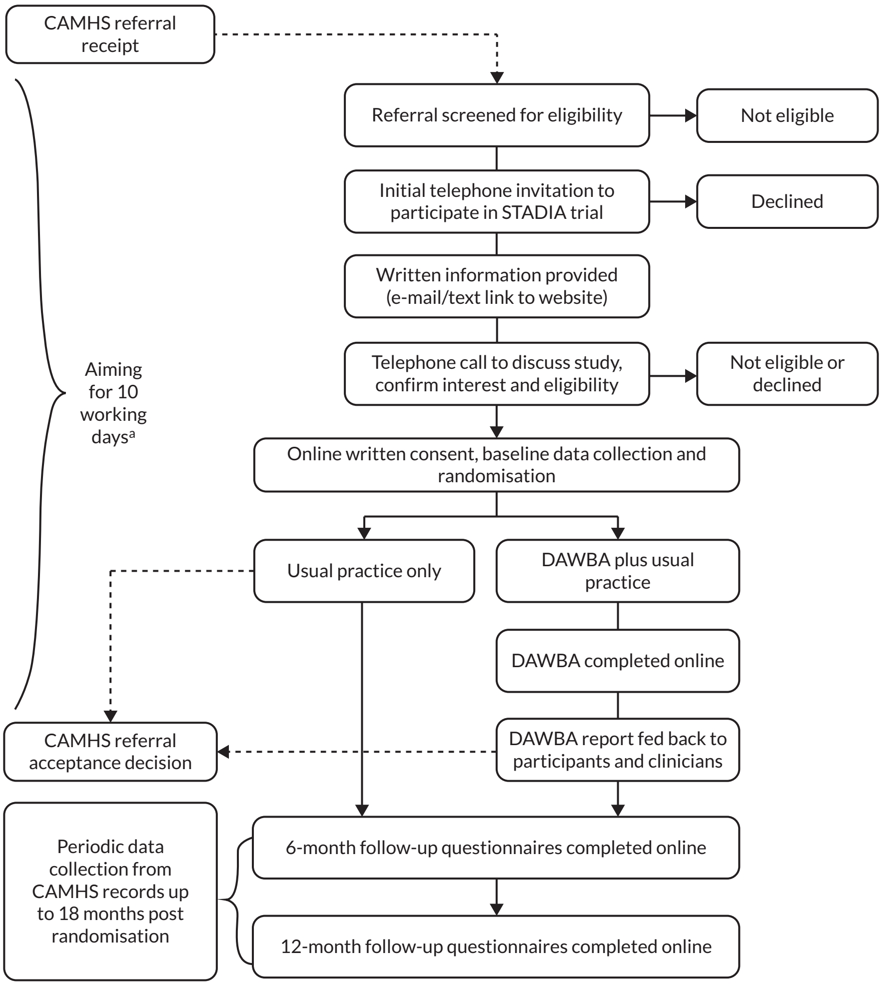

FIGURE 1 Participant flow. a, For sites where the waiting time for the CAMHS acceptance decision usually exceeds 10 working days from referral receipt, recruitment activities may start and/or continue beyond 10 working days from referral receipt, providing the intervention period can be completed prior to the CAMHS referral decision.

It was not possible to mask participants, site researchers, clinicians and some trial staff to treatment allocation, nor was it possible to blind researchers collecting outcome data from records. However, any possible diagnoses identified from the CAMHS records were recorded verbatim on the CRF and were subjected to adjudication by the outcome adjudication committee (members of the trial management group). The adjudication committee and trial data analysts were blinded to treatment allocation and participant ID. The outcome definition and adjudication procedures are described in *Report Supplementary Material 3*.

Procedures

Participant-reported data were collected through online questionnaires (parent/carer and CYP self-report, aged 11+ years), at baseline and 6 and 12 months post randomisation. Questionnaires were completed by the primary participant (parent/carer for CYP 5–15 years, and young people aged 16–17 years), with the option for the secondary participant to also contribute. Baseline measures collected included: sociodemographic data, Mood and Feelings Questionnaire (MFQ), Revised Children's Anxiety and Depression Scale (RCADS) and Strengths and Difficulties Questionnaire (SDQ) (a list of assessments is included in *Appendix 1*, *Table 4*).

Intervention group

The intervention was the DAWBA,[16,22] which was completed by participants (after completion of the baseline questionnaire) via the secure online platform maintained by the DAWBA developer.[16] Modules related to emotional and other specific comorbid disorders: separation anxiety disorder, specific phobia, social phobia, panic disorder and agoraphobia, generalised anxiety disorder, post-traumatic stress disorder (PTSD), obsessive–compulsive disorder (OCD), depression, oppositional defiant disorder and conduct disorder. In conjunction with study patient and public involvement

(PPI) panels, a trial-specific DAWBA report template (*Report Supplementary Material 4*) was developed. A DAWBA report was prepared for each participant, with the algorithm-derived diagnostic predictions[23] used to highlight the likelihood of a CYP meeting *International Statistical Classification of Diseases and Related Health Problems*, Tenth Revision (ICD-10) criteria[24] for the disorders assessed (close to average, slightly raised, high and very high); the report was based entirely on the algorithm-derived predictions. The report was sent to participants and also uploaded to the CAMHS clinical record for clinicians to access, as an adjunct to usual clinical care (see below).

Control group

Participants randomised to the control group received usual clinical care. Usual care in CAMHS involves the consideration and review of the referral, a clinical assessment (if the referral is accepted) and the offer/delivery of a clinical intervention.

Outcomes

The primary outcome was a clinician-made diagnosis decision about the presence of an emotional disorder within 12 months of randomisation. Eligible diagnoses were predefined (see *Appendix 1*, *Table 5*) using precise diagnostic terminology and reflected emotional or internalising disorders as outlined in ICD-10/*Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition (DSM-IV). Classification of a diagnosis required the suffix 'disorder' for certain types of difficulties, for example 'generalised anxiety disorder'. Where similar terminology was used, for example 'anxiety' without 'disorder', 'symptoms of …', '…-type symptoms/behaviour', etc., these were referred for adjudication and were classified as not constituting a clinical diagnosis due to uncertainty around the presence of an emotional disorder. The diagnosis must have been documented in the CAMHS clinical record within 12 months of randomisation by a mental health services clinician in an NHS-delivered or NHS-commissioned service.

Secondary outcomes collected were service-related or participant-reported (see *Appendix 1*, *Table 6*). During the trial, additional secondary outcomes were included to extend follow-up to 18 months post randomisation due to the impact of COVID-19 pandemic-related delays to service access and receipt (see *Appendix 1*, *Table 2*). Following the pandemic, symptoms of PTSD in the CYP were collected using the Children's Revised Impact of Event Scale-8 (CRIES-8).

Service-related secondary outcomes over the 12- and 18-month period from randomisation were: referral acceptance (index and subsequent); discharge from CAMHS; confirmed diagnosis decision; time from randomisation to diagnosis of an emotional disorder; decision to offer and start treatment/intervention for a diagnosed emotional disorder and time to offer or start any treatment/intervention (in addition to recording diagnoses and all treatments/interventions given).

Participant-reported secondary outcomes were participant–self-reported diagnoses, depression symptoms (MFQ), anxiety symptoms (RCADS), oppositional defiant/conduct disorder symptoms and functional impairment (SDQ). For participants in the intervention group, the SDQ was part of the DAWBA. Self-harm thoughts and behaviours were self-reported by CYP. Parent-reported depression and anxiety symptoms were collected [Patient Health Questionnaire-9 items (PHQ-9) and Generalised Anxiety Disorder-7 (GAD-7), respectively]. Health-related quality of life (HRQoL) measures collected for the economic evaluation were the 5-level EQ-5D version Youth Version (EQ-5D-Y) and the Child Health Utility 9D (CHU9D) for CYP and the EuroQol-5 Dimensions, five-level version (EQ-5D-5L) for parents/carers. Further details and references are found in the *Appendix 1*, *Table 6*.

A study within a trial (SWAT) was nested within the main RCT to investigate the timing and value of participant vouchers to improve questionnaire return rates. The methods and results for this will be published elsewhere.[35]

Process evaluation

A nested qualitative process evaluation was conducted alongside the trial. Young people aged 16–17 years and the parents/carers of children aged < 16 years, who were participating in both arms of the trial, were invited to take part in semistructured interviews. Parents/carers and young people who had consented to be contacted about the interviews were sent further information about this part of the study after they had been randomised and completed the DAWBA if in the intervention arm. A range of CAMHS staff were also interviewed, including clinicians, service managers, commissioners and researchers working in CAMHS. Recruitment of staff occurred later in the study to allow for them to have the experience of using DAWBA reports as part of their clinical work. The overarching framework guiding the process evaluation was the Consolidated Framework for Implementation Research (CFIR).[36,37] The five domains of the CFIR (the innovation, the outer setting, the inner setting, individual roles and characteristics and the implementation process) guided the interview questions, the development of a logic model for the trial and the data analysis.

Data collection took place in two phases: during the internal pilot (involving participants from both arms) and the main trial (involving participants from the intervention arm). Data from the first phase of interviews were used to develop a logic model to represent the underlying programme theory for the trial. The second phase interviews allowed us to further test aspects of this logic model, and the interview schedule was amended accordingly. Young people and family members who took part in interviews were compensated for their time (£10 voucher). All interviews were conducted by an experienced qualitative researcher (KN) and were recorded and transcribed verbatim.

The qualitative analysis adopted a framework approach,[38] in which the steps of thematic analysis[39] were undertaken within the overarching framework of the five domains of the CFIR.[36,37]

A schematic diagram illustrating the trial design and interlinking of the main RCT, nested process evaluation and nested SWAT is shown in *Figure 2*.

Sample size and statistical analysis

A sample size of 1210 was needed to detect an absolute difference of 10 percentage points with 90% power and a 5% two-sided alpha, under the assumption that 45% of the control group would have an emotional disorder diagnosis at 12 months (based on unpublished data obtained from the trial sites) and 10% of participants would not provide primary outcome data.

A comprehensive description of the planned analyses is included within the statistical analysis plan, which was finalised and approved prior to database lock and is publicly available from the ISRCTN registry.[3] All planned analyses are reported elsewhere within the main trial publication and associated supplementary material.[1]

The primary approach to between-group comparative analyses was to include all participants with observed outcome data according to randomised allocation. The primary analysis employed a generalised linear mixed model to compare the proportions in each group with a clinician-made diagnosis decision within 12 months of randomisation, adjusted for minimisation variables. Secondary outcomes were analysed using appropriate mixed-effect regression models dependent on data type.

Health economic analysis

The primary objective of the health economic analysis was to evaluate the cost-effectiveness of the intervention compared to usual care from an NHS and Personal Social Services (PSS) perspective;[40] it is fully reported elsewhere[1] and in the Health Economics Analysis Plan, publicly available on the registry.[3] Resource use, costs and HRQoL

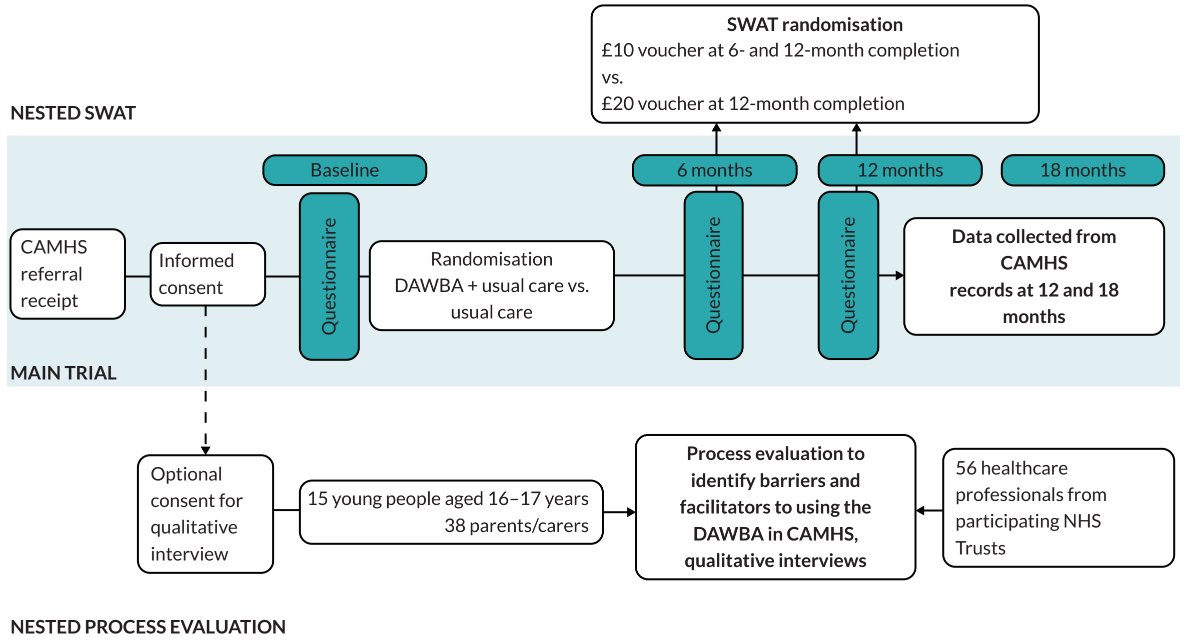

FIGURE 2 Schematic diagram illustrating the trial design and interlinking of the main RCT, nested process evaluation and nested SWAT.

outcomes were assessed at baseline, 6 and 12 months. The analysis considered responses directly from CYP aged 16–17 years and from proxy parent/carer responses for 5- to 15-year-olds. The primary outcome used to assess cost-effectiveness was the quality-adjusted life-year (QALY). Secondary analyses considered costs from a broader societal perspective that included productivity losses and out-of-pocket expenses. Exploratory analyses investigated cost-effectiveness with NHS and PSS costs and broader societal costs for three subgroups: (1) complete cases (i.e. participants with complete data); (2) participants whose referral was accepted and (3) participants receiving an emotional disorder diagnosis.

