

# 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)?

<b>Submission date</b> 03/05/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/05/2019	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 19/03/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input checked="" type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

## Contact information

**Type(s)**

Public

**Contact name**

Dr Laura Wyatt

**ORCID ID**

<https://orcid.org/0000-0002-9817-5356>

**Contact details**

Nottingham Clinical Trials Unit  
Applied Health Research Building  
School of Medicine  
University of Nottingham  
University Park  
Nottingham  
United Kingdom

NG7 2RD  
+44 (0)1158231588  
stadia@nottingham.ac.uk

**Type(s)**  
Scientific

**Contact name**  
Prof Kapil Sayal

**ORCID ID**  
<https://orcid.org/0000-0002-2050-4316>

**Contact details**  
Institute of Mental Health  
University of Nottingham Jubilee Campus  
Triumph Road  
Nottingham  
United Kingdom  
NG7 2TU  
+44 (0)1158230264  
kapil.sayal@nottingham.ac.uk

## **Additional identifiers**

**Integrated Research Application System (IRAS)**  
255635

**Protocol serial number**  
41507

## **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

## **Study type(s)**

Treatment

## **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(s)**

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'.

## **Key secondary outcome(s)**

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.
- 

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

16. Anxiety symptoms (child/young person) – measured using the Revised Children’s Anxiety and Depression Scale (RCADS) at Baseline, 6 and 12 months post-randomisation

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

21. Depression symptoms (parent/carer) – measured using the PHQ-9 questionnaire at Baseline, 6 and 12 months post-randomisation

22. Anxiety symptoms -(parent/carer) – measured using the GAD-7 questionnaire at Baseline, 6 and 12 months post-randomisation

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

---

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
  16. Anxiety symptoms -(parent/carer) – measured using the GAD-7 questionnaire at Baseline, 6 and 12 months post-randomisation
  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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

5 years

### **Upper age limit**

17 years

### **Sex**

All

### **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**

United Kingdom

England

**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  
United Kingdom  
KT22 7AD

**Study participating centre****Rotherham Doncaster and South Humber NHS Foundation Trust**

Woodfield House  
Tickhill Road Site  
Balby  
Doncaster  
United Kingdom  
DN4 8QN

**Sponsor information****Organisation**

Nottinghamshire Healthcare NHS Foundation Trust

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

### 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](mailto: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?
<a href="#">Results article</a>		07/01/2025	09/01/2025	Yes	No
<a href="#">Protocol article</a>		11/05/2022	12/05/2022	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Other files</a>	Health Economics Analysis Plan version 1.0	30/01/2023	24/01/2024	No	No
<a href="#">Other publications</a>	qualitative process evaluation	18/03/2025	19/03/2025	Yes	No
<a href="#">Protocol file</a>	version 4.1	01/08/2022	14/08/2023	No	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	10/08/2023	14/08/2023	No	No
<a href="#">Statistical Analysis Plan</a>	version 2.0	24/10/2023	24/01/2024	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes