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Parenting intervention for parents with psychosis in adult mental health services

Submission date
21/12/2023

Recruitment status
Recruiting

Registration date
08/01/2024

Overall study status
Ongoing

Last Edited
06/01/2026

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
Around 2 in 100 people in the UK experience psychosis and the majority of these are parents. The stress of parenting can worsen psychotic symptoms and parents with psychosis need help early. Their children tend to do less well in life and are more likely to develop mental health problems themselves. Several government and NHS bodies recognise the importance of good parenting in preventing poor mental health and breaking this cycle.
A self-directed parenting programme, called TripleP, could be useful for parents with psychosis. TripleP reduces parenting stress by improving parenting skills and child behaviour but we do not yet know how well it works for parents with psychosis. We offered it to ten parents in a small pilot study. Afterwards, parents reported feeling less stressed and more confident as parents. Their psychotic symptoms and their children's behaviours improved.
Parents have told us that they do not want parenting support from family services, because these services do not understand the added burden that psychosis brings. Parents would rather receive this type of support from mental health staff, with whom they have an established relationship. Staff say they would be willing to help parents, but services do not routinely offer this type of intervention.
This study will compare TripleP to usual care within adult mental health services. People taking part will receive either TripleP in addition to their usual care or usual care alone. Which group people are in will be selected at random.
Parents offered TripleP can choose to access it online or via a workbook because both approaches work equally well and not all families have internet access.
The aim of the study is to find out if the researchers can recruit 75 parents with psychosis, whether they will complete TripleP, and whether they can be retained in the study.
The researchers will measure parenting stress, confidence, mental health and wellbeing alongside children's behaviour at the start (baseline), after 16 weeks (end of programme) and after 39 weeks (follow-up), comparing the two groups at the end. They will also interview parents and staff to explore their experiences of taking part. The researchers want to find out what was easy or difficult, and if there were any benefits or otherwise. This information will help determine the best way of delivering TripleP to parents with psychosis and to design a full clinical trial to test TripleP further in the future.
The study was designed by researchers, clinicians and parents with lived experience of psychosis. Parents will continue to be involved throughout. They will contribute to all aspects of the study,

from designing materials at the start, to producing reports at the end. This co-production will ensure the study is relevant to their needs.

Who can participate?
People aged 18 years or over who have experienced psychosis, are under the care of an adult mental health team, and who have a child aged 2 and 12 years old.

What does the study involve?
Following consent, participants will be asked to meet with a researcher to complete some questionnaires about parenting stress, parenting confidence and child behaviour as well as an interview about how they have been feeling. We will then allocate participants, by chance, into one of two groups. The first group will receive usual NHS care. The second group will receive usual NHS care and will also be given access to the Triple P parenting programme. Parents in the Triple P group will choose whether they want to access it online, or via a workbook. They will be given 15 weeks to work through the activities in the book or online programme. The activities focus on 'positive parenting' for example spending quality time with children; using good behaviour charts; planning activities to prevent problems and encouraging independence. The care coordinators of parents in this group will be asked to check in with parents to see how they are getting on with the programme.
After completing the programme, roughly 4 months into the study, a member of the research team will meet with participants for the follow-up assessment, which involves completing the questionnaires they helped the team with at the beginning of the study and taking part in another interview about how they are feeling. They may also be asked to take part, if they wish to, in a more in-depth interview with a member of the research team about their experiences of the programme. Another 3 months after this, participants will be asked to complete the same questionnaire and interview again.
Participants who were allocated to receive usual NHS care will be asked to complete the questionnaires and take part in an interview about how they are feeling 4 months and 7 months after starting the study. They will be offered a copy of the Triple P workbook after these last assessments.
The researchers will interview 12-15 care coordinators to explore their experiences of supporting parents to take part.

What are the possible benefits and risks of participating?
About two-thirds of the parents in the study will be allocated at random to the Triple P group. It is possible that accessing Triple P will improve how they manage their children their and benefit their mental health. However, this cannot be guaranteed. The information we get from this study will help us to better support parents with psychosis in the future.
The assessments involve parents talking about their children and how they are feeling, which they may find upsetting. Participants will have the opportunity to discuss any concerns they have with the researchers, and they are free to withdraw from the study at any point without giving a reason. If they decide they would like to withdraw from the research, this decision will not affect any care they may receive now or in the future.

Where is the trial run from?
Greater Manchester Mental Health NHS Foundation Trust (UK)

When is the trial starting and how long is it expected to run for?
January 2023 to September 2025

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

Who is the main contact?
Lynsey Gregg, lynsey.gregg@manchester.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
330481

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NHS002117, IRAS 330481, CPMS 60061

Study information

Scientific Title
Parenting Intervention for Parents with Psychosis in Adult mental health services (PIPPA): an acceptability and feasibility trial

Acronym
PIPPA

Study objectives

It is feasible to deliver a randomised controlled trial of a parenting intervention (self-directed Triple P) to parents with psychosis within adult mental health services

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/03/2024, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (2 Redman Place, London, EC20 1JQ, United Kingdom; +44 (0)207 104 8096; cambsandherts.rec@hra.nhs.uk), ref: 23/EE/0273

Study design
Assessor-blind feasibility randomized controlled trial with nested process evaluation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adults with psychosis who have dependent children aged 2-12 years old

Interventions
Following baseline assessment, participants (parents, n = 75) will be allocated in random permuted blocks using an online service (REDCap) to either Triple P plus TAU or TAU only. Allocation will be in a ratio of 2:1 to maximise information collected on Triple P and will be concealed until participants are randomised. Randomisation will be stratified according to baseline parenting stress scores.