Results summary

Main trial

Results have been reported in full.[1] The Consolidated Standards of Reporting Trials participant flow is illustrated in *Figure 3*. We recruited 1225 participants from eight NHS Trusts in England; 615 to the intervention group and 610 to the control group (58% female sex in both groups). The primary participant was the parent/carer in 87% of cases. Baseline characteristics were well balanced across randomised groups for both CYP and parents/carers.

Adherence to the intervention, defined as either full completion of the DAWBA, or partial completion (at least one DAWBA module completed), was 80% (494/615). Of these, 332 (67%) scored 'very high' in at least one emotional disorder domain, most commonly depression and generalised anxiety.

There was a high retention for the primary outcome (> 99%); six participants (five intervention, one control) withdrew consent to access CAMHS records within 12 months and prior to any emotional disorder diagnosis; therefore, we included 610 participants in the intervention group and 609 in the control group in the primary analysis.

There was no evidence of a difference between groups for the primary outcome. At 12 months, 68 (11%) participants in the intervention group received an emotional disorder diagnosis versus 72 (12%) in the control group {adjusted risk ratio (RR) 0.94 [95% confidence interval (CI) 0.70 to 1.28]; $p = 0.71$}.

Child and Adolescent Mental Health Services' acceptance of the index referral [intervention 277 (45%) vs. control 262 (43%); RR: 1.06 (95% CI: 0.94 to 1.19)] or any referral by 18 months [intervention 374 (61%) vs. control 352 (58%); RR: 1.06 (95% CI: 0.97 to 1.16)] was similar between groups.

There was no evidence of any differences between groups for the other secondary outcomes.

None of the analyses demonstrated that the intervention was cost-effective. Results are reported in the appendix of the main trial report.[1] An outline of the main RCT is provided in *Appendix 2*.

Qualitative process evaluation

The qualitative process evaluation is reported in full[2] and is summarised in *Appendix 3*. In summary, 109 participants were interviewed, 52 during the internal pilot and 57 during the main trial. Participants came from all trial sites and included 15 young people, 38 parents or carers and 56 staff. Of the young people and parents and carers interviewed, 79% were in the intervention arm and 21% in the control arm.

Eleven themes were identified as factors acting as barriers and facilitators to influence the experience and use of the DAWBA within the trial. These acted within broader *context* of mental health services for CYP, influenced the *implementation process* within the trial and acted as specific *mechanisms* expected to affect the trial outcomes.[41,42]

Facilitators were the willingness of young people and parents and carers to engage in the trial; the acceptability of the DAWBA to young people and parents and carers, who found it a useful and reassuring validation of symptoms and a form of evidence to help access other services; the leadership by site principal investigators and research assistants within CAMHS to raise awareness of the study, develop understanding and trust in the DAWBA as a validated tool and encourage the use of the DAWBA by clinicians; the dedicated research resources that gave additional capacity to support the completion of the DAWBA by participants as well as adding it to CAMHS clinical records and highlighting its presence to clinicians; and the provision of additional information by the DAWBA for clinicians to use, especially for those making referral decisions in single point of access (SPA) teams and when compared to other tools that clinicians had experience of.

Barriers were: the broader impact of the COVID-19 pandemic and rapid changes to service delivery required during lockdowns, which meant that communication was disjointed and the DAWBA was not at the forefront of clinicians' minds; the experience of long waiting times for CAMHS prior to the first assessment, which were exacerbated by the pandemic and increased the pressure on clinicians and led to a reliance on usual practice rather than taking time to incorporate new information from the DAWBA; limited capacity, due to high workloads, led to difficulties for clinical staff easily finding the DAWBA

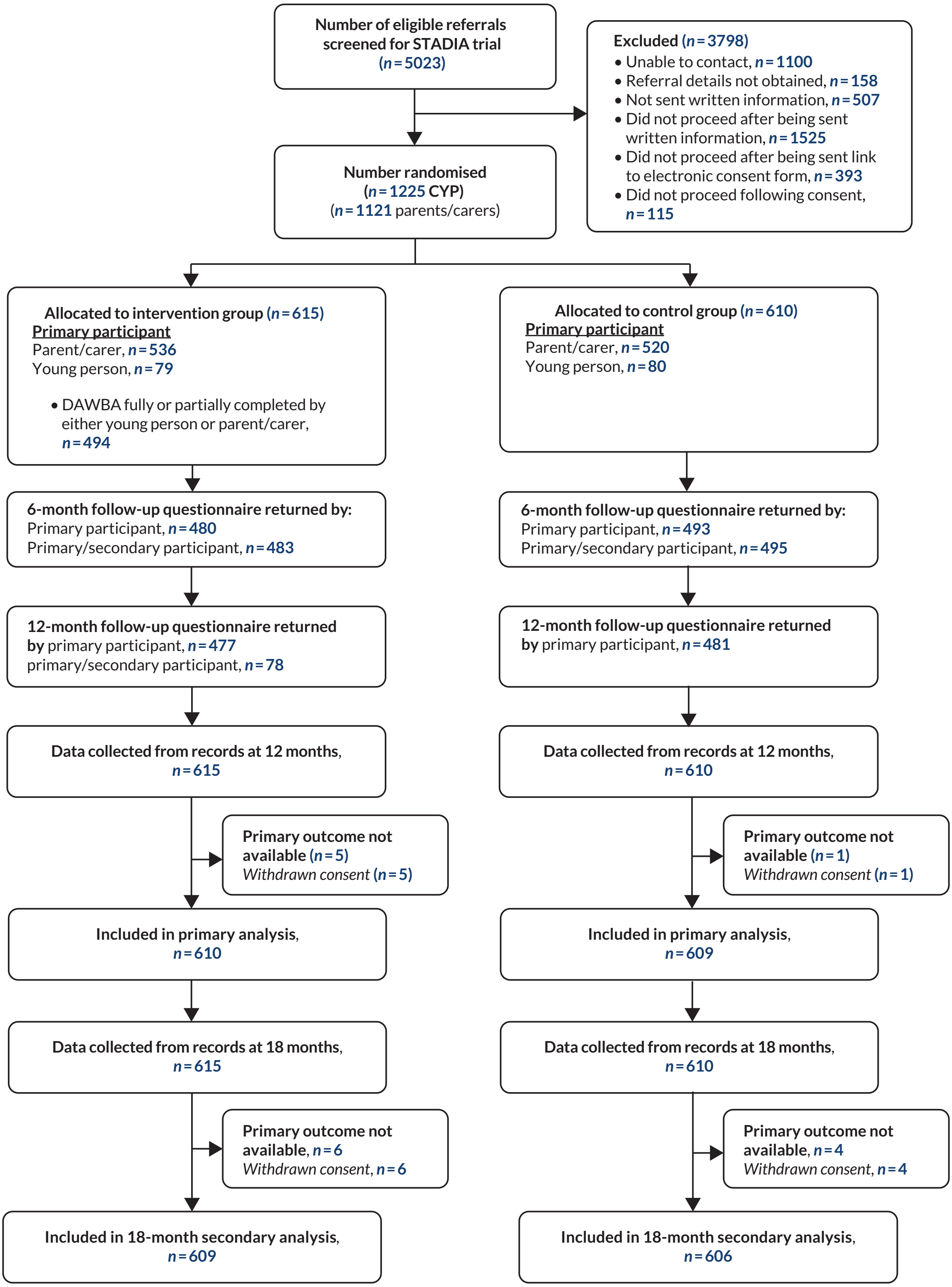

FIGURE 3 Participant flow. Reproduced with permission from Sayal *et al.*[1] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

report within the electronic records and then using it as part of their assessment – clinicians had to remember to look for it and take additional time to find it; challenges with ongoing communications with staff and the need for more reminders to use the DAWBA; and there was also a reluctance to use a tool such as DAWBA which facilitated a diagnostic process, arising from clinicians' attitudes to diagnosis and hesitancy to use diagnostic terminology due to its stigmatising potential – clinicians expressed a preference for formulation instead of diagnosis, which directly impacted on the primary outcome measure for the trial. All of these factors combined to result in the DAWBA not being seen or used widely at the consultation/assessment stage in the way intended, which was one of the main mechanisms through which the intervention was expected to be used to affect outcomes.

Research papers cited within this synopsis

Sayal K, Wyatt L, Partlett C, Ewart C, Bhardwaj A, Dubicka B, *et al*. The clinical and cost effectiveness of a STAndardised DIagnostic Assessment for children and adolescents with emotional difficulties (STADIA); multi centre randomised controlled trial. *J Child Psychol Psychiatry* 2025;**66**:805–20. https://doi.org/10.1111/jcpp.14090

Thomson L, Newman K, Ewart C, Bhardwaj A, Dubicka B, Marshall T, *et al*. Barriers and Facilitators to using standardised diagnostic assessments in child and adolescent mental health services: a qualitative process evaluation of the STADIA trial. *Eur Child Adolesc Psychiatry* 2025;**34**:2763–77. https://doi.org/10.1007/s00787-025-02678-w, which is summarised in *Appendix 3* and *Figure 4*.

Day F, Wyatt L, Bhardwaj A, Dubicka B, Ewart C, Gledhill J, *et al*. STAndardised DIagnostic Assessment for CYP with emotional difficulties (STADIA): protocol for a multicentre randomised controlled trial. *BMJ Open* 2022;**12**:e053043.

Discussion/interpretation

In this large, multicentre, pragmatic RCT, we found no evidence for the clinical or cost effectiveness of introducing a SDA tool for CYP with emotional difficulties referred to CAMHS. There was no discernible effect on the primary outcome (clinical diagnosis of an emotional disorder) or secondary outcomes (either participant-reported or service-related). In terms of the economic evaluation, we found no evidence to suggest that the intervention impacted health service utilisation, broader societal costs or quality-of-life outcomes for CYP or their parents/carers.

To our knowledge, this is one of the largest RCTs involving CYP who have been referred to mental health services and has a number of notable strengths. This rigorously conducted trial had a national spread of sites with good geographical representation across the UK. Our sample was representative of the target population of CYP seen by CAMHS in terms of demographics, including ethnicity.[43] Trial procedures were conducted remotely, enabling recruitment and retention to continue throughout the COVID-19 pandemic period. Follow-up and retention rates were excellent, with primary outcome data collected for > 99% of participants. Adherence to the intervention was good (80%), and participant-reported questionnaire completion remained high at 6 and 12 months post randomisation. Qualitative data from the process evaluation[2] showed that young people and parents/carers valued the information provided by the DAWBA report and showed high levels of engagement with the intervention and research study. Crucially, PPI was very strongly embedded throughout the life cycle of the research.

In terms of limitations, we were unable to blind participants, researchers collecting source data or clinicians to treatment allocation, however, we did have robust adjudication procedures in place. Any data inaccuracies would need to be substantial for any true effect to be negated. Although routinely collected data may have some shortcomings for carrying out wider research which relies on these data for case identification for samples (e.g. a systematic review found wide variation on the quality of source data,[44] and clinician-level perceived challenges about implementing routine outcome monitoring include poor technological support and additional workload[45]), for the STADIA trial, the main focus of interest was routinely made clinical diagnoses, that is the diagnoses that clinicians make and record in the clinical records. Additionally, given the nature of the intervention (i.e. the DAWBA is not a 'treatment' for emotional difficulties), there is likely to be a low risk of bias on the participant-reported secondary outcomes. Due to the pragmatic nature of the trial, we did not ask clinicians to record whether or not they saw the DAWBA report in the CAMHS clinical records. The complexity of the CAMHS clinical records (multiple progress notes/running records tabs and correspondence and letters) may have decreased visibility of the DAWBA report. We did, however, ensure that site researchers informed clinicians in the SPA triage teams that the report was available for their review and added periodic reminders into the CAMHS clinical records in addition to regular (6-monthly) presentations from the site principal investigators to their local community-based CAMHS teams to maintain awareness of the trial.

