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A trial of antipsychotic medication in comparison to cognitive behaviour therapy or a combination of both in adults with psychosis

Submission date
20/03/2014

Recruitment status
No longer recruiting

Registration date
20/03/2014

Overall study status
Completed

Last Edited
03/04/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The standard treatment for psychosis is antipsychotic medication. Antipsychotics have been proven to be helpful in reducing symptoms of psychosis for some people, but evidence suggests that many people choose to discontinue their medication due to side effects. Several studies have concluded that having a talking therapy called Cognitive Behavioural Therapy (CBT) as well as medication can help reduce symptoms further. Furthermore, a recent study concluded that CBT can be acceptable and effective in reducing psychotic symptoms in those who choose not to take antipsychotics, especially among young people and those with a short duration of illness. Whilst CBT may reduce symptoms and quality of life in people who are currently taking antipsychotics and those who choose not to take antipsychotics, there is insufficient research to support one treatment over another in terms of symptom reduction. The National Institute of Clinical Excellence (NICE) currently recommend CBT and/or medication for the treatment of psychosis and suggest that treatment should include choice. Furthermore, a recent review of studies examining the effectiveness of antipsychotics versus placebo/psychosocial interventions found that there was too little information to assess the effects. Therefore, the aim of this study is to explore the acceptability of CBT compared to antipsychotics and a combination of both in adults with psychosis.

Who can participate?
Men and women aged 16 or over with psychosis

What does the study involve?
Anyone who wants to take part is sent some more detailed information and given time to think about it. The researchers also need to talk to the persons care coordinator or doctor at this stage. The participant is then given an appointment with the researcher to check in more detail that they can take part. This involves answering some questions about their experiences and filling in some questionnaires with a research assistant. They are also asked to have some physical checks such as weight and BMI and to provide a blood sample. This is done by a trained professional. Following this the participant is randomly allocated to one of three treatment options: antipsychotic medication prescribed by their own healthcare team, CBT, or a

combination of both. If they are allocated to receive CBT, these sessions can be carried out at home or at another convenient location. Everyone who takes part in the study also meets a research assistant four times during a 12-month period for follow-up appointments. They are compensated £10 at the initial appointment and at the four follow-up appointments. They are also compensated £10 if they are asked to take part in an interview about their experience at the end of the study. Participants are free to leave the study at any point if they change their mind and this does not affect the usual care they receive.

What are the possible benefits and risks of participating?
The current NICE guidelines recommend both CBT and medication for the treatment of psychosis so it is expected that the treatment participants receive will be helpful to them. It is possible that they will improve any mental health difficulties that the participant is experiencing. If the participant is allocated to receive CBT it is possible that talking about some of these issues may be upsetting. Similarly, if they are allocated to receive antipsychotics it is possible, as with any medication, that they will experience some side effects such as weight gain and an increased risk of the development of diabetes. Participants can talk to their CPN, GP or psychiatrist about participation in this study and any concerns they may have. They will also have the opportunity to discuss any concerns with the researcher.

Where is the study run from?
Prestwich Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2014 to July 2016

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

Who is the main contact?
Miss Heather Law
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Study website
http://www.psychosisresearch.com/research/compare/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16388

Study information

Scientific Title
A pilot study of a randomised controlled trial of antipsychotic medication in comparison to cognitive behaviour therapy and a combined treatment in adults with psychosis

Acronym
COMPARE (COgnitive behavioural therapy or Medication for Psychosis A Randomised Evaluation)

Study objectives
The current NICE guidelines recommend a talking treatment called Cognitive Behavioural Therapy (CBT) and/or medication for people who are experiencing things like hearing voices or having very strong beliefs that others do not seem to share or agree with. These experiences are sometimes referred to using the term psychosis. Currently the evidence suggests that CBT and /or antipsychotic medication are equally helpful for people experiencing psychosis. Further research is needed to identify which of these treatment options is the most helpful in reducing symptoms or whether a combination of treatments is needed. Also, other important results of treatment have not been measured, such as recovery defined by service users themselves, or how well the person copes with daily life, relationships and the demands of a job or education.