Participants in the control group will receive usual NHS care, which will be in line with all standard and individually prescribed clinical interventions as directed by national clinical guidelines for psychosis (National Institute for Health and Care Excellence, 2014) and the participants' clinical teams.

Participants in the Triple P group will be given access to the Triple P programme either online or via the workbook (according to individual preference) and will be given 15 weeks to work through the activities within it. Care coordinators will be asked to check in with participants, to prompt engagement.

Care coordinators (n = 12-15) will not receive an intervention and will take part in qualitative interviews only.

Intervention Type
Behavioural

Primary outcome(s)
The feasibility of delivering a full-scale, assessor-blind, randomised controlled trial within adult mental health services in the future regarding:
1. Recruitment: Number of potential participants referred to the study and percentage of those

who consent to take part (target sample = 75) at baseline
2. Retention: Percentage of participants retained to 16-week follow-up (target = 70%)
3. Engagement with intervention: Percentage of participants who complete at least half of the Triple P programme within 15 weeks. Data on differential engagement (workbook versus online format Triple P) will also be reported.
4. Outcome completion: Percentage completion of the candidate primary outcome measure (Parenting Stress Index) at 16 weeks
5. Risk: Number and type of adverse events identified by or reported to the research team from baseline to 39 weeks
6. The measurement of health economic outcomes in a future definitive trial using two quality of life and health economic measures (described in the secondary outcome measures below)
7. Sample size calculations for a future larger scale trial informed by examining the 'promise of efficacy' of Triple P on important quantitative clinical outcomes (outlined below) at the 16-week and 39-week follow-up and the variance of these outcomes

Key secondary outcome(s))
1. Acceptability of the intervention: measured using qualitative interviews with parent participants and health professionals and questionnaires with parents between 16 and 39 weeks. Interview topic guides contain a priori themes relating to acceptability, for example, the degree of support required for parents to engage with Triple P successfully. Data from a post-randomisation satisfaction survey and a post-intervention client satisfaction questionnaire will also be examined.
2. Clinical outcome measures: a range of validated questionnaires and assessment tools, chosen according to their psychometric properties and widespread use in relevant research will be conducted by research assistants blind to treatment allocation after randomisation. As follows:
2.1. Parenting stress is measured using the Parenting Stress Index (PSI) at baseline, 16 weeks, 26 weeks and 39 weeks
2.2. Parenting efficacy is measured using the Child Adjustment and Parenting Efficacy Scale (CAPES) at baseline, 16 weeks, 26 weeks and 39 weeks
2.3. Parental Mental Health is measured using the Positive and Negative Syndrome Scale (PANSS) at baseline, 16 weeks and 39 weeks
2.4. Parental well-being is measured using the Warwick Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline, 16 weeks and 39 weeks
2.5. Child behaviour and well-being are measured by the Strengths and Difficulties Questionnaire (SDQ) at baseline, 16 weeks and 39 weeks
2.6. Quality of life is measured using the Recovering Quality of Life (ReQoL) and European Quality of Life (EQ-5D-5L) scales at baseline, 16 weeks and 39 weeks

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Inclusion criteria for the feasibility randomized controlled trial (RCT):
1. Aged 18 years or over
2. Parent of child aged 2–12 years with whom they live, or have parental responsibility
3. Experienced at least one episode of non-affective psychosis after the age of 18 years
4. Under the care of an adult mental health team within the participating trusts
5. With sufficient English fluency to engage with intervention and complete assessments
6. Capable of giving informed consent

Inclusion criteria for the nested qualitative study with RCT participants:
1. Participated in the feasibility RCT
2. Capacity and willingness to provide informed consent

Inclusion criteria for nested qualitative study with NHS professionals (care coordinators):
1. Named care coordinator of a parent participant
2. Employed by GMMH or PCFT
3. Capacity and willingness to provide informed consent

Participant type(s)
Health professional, Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Parents:
1. Inpatient at the time of recruitment
2. Diagnosis of postpartum psychosis without an existing or subsequent diagnosis of psychosis
3. Judged by the assigned care coordinator/responsible clinician and the research team as not being sufficiently clinically stable to engage safely in a clinical trial (e.g. in a current mental health crisis; acutely suicidal; not in stable housing)

Nested qualitative study RCT participants:
1. Unwilling or unable to provide consent

Date of first enrolment
16/04/2024

Date of final enrolment
30/04/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
England
M25 3BL

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
England
OL6 7SR

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

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 quantitative datasets (trial data) generated and/or analysed during the current study will be stored in a publicly available repository. The qualitative datasets (process evaluation data) generated and/or analysed during the current study are not expected to be made available to preserve participant anonymity.

Anonymised quantitative data (but not qualitative, i.e. interview transcripts) will be stored on figshare (https://figshare.manchester.ac.uk/). Qualitative data will not be shared due to the risk of identification of participants and the possibly sensitive nature of the data.

IPD sharing plan summary
Available on request, Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes