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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)?

Submission date
03/05/2019

Recruitment status
No longer recruiting

Registration date
29/05/2019

Overall study status
Completed

Last Edited
19/03/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This research focuses on children with emotional difficulties who have been referred to Child and Adolescent Mental Health Services (CAMHS). Referrals are sometimes turned down by CAMHS, often because of insufficient information. Even if the referral is accepted, assessments are often carried out without reaching a clinical diagnosis. This is important because receiving the correct diagnosis is vital so that appropriate help can be offered. We want to find out whether the use of a standard information-gathering package helps with the assessment and diagnosis process in CAMHS. Children referred to CAMHS will be randomly selected to go into one of two groups. Either the referral will be looked at as usual, or the package will be tested. This involves information being collected from the parent (and the child, if aged 11+) soon after the referral is received but before any decision has been made about accepting the referral. This information will then be passed on to the CAMHS clinicians and the family. We will assess how effective and cost-effective this approach is by seeing whether it makes any difference to whether or not a diagnosis is made and whether this better helps children and their families. We will follow the children up for 12 months to assess the impact on their emotional difficulties, day-to-day functioning and quality of life. For children and their families, receiving the right help at the right time can make a huge difference to their lives. By evaluating different approaches to assessment within CAMHS, and publicising our findings, our research will help improve care and inform clinical guidelines. Our findings will help the NHS decide how best to ensure value for money for how emotional difficulties are diagnosed.

Who can participate?
Children and young people (age 5-17 years) presenting with emotional difficulties referred to Child and Adolescent Mental Health Services (CAMHS), as well as their parents/carers.

What does the study involve?
Participants are randomly allocated to one of two groups. One group will be asked to complete an online package of questionnaires called the Development and Well-Being Assessment tool (DAWBA) in addition to the usual referral process. This will be completed after participants have been referred to CAMHS- but before a referral decision has been made. A summary report will be provided to both participants and clinical staff. The other group will receive usual care only, i. e. the referral will be reviewed based on the usual information provided to clinicians. All participants, regardless of group, will be asked to complete some online questionnaires 6 months and 12 months after joining the study.

What are the possible benefits and risks of participating?
Young people aged 11 and over, as well as all participating parents or carers, will receive a £20 voucher (upon receipt of the 12-month follow up questionnaire) as a thank you for the additional time spent on involvement in the research. By taking part in this study, there are no additional risks beyond undergoing usual referral and treatment to CAMHS. Participants may experience some worry or distress due to some of the questions asked in the questionnaires, but this is expected to be a similar experience to usual practise.

Where is the study run from?
The STADIA Trial is being run by the University of Nottingham, and takes place in a number of participating CAMHS in England.

When is the study starting and how long is it expected to run for?
June 2019 to December 2023

Who is funding the study?
The National Institute for Health Research, UK.

Who is the main contact?
Dr Laura Wyatt
stadia@nottingham.ac.uk

Study website
https://www.journalslibrary.nihr.ac.uk/programmes/hta/169609/

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
255635

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
41507, IRAS 255635

Study information

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

Acronym
STADIA

Study objectives

The study aims to find out whether the use of a standardised diagnostic assessment (SDA) tool improves the detection and treatment outcomes of emotional disorders in young people referred to CAMHS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/06/2019, West Midlands - South Birmingham Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; 0207 1048101; nrescommittee.westmidlands-southbirmingham@nhs.net), ref: 19/WM/0133

Study design
Randomised; Both; Design type: Diagnosis, Process of Care, Management of Care, Other, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Behavioural and emotional disorders with onset usually occurring in childhood and adolescence

Interventions
This research focuses on children with emotional difficulties who have been referred to Child and Adolescent Mental Health Services (CAMHS). Referrals are sometimes turned down by CAMHS, often because of insufficient information. Even if the referral is accepted, assessments are often carried out without reaching a clinical diagnosis. This is important because receiving the correct diagnosis is vital so that appropriate help can be offered.

We want to find out whether the use of a standard information-gathering package helps with the assessment and diagnosis process in CAMHS. Children referred to CAMHS will be randomly selected to go into one of two groups. Either the referral will be looked at as usual, or the package will be tested. This involves information being collected from the parent (and the child, if aged 11+) soon after the referral is received but before any decision has been made about accepting the referral. This information will then be passed on to the CAMHS clinicians and the family.

We will assess how effective and cost-effective this approach is by seeing whether it makes any difference to whether or not a diagnosis is made and whether this better helps children and their families. We will follow the children up for 12 months to assess the impact on their emotional difficulties, day-to-day functioning and quality of life.

