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Evaluation of intensive community care services for young people with psychiatric emergencies

Submission date
20/04/2020

Recruitment status
No longer recruiting

Registration date
29/04/2020

Overall study status
Completed

Last Edited
20/02/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Current plain English summary as of 11/02/2022:
Background and study aims
About 10% of adolescents experience severe mental health disorders and over 4000 are admitted to hospital every year. The main aim of this study is to establish which of the two ways of providing care to youths aged 12 to 18 is better. One way, treatment as usual (TAU), involves usual admission to a psychiatric hospital or other community CAMHS except ICCS. The other, Intensive Community Care Service (ICCS), provides treatment at home instead of hospital. ICCS teams quickly assess all young people being considered for admission, start home treatment with frequent visits and then connect youths and their families with other services if needed.

Who can participate?
Young people aged 12 years 0 months to 17 years 11 months with psychiatric emergencies who can consent and who are being considered for inpatient admission within participating NHS Trusts

What does the study involve?
All participants will be treated in one of two settings: treatment-as-usual or intensive community treatment (ICCS). Young people willing to take part in the study will be randomly allocated to one of the two treatment pathways. If the young person is selected by chance to have treatment-as-usual, this may involve an inpatient admission. If the young person is selected by chance to have Intensive Community Care Service (ICCS) s/he may have a more intense community treatment instead of a hospital admission. This may include attending more follow-up sessions, having home treatment or attending day hospital.

Young people who decide to take part in the study will initially be asked to fill out some brief questionnaires looking at various aspects of their psychological wellbeing and will have an interview with a trained clinical researcher to ascertain a diagnosis. Six months after the young person begins treatment and involvement in the study, researchers from King's College London will be in touch to find out how they are doing and ask them to complete some brief questionnaires like the ones they initially completed. In addition, participants may be asked to take part in a brief interview to gather feedback on how they found their care. The time it takes for young people to return or to start education, employment or training (EET) will be compared

between the two groups. The researchers will also compare the two groups in terms of their mental health, well-being and service satisfaction. They will also collect information on all the health and social care services that these young people will have received so that we can compare how much their care cost. They will do a smaller study, to begin with. If they can recruit enough participants in the smaller study, they will then proceed to complete the full study. The full study should show which is the best way to provide care to young people with severe mental health disorders The researchers also will interview young people to understand their experience of receiving care and interview healthcare workers to understand their experience of delivering care.

What are the possible benefits and risks of participating?
By taking part in this study, participants and their families will be helping to add to the understanding of what treatment settings are most effective for young people experiencing psychiatric emergencies, and ultimately improve NHS mental health service provision for young people in the future. In terms of risks, when conducting a standard clinical interview, it is possible that the participant could become upset when discussing emotional problems. The interviewers are clinically experienced, and they will be sensitive to the reactions of the patients during the interview. If necessary, the interview can be interrupted or terminated. The patient will be clearly informed that they may choose not to answer particular questions and are free to terminate participation in the interview at any point. Patients are not entered into the comparison study if they and their doctor do not feel this is suitable for them. In addition, completing questionnaires and research interviews all take people's time.

Where is the study run from?
King’s College London and South London and Maudsley NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2020 to July 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Dennis Ougrin
Dennis.Ougrin@kcl.ac.uk

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Previous plain English summary:
Background and study aims
About 10% of adolescents experience severe mental health disorders and over 4000 are admitted to hospital every year. The main aim of this study is to establish which of the two ways of providing care to youths aged 12 to 18 is better. One way, treatment as usual (TAU), involves usual admission to a psychiatric hospital. The other, Intensive Community Care Service (ICCS), provides treatment at home instead of hospital. ICCS teams quickly assess all young people being considered for admission, start home treatment with frequent visits and then connect youths and their families with other services if needed.

