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The SAFE study: Exploring a new support package for autistic children and their families

Submission date
18/03/2026

Recruitment status
Not yet recruiting

Registration date
22/04/2026

Overall study status
Ongoing

Last Edited
06/05/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Autism affects around 2% of people in the UK. Autistic children often struggle with communication and social interaction, and may experience distress or challenging behaviour. This can be hard for families, who often face poor mental health. Support after diagnosis is often not enough or suitable. A new support programme (called SAFE) has been developed with families of autistic children. SAFE includes proven approaches to help families manage the challenges of autism, such as so-called meltdowns. SAFE supports the whole family. Sessions are led by trained therapists and use talking, images, and play to explore autism-related challenges, behaviour, well-being, and coping. In the SAFE programme, there are two sessions where all the parents from 8 (+/-2) families meet with the therapists as a group, and five sessions where each family meets with the therapist separately. These seven sessions take about 20 weeks.

This study will test whether SAFE improves family mental health and coping compared to usual care, and whether it is feasible and affordable for the NHS. Usual care is what families receive from the NHS or local authority

Who can participate?
Families including a child aged 3-16 years with a diagnosis of autism severity level 1 or 2, and a Primary Caregiver. If co-morbid conditions are present in addition to autism (e.g. Attention-Deficit Hyperactivity Disorder (ADHD), Obsessive-Compulsive Disorder (OCD), Eating Disorder (ED), epilepsy), autism must be the primary diagnosis.

What does the study involve?
All families will attend an initial meeting with a study researcher to confirm eligibility and to complete some questionnaires and carry out a Lego play activity.

Two-thirds of the families taking part will be randomly selected to receive the SAFE support package and usual care. One third of families will just receive usual care. Usual care is the standard care that is offered locally.

Taking part in SAFE involves attending two three-hour sessions for parents in a group with other parents of autistic children. There are also five two-hour sessions for each family, including

children. All sessions take place in community rooms. Families will work with specially trained therapists.

Follow-up meetings take place at 5 and 12 months after random selection, where all families will meet our researchers again. They will be asked to complete the same questionnaires as per the initial meeting and will do the same Lego activity.

Families may also be invited to share their experience of the study in group feedback events.

What are the possible benefits and risks of participating?
Possible benefits:
By participating, all families will enable this study to report on the effectiveness of SAFE versus usual care and whether SAFE is cost-effective. If SAFE is shown to be beneficial and value for money in the NHS, it may be provided to families in the future. Those families who receive the SAFE intervention in the trial may directly benefit from this support programme. Families may learn different ways of helping their family cope with the challenges associated with autism. Families attending the focus group may indirectly derive peer support from sharing time with other families in a similar situation.

All families have access to usual care. At each trial location, there will be clinicians who can offer support as part of usual care, which may also be GP practices, to include those families who self-refer. In addition, families will be signposted to further support, including that provided by the NHS, local authority and third sector during the study.

Possible risks:
This is considered a low-risk study. Study procedures are not invasive and pose no significant risk to participants. A risk protocol will be initiated by research staff if a participant is perceived to exhibit new instances of suicide risk, i.e., expresses suicidal ideation, thoughts of self-harm, or thoughts of harm to others. Risk may present through responses to questionnaire items, or the participant may disclose information during study visits, e.g., SAFE sessions.

The SAFE family sessions will involve discussing difficulties and may bring about emotions and strong feelings. The SAFE family therapists will be available to discuss any thoughts and feelings that participants have at the start of each session and in between sessions.

There is a slight chance that the SAFE intervention sessions could lead to an initial increase in family disagreements as family members learn how to change the way they solve problems and talk with one another. However, the purpose of the intervention is ultimately to equip families with skills to handle these difficulties by learning how to change the way they solve problems and talk with one another, and the SAFE family therapists will be available to provide support and will be trained to handle any emerging problems

Over 12 months, a participating family will attend baseline and follow-up visits and SAFE sessions (if randomised to SAFE), and a subset will be invited to take part in interviews and focus groups. To manage burden, flexibility for families has been embedded in the trial protocol, e.g. to allow for re-arrangement of SAFE sessions, and to have additional time at baseline and follow-up to complete trial assessments.

Where is the study run from?
1. Devon Partnership NHS Trust (Sponsor site)
2. Peninsula Clinical Trials Unit (CTU)

When is the study starting and how long is it expected to run for?
August 2026 to March 2029

Who is funding the study?
National Institute for Health and Care Research (NIHR) - Health Technology Assessment (HTA) Programme, UK.