For children and their families, receiving the right help at the right time can make a huge difference to their lives. By evaluating different approaches to assessment within CAMHS, and publicising our findings, our research will help improve care and inform clinical guidelines. Our findings will help the NHS decide how best to ensure value for money for how emotional difficulties are diagnosed.

The study aims to find out whether the use of a standardised diagnostic assessment (SDA) tool improves the detection and treatment outcomes of emotional disorders in young people referred to CAMHS. SDA tools are structured assessments that indicate the presence of difficulties according to established diagnostic criteria. There are several valid and reliable SDA tools, however, there is uncertainty over the value of these in clinical practice and they are not routinely used. Because there is uncertainty a randomised controlled trial is the appropriate methodology. The SDA tool will be tested as an addition to usual practice and this will be compared with current usual practice only.

The SDA tool to be tested in the current study is the Development and Well-Being Assessment (DAWBA). The DAWBA has been widely used and has established reliability and validity.

Participants will be recruited through CAMHS services (including triage/single point of access [SPA] teams) in the participating NHS sites and identified at the point of referral receipt. Participants will be randomised to the DAWBA in addition to usual practice, or usual practice only. Those allocated to complete the DAWBA will be provided with a link to the online system and will be offered additional telephone support to complete the online questionnaire if required. Following completion, the results of the DAWBA will be provided to the participant and to the CAMHS team considering the referral. A copy will be saved in the young person's CAMHS record.

Data collection from participants will be completed online, and supplemented by collection of data from CAMHS records. Participants will be followed up for 12 months, with data collection at 6 and 12 months post-randomisation. A subset of participants will also be invited to take part in qualitative interviews.

Alongside this, qualitative interviews will also be carried out with clinicians, service managers and commissioners.

This is a 4-year study, which started in November 2018. Recruitment of participants is due to commence in June 2019 and will continue for up to 2 years. There is a 12 month follow-up period, followed by 6 months for analysis and reporting.

Intervention Type
Behavioural

Primary outcome measure
Clinician-made diagnosis decision about the presence of an emotional disorder within 12 months of randomisation. Diagnosis of an emotional disorder will be coded as 'yes'; absence or uncertainty (for example, reflecting ongoing assessment / investigation) about the presence of an emotional disorder will be coded as 'no'.

Secondary outcome measures

Current secondary outcome measures as of 14/08/2023:

1. A clinician-made diagnosis decision about the presence of an emotional disorder within 18 months of randomisation. Diagnosis of an emotional disorder will be coded as 'yes'; absence or uncertainty (for example, reflecting ongoing assessment / investigation) about the presence of an emotional disorder will be coded as 'no'.
2. Acceptance of index referral – measured as: accepted by CAMHS = yes vs. declined by CAMHS= no; collected within 12 months of randomisation.
3. Acceptance of any referral within a) 12 months and b) within 18 months of randomisation – measured as: any referral accepted by CAMHS = yes vs. no referrals accepted by CAMHS= no; collected within 12 months and 18 months of randomisation.
4. Discharge from CAMHS within a) 12 months and b) within 18 months of randomisation– measured as; date of discharge within 12 months or 18 months recorded in notes = yes, no date of discharge or discharge date after 18 months = no; collected within 12 months and 18 months of randomisation.
5. Re-referral to CAMHS within 12 months and 18 months - measured as; re-referral documented within 12 or 18 months = yes, no re-referral documented within 18 months = no; collected within 12 months and 18 months of randomisation.
6. Confirmed diagnosis decision – measured as: 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'; collected within 12 months and within 18 months of randomisation.
7. Time from randomisation to diagnosis of emotional disorder – measured as: the time (in days) as derived from the randomisation date and date of diagnosis; collected within 12 months and 18 months of randomisation.
8. Diagnoses made over the 12 month and 18 month period from randomisation – measured using: standard proforma (pre-specified diagnoses). Alternative possible diagnoses identified from the clinical notes will be recorded verbatim on the data capture form and will be subject to adjudication by members of the trial management group; collected within 12 months and 18 months of randomisation.
9. Treatment offered for diagnosed emotional disorder – measured as: documented diagnosis of an emotional disorder AND documented treatment offered = yes vs. no documented diagnosis of emotional disorder and/or no documented treatments offered = no; collected within 12 months and 18 months of randomisation.
10. Treatments/interventions given – measured as: Pre-specified treatments will be captured using a standard proforma. Alternative possible treatments identified from the clinical notes will be recorded verbatim on the data capture form and will be subject to adjudication by members of the trial management group; collected within 12 months and 18 months of randomisation.
11. Time from randomisation to the decision to offer treatment for a diagnosed emotional disorder – measured as: the time (in days) from randomisation to the date of the decision to offer treatment for a diagnosed emotional disorder, derived from the randomisation date and the date of the documented decision; collected within 12 months and 18 months of randomisation.
12. Time from randomisation to start of first treatment for a diagnosed emotional disorder – measured as: the time (in days) from randomisation to start of first treatment for a diagnosed emotional disorder, derived from the randomisation date and documented start date of first relevant treatment ;collected within 12 months and 18 months of randomisation.
13. Time from randomisation to the decision to offer any treatment – measured as: the time (in days) from randomisation to the date of the decision to offer any treatment will be derived from the randomisation date and the date of the documented decision; collected within 12 months and 18 months of randomisation.