Who can participate?
Young people aged 12-18 with psychiatric emergencies who can consent/assent and who are being considered for inpatient admission within participating NHS Trusts

What does the study involve?
All participants will be treated in one of two settings: treatment-as-usual or intensive community treatment (ICCS). Young people willing to take part in the study will be randomly allocated to one of the two treatment pathways. If the young person is selected by chance to have treatment-as-usual, this may involve an inpatient admission. If the young person is selected by chance to have Intensive Community Care Service (ICCS) s/he may have a more intense community treatment instead of a hospital admission. This may include attending more follow-up sessions, having home treatment or attending day hospital.
Young people who decide to take part in the study will initially be asked to fill out some brief questionnaires looking at various aspects of their psychological wellbeing and will have an interview with a trained clinical researcher to ascertain a diagnosis. Six months after the young person begins treatment and involvement in the study, researchers from King's College London will be in touch to find out how they are doing and ask them to complete some brief questionnaires like the ones they initially completed. In addition, participants may be asked to take part in a brief interview to gather feedback on how they found their care. The time it takes for young people to return or to start education, employment or training (EET) will be compared between the two groups. The researchers will also compare the two groups in terms of their mental health, well-being and service satisfaction. They will also collect information on all the health and social care services that these young people will have received so that we can compare how much their care cost. They will do a smaller study, to begin with. If they can recruit enough participants in the smaller study, they will then proceed to complete the full study. The full study should show which is the best way to provide care to young people with severe mental health disorders is. The researchers also will interview young people to understand their experience of receiving care and interview healthcare workers to understand their experience of delivering care.

What are the possible benefits and risks of participating?
By taking part in this study, participants and their families will be helping to add to the understanding of what treatment settings are most effective for young people experiencing psychiatric emergencies, and ultimately improve NHS mental health service provision for young people in the future. In terms of risks, when conducting a standard clinical interview, it is possible that the participant could become upset when discussing emotional problems. The interviewers are clinically experienced, and they will be sensitive to the reactions of the patients during the interview. If necessary, the interview can be interrupted or terminated. The patient will be clearly informed that they may choose not to answer particular questions and are free to terminate participation in the interview at any point. Patients are not entered into the comparison study if they and their doctor do not feel this is suitable for them. In addition, completing questionnaires and research interviews all take people's time.

Where is the study run from?
1. South London and Maudsley NHS Foundation Trust (UK)
2. Betsi Cadwaladr University Health Board (UK)
3. Central and North West London NHS Foundation Trust (UK)
4. North East London NHS Foundation Trust (UK)
5. Oxford Health NHS Foundation Trust (UK)
6. NHS Lothian (UK)
7. Berkshire Health Care NHS Foundation Trust (UK)
8. Hertfordshire Partnership University NHS Foundation Trust (UK)
9. Oxleas NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2020 to April 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Dennis Ougrin
Dennis.Ougrin@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Dennis Ougrin

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Type(s)
Scientific

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Dr Izabela Pilecka

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Additional identifiers

Integrated Research Application System (IRAS)
271156

National Institute for Health and Care Research (NIHR)
HTA - NIHR127408

Protocol serial number
1/07082019

Study information

Scientific Title
Comparison of effectiveness and cost-effectiveness of intensive community care services versus treatment as usual including inpatient care for young people with psychiatric emergencies (IVY): An internal pilot followed by a randomised controlled trial comprising all intensive community service care teams in Great Britain

Acronym
IVY

Study objectives
Current study hypothesis as of 11/02/2022:
The IVY trial is a parallel group multi-centre randomised controlled trial, examining the hypothesis that the time to returning to/time to gaining education, employment or training (EET) will be significantly faster among the young people randomised to the ICCS group compared to young people who will receive treatment as usual (TAU). This will be tested at 6 months post randomisation (a follow-up).

