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Managing adolescent first episode psychosis: a feasibility study

Submission date
27/02/2017

Recruitment status
No longer recruiting

Registration date
27/02/2017

Overall study status
Completed

Last Edited
27/01/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Psychosis is a mental health problem that causes people to perceive or interpret things differently from those around them. Common symptoms of psychosis are unusual beliefs (delusions) and hallucinations (most often, hearing voices). Antipsychotics are the standard medication for these problems and are often often helpful but can have serious side effects. There is also evidence that talking therapies (such as cognitive behaviour therapy (CBT) or family intervention) can help reduce symptoms and prevent relapse. The guidelines suggest that treatment options should include the possibility of choice between CBT, antipsychotic medication or both. However, more research is needed to see how well psychological treatment works when used alone, compared with antipsychotic medication and compared with psychological treatment and antipsychotic medication combined. The first stage to better understanding what is most helpful is to conduct a small study to see if young people and their families want to take part in this kind of research and to find out what they think of taking part. This will show whether a larger study should be done and the best way to do it.

Who can participate?
Patients aged 14-18 diagnosed with psychosis

What does the study involve?
Participants are randomly allocated to one of three groups. Participants in the first group are treated with psychological therapy, which involves up to 30 sessions of CBT plus 6 sessions of family intervention (this is optional). Participants in the second group are treated with antipsychotic medication prescribed by the participant's own psychiatrist. Participants in the third group are treated with a combination of psychological therapy and antipsychotic medication. All participants are also asked to attend four research assessments and physical health checks: at the first visit, then at 3, 6 and 12 months after the first visit. Participants who are recruited into the study after February 2018 are not seen for a research assessment and physical health check at 12 months because of the study end date.

What are the possible benefits and risks of participating?
Each participant benefits from access to one or more currently recommended treatments for psychosis. The likelihood of risk from the treatments is minimal. The investigators have

considerable experience of the treatments and assessments used in this study and are not aware of any risks to participants. While the risks are minimal there may be a risk of side effects from antipsychotic medication. Although this is a standard treatment for young people with psychosis there are side effects from antipsychotics. To address this risk, the antipsychotic medication is prescribed by the participant's psychiatrist, based in the care team they are under. The choice of antipsychotic medication is made jointly with the young person and their parents or carers, and healthcare professionals. Age-appropriate information is provided by prescribers to help with this and the likely benefits and possible side effects of each drug are discussed. The prescribing psychiatrist is free to change the dose and type of antipsychotic in response to the effectiveness and side effects, which is consistent with current guidelines. If a participant allocated to either the psychological intervention alone or antipsychotic medication alone group experiences a deterioration in their mental state, they are offered the option to move into the combined treatment arm and psychological intervention or antipsychotic medication is started. Participants stay in the study and continue to follow the schedule of assessments. In order to minimise burden participants are asked their preference on the venue for the assessment and are seen in their own home if preferred, unless there is a reason which would prevent this. During assessment and testing, breaks are provided to minimise possible fatigue or stress, and if indicated, can be spread over several days.

Where is the study run from?
1. Greater Manchester Mental Health NHS Foundation Trust (UK)
2. Oxford Health NHS Foundation Trust (UK)
3. Sussex Partnership NHS Foundation Trust (UK)
4. Birmingham Children's Hospital NHS Foundation Trust (UK)
5. Lancashire Care NHS Foundation Trust (UK)
6. Northumberland Tyne and Wear NHS Foundation Trust (UK)
7. Norfolk and Suffolk NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2017 to June 2019

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

Who is the main contact?
Mrs Melissa Pyle

Contact information

Type(s)
Public

Contact name
Mrs Melissa Pyle

Contact details
Greater Manchester Mental Health NHS Foundation Trust
The Psychosis Research Unit
Psychology Department
Harrop House
Prestwich Hospital

Bury New Road
Manchester
United Kingdom
M25 3BL

Additional identifiers

Protocol serial number
33209; HTA 15/31/04

Study information

Scientific Title
A randomised controlled trial of antipsychotic medication in comparison to psychological intervention and a combined treatment in children and young people with first episode psychosis: a feasibility study

Acronym
MAPS

Study objectives
The aim of this study is to determine whether it is feasible to conduct a study to examine the effectiveness of a psychological intervention (Cognitive Behaviour Therapy plus family intervention), antipsychotic medication or a combination of both, in adolescents with first episode psychosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West – Greater Manchester East Research Ethics Committee, 06/02/2017, ref: 16/NW/0893

Study design
Randomised; Interventional; Design type: Treatment, Drug, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Psychosis; UKCRC code/ Disease: Mental Health/ Organic, including symptomatic, mental disorders

Interventions
Randomisation will be in the ratio 1:1:1 to the three groups and will be stratified by site and family contact (since participants who do not have regular contact with their families will not receive the family intervention components of psychological intervention, although they will still be included). Randomisation (at the individual level) will be independent and concealed, using

randomised-permuted blocks of random size administered via a study-specific web-based system developed by the Clinical Trials Unit.