Who is the main contact?
safe2.penctu@plymouth.ac.uk

Contact information

Type(s)
Public, Scientific

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
343024

Central Portfolio Management System (CPMS)
62076

National Institute for Health and Care Research (NIHR)
167788

Study information

Scientific Title
A randomised controlled trial comparing the effectiveness of a therapist-led intervention (SAFE: Systemic Autism-related Family Enabling) plus treatment as usual versus treatment as usual only on global family functioning and mental health in three dimensions (strengths and adaptability, coping with difficulties and problem solving, communication and understanding) in families of autistic children: a multicentre assessor-blinded trial with parallel process evaluation and economic evaluation.

Acronym
The SAFE Trial V1.0

Study objectives
To compare the effectiveness of SAFE + Treatment As Usual with Treatment As Usual alone for:
1. Longer-term family functioning: measured for the main caregiver in the family, using the SCORE-15 at 52 weeks.
2.1. Family functioning: measured for the main caregiver in the family, using the SCORE-15 at 52 weeks.
2.2. Family functioning: measured for the children aged 7 or above in the family using the Child SCORE-15 at 52 weeks at 22 weeks and 52 weeks.
3. Child-parent attachment: measured by the Coding of Attachment-Related Parenting for use in children with Autism (CARP-A) at 22 weeks and 52 weeks.
4. Anxiety and depression: measured by the Patient Health Questionnaire–9 (PHQ-9) and Generalised Anxiety Disorder–7 Questionnaire (GAD-7) score at 22 weeks and 52 weeks.
5. Frequency and severity of extreme behavioural outbursts (meltdowns) experienced by the autistic child: measured by the main caregiver using a monthly record.
Also:
To assess the cost-effectiveness of SAFE + Treatment As Usual with Treatment As Usual alone.
Process evaluation objectives to:
1. Monitor how SAFE is delivered by the therapists (delivery fidelity).
2. Confirm the 'core components' that underpin the SAFE intervention (the logic model).
3. Produce a guide/toolkit in readiness for use after the trial, if SAFE is shown to be effective and cost-effective.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 29/04/2026, London - Camden & Kings Cross Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 0207 104 8086; CamdenandKingsCross.REC@hra.nhs.uk), ref: 26/LO/0247

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diagnosis of autism; if other diagnoses are present (e.g., ADHD, OCD, ED), autism must be the primary diagnosis

Interventions
CHOICE OF STUDY DESIGN AND METHODOLOGY
This study has been informed by a successful feasibility randomised controlled trial. The study has been designed to compare the effectiveness of intervention against control as would be observed in routine practice, in a rigorous randomised controlled trial (RCT). This is a definitive RCT of SAFE+TAU (intervention) versus TAU alone (control) with an internal pilot and an embedded economic evaluation and process evaluation, to be conducted in secondary care NHS Trusts in the UK.

RESEARCH PROTOCOL
Potential eligible families will first hear about the study either from their clinical team or via advertising in trial locations.

Clinical pathway:
Potential eligible families will be provided with participant information documents (PID) and a letter of invitation, either in-person during a routine appointment, or via email or post by a member of the direct care team. The PID will be supplemented by a video explaining the study developed in collaboration with Patient and Public Involvement (PPI) study members. A main caregiver (Primary Caregiver) will be defined for the study, and they will be asked to explain the study information to younger children in a way which is appropriate for their child.

If approached in person, potential participant families will be asked if they wish to receive a follow-up call from a member of the research team. If they agree, this call will take place after the family has had sufficient time to consider participation. Usually, this will be at least 24 hours after provision of the study information, but may be sooner if the family wishes.

If the family does not wish to receive a follow-up call, they will be advised that, should they reconsider, they can use the information on the PID to contact the research team directly, or self-refer via the SAFE webpage on the PenCTU website.

A member of the direct care team may contact families directly to ascertain interest if they do not respond to the letter of invitation sent via email or post.

Community pathway:
The study will be advertised via community channels in our trial locations. Appropriate means for approaching local community members will be established with our PPI networks, e.g. posters and leaflets in community venues and sharing study information via social media. Families will be invited to self-refer to the research team, either by using the research team contact details provided in the PID or via an expression of interest form on the SAFE webpage.