Although previous trials[8,17,18] have suggested that SDA tools might have potential in routine care, these were relatively small studies based in single sites and local contextual factors may limit their generalisability to a wider range of CAMHS settings. The two previous RCTs[17,18] focused on comparisons of agreement levels between DAWBA and clinician-made diagnoses. By contrast, the STADIA trial was situated across eight large NHS Trusts, enabling a broad real-world evaluation of introducing a SDA tool at the point of referral receipt. Several aspects of our findings are particularly noteworthy. First, clinical diagnosis rates were much lower than expected and not dissimilar to community prevalence rates.[4] One would expect higher rates of disorder in CYP referred to community CAMHS as compared with population samples, which is borne out by the finding that 67% of those completing the DAWBA scored very high for at least one emotional disorder, particularly depression and generalised anxiety. Although our pre-trial data suggested an expected clinical diagnosis rate of 45%, this figure was based on service evaluation or audit data, which did not necessarily reflect the use of precise diagnostic terminology consistent with ICD and DSM classification systems, as used in the trial. It is of note, however, that when combining the firm and uncertain diagnoses in our study, these total 34–39% at 12 months and 39–43% at 18 months, which is closer to the originally expected figure. It is possible that the use of the DAWBA contributed to a shift from no diagnostic information being recorded to an attempt to record some information, albeit these being uncertain or unclear. The qualitative interviews identified a strong preference for formulation rather than diagnosis among CAMHS clinicians, who expressed concerns over the stigma associated with diagnostic labels.

Second, the intervention was situated at the point of referral receipt, which is in line with the recommendations from previous research.[18,20] Referral acceptance was therefore a proximal outcome in the care pathway timeline and there was a suggestion that the DAWBA had a small influence (by 3–6%) on increasing the likelihood of acceptance of the index referral or of any referral by 12 or 18 months. Findings from the qualitative process evaluation showed that young people, parents/carers and clinicians working with referrals found the DAWBA to be acceptable and useful when used at this stage of the pathway.

Third, our findings highlight the very high levels of need experienced by our sample in terms of severity of mental health difficulties and associated functional impairment. Despite this, only 44% of index referrals were accepted, and over one-third of our sample were rereferred to CAMHS over the 18-month period, resulting in delays in receiving help. Even though some regression to the mean might be expected, particularly given that referrals are most likely to be made at a point of greatest severity, it is striking that mental health difficulties remained persistent at 12-month follow-up. Our sample had high levels of self- and parent-reported mental health symptoms, functional impairment and self-harm thoughts and behaviour, even at 12-month follow-up. These findings suggest that current CAMHS provision, availability and capacity appear to be insufficient to meet the clinical demand and need.

There are several possible reasons why we found no clinical effectiveness or cost-effectiveness of the intervention. First, 20% did not complete the intervention. Second, the intervention involving the completion of an online questionnaire was perhaps too 'light touch' to change clinician behaviour, particularly as the intervention was completed at the level of the parent and/or young person, but its impact was assessed at the level of a different individual (i.e. the clinician). Third, the DAWBA report was added to the clinical records soon after referral receipt but may not have been seen by the clinician carrying out the assessment, often many months later.

Our operationalisation of the primary outcome adopted a strict approach, whereby clinically recorded diagnoses had to match with ICD or DSM diagnostic terminology, for example, requiring the term 'disorder' as a suffix for different types of anxiety difficulties, for example separation anxiety and generalised anxiety. There was a suggestion that clinicians often used diagnostic terminology imprecisely, for example not using the term 'disorder'. These descriptions were categorised as being uncertain diagnoses, and all such diagnoses were subjected to adjudication. It is possible that the DAWBA contributed to a greater proportion of uncertain diagnoses [e.g. 28% (intervention group) vs. 22% (control group) at 12 months], particularly as the DAWBA report was careful not to imply that diagnostic criteria were fully met and used language accordingly, highlighting that the ratings were a guide to the level of difficulties present for each assessed domain.

In terms of implications for clinicians and policy-makers, although the provision and completion of a remotely offered SDA tool (the DAWBA) is a relatively inexpensive intervention and acceptable for young people and their parents/carers; when it was administered at the point of referral receipt and delivered in the format used in this trial, there was no evidence for its effectiveness or cost-effectiveness. Despite some promising evidence from previous single-site studies, the findings from this trial do not support the wider roll-out and implementation of SDA tools at the point of referral receipt in the assessment of

This synopsis should be referenced as follows:
Sayal K, Wyatt L, Thomson L, Holt G, Ewart C, Bhardwaj A, *et al*. Clinical and cost-effectiveness of a standardised diagnostic assessment for children and adolescents with emotional difficulties: the STADIA multi-centre RCT. *Health Technol Assess* 2025;**29**(61). https://doi.org/10.3310/GJKS0519

child and youth emotional disorders in routine practice in community-based multidisciplinary CAMHS settings.

Overall, the recorded clinical diagnosis rates were similar to the prevalence rates in the community,[4] which suggests clinical underdiagnosis and possible under-recognition of emotional disorders. Through qualitative interviews, we identified clinicians' reluctance to make diagnoses.[2] Our findings have important implications for research – if clinical diagnoses are not made and recorded, it is challenging to rely on clinical records to study treatment response and outcomes in routine care. NICE guidelines for the assessment and treatment of various emotional disorders are based on diagnostic categories. However, from an individual patient's perspective, it remains unclear whether the receipt of a clinical diagnosis matters and makes a difference to clinical outcomes. It is possible that the same type of help might be received regardless of whether a diagnosis of emotional disorder is made.

These findings, in the context of the SDA, show high prevalence of likely emotional disorders in this group referred to CAMHS. Some young people in the study started interventions for an emotional disorder despite not having a confirmed diagnosis. This may reflect the controversy around the use of diagnoses among CAMHS clinicians and/or the grade and training of clinicians carrying out assessment and treatment. The intervention seems to have been insufficient to enable clinician behaviour change, particularly in terms of views towards making, sharing and recording diagnosis in the clinical records. In the format used in this trial, we found no evidence that the addition of a SDA at the point of referral receipt changes the likelihood of CYP being seen, diagnosed or treated within a community-based CAMHS setting.

Process evaluation

The qualitative process evaluation identified a number of barriers and facilitators to the implementation and use of the DAWBA in CAMHS as well as those related to the contextual factors and causal mechanisms that might affect intended outcomes within the STADIA trial. Insights into the unique challenges of implementing new diagnostic tools and processes into overstretched, highly pressured CAMHS were gained, which can provide future guidance to both research and implementation activities.

A number of facilitators were identified, which supported the use of the DAWBA in CAMHS during the trial. At each site, leadership and researcher input was critical in raising awareness and understanding of the DAWBA among clinical teams as well as in getting DAWBAs completed and uploaded to patients' electronic records. Given the strain that clinical teams were experiencing, the administrative input provided by researchers was important for implementation of the DAWBA at sites. Staff also acknowledged that the DAWBA report provided easy-to-use information, which could supplement other assessments and provide an initial focus for conversations during a consultation. The use of the DAWBA during the screening of referrals was seen as having the potential to reduce waiting times and identify appropriate care pathways. Thus, the DAWBA was perceived as offering a way to improve the efficiency of referral decision-making, acting as a catalysing mediating factor.[46]

However, few clinicians who took part in the interviews had used the DAWBA report in consultations with CYP after a referral had been made. A number of barriers appear to have led to the DAWBA not being integrated into CAMHS clinical practice at the assessment consultations stage, when it was anticipated to influence diagnostic decisions. External contextual factors played a role through the impact of the COVID-19 pandemic on service delivery and subsequent increased referral numbers and long waiting times for CYP. Internally, clinicians in CAMHS felt a lack of capacity due to their workload, which limited the time available to understand the DAWBA and access the report in electronic clinical records. The pressure of long waiting lists of patients with worsening symptoms appears to have led clinicians to prefer their tried-and-tested approaches rather than spend additional time in looking for and understanding the DAWBA report during a consultation. Additional communication about the DAWBA with clinical staff undertaking assessments may have improved their understanding and confidence in using the DAWBA. However, the interviews also identified a general reluctance towards diagnosis from clinicians, and many expressed a professional preference for formulation rather than formal diagnoses for CYP. There was a hesitancy about the use of diagnostic terminology and labels due to the potential to stigmatise CYP. In relation to the DAWBA specifically, concerns were expressed by clinicians about the length of time between the generation of the DAWBA report at the point of referral and the initial assessment.

There were high levels of engagement with the DAWBA tool, as shown by young people and their parents/carers. The qualitative interviews identified that the DAWBA report gave them a sense of reassurance and acknowledgement during waiting times. They frequently described how the report felt like tangible 'evidence' of their symptoms, which validated their concerns and experiences and could be used to access other services outside CAMHS. The provision of the DAWBA report at the point of referral improved their experience even though it did not affect their clinical outcomes specifically.

Patient and public involvement

The STADIA parent/carer co-investigator (PPI Co-I) was involved from STADIA inception, helping to develop the research question and protocol. Extensive consultation, visiting local groups supporting parents/carers and their children with mental health/emotional difficulties led to establishing our PPI teams in the summer of 2019. Membership is diverse with representation from male/female; lesbian, gay, bisexual, transgender and queer people (LGBTQI+); Roma; East European and Asian communities along with single parents and foster parents.

The partnership between the PPI Co-I (supported by AL and KSp), the wider research team, PPI teams and outreach to involve other representatives has seen coproduction on a wide range of formative and summative tasks. The following list outlines some broad categories of activities and outputs, but it is not exhaustive:

- *Recruitment:* Two PPI teams involving parents and carers with lived experience of CAMHS and a committed group of young people with experience of help-seeking and services. The PPI team supported the recruitment process of research assistants, PPI members for the Trial Steering Committee (TSC) and parent/carer and young person's PPI teams.
- *Research documentation:* Contributions to the development of accessible participant-facing documentation for ethics, study resources, qualitative and health economic work packages saw meaningful change following PPI input.
- *Consultation and coproduction of responses on complex issues:* Significant time was spent consulting with the PPI teams on the issue of data linkage and in the design of the SWAT. The input from the PPI teams provided invaluable information to help the research team in how they considered and actioned these issues.
- *Publications and communication:* The PPI Co-Is and teams have independently and collaboratively produced many outputs to support the communication of STADIA, including but not limited to blogs, conference posters and a book chapter in an international book on PPI in research with patients.
- *Upskilling in research methods:* The parent/carer PPI Co-I has had the opportunity to learn about thematic analysis to contribute to the process evaluation qualitative analysis, introducing an important PPI lens to that process.

The impact throughout the project from both teams (parent/carers and young people) has been significant and consistent. For example, debating the addition of 'data linkage' from participants generated considerable discussion, and the 'team spirit' developed over time ensured that all views could be expressed openly and captured succinctly for the study trial management group to consider going forward. The group's members have trust and respect for each other, and this has resulted in the ability to communicate difficult concepts and sometimes opposing views on topics while not detrimentally impacting the working of the group.

To help optimise follow-up rates at the 6- and 12-month repeat questionnaire timelines, PPI teams were asked to help design a 'SWAT' exploring different approaches utilising the timing of the reward vouchers as a possible incentive. Both teams were thoroughly invested and helped to design two alternative pathways. This forms an additional study output to be shared with research community colleagues and through a stand-alone publication.

The STADIA PPI teams have given back to the community by taking part in research days and producing blogs to help inform people about the study and the PPI experience more generally. For many, these extensive opportunities have led to an increase in confidence and personal growth. Several members from both teams have been able to embrace new research/career opportunities as a result. This impact (of upskilling the teams and supporting in their personal and professional development) has been communicated via a conference poster and also verbally at several local events.

The PPI Co-Is have codeveloped content for our dissemination of the STADIA results to be used at multiple events. At the STADIA Results Conference in Nottingham, 13 PPI representatives attended and contributed to a whole session on STADIA PPI. They presented to an audience of clinicians, service managers, academics and researchers. The PPI Co-Is will be jointly preparing and delivering content for the London STADIA conference in May 2024.

The parent/carer PPI Co-I is fully involved in the writing of STADIA outputs and specifically ensuring that their contribution is fully integrated into academic outputs and a named author. The PPI Co-I (academic) invited their parent/carer PPI Co-I to jointly author a book chapter on PPI practices in healthcare research. This was a rewarding experience and significant achievement. Regular planning meetings for secondary papers are taking place and PPI, as always, will be closely embedded in the development of all appropriately related papers. Finally, PPI contributions will be integral to subsequent research bids associated with

STADIA. This will capitalise on the learning to date and also continue to ensure that people with lived experience of mental health difficulties and services are at the heart of our investigations and enquiries.