Therefore, the COMPARE study will be a pilot randomised controlled trial to explore the feasibility and acceptability of CBT, APs and a combination in adults with psychosis. The aim is to recruit 75 participants who will be randomised to one of three treatment arms: CBT, APs or a combination of both. Symptoms, functioning, quality of life and wellbeing, side effects and acceptability will be measured at four timepoints over a 12-month follow-up period. Qualitative interviews with participants will also be conducted to examine their views of the different treatments. The data from this study will help to plan a large multisite trial that will examine clinical and cost-effectiveness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Preston, 25/02/2014, 14/NW/0041

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.psychosisresearch.com/research/compare/

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Schizophrenia, Psychosis; Disease: Schizophrenia, Psychosis

Interventions
Description: We aim to have usable data on 60 participants. If we recruit 75 participants (25 per condition) over the 28-month recruitment period this would allow for a dropout rate of 20%.

Antipsychotic medication: The APs will be selected from those commonly used in the treatment of psychosis, with dosages within recommended limits; the responsible consultant psychiatrists will choose the individual AP before randomisation.

Cognitive behaviour therapy: Up to 25 sessions will be delivered over the 6-month treatment period.

Combined treatment: antipsychotics plus cognitve behaviour therapy.

Follow Up Length: 6 month(s)
Study Entry : Single Randomisation only

Intervention Type
Mixed

Primary outcome measure
Positive and Negative Syndrome Scale (PANSS); Timepoint(s): 6 weeks, 12 weeks, 24 weeks, 52 weeks

Secondary outcome measures
1. Clinical Global Impression scales (CGI); Timepoint(s): 6 weeks, 12 weeks, 24 weeks, 52 weeks
2. Hospital Anxiety and Depression Scale (HADS); Timepoint(s): 24 weeks, 52 weeks
3. Personal and social performance scale (PSP); Timepoint(s): 24 weeks, 52 weeks
4. Questionnaire about the process of Recovery (QPR); Timepoint(s): 24 weeks, 52 weeks
5. WHOQOL- quality of life; Timepoint(s): 6 weeks, 12 weeks, 24 weeks and 52 weeks

Overall study start date
01/04/2014

Completion date
01/04/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 25/07/2014:
1. In contact with mental health care services (under the care of a consultant)
2. 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) in order to allow for diagnostic uncertainty in early phases of psychosis
3. Aged 16+
4. Competent and willing to provide written, informed consent
5. Score at least 4 on PANSS delusions or hallucinations or at least 5 on Suspiciousness /Grandiosity
6. Help seeking

Previous inclusion criteria:
1. Aged 18+
2. In contact with mental health services
3. Competent to provide written, informed consent.
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) in order to allow for diagnostic uncertainty in early phases of psychosis
5. Score at least 4 on PANSS delusions or hallucinations or at least 5 on suspiciousness /grandiosity
6. Help seeking

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 75; UK Sample Size: 75

Key exclusion criteria
Current exclusion criteria as of 25/07/2014:
1. Primary diagnosis of alcohol/substance misuse
2. Moderate or severe learning disability

3. Score 5+ on PANSS conceptual disorganisation
4. Non-English speaking
5. Current receipt of structured CBT from a qualified psychologist in accordance with NICE guideline recommendations (as opposed to more generic psychosocial interventions) OR receipt of antipsychotics, OR receipt of either within the past 3 months.
6. Immediate risk to self or others
7. Organic Impairment

Previous exclusion criteria:
1. Primary diagnosis of alcohol/substance dependence
2. Moderate or severe learning disability
3. Score 5+ on PANSS conceptual disorganisation
4. Non-English speaking
5. Current receipt of structured CBT or APs, or receipt within the last 3 months
6. Inpatient
7. Immediate risk to self or others
8. Organic Impairment

Date of first enrolment
01/04/2015

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Prestwich Hospital
Manchester
United Kingdom
M25 3BL

Sponsor information

Organisation
Greater Manchester West Mental Health NHS Foundation Trust (UK)

Sponsor details
Psychology Department
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M25 3BL

Sponsor type
University/education

Website
http://www.gmw.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme (RfPB); Grant Codes: PB-PG-1112-29057

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version v1	28/06/2016	28/06/2016	No	No
Results article	results	01/05/2018		Yes	No
HRA research summary			28/06/2023	No	No