14. Time from randomisation to start of any treatment – measured as: the time (in days) from randomisation to start of any treatment as derived from the randomisation date and documented start date of first treatment; collected within 12 months and 18 months of randomisation.
15. Participant-reported diagnoses received in the 12 months post-randomisation – collected at 6 and 12 months post-randomisation.
16. Depression symptoms (child/young person) – measured using the Mood and Feelings Questionnaire (MFQ) at Baseline, 6 and 12 months post-randomisation.
17. Anxiety symptoms (child/young person) – measured using the Revised Children's Anxiety and Depression Scale (RCADS) at Baseline, 6 and 12 months post-randomisation.
18. Comorbid oppositional defiant / conduct disorder symptoms (child/young person) – measured using the Strengths & Difficulties Questionnaire (SDQ) at Baseline, 6 and 12 months post-randomisation.
19. Functional Impairment (child/young person) – measured using the Strengths & Difficulties Questionnaire (SDQ) at Baseline, 6 and 12 months post-randomisation.
20. Self-harm thoughts (child/young person) – measured via self-report at baseline, 6 and 12 months post-randomisation.
21. Self-harm behaviours (child/young person) – measured via self-report at baseline, 6 and 12 months post-randomisation.
22. Depression symptoms (parent/carer) – measured using the PHQ-9 questionnaire at Baseline, 6 and 12 months post-randomisation.
23. Anxiety symptoms -(parent/carer) – measured using the GAD-7 questionnaire at Baseline, 6 and 12 months post-randomisation.
24. Health related quality of life (Child/young person QoL measured using the Child Health Utility 9D (CHU9D) questionnaire and the EuroQol Quality of Life Questionnaire 5 Domains for Young People (EQ5DY) at baseline, 6 and 12 months post-randomisation. Parent/carer QoL measured using the EuroQol Quality of Life Questionnaire 5 Domains, 5 Levels (EQ5D5L) at baseline, 6 and 12 months post-randomisation.
25. Time off education, employment or training because of emotional difficulties for the child /young person – measured as the days missed from education, employment or training (as applicable) for the child/young person due to emotional difficulties; collected at baseline, 6 and 12 months post-randomisation.

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Previous secondary outcome measures as of 22/02/2022:
1. Acceptance of index referral – measured as: accepted by CAMHS = yes vs. declined by CAMHS= no; collected within 12 months of randomisation
2. Acceptance of any referral within 12 months of randomisation – measured as: any referral accepted by CAMHS = yes vs. no referrals accepted by CAMHS= no; collected within 12 months of randomisation
3 Discharge from CAMHS within 12 months – measured as; date of discharge within 12 months recorded in notes = yes, no date of discharge or discharge date after 12 months = no; collected within 12 months of randomisation.
4 Re-referral to CAMHS within 12 months - measured as; re-referral documented within 12 months = yes, no re-referral documented within 12 months = no; collected within 12 months of randomisation.
5. Confirmed diagnosis decision – measured as: 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'; collected within 12 months of randomisation
6. Time from randomisation to diagnosis of emotional disorder – measured as: the time (in days) as derived from the randomisation date and date of diagnosis; collected within 12 months of