Equality, diversity and inclusion

The trial participants were 5- to 17-year-olds with emotional difficulties who had been referred to CAMHS, and their parents/carers. We recruited CYP from community-based multidisciplinary CAMHS in eight geographically dispersed NHS Trusts covering urban and rural areas across different regions of England. In terms of the participating NHS Trusts, there was wide geographical diversity, with the CAMHS' catchment area footprint covering major cities, towns and suburban and rural areas.

In terms of the index CYP, the mean age was 12 years and 86% of the sample were from a White ethnic background. We collected information on sex (58% female) and gender (57% female; 1% other). In terms of ethnicity and neighbourhood-level deprivation data, the sample was broadly representative of wider population-level data for this age group. Our sample was also representative of the target population of CYP seen by CAMHS in terms of demographics, including ethnicity.[43] In terms of the participating parents/carers of the CYP, 6% were fathers and 1% grandparents, and 91% were from a White ethnic background.

Collectively, the broad geographical diversity captured by the trial, inclusive approach to trial recruitment and participation of CYP (as well as adults) from non-White ethnic minority groups was in keeping with the wider population of CYP and adults. This suggests that the trial's participants reflected a diverse group of children, young people and parents and that our study findings are widely generalisable.

Participants in the qualitative study were recruited from across all eight NHS sites. In terms of the young people (n = 15), eligible participants were aged 16–17 years. They were recruited from five of the sites (including four of the original trial sites) – 13% were male and 27% from non-White ethnic backgrounds. Participating parents/carers had index children of ages across each of age-range categories of the trial. They were recruited from six of the sites (including all five of the original trial sites) – 16% were male and 11% from non-White ethnic backgrounds. Participating professionals were from a range of professional backgrounds, including clinicians, service managers, service commissioners and embedded researchers.

Our study used inclusive language throughout the participant-facing documents, which were informed by our PPI panels to improve inclusivity. The participant information sheets were written in gender-neutral language. The child was referred to as 'your child' rather than by specifying gender, that is 'she/hers/her', 'he/his/him', etc. Separate participant information sheets and consent forms were produced for children, and these were a shorter length than the 'parent/carer' versions and used simple language. Trial procedures were conducted remotely, enabling recruitment and retention to continue throughout the COVID-19 pandemic period.

Recruitment of our two PPI groups was conducted across a variety of voluntary groups in addition to widespread advertisements through voluntary sector newsletters and existing support groups. This robust approach provided a richly diverse group of parent/carers and young people with lived experience of mental health difficulties. Representation across many of the protected characteristics of equality, diversity and inclusion was achieved organically using this approach. Representation covered age (17–70 years), gender with one male in each group, members with disabilities across both groups, one member of the LGBTQI+ community and members from ethnic minorities.

Impact and learning

Given the scale and methodological rigour of this trial, this is likely to be a definitive trial. The findings do not support the wider roll-out and implementation of SDA tools (as delivered in this format and situated at the point of referral receipt) in the assessment of child and youth emotional disorders in routine CAMHS practice. Nevertheless, the methodology of this trial and the lessons learnt have the potential to inform clinical practice and research questions more widely across other parts of the CAMHS pathway (e.g. with pre-referral decision-making by caregivers or professionals, including for looked-after children; CYP requiring urgent/crisis care where further background information could be collected after the first assessments) and also in other mental health specialties where referrals and demand for services exceed service capacity. That is, in terms of the acceptability and feasibility of gathering assessment information (using an online SDA tool) in advance of clinicians making decisions around referral acceptance and informing the clinical assessment. The intervention was situated at the point of referral receipt, which is in line with recommendations from previous research.[18,20] Referral acceptance was therefore a proximal outcome in the care pathway timeline, and there was a suggestion that the DAWBA had a small influence (by 3–6%) on increasing the likelihood of acceptance of the index referral or of any referral by 12 or 18 months.

Our intervention approach was well received by young people and parents, and it was partially/fully completed by 80% of participants randomised to this group, indicating that this is an acceptable and effective method of collecting pre-assessment data. Further work needs to be done to influence clinicians' behaviour, particularly in terms of views towards making, sharing and recording diagnosis in the clinical records. The process evaluation study sheds some light on why the intervention might not have been clinically effective. The context of high workload and worsening cases meant that clinicians felt that they did not have capacity to find and use the additional information in the DAWBA as part of their assessment. This was compounded by a reluctance towards diagnosis and a preference for formulation. This qualitative process evaluation commenced just before the onset of the COVID-19 pandemic. As such, changes to practice in how clinicians used the DAWBA had to be adapted to fit the rapidly changing context of lockdowns and virtual support. There was a positive response towards the DAWBA from young people and parents/carers in the interviews, reporting an increased understanding of their symptoms and the DAWBA report as evidence of their experiences, which could be used in CAMHS or in other services. Although clinicians had limited experiences of encountering DAWBA reports as part of their clinical assessments, they could see the benefit of increased information provided in an accessible report that could help with referral decisions at the ‘front door’ of services as well as facilitating conversations with young people. However, its full use in clinical practice in assessment consultations following referral acceptance was impacted by a combination of limited capacity, difficulty in finding the report in clinical records and a general reluctance towards making diagnoses.

Although our pre-trial data suggested an expected clinical diagnosis rate of 45%, this figure was based on service evaluation or audit data, which did not necessarily reflect the use of precise diagnostic terminology consistent with ICD and DSM classification systems as used in the trial. It is of note, however, when combining the firm and uncertain diagnoses in the trial, these totalled 34–39% at 12 months and 39–43% at 18 months, closer to the originally expected figure – so perhaps, the DAWBA contributed to a shift from no diagnostic information being recorded to an attempt to record some information.

In this representative multisite study in the UK, only 11% of CYP with emotional difficulties referred to CAMHS received a clinical diagnosis of an emotional disorder within 12 months (and only 14% within 18 months). However, from an individual patient’s perspective, it remains unclear whether receipt of a clinical diagnosis matters and makes a difference to clinical outcomes. This question could be tested in future research. It is also possible that the same type of help might be received regardless of whether a diagnosis of emotional disorder is made.

The trial’s methodology and findings are of wide international relevance to a broad range of healthcare professionals [particularly, psychiatrists and other mental healthcare professionals and also referrers such as general practitioners (GPs), paediatricians and physicians who look after people with coexisting mental health problems, such as anxiety and depression], other professionals who have regular contact with CYP, such as teachers and wider education-based professionals, service commissioners, policy-makers, researchers, young people and parents/caregivers. In terms of dissemination activities, the study leads have already met with the national Children & Young People's Mental Health Clinical Director and Lead Service Advisors in NHS England, and we will be holding two in-person events (in Nottingham and London) to share our findings with young people, parents/caregivers, clinicians, researchers, service commissioners and policy-makers.

Our findings have important implications for research – if clinical diagnoses are not made and recorded, it is challenging to rely on clinical records to study treatment response and outcomes in routine care. NICE guidelines for the assessment and treatment of various emotional disorders are based on specific diagnostic categories, for example depression, OCD, PTSD, social anxiety disorder, etc.

Implications for decision-makers

Although the provision and completion of a remotely offered SDA tool (the DAWBA) is a relatively inexpensive intervention and was acceptable for young people and their parents/carers, when administered at the point of referral receipt and delivered in the format as used in this trial, there was no evidence for its effectiveness or cost-effectiveness. Despite some promising evidence from previous smaller-scale single-site studies in several countries,[8,17,18] the findings from the STADIA trial do not support the wider roll-out and implementation of SDA tools at the point of referral receipt in the assessment of child and adolescent emotional disorders in routine practice in community-based multidisciplinary CAMHS settings.

Despite the 'negative' main finding from the trial (i.e. this study found no effect), there are some important implications for clinicians and service commissioners from the wider findings from STADIA. First, the rates of clinical diagnosis of emotional disorders among child and young people referred to CAMHS were much lower than might be expected and, in fact, not that dissimilar to prevalence rates found in non-referred community samples.[4] One might expect higher rates of disorder in CYP referred to community CAMHS as compared with population samples. This was borne out by our finding that 67% of those completing the DAWBA scored very high for at least one emotional disorder, particularly depression and generalised anxiety. These findings imply a reluctance among CAMHS clinicians to make, share (with CYP and families) and record diagnoses of emotional disorders. This could potentially contribute to other challenges. For example, service commissioners and funders may only have partial data about the types and severity of difficulties among CYP seen by CAMHS. There are related implications for informing and updating the evidence base about effective interventions for and outcomes of mental health disorders. NICE guidelines outline the best practice for the assessment and treatment of various emotional disorders, but the underpinning evidence is based on diagnostic categories. If clinical diagnoses are not made and recorded in routine practice, it will be very challenging to rely on clinical records to study treatment response and outcomes in routine care and to identify potentially eligible participants for future clinical trials. If decision-makers wish to address this 'gap' between administrative and actual prevalence rates of emotional disorder in clinically referred CYP, consideration needs to be given to the content of the pre-qualification and in-service education and training of the CAMHS professional workforce, for example through the Workforce, Education and Training Directorate within NHS England.

Second, our findings highlight the very high levels of need experienced by our sample in terms of severity of mental health difficulties and associated functional impairment. Despite this, only 44% of index referrals were accepted, and over one-third of our sample were rereferred to CAMHS over the 18-month period, resulting in delays in receiving help. Even though some regression to the mean might be expected, particularly given that referrals are most likely to be made at a point of greatest severity, it is striking that mental health difficulties remained persistent at 12-month follow-up. Our sample had high levels of self- and parent-reported mental health symptoms, functional impairment and self-harm thoughts and behaviour even at 12-month follow-up. These findings suggest that current CAMHS provision, availability and capacity appear to be insufficient to meet clinical demand and need.

Recommendations for practice

The results of the embedded qualitative process evaluation study focused on the implementation and use of a SDA tool as part of a research RCT rather than a full-scale implementation and permanent change to clinical practice. As such, recommendations around the generalisability of the intervention beyond its delivery within a research trial should be considered to be tentative. Nevertheless, the research found considerable benefits to engaging with children, young people and their families/carers soon after a referral is received by CAMHS. While waiting for referrals to be processed, they valued acknowledgement about the receipt of the referral and being asked to provide additional information and for the sharing of results with them.

Given the size and complexity of CAMHS within NHS Trusts, it was not feasible or within the scope of the trial to engage in a large change project to bring about consistent changes to practice. However, the use of the DAWBA, as an instrument to provide additional clinical information to clinical teams at the 'front door' (e.g. in SPA teams) offered useful additional information, which appeared to be acceptable and accessible for clinician use. Where additional assessment information is made available for more 'downstream' clinicians (e.g. those carrying out the first assessment with the child or young person), there needs to be consideration about how accessible and visible this is within the electronic records (as these tend to be busy and complex, with multiple tabs and uploads) and how it might best be flagged to be accessed quickly and save clinicians' time.

Research recommendations

The STADIA study team, in conjunction with and following discussions with key stakeholders, including our PPI advisory panels, clinicians, commissioners and broader organisations with a remit to improve CYP's mental health, have identified the following future research questions and recommendations.

Predictors of clinical and service-related outcomes

At an individual level, it remains unclear whether receiving input from CAMHS or a clinical diagnosis matters and makes a difference to clinical outcomes. It is possible that the same type of help might be received regardless of whether a diagnosis of emotional disorder is made.

- Which factors predict whose referral gets accepted by CAMHS?
- Which factors predict who receives a clinical diagnosis of an emotional disorder in CAMHS?
- Which factors predict who is offered and receives help (i.e. a clinical intervention) from CAMHS?
- What are the clinical outcomes 12 months after being referred to CAMHS and does referral acceptance or receipt of a clinical diagnosis make a difference to these outcomes?

Future intervention research

1. Any future trial of situating a SDA tool within CAMHS will need to test a more complex intervention that incorporates clinician education/training around the diagnostic criteria for mental health disorders, and barriers and facilitators to making such diagnoses in routine practice, in addition to the completion of the SDA tool and sharing of the SDA findings.
2. Alternatively, a SDA tool could be tested when situated earlier in the referral pathway, that is at the point a professional referrer (e.g. a GP) is considering whether to make a referral to CAMHS.
3. The acceptability and feasibility of using a SDA tool with CYP who need acute or crisis care from CAMHS. Often, these assessments focus much more on risk and safety, risking the possibility that underlying mental health disorders might go undetected.

Longer-term follow-up

Since the pandemic, there has been a great increase in the demand for and referrals to CAMHS, with lengthy delays in CYP being seen (often waiting > 12 months). Through data linkage with routinely collected data by NHS England, longer-term service-related outcomes can be investigated, for example future referrals to NHS mental health services, presentations to the emergency department/general hospitals with self-harm and hospital admissions.

