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Development and preliminary evaluation of a Medication Review Tool for people taking antipsychotic medication

Submission date
21/10/2013

Recruitment status
No longer recruiting

Registration date
09/12/2013

Overall study status
Completed

Last Edited
13/03/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Antipsychotic drugs are the main drugs prescribed to people who suffer from psychosis or schizophrenia. They can help reduce symptoms and rates of relapse, but they have some significant unpleasant and harmful effects. Existing research suggests that people are more troubled by the adverse physical and mental effects of drug treatment than professionals recognise and these effects reduce the overall quality of life. Despite these concerns, patients experiences of taking antipsychotic drugs have received little attention. Research on shared decision making for people with depression and schizophrenia shows benefits in patient participation, satisfaction, improved adherence and symptoms. A government report has highlighted that people should be more fully involved in their medication reviews and that there is a need for a more systematic consideration of the pros and cons of taking the medication, to improve their satisfaction, attitudes to treatment, adherence and rates of relapses. Furthermore, guidelines on the treatment of schizophrenia have also emphasised the importance of doctors and patients making joint decisions about their drug treatment, based on informed discussions. However, little research has been done on the process of making decisions in antipsychotic medication.
The first part of the study consisted of a survey of the views of people who are taking or have taken antipsychotic medications. People were asked about the main benefits and harms they experience when taking antipsychotic medication, as well as how much they are able to participate in discussions about medication with doctors and professionals, whether they are able to express their views and how far their views are taken into consideration. All this information was then used to construct a Medication Review Tool. This is an instrument to help people weigh up the likely benefits and harms of taking various types of antipsychotic drugs, so they can participate more fully in discussions and decisions about their medication. This study will assess whether using the Medication Review Tool helps people to participate more fully in discussions about medication, whether it changes people's attitudes to medication, and whether people are more or less likely to take the medication that is prescribed. It will also look at whether using the Medication Review Tool helps improve prescribing and whether it reduces side effects. The study will also explore the experiences of people who take or have taken antipsychotic drugs and assess which positive and negative effects are most important to them.

This is an initial study which means that one aim of the study is to see if it is worthwhile conducting a larger study in the future.

Who can take part?
Adults aged 18 years or over who have a diagnosis of schizophrenia, psychosis or affective disorder (depression or mania) with psychotic symptoms that are currently on antipsychotic medication.

What does the study involve?
Participants will be randomly allocated to one of two groups: use the Medication Review Tool in their consultations with the psychiatrist or continue to receive their usual treatment. We will compare the two groups to see if using the Medication Review Tool helps participants to highlight their concerns and make decisions about their antipsychotic medication.

What are the potential benefits and risks to the participants?
The participants will have the opportunity to discuss any issues regarding side effects of their medication and to express their concerns about the medication that they may not have had the opportunity to do so previously. Overall, the direct risks of participation are minimal. It is however possible that answering particular questions, describing certain aspects of their mental disorder and/or side effects of the medication may cause some distress or feelings of embarrassment to some participants. It is hoped that this will be minimized by the experience and sensitivity of the researcher. Furthermore, if participants report suicidal thoughts, we will flag these up and encourage participants to seek help from their local doctor or health service. Participants may also find the interviews inconvenient and some may find it difficult to sustain their concentration or interest for as long as the interview requires. To minimize these inconveniences, interviews will be contacted at a place and time convenient to the participant and they will be informed that the interviews can be terminated if they feel unable to continue with them.

When does the study take place?
September 2012 to June 2014

Where does the study take place?
North East London NHS Foundation Trust (UK)

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

Who is the main contact?
1. Ms Kiran Azam, Research Assistant (kiran.azam@nelft.nhs.uk)
2. Dr Joanna Moncrieff, Principle Investigator (j.moncrieff@ucl.ac.uk)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Development and preliminary evaluation of a Medication Review Tool for people taking antipsychotic medication: a cluster randomised controlled trial

Study objectives
Using the Medication Review Tool will increase service user participation in discussions and decision-making relating to antipsychotic medication, improve attitudes to drug treatment, and improve general satisfaction with care. Effects on patterns of prescribing, adherence and side effects will also be investigated. A subsidiary aim of this part of the research is to describe in quantitative terms how patients evaluate the various possible benefits and harms of drug treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Camden & Islington, 19/07/2012, REC reference: 12/LO/0959

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Conditions treated with antipsychotic medication, including psychosis, schizophrenia, schizoaffective disorder and affective disorder with psychotic symptoms

Interventions
Care coordinators (with all their allocated participants) will be randomised to either using the Medication Review Form or continue with treatment as usual.

1. Using the Medication Review Tool:
The care coordinators will receive training on using the review tool with the participants, and how to use the associated website to access information about different drugs. Participants allocated to this group will fill out the form with their care coordinator up to one week before their meeting with the psychiatrist. The form will then be taken into the meeting with the psychiatrist and used as a point of discussion regarding their antipsychotic medication.
2. Treatment as usual:
The care coordinators will continue to provide the usual standard care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Decision Self-Efficacy Scale, which is a brief 11 item questionnaire that assesses service users confidence in participating in medication-related discussions and decisions

Secondary outcome measures
1. Drug Attitude Inventory 10 item scale (DAI)
2. Brief Positive and Negative Syndrome Scale (PANSS) consisting 7 subscales
3. Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS) Questionnaire
4. Medication Adherence Questionnaire
5. Tablets Routine Questionnaire
6. Changes in Medication
7. Qualitative data on service users experiences of using the Medication Review Tool

Feedback from prescribers and care coordinators: The Service Engagement Subscale will be administered over the telephone in brief telephone interviews with care coordinators involved in the study. An adapted version of the Physician Satisfaction Questionnaire (PSQ) will be administered with psychiatrists involved in the study. Qualitative feedback on the use of the Medication Review Tool will also be obtained from psychiatrists and care coordinators.

Overall study start date
01/09/2012

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Over 18 years
2. Currently taking antipsychotic medication
3. Have a diagnosis of psychosis, schizophrenia, schizoaffective disorder or affective disorder with psychotic symptoms

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
Non-English speakers

Date of first enrolment
01/09/2012

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University College London
London
United Kingdom
W1W 7EJ

Sponsor information

Organisation
North East London NHS Foundation Trust (UK)

Sponsor details
Goodmayes Hospital
157 Barley Lane
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB); Grant code: PB-PG-0909-20026

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?
Results article	results	04/07/2016		Yes	No