Participants will be randomly allocated to one of three treatment arms:
1. Psychological Intervention alone: This will comprise of up to 30 sessions of individual Cognitive Behaviour Therapy (CBT) plus the option of up to six sessions of family intervention (FI) over a 6-month treatment window.
2. Antipsychotic medication alone: The antipsychotics (AP) will be selected by the participants own psychiatrist from their care team. The APs will be selected from those commonly used in the treatment of young people with psychosis, with dosages within recommended limits; the responsible consultant psychiatrists will choose the individual AP. The choice of antipsychotic medication should be made jointly with the young person and their parents or carers, and healthcare professionals. The psychiatrists will initiate the first dose of AP as soon as possible and will be encouraged to keep patients on their AP for a minimum of 12 weeks, and preferably for 26 weeks; however, they will be free to change dose and type of antipsychotic in response to monitoring of efficacy and adverse effects, which is consistent with current NICE guidelines.
3. Combine psychological intervention and antipsychotic medication: a combination of both treatments as outlined above.

All participants will be invited to a research assessment and physical health check with a blind (independent) assessor. These will take place at baseline and then again at 3 months, 6 months and 12 months' post randomisation. Participants who are recruited into the study after February 2018 will not be seen for a research assessment and physical health check at 12 months because of the study end date.

Intervention Type
Other

Primary outcome(s)
Primary outcome measures as of 09/10/2018:
As this is a feasibility trial, a single primary outcome is not meaningful and the key outcomes to inform a future trial are:
1. Referral rates and recruitment rates, assessed at the end of the recruitment window in October 2018
2. Attendance at therapy sessions, compliance with medication and follow-up and questionnaire response rates, assessed at the end of the follow-up window in April 2019
3. Acceptability of treatment, measured using rates of drop-out from treatment at the end of the follow-up window by April 2019

Measurement of feasibility success criteria:
i) Recruitment ≥80% of planned (green), recruitment within 79 -60% of planned (amber), recruitment < 60% of planned (red).
ii) Retention of participants within the study with baseline and outcome assessments at primary end point (6 months, end of treatment) ≥80% of primary outcome completed (green), 79 -60% of primary outcome completed (amber), < 60% of primary outcome completed (red).
iii) Satisfactory delivery of adherent therapy to ≥80% of groups receiving PI (green), 79-60% of groups receiving PI (amber), < 60% of groups receiving PI (red). Satisfactory delivery of adherent therapy will be operationalised as attending 6 or more sessions of CBT.
iv) Satisfactory delivery of antipsychotic medication to ≥80% of groups receiving AP (green), 79-60% of groups receiving AP (amber), < 60% of groups receiving AP (red). Satisfactory delivery of antipsychotic medication will be operationalised as any exposure of AP for 6 consecutive weeks

(this would include a dose below BNF lower limits given this is a frequent clinical practice for people of this age and the drugs are licensed for adults).

Primary outcome measure as of 03/08/2018:
As this is a feasibility trial, a single primary outcome is not meaningful and the key outcomes to inform a future trial are:
1. Referral rates and recruitment rates, assessed at the end of the recruitment window in October 2018
2. Attendance at therapy sessions, compliance with medication and follow-up and questionnaire response rates, assessed at the end of the follow-up window in April 2019
3. Acceptability of treatment, measured using rates of drop-out from treatment at the end of the follow-up window by April 2019

Previous primary outcome measure:
As this is a feasibility trial, a single primary outcome is not meaningful and the key outcomes to inform a future trial are:
1. Referral rates and recruitment rates, assessed at the end of the recruitment window in June 2018
2. Attendance at therapy sessions, compliance with medication and follow-up and questionnaire response rates, assessed at the end of the follow-up window in December 2018
3. Acceptability of treatment, measured using rates of drop-out from treatment at the end of the follow-up window by December 2018

Key secondary outcome(s))

Current secondary outcome measures as of 03/08/2018:
All secondary outcomes are being collected to determine their suitability for use in a subsequent trial, rather than to draw conclusions about safety or efficacy of treatments.