The impact of the pandemic on children and young people's mental health

Following on from our preliminary work using repeated cross-sectional baseline data,[47] an investigation of the longitudinal 6- and 12-month follow-up data collected in STADIA could evaluate changes in mental health symptomatology and associated functioning across different phases of the pandemic, including periods of lockdown-related school closures.

Perspectives of stakeholders

Based on the findings of the trial, what are the views of CYP (including those aged under 16 years), parents/carers, referrers and CAMHS professionals about:

1. referral processes and outcomes
2. routinely completing clinical questionnaire measures online in advance of referrals being processed and the first clinical appointment, and barriers and facilitators to achieving this.
3. the most important components of a clinical assessment in CAMHS.

Conclusions

We found no evidence for the clinical or cost effectiveness of introducing a SDA tool for CYP with emotional difficulties referred to CAMHS. There was no discernible effect on the primary outcome (clinical diagnosis of an emotional disorder) or secondary outcomes (either participant-reported or service-related).

These findings, in the context of the SDA, show high prevalence of likely emotional disorders in this group referred to CAMHS. Some CYP in the study started interventions for an emotional disorder despite not having a confirmed diagnosis. This may reflect the controversy around the use of diagnoses among CAMHS clinicians and/or the grade and training of clinicians carrying out assessment and treatment. The intervention seems to have been insufficient to enable clinician behaviour change, particularly in terms of views towards making, sharing and recording diagnosis in the clinical records. In conclusion, in this setting, we found no evidence that the addition of a SDA at the point of referral receipt changes the likelihood of CYP being seen, diagnosed or treated within a community-based CAMHS setting and does not represent a cost-effective allocation of NHS resources.

Additional information

CRediT contribution statement

Kapil Sayal (https://orcid.org/0000-0002-2050-4316): Conceptualisation (equal), Funding acquisition (equal), Investigation (equal), Methodology (equal), Project administration (equal), Supervision (equal), Visualisation (equal), Writing

– original draft (equal), Writing – review & editing (equal), Other contributions (PPI contributions).

Laura Wyatt (https://orcid.org/0000-0002-9817-5356): Investigation (equal), Methodology (equal), Project administration (equal), Supervision (equal), Visualisation (equal), Writing – original draft (equal), Writing – review & editing (equal).

Louise Thomson (https://orcid.org/0000-0003-1736-7506): Data curation (equal), Formal analysis (equal), Funding acquisition (equal), Investigation (equal), Methodology (equal), Project administration (equal), Supervision (equal), Visualisation (equal), Writing – original draft (equal), Writing – review & editing (equal).

Grace Holt (https://orcid.org/0000-0002-1123-7471): Data curation (equal), Formal analysis (equal), Software (equal), Visualisation (equal), Writing – original draft (equal), Writing – review & editing (equal).

Colleen Ewart (https://orcid.org/0000-0001-5736-9800): Funding acquisition (equal), Methodology (equal), Project administration (equal), Supervision (equal), Writing – review & editing (equal), Other contributions (PPI contributions).

Anupam Bhardwaj (https://orcid.org/0009-0003-3299-0707): Funding acquisition (equal), Investigation (equal), Methodology (equal), Supervision (equal), Writing – review & editing (equal).

Bernadka Dubicka (https://orcid.org/0000-0002-8907-8589): Funding acquisition (equal), Investigation (equal), Methodology (equal), Supervision (equal), Writing – review & editing (equal).

Tamsin Marshall (https://orcid.org/0009-0004-8618-0889): Funding acquisition (equal), Investigation (equal), Methodology (equal), Supervision (equal), Writing – review & editing (equal).

Julia Gledhill (https://orcid.org/0000-0002-5677-7981): Funding acquisition (equal), Investigation (equal), Methodology (equal), Supervision (equal), Writing – review & editing (equal).

Alexandra Lang (https://orcid.org/0000-0002-7332-9443): Funding acquisition (equal), Methodology (equal), Supervision (equal), Writing – review & editing (equal), Other contributions (PPI contributions).

Kirsty Sprange (https://orcid.org/0000-0001-6443-7242): Conceptualisation (equal), Funding acquisition (equal), Methodology (equal), Project administration (equal), Supervision (equal), Writing – original draft (equal), Writing – review & editing (equal).

Christopher Partlett (https://orcid.org/0000-0001-5139-3412): Data curation (equal), Formal analysis (equal), Methodology (equal), Software (equal), Visualisation (equal), Writing – original draft (equal), Writing – review & editing (equal).

Kristina Newman (https://orcid.org/0000-0002-3611-6764): Data curation (equal), Formal analysis (equal), Investigation (equal), Methodology (equal), Project administration (equal), Visualisation (equal), Writing – original draft (equal), Writing – review & rditing (equal).

Sebastian Moody (https://orcid.org/0009-0001-2442-0750): Investigation (equal), Project administration (equal), Writing – review & editing (equal).

Helen Bould (https://orcid.org/0000-0001-8163-3210): Investigation (equal), Methodology (equal), Supervision (equal), Writing – review & editing (equal).

Clare Upton (https://orcid.org/0000-0003-2352-6315): Senior Methodology (equal), Project administration (equal), Writing – review & editing (equal).

Matthew Keane (https://orcid.org/0000-0002-8428-9870): Data curation (equal), Formal analysis (equal), Software (equal), Supervision (equal), Visualisation (equal), Writing – original draft (equal), Writing – review & editing (equal).

Edward Cox (https://orcid.org/0000-0001-8981-0699): Data curation (equal), Formal analysis (equal), Software (equal), Validation (lead), Visualisation (equal), Writing – original draft (equal), Writing – review & editing (equal).

Marilyn James (https://orcid.org/0000-0003-0408-7898): Data curation (equal), Formal analysis (equal), Funding acquisition (equal), Methodology (equal), Software (equal), Supervision (equal), Visualisation (equal), Writing – original draft (equal), Writing – review & editing (equal).

Alan Montgomery (https://orcid.org/0000-0003-0450-1606): Conceptualisation (equal), Data curation (equal), Formal analysis (equal), Funding acquisition (equal), Methodology (equal), Software (equal), Supervision (equal), Visualisation (equal), Writing – original draft (equal), Writing – review & editing (equal).

Acknowledgements

We would like to thank the parents, young people and children who participated in this trial. We would like to thank the independent members of the Trial Steering Committee: Helen Minnis (Chair, Professor of Child & Adolescent Psychiatry, University of Glasgow), Nicola Wiles (Professor of Epidemiology, University of Bristol), Dr Eilis Kennedy (Consultant Child and Adolescent Psychiatrist and Director of Research and Development, The Tavistock and Portman NHS Foundation Trust), Kate Arron (Clinical Psychologist, Leicestershire Partnership NHS Trust), Paul McClure (PPI Member), Clare Saffin (PPI Member) and Mark Howells (Head of Research and Evidence, Sponsor representative). In addition to the independent members of the Data Monitoring Committee, we would like to thank Elena Garralda (Chair, Emeritus Professor, Imperial College London), Raphael Kelvin (Consultant in Child and Adolescent Psychiatry, NHS England MindEd National Clinical Educator Lead) and Amanda Farrin (Professor of Clinical Trials & Evaluation of Complex Interventions, University of Leeds). We would like to acknowledge and thank the site research assistants at the participating trusts for their work for their contributions to screening, consenting and randomising participants in addition to carrying out the case record form completion. Thank you to Ellen Bradley, Ginette Taylor, Chrissy Bailey, Sarah Jones and Shirley Reynolds for their input with the study. We thank the following for their work on STADIA at the Nottingham Clinical Trials Unit:

Senior Trial Manager: Kath Starr.

Trial Manager: Florence Day.

Trial co-ordinators: Aneesa Mehmood, Samantha Beard and John Watson.

Health Economist: James Lathe.

Database Programmers: Nina Clayton, Chien May and Nick Hilken.

Data Management: Stella Tarr, Lisa Evans, Tobey Allport, Sara May, Omphemetse Motswagole, Hollie Harvey, Arfan Ali, Natasha Johnson and Richard Swinden.

Statisticians: Wei Tan and Lucy Bradshaw.

Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. *#datasaveslives* You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation

Data-sharing statement

Anonymised trial data may be shared with researchers external to the trial research team in accordance with the NCTU's data-sharing procedure. The data sets containing individual participant data analysed during the STADIA trial will be available upon request from the NCTU (ctu@nottingham.ac.uk) a minimum of 6 months after publication of this threaded publication. Access to the data will be subject to review of a data-sharing and use request by a committee, including the Chief Investigator and Sponsor, and should reflect a proposed collaboration with the STADIA trial team and will only be granted upon receipt of a data-sharing and use agreement. Any data shared will be anonymised, which may impact on the reproducibility of published analyses. The protocol and statistical analysis plan are freely available on the NIHR Journals Library website (https://fundingawards.nihr.ac.uk/award/16/96/09).

Ethics statement

The study received favourable opinion from the South Birmingham Research Ethics Committee (Ref. 19/WM/0133) on 12 June 2019 prior to the start of recruitment.

Information governance statement

Nottinghamshire Healthcare NHS Foundation Trust is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, the University of Nottingham, through the Nottingham Clinical Trials Unit (NCTU) is the Data Processor; Nottinghamshire Healthcare NHS Foundation Trust is the Data Controller and we process personal data in accordance with their instructions. You can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for Nottinghamshire Healthcare NHS Foundation Trust's Data Protection officer here (www.nottinghamshirehealthcare.nhs.uk/your-information/).

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/GJKS0519.

Primary conflicts of interest: Kapil Sayal is a NIHR Senior Investigator and a member of the NIHR HTA Prioritisation Committee (Primary and Community Based Care) and NIHR Research for Patient Benefit (NIHR – RfPB) East Midlands Regional Advisory Committee. He was also on the HTA Clinical Evaluation and Trials Committee (2019–23). Christopher Partlett is a member of the National Institute of Health and Social Care Research – Research for Patient Benefit (NIHR – RfPB) East Midlands Scientific Advisory Group. Anupam Bhardwaj is employed by CPFT who have supported him to do research work. He has received funding from the Clinical Research Network. He is receiving funding from the University College. He is Chair of the Child and Adolescent Psychiatry Specialist Advisory

Committee – RCPsych. Bernadka Dubicka has received payment as an expert witness report on climate change and mental health for defendants against the European parliament. She is chair of the Trial Steering Committee for the SASH self-harm trial. She is a board member and CAMH Editor in Chief, ACAMH Treasurer CAP section Union European Medical Societies. She is also on the HTA Prioritisation Committee C 2014–8. Helen Bould received funding from the MRC/MRF and NIHR through an Advanced Fellowship. Alan Montgomery was a member of NIHR HTA Clinical Evaluation and Trials Committee (2015–21). Nottingham CTU received NIHR CTU Support Funding (2008–23) and NIHR Research Support Service Funding (2023–8). All other authors declare no conflicts of interest.

Department of Health and Social Care disclaimer

Trial registration

This study is registered as ISRCTN15748675.

Funding

This synopsis presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number 16/96/09.

Award publications

This synopsis provided an overview of the research award *STAndardised DIagnostic Assessment for children and adolescents with emotional difficulties (STADIA): a multi-centre randomised controlled trial*.

Other articles published as part of this thread are:

Sayal K, Wyatt L, Partlett C, Ewart C, Bhardwaj A, Dubicka B, *et al*. The clinical and cost effectiveness of a STAndardised DIagnostic Assessment for children and adolescents with emotional difficulties (STADIA); multi centre randomised controlled trial. *J Child Psychol Psychiatry* 2025;**66**:805–20. https://doi.org/10.1111/jcpp.14090

Thomson L, Newman K, Ewart C, Bhardwaj A, Dubicka B, Marshall T, *et al*. Barriers and facilitators to using standardised diagnostic assessments in child and adolescent mental health services: a qualitative process evaluation of the STADIA trial. *Eur Child Adolesc Psychiatry* 2025;**34**:2763–77. https://doi.org/10.1007/s00787-025-02678-w

For more information about this research please view the award page (www.fundingawards.nihr.ac.uk/award/16/96/09).

Additional outputs

Ewart C, STADIA Youth Lab, STADIA Parents and Carers, STADIA TSC PPI representatives, Sprange K, Bradley, E *et al*. Understanding participation benefits to Patient and Public Involvement as an enabler to engagement in Clinical trials: reflections from the STADIA Trial. Sixth International Clinical Trials Methodology Conference (ICTMC) Harrogate, UK, 2022.

Sayal K, Partlett C, Bhardwaj A, Dubicka B, Marshall T, Gledhill J, *et al*. Mental health in clinically referred children and young people before and during the COVID-19 pandemic. *Eur Child Adolesc Psychiatry* 2023;**32**:2657–66.