For families whose first language is not English:
Translated versions of the PID can be provided on request. Such families will be encouraged to bring a 'conversational partner' to all study visits; this is a trusted person who speaks both the family's native language and English. Conversational partners may also assist families in other contexts, e.g. families with hearing impairments or single parents who would benefit from additional support in sessions. Note that all participant-reported outcome measures must be completed in English and by the participant to ensure the validity of such measures.

Baseline visit and consent:
Initially, eligible and amenable families will be invited to attend a face-to-face visit with the research team at a suitable local venue at the trial location itself or in the community. For community referrals, eligibility must be confirmed via diagnostic letters and reports held by the family.

If eligible and willing to participate, a delegated member of the research team will obtain informed consent from the
adult family members and continue with the baseline assessments. Children aged under 16 years will be given the option of completing a separate study-specific assent form if they wish. Where the child does not provide assent, the researcher will work with the Primary Caregiver to address the child's concerns.

The composition of the family will be defined at this visit, including confirming the Primary Caregiver. All family members participating in the study must attend the baseline visit. The minimum requirement for each family unit is the autistic child and the Primary Caregiver, and the maximum number is 7 family members. Participants will be given the option to complete self-report measures digitally (e.g., direct entry into the survey or the MyCap app) or using paper CRFs, which will be uploaded to the study database by the researcher.

Baseline data collection (approximately 2 hours):
Following receipt of informed consent/assent, the family history and demographic data of all family members will be collected. At the same visit, the researcher will support the participant family to complete the following baseline assessments: Systemic CORE 15 (SCORE-15), Child SCORE-15, Patient Health Questionnaire - 9 (PHQ-9), Generalised Anxiety Disorder-7

Questionnaire (GAD-7), Coding of Attachment-Related Parenting for use in children with Autism (CARP-A), (EQ-5D-5L), Child Health Utility 9 Dimensions (CHU-9D), ICEpop CAPability (ICECAP-A), Resource Use Questionnaire (RUQ). Primary caregivers will also be given a template to record the monthly incidence of meltdowns.

All assessments should be completed during a single visit. If this is not possible, families will be given the option to complete the remaining assessments either online or using paper booklets within two weeks of the baseline visit. If additional support is required, the researcher may schedule a second in-person study visit with the family. In all cases, the primary outcome measure (SCORE-15) must be completed by the Primary Caregiver at the first in-person visit.

Randomisation:
Once twelve (+/-3) families have consented and completed the baseline assessments, they will be randomised en bloc to receive intervention or control. The randomisation sequence will be in place and will have been generated by a member of the Peninsula Clinical Trial Unit (PenCTU) statistics team and implemented through a secure web-based system on REDCap, ensuring allocation concealment. The system will be developed in conjunction with a statistician independent from the trial
team and will use random permuted blocks and stratified by recruiting location. The PenCTU data management team
will run checks before and during the trial to verify the integrity of the randomisation system.

Randomisation en bloc is necessary as the intervention comprises group sessions for parents. Families are randomised in a 2:1 (SAFE+TAU: TAU) ratio. Advantages of 2:1 allocation include: an increased appeal for families deciding whether to consent to randomisation based on PPI feedback; minimal reduction in statistical power for between-groups comparisons in a full-scale evaluation.

Post-randomisation:
All participating families will receive Treatment As Usual for the duration of the study (Weeks 1 to 52).

Assessments and intervention sessions for the SAFE group (Weeks 1 -20):

At an introductory visit, which is expected to take approximately 2 hours, the Family Therapist will explain the intervention schedule and answer any questions the family may have. The Family Therapist will conduct the Parent Development Interview (PDI) with each parent in preparation for the SAFE therapy sessions. Where the Primary Caregiver is not a parent, the PDI will be conducted with the PC instead. The PDI is an audio-recorded interview consisting of 20 items and takes approximately 40 minutes to complete. The full interview schedule provides background information on the relationship between the Primary Caregiver and the child, which will inform the SAFE sessions. If both parents are participating, they will both be interviewed.

The Family Therapist will also check during this visit that the family can attend the next scheduled group therapy session, explain the family reflection activity and answer any questions the family may have. The Family Therapist will also provide a schedule of the subsequent SAFE sessions scheduled for the relevant cohort to the family (two multi-parent group sessions and five individual family therapy sessions).