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Previous study hypothesis:
The IVY trial is a two-arm, multicentre, blinded RCT examining the hypothesis that the time to returning to/time to gaining education, employment or training (EET) will be significantly faster among the young people randomised to the ICCS group compared to young people who will receive usual in-patient care (TAU). This will be tested at 6 months post randomisation (a follow-up).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/04/2020, West Midlands - Black Country Research Ethics Committee (West Midlands - Black Country Research Ethics Committee, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8010; blackcountry.rec@hra.nhs.uk), REC ref: 20/WM/0069

Primary study design
Interventional

Study design
Parallel group multi-centre randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psychiatric emergencies

Interventions
Current intervention as of 11/02/2022:
Randomisation will be at the level of the individual. Young people will be randomised to either the Intensive Community Care Service (ICCS) or the treatment as usual (TAU) pathway (1:1 ratio). Randomisation will be stratified by the NHS Trust and within Trusts blocks with random block sizes will be used to ensure that the site distribution is similar in the two trial arms. Thus, within a Trust all participants randomized to the ICCS will be in contact with the same ICCS team.

Treatment as usual (TAU) might include usual admission to a psychiatric hospital or other community CAMHS except ICCS. Intensive Community Care Service (ICCS) provides treatment at home instead of hospital. ICCS teams quickly assess all young people being considered for admission, start home treatment with frequent visits and then connect youths and their families with other services if needed.

Intensive Community Care Service (ICCS), as defined for the purposes of this study, will consist of the following essential components:
1. SMALL CASELOAD: service user/provider ratio of no more, than 10:1.
2. TEAM APPROACH: Provider group functions as team rather than as individual practitioners; clinicians know and work with all clients.
3. ICCS TEAM MEETING: ICCS Team meets frequently to plan and review services for each service user.
4. PRACTICING TEAM LEADER: Supervisor of front-line clinicians provides direct services.
5. CONTINUITY OF STAFFING: ICCS Team aims to maintain same staffing over time.
6. STAFF CAPACITY: ICCS Team operates at full staffing.
7. PSYCHIATRIST/ PSYCHIATRIC PRESCRIBER ON STAFF: there is at least one full-time psychiatrist per 100 service users assigned to work with the ICCS Team.
8. NURSE (RMN) ON STAFF: there are at least two full-time nurses (RMNs) assigned to work with a 100-client ICCS Team.
9. ICCS TEAM SIZE: team is of sufficient absolute size to provide consistently the necessary staffing diversity and coverage.
10. EXPLICIT ADMISSION CRITERIA: ICCS Team has clearly identified mission to serve a particular population and has and uses measurable and operationally defined criteria to screen out inappropriate referrals.
11. INTAKE RATE: ICCS Team takes clients in at a low rate to maintain a stable service environment.
12. RESPONSIBILITY FOR HOSPITAL ADMISSIONS: ICCS Team is involved in hospital admissions.
13. COMMUNITY-BASED SERVICES: ICCS Team works to monitor status and develop skills in the community rather than function as an office-based team.
14. NO DROPOUT POLICY: ICCS Team engages and retains service users at a mutually satisfactory level.
15. ASSERTIVE ENGAGEMENT MECHANISMS: ICCS Team uses community outreach, motivational/ engagement techniques, as well as legal mechanisms or other techniques to ensure ongoing

engagement.
16. INTENSITY OF SERVICE: high amount of face-to-face service time as needed.
17. FREQUENCY OF CONTACT: high number of face-to-face service contacts as needed.
18. WORK WITH INFORMAL SUPPORT SYSTEM: with or without service users present, ICCS Team provides support and skills for service user's support network: family, school, extracurricular activities coordinators etc.
19. ROLE OF SERVICE USERS ON TREATMENT TEAM: Service users are involved in the functioning of the team (e.g. as members of the interview panels).
20. PROVISION OF A DAY SERVICE: ICCS Team provides a form of day service, such as a day school or partial hospitalisation to those service users who need it

In summary, ICCS involves intensive treatment of young people with severe mental illness in community setting. Following the initial assessment, individualised goals are set with the family. The treatment includes a combination of psychological, pharmacological and/or social interventions as needed to achieve the goals. The interventions could be delivered up to several times a day. The treatment is not time-limited, but the aim is to achieve the goals within 3 months of the initial assessment. ICCS is followed by standard community treatment.