Newman KL, Sayal K, Ewart C, Lang A, Bhardwaj A, Dubicka B, *et al*. Snakes and ladders: the experience of being referred to and seen by Child and Adolescent Mental Health Services. *SSM Ment Health* 2024;**6**:100343.

About this synopsis

The contractual start date for this research was in November 2018. This article began editorial review in May 2024 and was accepted for publication in May 2025. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The Health Technology Assessment editors and publisher have tried to ensure the accuracy of the authors' article and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

Copyright

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).

Disclaimer

List of supplementary material

Report Supplementary Material 1
STADIA screening form

Report Supplementary Material 2
Consent and participation

Report Supplementary Material 3
STADIA outcome definition and adjudication

Report Supplementary Material 4
DAWBA report template

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/GJKS0519).

Supplementary material has been provided by the authors to support the article and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

CAMHS	Child and Adolescent Mental Health Services
CFIR	Consolidated Framework for Implementation Research
CHU9D	Child Health Utility 9D
CI	confidence interval
CRF	case report form
CRIES-8	Children's Revised Impact of Event Scale-8
CYP	children and young people
DAWBA	development and well-being assessment
DSM	*Diagnostic and Statistical Manual of Mental Disorders*
DSM-IV	*Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
EQ-5D-Y	The 5-level EQ-5D version Youth Version
GAD-7	Generalised Anxiety Disorder-7
GP	general practitioner
HRQoL	health-related quality of life
ICD-10	*International Statistical Classification of Diseases and Related Health Problems*, Tenth Revision
LGBTQI+	lesbian, gay, bisexual, transgender and queer people
MFQ	Mood and Feelings Questionnaire
NCTU	Nottingham Clinical Trials Unit
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
OCD	obsessive–compulsive disorder
PHQ-9	Patient Health Questionnaire-9 items
PPI	patient and public involvement
PPI Co-I	patient and public involvement co-investigator
PSS	Personal Social Service

This synopsis should be referenced as follows:
Sayal K, Wyatt L, Thomson L, Holt G, Ewart C, Bhardwaj A, *et al.* Clinical and cost-effectiveness of a standardised diagnostic assessment for children and adolescents with emotional difficulties: the STADIA multi-centre RCT. *Health Technol Assess* 2025;**29**(61). https://doi.org/10.3310/GJKS0519

PTSD	post-traumatic stress disorder
QALY	quality-adjusted life-year
RCADS	Revised Children's Anxiety and Depression Scale
RCT	randomised controlled trial
RR	risk ratio
SDA	standardised diagnostic assessment
SDQ	Strengths and Difficulties Questionnaire
SPA	single point of access
STADIA	standardised diagnostic assessment for children and adolescents with emotional difficulties
SWAT	study within a trial
TSC	Trial Steering Committee

References

1. Sayal K, Wyatt L, Partlett C, Ewart C, Bhardwaj A, Dubicka B, *et al*. The clinical and cost effectiveness of a STAndardised DIagnostic Assessment for children and adolescents with emotional difficulties: the STADIA multi-centre randomised controlled trial. *J Child Psychol Psychiatry* 2025;**66**:805–20.
2. Thomson L, Newman K, Ewart C, Bhardwaj A, Dubicka B, Marshall T, *et al*. Barriers and facilitators to using standardised diagnostic assessments in child and adolescent mental health services: a qualitative process evaluation of the STADIA randomised controlled trial [published online ahead of print March 18 2025]. *Eur Child Adolesc Psychiatry* 2025. https://doi.org/10.1007/s00787-025-02678-w
3. Sayal K, Wyatt L. Does the use of a standard information-gathering package help with assessment and diagnosis for children and young people with emotional difficulties who have been referred to Child and Adolescent Mental Health Services (CAMHS)? ISRCTN. 2019. https://doi.org/10.1186/ISRCTN15748675
4. Sadler K, Vizard T, Ford T, Marcheselli F, Pearce N, Mandalia D, *et al*. *Mental Health of Children and Young People in England, 2017*. London: NHS Digital; 2018. URL: https://digital.nhs.uk/data-and-information/publications/statistical/mental-health-of-children-and-young-people-in-england/2017/2017 (accessed 15 February 2024).
5. Clayborne ZM, Varin M, Colman I. Systematic review and meta-analysis: adolescent depression and long-term psychosocial outcomes. *J Am Acad Child Adolesc Psychiatry* 2019;**58**:72–9.
6. Pollard J, Reardon T, Williams C, Creswell C, Ford T, Gray A, *et al*. The multifaceted consequences and economic costs of child anxiety problems: a systematic review and meta-analysis. *JCPP Adv* 2023;**3**:e12149.
7. Costello EJ, Maughan B. Annual research review: optimal outcomes of child and adolescent mental illness. *J Child Psychol Psychiatry* 2015;**56**:324–41.
8. Hansen AS, Kjaersdam Telléus G, Mohr-Jensen C, Færk E, Lauritsen MB. The effect of the Development and Well-Being Assessment as an adjunct to standard referral letters on referral decisions by child and adolescent mental health services: a randomized feasibility trial. *Clin Child Psychol Psychiatry* 2023;**28**:434–49.
9. Michelson D, Rock S, Holliday S, Murphy E, Myers G, Tilki S, *et al*. Improving psychiatric diagnosis in multidisciplinary child and adolescent mental health services. *Psychiatrist* 2011;**35**:454–9.
10. Martin AM, Fishman R, Baxter L, Ford T. Practitioners' attitudes towards the use of standardized diagnostic assessment in routine practice: a qualitative study in two Child and Adolescent Mental Health Services. *Clin Child Psychol Psychiatry* 2011;**16**:407–20.
11. Craddock N, Antebi D, Attenburrow MJ, Bailey A, Carson A, Cowen P, *et al*. Wake-up call for British psychiatry. *Br J Psychiatry* 2008;**193**:6–9.
12. Simmons M, Wilkinson P, Dubicka B. Measurement issues: depression measures in children and adolescents. *Child Adolesc Ment Health* 2015;**20**:230–41.
13. National Institute for Health and Clinical Excellence. *Depression in Children and Young People: Quality Standard*. London: National Institute for Health and Clinical Excellence; 2013. URL: www.nice.org.uk/guidance/qs48/chapter/Quality-statement-1-Confirming-and-recording-a-diagnosis (accessed 13 December 2023).
14. Fitzpatrick C, Abayomi NN, Kehoe A, Devlin N, Glackin S, Power L, *et al*. Do we miss depressive disorders and suicidal behaviours in clinical practice. *Clin Child Psychol Psychiatry* 2012;**17**:449–58.
15. National Institute for Health and Clinical Excellence. *Depression in Children and Young People: Identification and Management*. London: National Institute for Health and Clinical Excellence; 2019. URL: www.nice.org.uk/guidance/ng134 (accessed 15 February 2024).
16. Youth in Mind. *Information for Researchers and Clinicians about the Development and Well-Being Assessment*. Youth in Mind; 2012. URL: www.dawba.info/ (accessed 15 February 2024).

17. Aebi M, Kuhn C, Metzke CW, Stringaris A, Goodman R, Steinhausen HC. The use of the development and well-being assessment (DAWBA) in clinical practice: a randomized trial. *Eur Child Adolesc Psychiatry* 2012;**21**:559–67.
18. Ford T, Last A, Henley W, Norman S, Guglani S, Kelesidi K, *et al*. Can standardized diagnostic assessment be a useful adjunct to clinical assessment in child mental health services? A randomized controlled trial of disclosure of the Development and Well-Being Assessment to practitioners. *Soc Psychiatry Psychiatr Epidemiol* 2013;**48**:583–93.
19. Last A, Henley W, Norman S, Goodman R, Ford T. Innovations in practice: feasibility of the development and well-being assessment as an adjunct to clinical assessment in child and adolescent mental health services. *Child Adolesc Ment Health* 2014;**19**:142–6.
20. Reeves K, Charter E, Ford T. Measurement issues: is standardised diagnostic assessment feasible as an adjunct to clinical practice? A systematic review. *Child Adolesc Ment Health* 2016;**21**:51–63.
21. Perrin S, Meiser-Stedman R, Smith P. The children's revised impact of event scale (CRIES): validity as a screening instrument for PTSD. *Behav Cogn Psychother* 2005;**33**:487–98.
22. Goodman R, Ford T, Richards H, Gatward R, Meltzer H. The development and well-being assessment: description and initial validation of an integrated assessment of child and adolescent psychopathology. *J Child Psychol Psychiatry* 2000;**41**:645–55.
23. Goodman A, Heiervang E, Collishaw S, Goodman R. The 'DAWBA bands' as an ordered-categorical measure of child mental health: description and validation in British and Norwegian samples. *Soc Psychiatry Psychiatr Epidemiol* 2011;**46**:521–32.
24. World Health Organization. *The ICD-10 Classification of Mental and Behavioural Disorders: Clinical Descriptions and Diagnostic Guidelines*. Geneva: World Health Organization; 1992.
25. Angold A, Costello EJ, Messer SC, Pickles A. Development of a short questionnaire for use in epidemiological studies of depression in children and adolescents. *Int J Methods Psychiatr Res* 1995;**5**:237–49.
26. Wood A, Kroll L, Moore A, Harrington R. Properties of the mood and feelings questionnaire in adolescent psychiatric outpatients: a research note. *J Child Psychol Psychiatry* 1995;**36**:327–34.
27. Daviss WB, Birmaher B, Melhem NA, Axelson DA, Michaels SM, Brent DA. Criterion validity of the Mood and Feelings Questionnaire for depressive episodes in clinic and non-clinic subjects. *J Child Psychol Psychiatry* 2006;**47**:927–34.
28. Chorpita BF, Yim L, Moffitt C, Umemoto LA, Francis SE. Assessment of symptoms of DSM-IV anxiety and depression in children: a revised child anxiety and depression scale. *Behav Res Ther* 2000;**38**:835–55.
29. Goodman R. The Extended Version of the Strengths and Difficulties Questionnaire as a guide to child psychiatric caseness and consequent burden. *J Child Psychol Psychiatry* 1999;**40**:791–9.
30. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;**16**:606–13.
31. Spitzer RL, Kroenke K, Williams JW, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;**166**:1092–7.
32. Stevens K. Developing a descriptive system for a new preference-based measure of health-related quality of life for children. *Qual Life Res* 2009;**18**:1105–13.
33. Wille N, Badia X, Bonsel G, Burström K, Cavrini G, Devlin N, *et al*. Development of the EQ-5D-Y: a child-friendly version of the EQ-5D. *Qual Life Res* 2010;**19**:875–86.
34. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;**20**:1727–36.
35. Holt G, Wyatt L, Partlett C, Ewart C, Sprange K, Lang A, *et al*. Timing and value of participant vouchers to improve questionnaire return rates in the STADIA (STAndardised Diagnostic Assessment for children and adolescents with emotional difficulties) Trial [version 1; peer review: awaiting peer review]. *NIHR Open Res* 2025;**5**:58. https://doi.org/10.3310/nihropenres.13954.1
36. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009;**4**:50.
37. Damschroder LJ, Reardon CM, Widerquist MAO, Lowery J. The updated Consolidated Framework for Implementation Research based on user feedback. *Implement Sci* 2022;**17**:75.
38. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol* 2013;**13**:117.
39. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101.

40. National Institute for Health and Clinical Excellence. *NICE Health Technology Evaluations: The Manual. NICE Process and Methods [PMG36]*. 2023. URL: www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation (accessed 16 January 2024).

41. Pawson R, Tilley N. *Realistic Evaluation*. London: SAGE Publications Ltd; 1997.

42. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, *et al*. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* 2015;**350**:h1258.

43. Edbrooke-Childs J, Rashid A, Ritchie B, Deighton J. Predictors of child and adolescent mental health treatment outcome. *BMC Psychiatry* 2022;**22**:229.

44. Davis KA, Sudlow CL, Hotopf M. Can mental health diagnoses in administrative data be used for research? A systematic review of the accuracy of routinely collected diagnoses. *BMC Psychiatry* 2016;**16**:263.

45. Waldron SM, Loades ME, Rogers L. Routine outcome monitoring in CAMHS: how can we enable implementation in practice? *Child Adolesc Ment Health* 2018;**23**:328–33.

46. Sharples S, Martin J, Lang A, Craven M, O'Neill S, Barnett J. Medical device design in context: a model of user–device interaction and consequences. *Displays* 2012;**33**:221–32.

47. Sayal K, Partlett C, Bhardwaj A, Dubicka B, Marshall T, Gledhill J, *et al*. Mental health in clinically referred children and young people before and during the COVID-19 pandemic. *Eur Child Adolesc Psychiatry* 2023;**32**:2657–66.