The SAFE intervention consists of two sessions with all of the parents as a group (3 hours per session) and five sessions as an individual family (2 hours per session). The SAFE intervention can be delivered in 13 weeks, but the sessions are built in flexibility as standard practice to account

for family availability and rescheduling. 20 weeks will be allocated for the intervention. The aim is to schedule the first SAFE intervention session within two weeks of randomisation, but this will depend on family availability and time to recruit a full cohort at each trial location.

At a minimum, the autistic child and Primary Caregiver from each family must attend each intervention session. Where this is not possible, the family therapy session (including group sessions) must be rearranged. Individual catch-up sessions may be arranged for other family members who are unavailable to attend a session, though best endeavours should be made for all family members (as defined at the baseline visit) to attend every session. The number of sessions a family may reschedule will be at the Family Therapist's discretion, based on family circumstances, motivation and levels of problems/distress.

Assessments for all families (Weeks 22 and 52):
All families will be followed up at 22 weeks and 52 weeks via a face-to-face visit with a researcher. The visit will take place in a community venue or at another setting, such as a venue provided by the trial location, if convenient and acceptable to both the family and the researcher.

All outcome measures conducted at the baseline visit will be repeated at both follow-up visits, with support from the researcher. Families will be reminded to bring their diary of behavioural meltdowns to each follow-up visit. The same arrangements as described for the baseline visit will be in place, i.e., prioritising competition of the primary outcome at the visit and arranging a second visit with support as necessary to complete the full set of measures.

Separately, a subset of families will be invited to take part in focus groups. Families from both arms of the study will be approached to take part in a focus group by the researcher via a verbal discussion and provision of a Participant Information Sheet. Informed consent will be obtained by the suitably qualified member of staff prior to any data collection. The aim of the focus group is to hear about the families' experiences of being in the SAFE study (what has changed for the family, what was good, what was not good, and what is next for the family)

Focus groups at Week 22 will be conducted in person at an acceptable and secure venue by the local researcher at each trial location. One focus group will be with the second cohort receiving the intervention to represent earlier delivery, and one focus group with the sixth (or final) cohort receiving the intervention to represent later delivery. This is 18 focus groups in total. Each focus group will consist of 6-10 families and last up to 3 hours.

One focus group will be conducted at each location by the local researcher following the week 22 post-randomisation visit of the sixth (or final) cohort, inviting all families who have participated in the control arm across all previous cohorts at each location (to compensate for the 2:1 randomisation). This is 6 focus groups in total. Each focus group will consist of 6-10 families.

Following the week 52 post-randomisation visit of the 6th (or final) cohort at one trial location, two separate focus groups will be conducted for the intervention and control arm. Invitations will extend backwards through the cohorts to recruit 6-10 families still engaged in the study.

All in-person and remote data collection for focus groups and interviews will be digitally recorded and transcribed verbatim.

Interviews with families who decline participation:

When an eligible family declines to participate in the study, the primary caregiver will be invited by the local researcher to engage in a short, focused telephone interview (~10 mins) to discuss their decision not to participate, and the findings will be reported to the Trial Management Group for consideration.

Interviews with families who withdrew participation:
When a family withdraws from the study, the local researcher will make a phone call to invite the primary caregiver to engage in a short, focused telephone interview (~10 mins) with them to discuss the reasons for their decisions, and how the main trial can be designed to address these issues. The findings will be reported to the Trial Management Group for consideration.

PROCEDURES TO DETECT POSSIBLE RESEARCHER EFFECTS:
1) Blinding
The coordinating trial management team will be blinded to treatment allocation.

It's not possible to conceal from families whether they will receive intervention or control: the trial is not blinded to participants.

Family therapists will also be aware of the participant's allocation to intervention or control, and they will be discouraged from communicating with other members of the local research team about this.

Family therapists will be responsible for scheduling intervention sessions for those allocated to intervention to protect the blind as much as possible from the researchers (assessors) undertaking the follow-up assessments at weeks 22 and 52. Families will be asked not to reveal their allocation to the assessor, but it is possible that this will occur. The success of outcome assessor-blinding will be evaluated at each follow-up visit by asking assessors to record the treatment group to which they think a participant has been allocated, and any cases of inadvertent unblinding, in the case report form.

The data collection at all follow-up assessments is largely self-reported by the participant families, which reduces the possibility of introducing reporter bias for these assessments. The CARP-A is an observational measure; therefore, to minimise bias, a sub-sample of videos of the participant families will be viewed and assessed by a Research Fellow in the central team at the University of Plymouth.