The inpatient care aspect of treatment as usual will be based on the model developed by one of the co-applicants (Richard Corrigall), which has since been adopted widely in the UK (Corrigall R, Mitchell B. Service innovations: rethinking in-patient provision for adolescents: A report from a new service. Psychiatric Bulletin 2002; 26:388-92.) The inpatient care aspect of TAU is delivered in hospital. Following the initial assessment, young people are treated with a combination of psychological, pharmacological and/or social interventions as needed to achieve the goals set up in collaboration with the family. The treatment is not time-limited, but the average duration of treatment is approximately 50 days. The hospital treatment is followed by standard community treatment.

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Previous intervention:
Randomisation will be at the level of the individual. Young people will be randomised to either the Intensive Community Care Service (ICCS) or the treatment as usual (TAU) pathway (1:1 ratio). Randomisation will be stratified by the NHS Trust and within Trusts blocks with random block sizes will be used to ensure that the site distribution is similar in the two trial arms. Thus, within a Trust all participants randomized to the ICCS will be in contact with the same ICCS team.

Treatment as usual (TAU) involves usual admission to a psychiatric hospital. Intensive Community Care Service (ICCS) provides treatment at home instead of hospital. ICCS teams quickly assess all young people being considered for admission, start home treatment with frequent visits and then connect youths and their families with other services if needed.

Intensive Community Care Service (ICCS), as defined for the purposes of this study, will consist of the following essential components:
1. SMALL CASELOAD: service user/provider ratio of no more, than 10:1.
2. TEAM APPROACH: Provider group functions as team rather than as individual practitioners; clinicians know and work with all clients.
3. ICCS TEAM MEETING: ICCS Team meets frequently to plan and review services for each service user.
4. PRACTICING TEAM LEADER: Supervisor of front-line clinicians provides direct services.
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9. ICCS TEAM SIZE: team is of sufficient absolute size to provide consistently the necessary staffing diversity and coverage.
10. EXPLICIT ADMISSION CRITERIA: ICCS Team has clearly identified mission to serve a particular population and has and uses measurable and operationally defined criteria to screen out inappropriate referrals.
11. INTAKE RATE: ICCS Team takes clients in at a low rate to maintain a stable service environment.
12. RESPONSIBILITY FOR HOSPITAL ADMISSIONS: ICCS Team is involved in hospital admissions.
13. COMMUNITY-BASED SERVICES: ICCS Team works to monitor status and develop skills in the community rather than function as an office-based team.
14. NO DROPOUT POLICY: ICCS Team engages and retains service users at a mutually satisfactory level.
15. ASSERTIVE ENGAGEMENT MECHANISMS: ICCS Team uses community outreach, motivational/ engagement techniques, as well as legal mechanisms or other techniques to ensure ongoing engagement.
16. INTENSITY OF SERVICE: high amount of face-to-face service time as needed.
17. FREQUENCY OF CONTACT: high number of face-to-face service contacts as needed.
18. WORK WITH INFORMAL SUPPORT SYSTEM: with or without service users present, ICCS Team provides support and skills for service user's support network: family, school, extracurricular activities coordinators etc.
19. ROLE OF SERVICE USERS ON TREATMENT TEAM: Service users are involved in the functioning of the team (e.g. as members of the interview panels).
20. PROVISION OF A DAY SERVICE: ICCS Team provides a form of day service, such as a day school or partial hospitalisation to those service users who need it
In summary, ICCS involves intensive treatment of young people with severe mental illness in community setting. Following the initial assessment, individualised goals are set with the family. The treatment includes a combination of psychological, pharmacological and/or social interventions as needed to achieve the goals. The interventions could be delivered up to several times a day. The treatment is not time-limited, but the aim is to achieve the goals within 3 months of the initial assessment. ICCS is followed by standard community treatment.

