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Co-design and feasibility trial of well-being groups for autistic 11-16 year olds

Submission date
08/12/2025

Recruitment status
Recruiting

Registration date
11/12/2025

Overall study status
Ongoing

Last Edited
11/12/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This is a feasibility study of psychological well-being groups for autistic teenagers, called an autism social identity group (a-island). The aim is to check if it is possible to do a larger study in future to see if a-island is effective in improving well-being.

Who can participate?
Autistic 11-16-year-olds

What does the study involve?
Participants will be randomly placed into two groups. One group will be signposted to the standard care offered to autistic teenagers in their area. The other group will attend a-island groups. Participants will be asked to fill out questionnaires before receiving any support, and after 10, 16, and 24 weeks. The questionnaires will measure psychological well-being, mental health, and use of health and care services. A real-time app measure of autism identity and well-being will be completed over 5 days at the beginning of the study and again after 16 weeks. Participants will be paid with a shopping voucher for completing questionnaires. The researchers will hold focus groups with autistic young people, parents, and a-island facilitators to understand what it was like taking part in the research. This will then be used to improve a-island before doing the next, bigger study.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
January 2026 to October 2030

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

Who is the main contact?
Dr Kate Cooper, k.r.cooper@ucl.ac.uk

Contact information

Type(s)
Scientific

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Central Portfolio Management System (CPMS)
70134

National Institute for Health and Care Research (NIHR)
303189

Integrated Research Application System (IRAS)
349807

Study information

Scientific Title
Feasibility trial of autism social identity groups for psychological well-being in autistic adolescents

Study objectives
1. Assess the rates of recruitment and retention to inform the design of a full-scale RCT
2. Assess the acceptability of randomisation and outcome measurement procedures to participants
3. Characterise usual practice
4. Assess the acceptability of a-island groups and usual practice interventions

5. Calculate outcome measure variances with confidence intervals for use in a power calculation for a full trial
6. Evaluate psychometric properties of the EMA measure

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/11/2025, West of Scotland REC 1 (West of Scotland Research Ethics Service, Admin Building, Level 2, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12 0XH, UK; Tel: Not available; ggc.wosrec1@nhs.scot), ref: 25/WS/0137

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Autism

Interventions
A feasibility design has been selected because this will be the first trial of its kind, testing a new co-designed intervention in autistic young people.

The study will assess the feasibility and acceptability of conducting an Randomised Controlled Trial (RCT) with two arms:
1. a-island groups, a co-designed online peer-group intervention to promote well-being in autistic 11-16 year olds
2. Care as Usual (CAU) for autistic young people

The study sponsor and site will be University College London (UCL). This is where all eligibility assessments and following research procedures will be conducted, and all data will be held at UCL.

Recruitment will take place across a wide range of settings. These will include: NHS Participant identification centres (PICs) including secondary care autism diagnostic clinics and CAMHS; educational settings; autism research databases; social media (e.g., TikTok; Facebook parent groups; Instagram; X).

We aim to recruit 70 participants (with a maximum sample size of 84) to be recruited and randomised to a-island and usual practice. A sample size of 70, with 80% follow-up rates, is deemed sufficient to inform a sample size calculation for a full RCT and to evaluate the rates of recruitment and retention with sufficient precision. The same sample size was used in the HTA-funded ADEPT feasibility trial, which recruited autistic adults. This study successfully met its feasibility aims including the sample size calculation for the definitive ADEPT-2 study. We will recruit a maximum of 84 participants to allow for appropriate group sizes.

Recruitment will be through national autism charities such as the NAS and Ambitious about Autism, as well as NHS services (CAMHS and paediatric autism diagnostic assessment clinics); social media; charities; research registers. Interested participants and/or their parents will complete the expression of interest form which will be screened by study staff. Potentially eligible participants will be invited to a baseline assessment via video call (or in person if that is the participant's preference). Participants will be sent the information sheet in advance. They will also be sent the questionnaires, which they can complete in advance of the appointment, or with support of a researcher, if they prefer.

The questionnaires include validated measures of well-being, quality of life, mental health, self-esteem, loneliness, and for parents, resource use and carer impact. In the appointment, consent /assent procedures will be followed as above. The risk SOP will be followed throughout. The researcher will help the young person set up the ecological momentary assessment app and check that it is working. Ecological momentary assessment measures will be taken for 5 days following baseline, with three app alerts per day for 5 consecutive days. The app will ask brief questions about well-being, mental health and autism social identity.

Following the baseline appointment, and within 2 weeks before the next group start date, the researcher will complete randomisation via sealed envelope. Randomisation will allocate participants on a 1:1 ratio to receive either the autism social identity groups or usual care. Randomisation will be stratified by age (11-13 or 14-16 years). Participants will be notified of the outcome using the approved email template. GPs will also be notified via letter.

Participants allocated to a-island groups will attend the groups online for eight consecutive weeks. Sessions will be 1 hour long and facilitated by two adults, one of whom will be autistic. The groups will involve storytelling and character development with the aim of helping participants learn about autism, create a group identity, identify strengths linked to autism, and navigate challenges. In week one and week eight of group attendance, participants will be asked to complete ecological momentary assessment measures. They will be notified on an app to complete brief measures relating to autism social identity, well-being, mood, and anxiety. This will happen three times a day for 5 days. All participants will be interviewed about their experiences of attending the groups and completing the EMA questionnaire. The interviews will be audio recorded and with permission, key parts of the interview will be played to the stakeholder group. The stakeholder group will work to improve the intervention and ecological momentary assessment measure.