PenCTU will hold the key to the allocation. The trial statistician responsible for undertaking the analyses will be blinded to allocated groups at least until the statistical analysis plan is finalised and signed off by an independent statistician. An unblinded statistician will assist with the preparation of the Data Monitoring and Ethics Committee report and perform treatment allocation balance checks.

Video analysis of intervention sessions will be used for supervision and also for oversight of therapist adherence by designated supervision therapists.

The Therapist Checklist Questionnaire (TCQ), assessing protocol adherence, ease of delivery, and therapist confidence, will be completed by SAFE family therapists after every SAFE intervention session. The Helpful Aspects of Therapy (HAT) questionnaire will be completed by families after each SAFE session, capturing satisfaction with sessions and contributing to fidelity checking.

SAMPLE SIZE FOR THE PROJECT:
Families will be recruited via six trial locations and associated community pathways. The target sample size is 494 families (330 in the intervention group and 164 in the control group). This has been calculated by the trial statisticians, based on available literature, including the SAFE Feasibility Study, to detect a minimal clinically important difference of three on the primary outcome measure. In brief, the sample size calculation takes into account a possible multi-parent group effect in the intervention group, and loss to follow-up in the trial.

The sampling strategy for the focus groups has been determined by the process evaluation and implementation co-applicants (TT and JG) in conjunction with the Chief Investigator, taking account of participant burden and researcher capacity.

Discussions with potential participating locations have informed the planned recruitment rate for the trial.

TIMETABLE FOR THE STAGES OF THE RESEARCH:
The project started in October 2025 and lasts 48 months as follows: set-up in months 1-9; recruitment, intervention and follow-up in months 10 to 32 months, analysis and write-up in months 41-48.

PLANNED INTERIM ANALYSES/REPORTS:
An internal pilot, lasting for 6-months after recruitment commences, will be conducted. Pre-defined progression criteria for the internal pilot will be used to determine whether the trial will progress. The internal pilot report will be submitted to the funder.

ADVICE FROM STAKEHOLDERS:
PPI contributors were consulted throughout. Feedback and insights were provided at the design stage on: all participant-facing documents, including the study logo, tone and language used (especially related to autism) and presentation of documentation (colourways); burden of outcome measures; topic guides for interviews and focus groups.

Intervention Type
Behavioural

Primary outcome(s)
1. Family functioning and caregiver mental health measured using the Systemic CORE-15 (SCORE-15) total score at at baseline and at 22 weeks post-randomisation

Key secondary outcome(s))
1. Family functioning measured using the Systemic CORE-15 (SCORE-15) total score at baseline and at 52 weeks post-randomisation

2. Family functioning strengths and adaptability measured using the strengths and adaptability dimension score of the Systemic CORE-15 (SCORE-15) at baseline, 22 and 52 weeks post-randomisation

3. Family functioning coping with difficulties and problem solving measured using the coping with difficulties and problem-solving dimension score of the Systemic CORE-15 (SCORE-15) at baseline, 22 and 52 weeks post-randomisation

4. Family functioning communication and understanding measured using the communication and understanding dimension score of the Systemic CORE-15 (SCORE-15) at baseline, 22 and 52 weeks post-randomisation

5. Family functioning from the child perspective for children aged 7 years or older measured using the Child Systemic CORE-15 (Child SCORE-15) total score at baseline, 22 and 52 weeks post-randomisation

6. Child-reported family strengths and adaptability for children aged 7 years or older measured using the strengths and adaptability dimension score of the Child Systemic CORE-15 (Child SCORE-15) at baseline, 22 and 52 weeks post-randomisation

7. Child-reported coping with difficulties and problem solving for children aged 7 years or older measured using the coping with difficulties and problem solving dimension score of the Child Systemic CORE-15 (Child SCORE-15) at baseline, 22 and 52 weeks post-randomisation

8. Child-reported communication and understanding for children aged 7 years or older measured using the communication and understanding dimension score of the Child Systemic CORE-15 (Child SCORE-15) at baseline, 22 and 52 weeks post-randomisation

9. Child-parent attachment measured using the Coding of Attachment-Related Parenting for use with autistic children (CARP-A) score at baseline, 22 and 52 weeks post-randomisation