Treatment as usual/Inpatient care will be based on the model developed by one of the co-applicants (Richard Corrigall), which has since been adopted widely in the UK (Corrigall R, Mitchell B. Service innovations: rethinking in-patient provision for adolescents: A report from a new service. Psychiatric Bulletin 2002; 26:388-92.) TAU, or the usual inpatient care is delivered in hospital. Following the initial assessment, young people are treated with a combination of psychological, pharmacological and/or social interventions as needed to achieve the goals set up in collaboration with the family. The treatment is not time-limited, but the average duration of treatment is approximately 50 days. The hospital treatment is followed by standard community treatment.

Six months after participants enter the study, the time it takes for young people to return or to start education, employment or training (EET) will be compared between the two groups. This will be collected by contacting the relevant clinical team or the relevant educational, employment or training establishments. This is a continuous variable that comprises of number of days to returning or gaining employment, education or training (“time to EET”). For those not returning/gaining education, employment or training, the time will be censored at the end of the follow-up period (6 months after randomisation) or consent withdrawal. The researchers will

contact the relevant clinical team providing care to the participant every two weeks to gather the most up-to-date information regarding the participants' education, employment or training status. They will then contact the relevant establishment and ask them to provide the first day the participant returned/started EET, irrespective of the duration of the attendance. They will also gather data on the specific dates the participant attended education, employment or training. If the participant attended more than one establishment on the same date, this will be counted as one attendance. The researchers will also compare the two groups in terms of their mental health, well-being and service satisfaction. They will also collect information on all the health and social care services that these young people will have received so that they can compare how much their care cost.

Intervention Type
Other

Primary outcome(s)
Time to returning to/time to gaining education/employment/training, collected by contacting the relevant clinical team or the relevant educational, employment or training establishments, measured from the day of randomisation to the first day of attending either an educational institution, employment or training at 6 months post randomisation

Key secondary outcome(s)
Current secondary outcome measures as of 11/02/2022:
1. Emotional and behavioural problems measured using the Strengths and Difficulties Questionnaire at baseline and 6 months post randomisation
2. Functioning measured using the Children's Global Assessment Scale at baseline (pre-randomisation)
3. Clinician's view of the patient's global functioning assessed using the Clinical Global Impressions Scale pre-randomisation and at 6 months post randomisation and Clinical Global Improvement Scale at 6 months post randomisation
4. Patients' satisfaction with services measured using Service Satisfaction Survey (ChASE self-report questionnaire) at 6 months post randomisation
5. General health and social functioning measured using the Health of the Nation Outcome Scales for Children and Adolescents at pre-randomisation and 6 months post randomisation
6. Health-related quality of life measured using EuroQol-5 dimensions, 3 levels (EQ-5D-3L) at baseline and 6 months post randomisation. The primary economic analysis will be a cost-utility analysis using Quality Adjusted Life Years (QALYs) derived from the EQ-5D-3L at 6-month follow-up
7. Self-harm thoughts and behaviours measured using Self-Harm Questionnaire at baseline and 6 months post randomisation
8. Time spent in hospital (in days) measured using electronic patient records at 6 months post randomisation
9. Participants' use of health and social care services (resource-use data) measured using Child and Adolescent Service Use Schedule (CA-SUS) covering participants' use of these services for the last 3 months (at baseline) and since they last completed the questionnaire (6 months prior) at 6 months post randomisation
10. Number of days attending education, training or employment, collected by contacting the relevant clinical team or the relevant educational, employment or training establishments, in the 6 months following the day of randomisation
11. Service users' subjective experiences of receiving ICCS vs TAU, determined from qualitative

interviews at 6 months post randomisation
12. Experiences of mental health professionals in relation to delivering ICCS vs TAU, determined from qualitative interviews at 6 months post randomisation