The proposed primary outcome measure for a subsequent definitive trial will be symptoms of psychosis and schizophrenia assessed using the Positive and Negative Syndrome Scale (PANSS), a commonly used outcome in psychosis trials, allowing comparison with wider evidence. The PANSS will be collected as a secondary outcome for this study and will be administered at baseline and then again at 3 months, 6 months and 12 months' follow-up.

Other secondary outcomes include:
1. Social/educational/occupational functioning, assessed using the First Episode Social Functioning Scale (FESFS) at baseline and then again at 3 months, 6 months and 12 months' follow-up
2. Self-rated recovery, assessed using the Questionnaire about the Process of Recovery (QPR) at baseline and then again at 3 months, 6 months and 12 months' follow-up
3. Dimensions of psychotic symptoms, assessed using the Specific Psychotic Experiences Questionnaire (SPEQ) at baseline and then again at 3 months, 6 months and 12 months' follow-up
4. Adverse effects (weight gain, sexual dysfunction, metabolic effects and extrapyramidal effects) assessed using the antipsychotic non-neurological side effects scale and a full physical health examination (weight, body mass index, waist circumference, blood pressure and fasting estimates of plasma glucose (FPG), HbA1c, lipids and serum prolactin levels) at baseline and then again at 3 months, 6 months and 12 months' follow-up
5. Common comorbidities, assessed using the Hospital Anxiety and Depression Scale (HADS), the Alcohol Use Disorder Identification Test (AUDIT), the Drug Abuse Screening Test (DAST) and autism spectrum conditions using the adult version of the Autism Spectrum Quotient (AQ-10) at baseline and then again at 3 months, 6 months and 12 months' follow-up

6. Basic data on health economics, including the health status questionnaire (EQ-5D) at baseline and then again at 3 months, 6 months and 12 months' follow-up
7. Hospital admissions and serious adverse events, recorded each time they occur over the duration of the study until the end of the follow-up window in December 2018
8. Dose of antipsychotic medication, measured using a review of patient notes at the end of the follow-up period in April 2019
9. Dose of psychological intervention, recorded at the end of therapy for each participant allocated to receive the psychological intervention; data will be available on this at the end of the follow-up window in April 2019

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Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Aged 14-18 (to ensure adolescent status)
2. In contact with Early Intervention Services/Child and Adolescent Mental Health Services (to ensure appropriate safety considerations can be implemented)
3. Competent to provide written, informed consent, with additional parental consent for those aged < 16 (for ethical considerations).
4. Either meet ICD-10 criteria for schizophrenia, schizoaffective disorder or delusional disorder or meet entry criteria for an Early Intervention for Psychosis service (operationally defined using PANSS) to allow for diagnostic uncertainty in early phases of psychosis
5. Within 1 year of onset of psychosis (to ensure first episode status)
6. Score 4+ on Positive and Negative Syndrome Scale (PANSS) delusions or hallucinations [for a minimum duration of seven consecutive days] (to ensure current psychosis)
7. Help-seeking (for ethical considerations)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
61

Key exclusion criteria
1. A primary diagnosis of alcohol/substance dependence *
2. A diagnosis of moderate or severe learning disability *
3. A diagnosis of ICD-10 organic psychosis *
4. Score 5+ on PANSS conceptual disorganisation / disorganised speech (since majority of participants will be randomised to a talking therapy, we require capacity to answer questions in an interview situation and engage in a conversation)
5. Non-English speaking (since majority of participants will be randomised to a talking therapy)
6. Received APs or structured PI within the last 3 months (to ensure treatment naivety)
7. Immediate risk to self or others (to ensure appropriate safety considerations can be addressed)

* These exclusions are to ensure that the participant population are representative of young people with a primary problem of first episode psychosis

Date of first enrolment

01/04/2017

Date of final enrolment
31/10/2018

Locations

Countries of recruitment
United Kingdom

England

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

Study participating centre
Oxford Health NHS Foundation Trust
Warneford Lane
Headington
Oxford
United Kingdom
OX3 7JX

Study participating centre
Sussex Partnership NHS Foundation Trust
Arundel Rd
Worthing
United Kingdom
BN13 3EP

Study participating centre
Birmingham Children's Hospital NHS Foundation Trust
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Sponsor information

Organisation
Greater Manchester West Mental Health NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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 current data sharing plans for the current study are unknown and will be made available at a later date

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	results	01/09/2020	13/07/2020	Yes	No
Results article	results	01/01/2021	27/01/2021	Yes	No
Protocol article	protocol	04/07/2019	08/07/2019	Yes	No
HRA research summary			28/06/2023	No	No

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