Appendix 1: Protocol changes, assessments and secondary outcomes

TABLE 1 Table of recruiting sites

Recruiting site	Principal investigator
Nottinghamshire Healthcare NHS Foundation Trust	Kapil Sayal (also the Chief Investigator for the trial)
Berkshire Healthcare NHS Foundation Trust	Tamsin Marshall
Cambridgeshire and Peterborough NHS Foundation Trust	Anupam Bhardwaj
Central and North West London NHS Foundation Trust	Julia Gledhill
Pennine Care NHS Foundation Trust	Bernadka Dubicka
Gloucestershire Health and Care NHS Foundation Trust	Helen Bould
Surrey and Borders Partnership NHS Foundation Trust	Asifa Zainab
Rotherham Doncaster and South Humber NHS Foundation Trust	Abdullah Kraam (June 2021–July 2022) Michael Seneviratne (from July 2022)

TABLE 2 Protocol substantial amendments since the start of the study

Protocol	Date	Summary of changes
2.0	16 December 2019	• Confirmation of reconsent procedure for 16-year-olds during follow-up • Clarification regarding outcome definitions • Minor corrections and clarifications throughout
3.0	13 August 2020	• Additional participant questionnaire (CRIES-8)
4.0	3 February 2021	• Implementation of SWAT and amendment to arrangements to voucher payments to participants
4.1	1 August 2022	• Extension of data collection up to 18 months post randomisation • Minor updates to administrative information • Addition of eligible emotional disorder (trichotillomania)

TABLE 3 Protocol deviations

Site ID	Deviation
Cambridgeshire and Peterborough NHS Foundation Trust	Young person DAWBA completed before written assent form. Parental consent had been obtained prior to randomisation in accordance with the protocol. Written assent from the young person was subsequently documented after DAWBA completion
All	Two issues with the STADIA database were identified: 1. A small number of secondary questionnaires were not sent to participants in error. There was an error in the database script where these questionnaires were erroneously locked if consent from the secondary participant was obtained on a day after that from the primary participant. Questionnaires were sent out to the secondary participants, which were still within the completion window 2. 6- and 12-month questionnaires were not automatically sent by the database between 28 February 2021 and 21 March 2021. Database script has been modified and corrected. Database script end date of 27 February 2021 has been removed so that 6-month and 12-month questionnaires are sent indefinitely. All 6- and 12-month questionnaires due in that period were sent out to the participants
03	Two participants were randomised at similar time to the STADIA trial at site 03. As is standard practice in the trial, at the first opportunity, the RA printed the DAWBA report (the trial intervention) alongside a covering letter to post out to the trial participants. The DAWBA report does not contain any directly identifiable information but is annotated with the participant's ID number. The cover letter includes the parent's/guardian's name and young person's NHS number as reference. The DAWBA covering letter and report were accidently mixed up, so 03402 received 03408's documents and vice versa. The breach was reported to the Sponsor who deemed the breach non-serious, REC were informed and they asked the trial team to contact both families and offer them the opportunity to meet with the Chief Investigator in order to apologise for the error personally. Both sets of parents were contacted by the site RA in the first instance and declined the opportunity for a further meeting with the Chief Investigator as they were happy that the breach had been dealt with appropriately. REC were satisfied with the actions that we had taken and considered the review of the breach closed with no further action required

RA, research assistant; REC, Research Ethics Committee.

This synopsis should be referenced as follows:
Sayal K, Wyatt L, Thomson L, Holt G, Ewart C, Bhardwaj A, *et al.* Clinical and cost-effectiveness of a standardised diagnostic assessment for children and adolescents with emotional difficulties: the STADIA multi-centre RCT. *Health Technol Assess* 2025;**29**(61). https://doi.org/10.3310/GJKS0519

TABLE 4 Summary of assessments

Time point	Maximum 10 working days from referral receipt[a]					6 months post randomisation	12 months post randomisation	18 months post randomisation
Activity	Screening and invitation	Eligibility and enrolment	Consent and baseline	Randomisation	Intervention DAWBA in addition to assessment as usual Or Assessment as usual	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					
Baseline demographics (parent/carer and CYP aged 16 and 17 years)			X					
MFQ			X			X	X	
RCADS			X			X	X	
SDQ[b]			X			X	X	
[c]CRIES-8[21]			X			X	X	
CYP self-report self-harm measure			X			X	X	
PHQ-9 – parent/carer only			X			X	X	
GAD-7 – parent/carer only			X			X	X	
CHU9D			X			X	X	
EQ-5D-Y			X			X	X	
EQ-5D-5L			X			X	X	
Resource Use Questionnaire – parent/carer and CYP aged 16 and 17 years			X			X	X	
Data collection from records[d]			X			X	X	X

a 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.
b For participants in the intervention arm, the baseline SDQ will be collected as part of the DAWBA, completed post randomisation.
c Additional data collection undertaken to explore PTSD symptoms in CYP during the COVID-19 pandemic.
d Data collection from records completed periodically throughout the 12- and 18-month follow-up period.

TABLE 5 Eligible emotional disorder diagnoses

Anxiety disorder
Separation anxiety disorder
Specific phobia (any)
Social phobia or social anxiety disorder
Agoraphobia
Panic disorder (DSM-V additionally has Panic Attack with a specifier)
Phobic anxiety disorder (unspecified)
Selective mutism
Generalised anxiety disorder
OCD and related disorders
Body dysmorphic disorder
Acute stress reaction
Acute stress disorder
PTSD
Adjustment disorder
Other anxiety disorder
Mixed anxiety and depressive disorder
Depression
Depressive episode (any/mild/moderate/severe)
Depressive disorder
Recurrent depressive disorder (any/mild/moderate/severe)
Major depressive disorder
Persistent depressive disorder
Other depressive episode
Persistent mood (affective) disorder (including cyclothymic disorder/dysthymic disorder)
Other/unspecified mood (affective) disorder
Bipolar disorder
Bipolar affective disorder
Manic episode
Childhood emotional disorder unspecified (F93.9)
Trichotillomania[a]

DSM-V, *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition.
a Added following agreement from adjudication committee.

TABLE 6 Secondary outcome measures

Outcome	Measurement	Definition
Clinician-made diagnosis decision about the presence of an emotional disorder within 18 months of randomisation	Collected from records	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 is included
Acceptance of index referral	Collected from records	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
Acceptance of any referral within 12 and 18 months	Collected from records	Whether the index referral or any subsequent referral to CAMHS (if made) was accepted or not. Acceptance as defined above for index referral. Collected within 12 and 18 months of randomisation
Discharge from CAMHS within 12 and 18 months	Collected from records	Whether the CYP was discharged from CAMHS (following acceptance of the index referral) during the 12 and 18 months post randomisation
Rereferral to CAMHS within 12 and 18 months	Collected from records	Whether the CYP was rereferred 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
Confirmed diagnosis decision	Collected from records	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 for primary outcome, collected within 12 and 18 months of randomisation
Time from randomisation to diagnosis of emotional disorder	Collected from records	Date of diagnosis will be the first documented eligible diagnosis. Diagnosis as defined above for primary outcome collected within 12 and 18 months of randomisation
Diagnoses made over the 12- and 18-month period from randomisation	Collected from records	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
Treatment offered for diagnosed emotional disorder	Collected from records	Whether treatment was offered for a diagnosed emotional disorder, as defined for primary outcome above, collected within 12 and 18 months of randomisation
Treatments/interventions given	Collected from records	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
Time from randomisation to the decision to offer treatment for a diagnosed emotional disorder	Collected from records	Date of decision will be the first date that the decision to offer treatment for a diagnosed emotional disorder is documented in the clinical note, collected within 12 and 18 months of randomisation
Time from randomisation to start of first treatment for a diagnosed emotional disorder	Collected from records	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, collected within 12 and 18 months of randomisation
Time from randomisation to the decision to offer any treatment	Collected from records	Date of decision will be the first date that the decision to offer any treatment is documented in the clinical notes, collected within 12 and 18 months of randomisation
Time from randomisation to start of any treatment	Collected from records	Date of treatment will be the first date that any treatment offered is started. Treatment as defined as above, collected within 12 and 18 months of randomisation
Participant-reported diagnoses	Participant self-report	Participants will be asked to report whether or not they received a diagnosis of the CYP difficulties from CAMHS in the 12 months post randomisation and if so, what diagnosis was given and by whom
Depression symptoms in the CYP	MFQ	MFQ[25] is a valid and reliable measure of depression in CYP;[26,27] 33 items are answered on a 3-point scale. Scores range from 0 to 66, with higher scores indicating more severe depressive symptoms. A score of ≥ 27 may be indicative of depression. MFQ is collected at baseline, 6 and 12 months post randomisation

TABLE 6 Secondary outcome measures (*continued*)

Outcome	Measurement	Definition
Anxiety symptoms in the CYP	RCADS	RCADS[28] 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 four-point scale. An overall anxiety and low mood score is generated, with separate subscale scores for separation anxiety, social phobia, generalised anxiety, panic, OCD and major depression Total anxiety and depression scores range from 0 to 141 We will record scores for each of the six subscales. For analysis metric, we will use the total anxiety score. RCADS is collected at baseline, 6 and 12 months post randomisation
Comorbid oppositional defiant/conduct disorder in the CYP	SDQ	SDQ:[29] A 25-item emotional and behavioural screening questionnaire for CYP Each item is rated on a three-point scale SDQ comprises five subscales and an impact supplement. The impact supplement asks effect of difficulties on home life, friendships, education and leisure activities Scores on the 'conduct problems' subscale will be used in the analysis of this outcome Subscale scores range from 0 to 10. SDQ is collected at baseline, 6 and 12 months post randomisation
Functional impairment in the CYP	SDQ	Impact supplement scores will be used to determine functional impairment. Impact scores range from 0 to 10. Collected at baseline, 6 and 12 months post randomisation
Self-harm thoughts in the CYP	CYP self-report self-harm measure	CYP 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) collected at baseline, 6 and 12 months post randomisation
Self-harm behaviours in the CYP	CYP self-report self-harm measure	CYP 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) collected at baseline, 6 and 12 months post randomisation
Depression symptoms in the parent/carer	PHQ-9	PHQ-9:[30] 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, collected at baseline, 6 and 12 months post randomisation
Anxiety symptoms in the parent/carer	GAD-7	GAD-7[31] is a measure of the severity of anxiety in general populations. Seven items are rated according to the frequency with which they have been experienced over the past 2 weeks. Total scores range from 0 to 21, with higher scores indicating more severe anxiety. Collected at baseline, 6 and 12 months post randomisation
Time out of education, employment or training for the CYP	Resource use questionnaire	Days missed from education, employment or training (as applicable) for the CYP due to emotional difficulties. Collected at baseline, 6 and 12 months post randomisation
Safety outcomes		
A significant deterioration in depression for the CYP	MFQ (as above)	A score indicative of depression (≥ 27) on the MFQ completed at follow-up, where this represents a deterioration from baseline of ≥ 5 points
A significant deterioration in depression for the parent/carer	PHQ-9 (as above)	A score indicative of depression (≥ 15) on the PHQ-9 completed at follow-up, where this represents a deterioration from baseline of ≥ 5 points
Frequency of self-harm	Self-harm measure (as above)	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) collected at baseline, 6 and 12 months post randomisation

continued

This synopsis should be referenced as follows:
Sayal K, Wyatt L, Thomson L, Holt G, Ewart C, Bhardwaj A, *et al.* Clinical and cost-effectiveness of a standardised diagnostic assessment for children and adolescents with emotional difficulties: the STADIA multi-centre RCT. *Health Technol Assess* 2025;**29**(61). https://doi.org/10.3310/GJKS0519

TABLE 6 Secondary outcome measures (*continued*)

Outcome	Measurement	Definition
Hospital admissions	Participant self-reported	The number of CYP 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	Resource use questionnaire	The number of CYP 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	Data collected from records	The number of deaths of participating CYP from randomisation until 18-month follow-up
Additional data collection		
PTSD symptoms in the CYP	CRIES-8	Scores range from 0 to 40, with higher scores indicating more severe symptoms There are two subscales: intrusion and avoidance. Subscale scores range from 0 to 20 There are eight items that are scored on a four-point scale
Health economic outcome measures		
HRQoL in the CYP	CHU9D and EQ-5D-Y	CHU9D[32] consists of nine individual items with five levels of response per question (scored 1–5), which assess the CYP functioning 'today'. The following domains are included: worry, sadness, pain, tiredness, annoyance, school, sleep, daily routine and activities EuroQol-5D youth descriptive system[33] comprises five domains: mobility, looking after myself, doing usual activities, having pain or discomfort and feeling worried, sad or unhappy; values of 1, 2 or 3 are assigned to each response. The EQ-VAS asks recipients to self-assess their health state 'today' from 0 (worst imaginable health) to 100 (best imaginable health), representing individual preferences These measures will be self-reported by CYP aged 11+ years, with proxy versions also completed by the parent/carer for CYP < 16 years. Both were collected at baseline, 6 and 12 months post randomisation
HRQoL in the parent/carer	EQ-5D-5L	The EuroQol 5-dimension multiattribute utility instrument[34] comprises five domains; mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each domain is scored between 1 and 5. This descriptive profile, in combination with a valuation set, produces a single index for health status representing societal preferences. The index score ranges from −0.59 to 1, with 0 representing death, 1 of perfect health, and < 0 of health states worse than death. The EQ-VAS is again included within the EQ-5D instrument collected at baseline, 6 and 12 months post randomisation

A&E, accident and emergency; EQ-VAS, EuroQol Visual Analogue Scale.