randomisation
7. Diagnoses made over the 12 month period from randomisation – measured using: standard proforma (pre-specified diagnoses). Alternative possible diagnoses identified from the clinical notes will be recorded verbatim on the data capture form and will be subject to adjudication by members of the trial management group; collected within 12 months of randomisation.
8. Treatment offered for diagnosed emotional disorder – measured as: documented diagnosis of an emotional disorder AND documented treatment offered = yes vs. no documented diagnosis of emotional disorder and/or no documented treatments offered = no; collected within 12 months of randomisation
9. Treatments / interventions given – measured as: Pre-specified treatments will be captured using a standard proforma. Alternative possible treatments identified from the clinical notes will be recorded verbatim on the data capture form and will be subject to adjudication by members of the trial management group; collected within 12 months of randomisation.
10. Time from randomisation to the decision to offer treatment for a diagnosed emotional disorder – measured as: the time (in days) from randomisation to the date of the decision to offer treatment for a diagnosed emotional disorder, derived from the randomisation date and the date of the documented decision; collected within 12 months of randomisation.
11. Time from randomisation to start of first treatment for a diagnosed emotional disorder – measured as: the time (in days) from randomisation to start of first treatment for a diagnosed emotional disorder, derived from the randomisation date and documented start date of first relevant treatment ;collected within 12 months of randomisation.
12. Time from randomisation to the decision to offer any treatment – measured as: the time (in days) from randomisation to the date of the decision to offer any treatment will be derived from the randomisation date and the date of the documented decision; collected within 12 months of randomisation.
13. Time from randomisation to start of any treatment – measured as: the time (in days) from randomisation to start of any treatment as derived from the randomisation date and documented start date of first treatment; collected within 12 months of randomisation
14. Participant-reported diagnoses received in the 12 months post-randomisation – collected at 6 and 12 months post-randomisation
15. Depression symptoms (child/young person) – measured using the Mood and Feelings Questionnaire (MFQ) at Baseline, 6 and 12 months post-randomisation
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17. Comorbid oppositional defiant / conduct disorder symptoms (child/young person) – measured using the Strengths & Difficulties Questionnaire (SDQ) at Baseline, 6 and 12 months post-randomisation
18. Functional Impairment (child/young person) – measured using the Strengths & Difficulties Questionnaire (SDQ) at Baseline, 6 and 12 months post-randomisation
19.Self-harm thoughts (child/young person) – measured via self-report at baseline, 6 and 12 months post-randomisation
20. Self-harm behaviours (child/young person) – measured via self-report at baseline, 6 and 12 months post-randomisation
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23. Health related quality of life (Child/young person QoL measured using the Child Health Utility 9D (CHU9D) questionnaire and the EuroQol Quality of Life Questionnaire 5 Domains for Young People (EQ5DY) at baseline, 6 and 12 months post-randomisation. Parent/carer QoL measured using the EuroQol Quality of Life Questionnaire 5 Domains, 5 Levels (EQ5D5L) at baseline, 6 and 12 months post-randomisation

24. Time off education, employment or training because of emotional difficulties for the child /young person – measured as the days missed from education, employment or training (as applicable) for the child/young person due to emotional difficulties; collected at baseline, 6 and 12 months post-randomisation

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Previous secondary outcome measures:
1. Acceptance of index referral – measured as: accepted by CAMHS = yes vs. declined by CAMHS= no; collected within 12 months of randomisation
2. Acceptance of any referral within 12 months of randomisation – measured as: any referral accepted by CAMHS = yes vs. no referrals accepted by CAMHS= no; collected within 12 months of randomisation
3. Confirmed diagnosis decision – measured as: 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'; collected within 12 months of randomisation
4. Time from randomisation to diagnosis of emotional disorder – measured as: the time (in days) as derived from the randomisation date and date of diagnosis; collected within 12 months of randomisation
5. Diagnoses made over the 12 month period from randomisation – measured using: standard proforma (pre-specified diagnoses); collected within 12 months of randomisation
6. Treatment offered for diagnosed emotional disorder – measured as: documented diagnosis of an emotional disorder AND documented treatment offered = yes vs. no documented diagnosis of emotional disorder and/or no documented treatments offered = no; collected within 12 months of randomisation
7. Treatments / interventions given – measured as: Pre-specified treatments will be captured using a standard proforma; collected within 12 months of randomisation
8. Time from randomisation to start of first treatment – measured as: the time (in days) from randomisation to start of first treatment as derived from the randomisation date and documented start date of first treatment; collected within 12 months of randomisation
9. Participant-reported diagnoses received in the 12 months post-randomisation – collected at 6 and 12 months post-randomisation
10. Depression symptoms (child/young person) – measured using the Mood and Feelings Questionnaire (MFQ) at Baseline, 6 and 12 months post-randomisation
11. Anxiety symptoms (child/young person) – measured using the Revised Children's Anxiety and Depression Scale (RCADS) at Baseline, 6 and 12 months post-randomisation
12. Oppositional defiant / conduct disorder symptoms (child/young person) – measured using the Strengths & Difficulties Questionnaire (SDQ) at Baseline, 6 and 12 months post-randomisation
13. Functional Impairment (child/young person) – measured using the Strengths & Difficulties Questionnaire (SDQ) at Baseline, 6 and 12 months post-randomisation
14. Self-harm (child/young person) – measured via self-report at Baseline, 6 and 12 months post-randomisation
15. Depression symptoms (parent/carer) – measured using the PHQ-9 questionnaire at Baseline, 6 and 12 months post-randomisation
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17. Health related quality of life – Child/young person QoL measured using the Child Health Utility 9D (CHU9D) questionnaire and the EuroQol Quality of Life Questionnaire 5 Domains for Young People (EQ5DY) at Baseline, 6 and 12 months post-randomisation. Parent/carer QoL measured using the EuroQol Quality of Life Questionnaire 5 Domains, 5 Levels (EQ5D5L) at Baseline, 6 and 12 months post-randomisation