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Previous secondary outcome measures:
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2. Functioning measured using the Children's Global Assessment Scale at baseline (pre-randomisation)
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4. Patients' satisfaction with services measured using Service Satisfaction Survey (ChASE self-report questionnaire) at 6 months post randomisation
5. General health and social functioning measured using the Health of the Nation Outcome Scales for Children and Adolescents at pre-randomisation and 6 months post randomisation
6. Health-related quality of life measured using EuroQol-5 dimensions, 3 levels (EQ-5D-3L) at baseline and 6 months post randomisation. The primary economic analysis will be a cost-utility analysis using Quality Adjusted Life Years (QALYs) derived from the EQ-5D-3L at 6-month follow-up
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10. Number of days attending education, training or employment, collected by contacting the relevant clinical team or the relevant educational, employment or training establishments, in the 6 months following the day of randomisation
11. Service users' subjective experiences of receiving ICCS vs TAU, determined from qualitative interviews at 6 months post randomisation
12. Experiences of mental health professionals in relation to delivering ICCS vs TAU, determined from qualitative interviews at 6 months post randomisation

Completion date
01/07/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 11/08/2022:
1. Young people aged 12 years 0 months to 17 years 11 months
2. Young people who can consent* and who are being considered for inpatient psychiatric admission or ICCS in the participating NHS Trusts

*Eligible participants under 16 years of age will require the consent of at least one person with parental responsibility.

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Previous participant inclusion criteria from 11/02/2022 to 11/08/2022:
1. Young people aged 12 years 0 months to 17years 11 months
2. Young people who can consent* and who are being considered for inpatient psychiatric admission in the participating NHS Trusts

*Eligible participants under 16-year of age will require the consent of at least one person with parental responsibility.

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Previous participant inclusion criteria:
1. Young people aged 12-18 who can consent/assent and who are being considered for inpatient admission in the catchment areas of one of 97 existing ICCSs or other ICCSs as they are developed will be eligible for recruitment
2. All under 16-year olds will require the consent of at least one person with parental responsibility

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 Years

Upper age limit
18 Years

Sex
All

Total final enrolment
35

Key exclusion criteria
Current participant exclusion criteria as of 11/08/2022:
1. Local ICCS teams or TAU unable to accept new referrals due to their full capacity being reached
2. Young people unable to consent due to their mental state
3. The risk profile of the young person is not compatible with ensuring their safety and/or the safety of others in the community*.

*We will use the Children Clinical Global Scale (CGAS) to standardise our approach to risk. The CGAS is used to rate the general functioning of young people under the age of 18. It has good validity and reliability. Scores range from 1 to 100, with high scores indicating better functioning.

A score of <20, indicating that the young person needs considerable supervision to prevent hurting others or self will be used as a guide to risk, indicating that the young person must be admitted for inpatient care and is therefore ineligible for randomisation

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1. Local ICCS teams unable to accept new referrals due to their full capacity being reached
2. Young people unable to consent due to their mental state
3. The risk profile of the young person is not compatible with ensuring their safety and/or the safety of others in the community*.

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Date of first enrolment
15/02/2022

Date of final enrolment
01/08/2023

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
South London and Maudsley NHS Foundation Trust
Enhanced Treatment Service
Snowsfields Adolescent Unit, Maudsley Hospital
Mapother House, De Crespigny Park
London
England
SE5 8AZ

Study participating centre
Central and North West London NHS Foundation Trust
Harrow Child and Adolescent Mental Health Service (CAMHS)
Ash Tree Clinic 322-326 Northolt Road
South Harrow
London
England
HA2 8EQ

Study participating centre
North East London NHS Foundation Trust
107A Barley Lane, Goodmayes
London
England
IG3 8XQ

Study participating centre
Oxford Health NHS Foundation Trust
The Highfield Unit Oxford
Warneford Hospital
Warneford Lane
Headington
Oxford
England
OX3 7JX

Study participating centre
NHS Lothian
Royal Edinburgh Hospital
Morningside Place
Edinburgh
Scotland
EH10 5HF

Study participating centre
Berkshire Health Care NHS Foundation Trust
Fitzwilliam House
Skimped Hill Lane
Bracknell
England
RG12 1JX

Study participating centre
East London NHS Foundation Trust
Newham Centre for Mental Health
London
England
E1 8DE

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

Sponsor information

Organisation
King's College London

Organisation
South London and Maudsley NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/02/2026	20/02/2026	Yes	No
Protocol article		22/02/2024	23/02/2024	Yes	No
HRA research summary			28/06/2023	No	No