Appendix 2 Main trial summary

Research aims

To evaluate the clinical effectiveness and cost effectiveness of the DAWBA as an adjunct to usual clinical care for CYP presenting with emotional difficulties referred to CAMHS.

Primary outcome

A clinician-made diagnosis decision about the presence of an emotional disorder within 12 months of randomisation.

Secondary outcomes

Outcome	Measurement
Clinician-made diagnosis decision about the presence of an emotional disorder within 18 months of randomisation	Collected from records
Acceptance of index referral	Collected from records
Acceptance of any referral within 12 and 18 months	Collected from records
Discharge from CAMHS within 12 and 18 months	Collected from records
Rereferral to CAMHS within 12 and 18 months	Collected from records
Confirmed diagnosis decision	Collected from records
Time from randomisation to diagnosis of emotional disorder	Collected from records
Diagnoses made over the 12- and 18-month period from randomisation	Collected from records
Treatment/intervention offered for diagnosed emotional disorder	Collected from records
Treatments/interventions given	Collected from records
Time from randomisation to the decision to offer treatment/intervention for a diagnosed emotional disorder	Collected from records
Time from randomisation to start of first treatment/intervention for a diagnosed emotional disorder	Collected from records
Time from randomisation to the decision to offer any treatment/intervention	Collected from records
Time from randomisation to start of any treatment/intervention	Collected from records
Participant-reported diagnoses	Participant self-report
Depression symptoms in the CYP	MFQ
Anxiety symptoms in the CYP	RCADS
Comorbid oppositional defiant/conduct disorder in the CYP	SDQ
Functional Impairment in the CYP	SDQ
Self-harm thoughts in the CYP	CYP self-report self-harm measure
Self-harm behaviours in the CYP	CYP self-report self-harm measure
Depression symptoms in the parent/carer	PHQ-9
Anxiety symptoms in the parent/carer	GAD-7
Time out of education, employment or training for the CYP	Resource use questionnaire
Safety outcomes	
A significant deterioration in depression for the CYP	MFQ
A significant deterioration in depression for the parent/carer	PHQ-9
Frequency of self-harm	Self-harm measure
Hospital admissions	Participant self-reported
Accident and emergency attendances	Resource use questionnaire
Deaths	Data collected from records
Additional mental health measure	
PTSD symptoms in the CYP	CRIES-8

This synopsis should be referenced as follows:
Sayal K, Wyatt L, Thomson L, Holt G, Ewart C, Bhardwaj A, *et al.* Clinical and cost-effectiveness of a standardised diagnostic assessment for children and adolescents with emotional difficulties: the STADIA multi-centre RCT. *Health Technol Assess* 2025;**29**(61). https://doi.org/10.3310/GJKS0519

Outcome	Measurement
Health economic outcome measures	
HRQoL in the CYP	CHU9D and EQ-5D-Y
HRQoL in the parent/carer	EQ-5D-5L

Methods for data collection

- Participants were randomised in a 1 : 1 ratio to either the DAWBA plus assessment as usual (intervention), or assessment as usual only (control).
- Service-related data were collected from CAMHS clinical records using CRFs by site researchers at 12 and 18 months post randomisation.
- Participant-reported data were collected through online questionnaires (parent/carer and CYP self-report aged 11+ years), completed at baseline and 6 and 12 months post randomisation.

Methods for analysis

- Baseline characteristics of the young person and parents/carers were summarised using mean, standard deviation, median, lower and upper quartiles, minimum, maximum and number of observations for continuous data, and frequency counts and percentages for categorical data.
- The primary approach to between-group comparative analyses was to include all participants with observed outcome data according to randomised allocation. The primary analysis employed a generalised linear mixed model to compare the proportions in each group with a clinician-made diagnosis decision within 12 months of randomisation, adjusted for minimisation variables.
- Secondary outcomes were analysed using appropriate mixed-effect regression models dependent on data type and adjusted for minimisation factors and baseline value of the outcome where measured. Outcomes measured at multiple time points were analysed using a mixed model with a treatment by time interaction to obtain estimates of treatment effect at each follow-up time.
- The primary viewpoint for the cost analysis was from an NHS and PSS perspective. A secondary analysis considered costs from a broader societal perspective. HRQoL of participants was measured using the EQ-5D-Y and CHU9D, with preference scores derived using relevant population tariffs, and QALY was estimated using an area under the curve approach.
- For the base-case cost-effectiveness analysis, between-group differences in costs and outcomes were estimated using seemingly unrelated regressions with multiple imputed data. Uncertainties in between-group differences were presented using scatter plots and cost-effectiveness acceptability curves and are further explored in subgroup analyses.

Key findings

- One thousand two hundred and twenty-five participants were recruited between 27 August 2019 and 17 October 2021; 615 to the intervention group and 610 to the control group.
- There was no evidence of a difference between groups for the primary outcome; 68 (11%) participants in the intervention group received an emotional disorder diagnosis within 12 months versus 72 (12%) in the control group.
- There were no differences between groups for any of the secondary outcomes from clinical records or participant-reported data.
- In terms of the economic evaluation, we found no evidence to suggest that the intervention impacted health service utilisation, broader societal costs or quality-of-life outcomes for CYP or their parents/carers.

Limitations

- We were unable to blind participants, researchers collecting source data or clinicians to treatment allocation; however, we did have robust adjudication procedures in place.
- Due to the pragmatic nature of the trial, we did not ask clinicians to record whether or not they saw the DAWBA report in the CAMHS clinical records.

Inter-relationships with other parts of the award

- Process evaluation nested within the main RCT.

Appendix 3 Qualitative process evaluation summary

Research aims

To identify any barriers and facilitators to implementing and using the DAWBA in CAMHS, including broader contextual factors within which CAMHS operates and specific causal mechanisms expected to affect intended outcomes within the trial.

Methods for data collection

- Semistructured interviews with 109 participants across eight trial sites: 15 young people aged 16 or 17 years; 38 parents or carers; 56 staff.
- Qualitative data were analysed using thematic analysis within a framework approach using the domains and constructs of the CFIR to reflect on the themes identified.

Key findings

Findings are summarised in *Figure 4*.

Facilitators which supported the use of the DAWBA were:

- Young people and their parents/carers engaging positively with the DAWBA report, which gave them a sense of reassurance and acknowledgement during long waiting times, as well as evidence of their symptoms, which they used to access other services outside CAMHS.
- Site principal investigators and researchers raising awareness and understanding of the DAWBA among clinical teams as well as ensuring DAWBAs were completed and uploaded to patients' electronic records.
- The DAWBA being seen by clinicians as providing easy-to-use information, which could supplement other assessments and provide an initial focus for conversations during a consultation.
- The use of the DAWBA during the screening of referrals was seen as having the potential to improve efficiency of referral decision-making.

Barriers to the use of the DAWBA were:

- The impact of COVID-19 on service delivery and increased referral numbers, long waiting times and worsening cases led to a context of a highly pressurised service.
- CAMHS clinicians feeling a lack of capacity and time due to this workload, which meant that few accessed the DAWBA report in electronic clinical records at the consultation/assessment stage.
- Clinical staff undertaking assessments had a lack of understanding and confidence in using the DAWBA, with specific concerns about the length of time between DAWBA completion (at point of referral) and initial assessment.
- Clinicians had a general reluctance and hesitancy towards diagnosis and many expressed a professional preference for formulation rather than formal diagnoses for CYP.

Limitations

- COVID-19 pandemic and workload pressures meant that NHS staff were difficult to recruit for the qualitative interviews.
- Only young people aged 16–17 years whose referrals were considered to be 'routine' and not 'high risk' were invited to take part in the study. Children under the age of 16 years were not invited to take part, so their experiences have not been explored in this study.

Inter-relationships with the other parts of the award

- Nested within the main RCT trial.

This synopsis should be referenced as follows:
Sayal K, Wyatt L, Thomson L, Holt G, Ewart C, Bhardwaj A, *et al.* Clinical and cost-effectiveness of a standardised diagnostic assessment for children and adolescents with emotional difficulties: the STADIA multi-centre RCT. *Health Technol Assess* 2025;**29**(61). https://doi.org/10.3310/GJKS0519

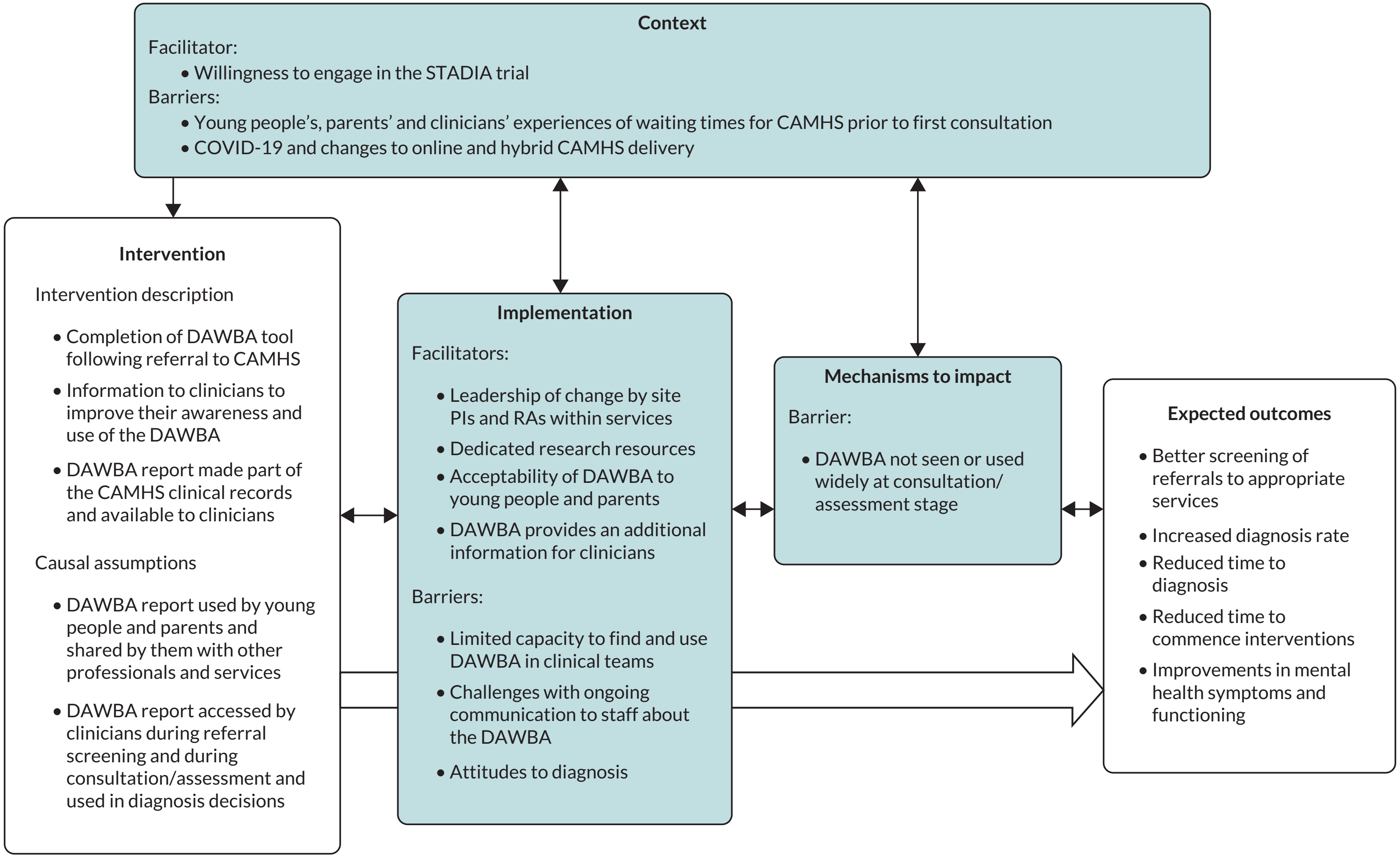

FIGURE 4 Summary of process evaluation results (blue boxes), framed within a simplified STADIA Trial logic model (white boxes). Reproduced with permission from Thomson *et al.*[2] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.