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A group psycho-education therapy intervention for adolescents with early-onset psychosis and their families

Submission date
13/07/2026

Recruitment status
No longer recruiting

Registration date
29/07/2026

Overall study status
Ongoing

Last Edited
29/07/2026

Condition category
Mental and Behavioural Disorders

[ ] 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
Early onset psychosis (EOP) refers to symptoms of psychosis occurring before the age of 18. Those with EOP experience 'positive' symptoms, which refer to delusions or hallucinations. They can also experience 'negative' symptoms such as loss of motivation or reduced emotional expression. EOP disrupts adolescents' familial and social relationships and their day-to-day functioning. Adolescents with EOP are particularly likely to develop 'negative' symptoms, but there are few effective treatment options available that target this. One possible way to help adolescents with negative symptoms is through group psycho-educational intervention which aims to provide adolescents and their families with information about psychosis and support them to develop strategies for managing symptoms.

The study aims to understand whether it is feasible to deliver this intervention via Child and Adolescent Mental Health Services (CAMHS) by recording the number of people who are interested, eligible, consent to and complete or drop out of the intervention. The study also aims to find out whether this type of intervention is acceptable to adolescents with EOP and their families through conducting interviews. It will gather initial information about how effective this intervention is at reducing negative symptoms and improving daily functioning in adolescents with EOP using questionnaires completed before and after the intervention.

Who can participate?
Adolescents aged 13 to 18 years, diagnosed with EOP who have at least one negative symptom and are living at home with their parent or caregiver.

What does the study involve?
Individuals will be recruited via CAMHS across the four NHS South London and Maudsley NHS Foundation Trust (SLaM) boroughs (Croydon, Lambeth, Lewisham and Southwark). The intervention will run for 10 one-hour sessions, and there will be separate group sessions for adolescents and their family/caregiver, taking place weekly. The intervention will take place over a three- to four-month period.

What are the possible benefits and risks of participating?
Participants may benefit from taking part in a psychological intervention that has been specifically developed for young people with psychosis and negative symptoms. As this is a new intervention being evaluated, it is not yet known whether it will have a positive effect. By participating, young people and their parents or carers will also contribute to research that may help improve future psychological therapies. Participants will have the opportunity to share their experiences and feedback on what they found helpful and what could be improved, helping to shape future interventions.

Disadvantages or risks to families are not anticipated. There is a time commitment required, but where possible the sessions will be scheduled to minimise any impact on participants' daily routine. Topics of a sensitive nature may be discussed during collection of questionnaires or group intervention sessions. These questions will be asked sensitively by trained members of the research team who will be available to support participants if they or the young person they care for experiences distress.

Where is the study run from?
King's College London, Institute of Psychiatry, Psychology and Neuroscience, UK.

When is the study starting and how long is it expected to run for?
May 2026 to April 2028.

Who is funding the study?
The Spanish Association of Child and Adolescent Psychiatry (AEPNyA).

Who is the main contact?
Dr Gonzalo Salazar de Pablo - Gonzalo.salazar_de_pablo@kcl.ac.uk (Chief Investigator)
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Additional identifiers

Integrated Research Application System (IRAS)
362216

Central Portfolio Management System (CPMS)
73340

Study information

Scientific Title
Group psycho-education intervention for negative symptoms in adolescents with early onset psychosis and their families: pilot acceptability and feasibility study

Study objectives
The principal objective is to understand whether a group psycho-education psychotherapy intervention for adolescents with early-onset psychosis and negative symptoms is acceptable to adolescents and their families and feasible to deliver via Child and Adolescent Mental Health Services.

The secondary objective is to examine the preliminary outcome data on the efficacy of the intervention in alleviating negative symptoms of psychosis and improving functioning.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/05/2026, North West - Liverpool Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 0207 104 8340; liverpoolcentral.rec@hra.nhs.uk), ref: 26/NW/0082

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Schizophrenia, schizotypal and delusional disorders

Interventions
This is a single-arm pilot feasibility and acceptability study. There will be no comparison group; all participants recruited in the study will be offered the intervention.

Recruitment:
Individuals will be recruited via CAMHS across the four SLaM boroughs (Croydon, Lambeth, Lewisham and Southwark).
The study aims to recruit between 6 and 8 adolescents and 12 to 16 parents in total.
To recruit a sufficient number of participants, at least 4 to 6 participants will need to be recruited per month over the
proposed recruitment period of six months.
Intervention sessions will commence once a sufficient group size has been recruited, of approximately 3 to 6 for the
adolescent groups and 6 to 8 for the parent/carer group.
Eligible participants will be identified by care team clinicians at each site via their current caseload. Participants who
have indicated Consent For Contact (C4C) for research studies will be identified by the CRIS team and screened by
age and diagnosis (if available).