10. Primary caregiver anxiety and depression measured using the Patient Health Questionnaire-9 (PHQ-9) score and the Generalised Anxiety Disorder-7 (GAD-7) questionnaire score at baseline, 22 and 52 weeks post-randomisation

11. Frequency and severity of extreme behavioural outbursts experienced by the autistic child participant measured using a non-validated measure at a monthly time point, from baseline to 52 weeks post-randomisation

12. Resources required to provide the SAFE intervention measured using participant-level intervention resource use data collected at time points during the course of the intervention

13. Health-related quality of life and quality-adjusted life years (QALYs) for adult participants measured using QALYs derived from the EQ-5D-5L at at baseline, 22 and 52 weeks post-randomisation

14. Health-related quality of life and quality-adjusted life years (QALYs) for child participants measured using QALYs derived from the Child Health Utility 9 Dimensions (CHU-9D) at baseline, 22 and 52 weeks post-randomisation, with proxy completion by the primary caregiver for children aged 5 to 6 years and the CHU-9D proxy version for children under 5 years of age

15. Capability wellbeing and years of full capability (YFCs) measured using YFCs derived from the ICEpop CAPability measure for Adults (ICECAP-A) at baseline, 22 and 52 weeks post-randomisation

16. Health, social care and wider societal resource use measured using a bespoke Resource Use Questionnaire informed by previous RUQs and co-developed with the PPI group at at baseline, 22 and 52 weeks post-randomisation

Completion date

31/03/2029

Eligibility

Key inclusion criteria
Families must satisfy all the following criteria to be enrolled in the study:
1. Family includes autistic child, aged 3-16 years*.
2. Diagnosis of autism, severity level 1 or 2 (in accordance with DSM-5).
3. If other diagnoses are present (e.g., ADHD, OCD, ED), autism must be the primary diagnosis.
4. Family are willing and able to comply with study requirements.

*In families with more than one eligible child, only one can be the family index case.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
3 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Families who meet any of the following criteria will be excluded from study participation:
1. Serious concomitant illness in the child or family, or other circumstances affecting compliance with study requirements.
2. Risk to the safety of research staff*.
3. Family currently or due to take part in family therapy-based intervention during study participation.
4. Individual family members already taking part in the SAFE trial as part of another family unit.
5. Unable to understand or communicate in English**.

*Examples of risk: Violent behaviour causing injury that requires treatment, or a family member who has a serious infectious disease.

**English language: This is due to the delivery of the SAFE intervention being in English. Those who speak English as an additional language will be eligible to take part, but will be encouraged to attend appointments with a conversational partner if necessary to assist with study delivery.

Date of first enrolment
01/08/2026

Date of final enrolment
31/03/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Prestwich Hospital
Bury New Road
Prestwich
Manchester
England
M25 3BL

Study participating centre
Kingsway Hospital (headquarters)
Kingsway
Derby
England
DE22 3LZ

Study participating centre
Wonford House Hospital
Dryden Road
Exeter
England
EX2 5AF

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
England
RM13 8GQ

Study participating centre
Leicestershire Partnership NHS Trust
Room 100/110 Pen Lloyd Building
County Hall
Leicester Road
Leicester
England
LE3 8RA

Study participating centre
Central and North West London NHS Foundation Trust
Trust Headquarters
350 Euston Road
Regents PLACE
London
England
NW1 3AX

Sponsor information

Organisation
Devon Partnership NHS Trust

ROR
https://ror.org/04fkxrb51

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the Devon Partnership NHS Trust (tobit.emmens@nhs.net).

- The type of data: Anonymised individual participant data and supplementary files (e.g. data dictionaries, blank data collection forms, analysis code)
- When the data will become available and for how long: After the trial has been reported, for 20 years
- By what access criteria data will be shared, including with whom, for what types of analyses, and by what mechanism: Requestors whose proposed use of the data has been approved by the Chief Investigator and Sponsor, under and an appropriate data sharing agreement
- Whether consent from participants was obtained: Participants have consented to the sharing of their anonymised data
- Comments on data anonymisation: Participants will be identified in all study-related documentation by their study number and initials, and all data collected and analysed will be pseudonymised by the use of this unique identifier. Audio data will be transcribed, pseudonymised and deleted as soon as is practicable
- Any ethical or legal restrictions: None
- Any other comments): None

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	20/02/2026	06/05/2026	No	No
Study website			21/04/2026	No	No