18. Time off education, employment or training because of emotional difficulties for the child /young person – measured as the days missed from education, employment or training (as applicable) for the child/young person due to emotional difficulties; collected at Baseline, 6 and 12 months post-randomisation

Overall study start date
01/11/2018

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Inclusion criteria for the child/young person:
1. Aged 5 to 17 years.
2. Referred to outpatient multidisciplinary specialist CAMHS.
3. Presenting with emotional difficulties.
4. If aged <16, has an eligible individual with parental responsibility (the parent/carer - see eligibility criteria below) willing and able to participate in the trial.
5. If aged 16-17, has capacity to provide valid written informed consent.
6. If aged 16-17 and participating without a parent/carer, able to complete the assessment tool in English.
7. If aged 16-17 and participating without a parent/carer, access to internet and email or telephone.

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

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
17 Years

Sex
Both

Target number of participants

Planned Sample Size: 1210; UK Sample Size: 1210

Total final enrolment
1225

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

Exclusion criteria for the parent/carer:
1. Local authority representatives designated to care for the child/young person.

Date of first enrolment
14/06/2019

Date of final enrolment
17/10/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
The Resource, Trust HQ
Duncan Macmillan House
Porchester Road
Nottingham
United Kingdom
NG3 6AA

Study participating centre
Berkshire Healthcare NHS Foundation Trust
Fitzwilliam House
Skimped Hill Lane
Bracknell
United Kingdom
RG12 1BQ

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Elizabeth House, Fulbourn Hospital
Cambridge
Cambridgeshire
United Kingdom
CB21 5EF

Study participating centre
Central And North West London NHS Foundation Trust
Stephenson House
75 Hampstead Road
London
United Kingdom
NW1 2PL

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
United Kingdom
OL6 7SR

Study participating centre
Gloucestershire Health and Care NHS Foundation Trust
Edward Jenner Court
1010 Pioneer Avenue
Gloucester Business Park
Brockworth
Gloucester
United Kingdom
GL3 4AW

Study participating centre
Surrey and Borders Partnership NHS Foundation Trust
Trust Headquarters
18 Mole Business Park
Randalls Road
Leatherhead
Surrey
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KT22 7AD

Study participating centre
Rotherham Doncaster and South Humber NHS Foundation Trust
Woodfield House
Tickhill Road Site
Balby
Doncaster
United Kingdom
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Sponsor information

Organisation
Nottinghamshire Healthcare NHS Foundation Trust

Sponsor details
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+44 (0)115 969 1300
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04ehjk122

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/96/09

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Nottingham Clinical Trials Unit (ctu@nottingham.ac.uk). Anonymised, participant level data will be available following publication of the results by the trial team.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/05/2022	12/05/2022	Yes	No
HRA research summary			26/07/2023	No	No
Protocol file	version 4.1	01/08/2022	14/08/2023	No	No
Statistical Analysis Plan	version 1.0	10/08/2023	14/08/2023	No	No
Other files	Health Economics Analysis Plan version 1.0	30/01/2023	24/01/2024	No	No
Statistical Analysis Plan	version 2.0	24/10/2023	24/01/2024	No	No
Results article		07/01/2025	09/01/2025	Yes	No
Other publications	qualitative process evaluation	18/03/2025	19/03/2025	Yes	No