Participants allocated to usual care will be provided with information about accessing services available to them. Follow-up assessments will occur at 10, 16 and 24 weeks after randomisation. They will be sent by email to participants and their parents, and the research team will send reminders if they are not completed. Participants will be sent a £10 shopping voucher for each follow-up assessment they complete. Ecological momentary assessment will be repeated at 16-weeks. Participants will receive a £5 voucher for each day of app measurement they complete, with up to £25 offered for each five-day period of app questionnaires.

Participants who consent to be contacted about attending focus groups will be invited to attend these. Four focus groups will be conducted: two groups with participants allocated to a-island (n = 12), one with parent/carers (n = 6), and one with intervention facilitators (n = 6). The aim will be to understand participant experiences of trial procedures including information about the study, baseline and follow-up procedures, and randomisation, as well as experience of the interventions. Focus groups will be audio recorded and transcribed, and analysed using reflexive thematic analysis. When participants have completed their final follow-up, an end of trial letter will be sent to their GP.

University College London is the data controller for the a-island trial. Data will conform to University College London Data Security Policy and in compliance with the UK GDPR, alongside the Data Protection Act 2018.

Intervention Type
Behavioural

Primary outcome(s)
1. Completion rates and outcome measure variances of the Warwick Edinburgh Wellbeing Scale (WEMWBS) measured using the WEMWBS at 16 weeks following randomisation

Key secondary outcome(s))
The 10-, 16- and 24- week completion rates and outcome measure variances of:
1. Identification with the autistic community measured using the Autism Social Identification Measure
2. Quality of life measured using EQ-5D-Y-5L
3. Mental health measured using the Revised Children's Anxiety and Depression Scale (RCADS) (self and parent report)
4. Social anxiety and fear of negative evaluation measured using the Social Anxiety Scale for Adolescents
5. Self-esteem measured using the Rosenberg Self-Esteem Scale (RSES)
6. Loneliness measured using the UCLA Loneliness Scale
7. Resource use measured using the Adapted Client Service Receipt Inventory (CSRI) (completed by parents)
8. Carer impact measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) and the Autism Parenting Stress Index (APSI)

Completion date
01/10/2030

Eligibility

Key inclusion criteria
1. Young people aged 11-16 years
2. A professional diagnosis of Autism Spectrum Disorder (ASD)
3. Residing in England or Wales
4. Willing and able to attend group sessions during the available dates and times

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 years

Upper age limit
16 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Participants who report that they have received 3 or more sessions of autism post-diagnostic support or psychoeducation from a health professional over the past 12 months will be excluded from the study
2. Risk of harm to self (suicidal intent and persistent serious self-harm) that would mean that a group well-being intervention is not appropriate. In terms of risk to self, the RCADS-25 will be administered to all potential participants. If the participant endorses (i.e. selects “sometimes, “often” or “always”) for items 18 (I think about death) and item 25 (I worry that something bad will happen to me), then follow-up will be conducted by the research assistant and qualified clinician where necessary, following the risk standardised operating procedure (SOP). Where clinic assessment or research follow-up is indicative that there is current suicidal intent, and/or self-harm which is serious and persistent, this will be communicated to the relevant health care professional (e.g., GP) and the participant will be excluded from the study.
3. Current mental health intervention such that this level of intervention is not clinically appropriate. During the expression of interest, potential participants will be asked if they are currently accessing mental health support. In such cases, permission to contact their mental health clinician will be sought to ensure that attending a group will not interfere with other ongoing interventions, and to ensure that the a-island groups would be a clinically appropriate intervention at the current time. If clinical discussion indicates that the well-being intervention is not clinically appropriate, the participant will be excluded from the study.
4. Risk of harm to others such that group participation would not be appropriate. This will be assessed by asking a series of questions about the individual’s school exclusion and forensic history (following the Risk SOP). If clinical or research follow-up identifies past behaviour towards others which has been directly related to an exclusion from a group environment or conviction/warning from the criminal justice system, the participant will be excluded from the study. In cases where the participant indicates that their GP or another relevant authority is not aware of this history, this will be communicated to the GP.
5. English, non-English & Welsh literacy levels such that the intervention materials are inaccessible without reasonable adjustments and a supporting person is not available. This will be established by information provided during the eligibility assessment when it is difficult to gain consent to participate in the research because of difficulties reading and thus comprehending the study information sheet. We will strive to include all potential participants in the study if supporters are available to help an individual access the treatment where written /spoken English, non-English & Welsh presents a barrier.

Date of first enrolment
05/01/2026

Date of final enrolment
01/02/2028

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
-
-
England
-

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

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 anonymised quantitative datasets generated during and/or analysed during the current study will be made available to other researchers upon request, including only participants who gave consent for this data sharing, once the study analysis is complete and published from Kate Cooper (k.r.cooper@ucl.ac.uk).

IPD sharing plan summary
Available on request