Screening:
The 4-item Negative Symptom Assessment will be used to screen for negative symptoms and the Schedule for
Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime version, or the Structured Clinical
Interview for DSM Disorders will be used to confirm diagnosis of EOP, depending on the participant's age.

Enrolment session:
Written consent/assent will be collected in person electronically at the Lambeth CAMHS site (35 Black Prince Road,

Kennington, London, SE11 6JJ), providing participants with the opportunity to ask questions prior to agreeing to take
part in the study. Baseline secondary outcome measures will also be collected at this time.

Intervention:
A culturally adapted version of the PIENSA programme psycho-education manual will be delivered. The sessions will
cover: negative symptoms and their impact, development of problem-solving strategies and coping skills,
management of medication and associated side effects and crisis management.

Participants will complete 10 60-minute psycho-education psychotherapy sessions. Adolescents and their families
will attend separate sessions on a weekly basis.

The intervention will take place online, via Microsoft Teams.

Post-intervention questionnaires and interview:
Post-intervention secondary outcome data will be collected within one week of intervention completion. Post-intervention semi-structured interviews will be delivered by a member of the research team with all participants. Post-intervention outcome data collection will take place online, via Microsoft Teams.

Intervention Type
Behavioural

Primary outcome(s)
1. Acceptability of the intervention measured using individual semi-structured post-intervention interviews, based on the Theoretical Framework of Acceptability (TFA), and the Experience of Service Questionnaire (ESQ) at the end of the intervention

2. Feasibility measured using data collected on the percentage of participants that 1) express interest in/ are referred to the study, 2) are eligible to take part, 3) consent, 4) complete/drop-out from the intervention at the end of the intervention

Key secondary outcome(s)
1. Negative symptoms measured using the Clinical Assessment Interview for Negative Symptoms (CAINS) at baseline and end of intervention

2. Overall severity of illness measured using the Clinical Global Impression – Severity scale (CGI-S) at baseline and end of intervention

3. Level of functionality measured using the Global Assessment of Functioning scale (GAF) at baseline and end of intervention

4. Depressive symptoms measured using the Montgomery-Åsberg Depression Rating Scale (MADRS) at baseline and end of intervention

5. Manic symptoms measured using the Young Mania Rating Scale (YMRS) at baseline and end of intervention

6. Wellbeing measures measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) at baseline and end of intervention

7. Quality of life measured using the Quality of Life Scale (QOLS) at baseline and end of intervention

8. Involuntary movements measured using the Abnormal Involuntary Movement Score (AIMS) at baseline and end of intervention

9. Healthcare resource use, comprising the number of adolescent hospital admissions, number of days of psychiatric hospitalisation, medications, and number of visits to the emergency department measured using data collected from patient medical records at the end of the study

10. Feasibility of the intervention, comprising the percentage of participants who 1) attend the enrolment session and 2) complete pre- and post-intervention measured using questionnaires and interviews at post-intervention

Completion date
01/04/2028

Eligibility

Key inclusion criteria
Adolescents must:
1. Aged 13 to 18 years
2. Living at home with either one or both parents, carers, or legal guardians
3. Diagnosed with schizophrenia or “unspecified schizophrenia spectrum and other psychotic disorder” according to established diagnostic instruments - K-SADS-PL, or SCID depending on the age, diagnosed with “major depression with psychotic features” or “bipolar disorder with mood congruent psychotic features” according to established DSM-5 criteria
4. Have at least one negative symptom according to NSA-4
5. Be currently allocated to a mental health team within SLaM

Parent/ Carer participants must:
1. Be the parent, carer or legal guardian of the adolescent participant
2. Be living at home with the adolescent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
13 Years

Upper age limit
18 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Adolescents must:
1. Be able to independently understand and provide spoken and written responses during study procedures
2. Not be diagnosed with an established neurological developmental disorder, which would mean that they are unable to engage with the intervention
3. Not be participating in other research projects involving psychological intervention for psychosis
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5. Not be diagnosed with an established neurological developmental disorder, which would mean that they are unable to engage with the intervention
6. Not be participating in other research projects involving psychological intervention for psychosis

Parent/ Carer participants must:
1. Be able to independently understand and provide spoken and written responses during study procedures
2. Not be diagnosed with an established neurological developmental disorder, which would mean that they are unable to engage with the intervention
3. Not be participating in other research projects involving psychological intervention for psychosis

Date of first enrolment
25/05/2026

Date of final enrolment
09/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
England
BR3 3BX

Study participating centre
Kings's College London, Institute of Psychiatry, Psychology & Neuroscience
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SE5 8AB

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
King's College London

Alternative Name(s)
King's College, King's College London UK, KCL, King's

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Spanish Association of Child and Adolescent Psychiatry (AEPNYA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date