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Combined individual and family cognitive behavioural therapy compared with treatment as usual

Submission date
13/06/2016

Recruitment status
No longer recruiting

Registration date
15/06/2016

Overall study status
Completed

Last Edited
25/05/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Psychosis is a serious mental disorder in which thought and emotions are impaired, causing a person to lose touch with reality. The onset of psychosis is a major challenge for the patient and everyone involved in his or her care. It is unusual for psychosis to come on suddenly, and the NHS is keen to look at treatments to help stop the progression of psychosis for people at risk of developing it. Prevention is preferable to treatment for fully developed psychosis, because it is usually more acceptable and is generally associated with fewer side effects. It can also be more cost effective to provide prevention-based treatments. It is now possible to identify people who are at a high risk of developing psychosis. Early intervention teams around the country are working to help prevent the full onset of psychosis, as otherwise about one third will develop a full psychosis within three years. This study is going to look at treatments that aim to help reduce the number of people who develop psychosis. The aim of this study is to find out if adding family therapy to individual treatment is a helpful preventative treatment for young people at risk of developing psychosis.

Who can participate?
Young people aged 16-35 who are living with at least one member of their family and are at risk of developing psychosis.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are offered combined individual and family Cognitive Behavioural Therapy plus their usual treatment. This involves a maximum of 25 individual cognitive behavioural therapy sessions (usually one per week) lasting up to an hour over a 6 month period, as well as 4-6 sessions of therapy with key family members or family support members. Therapy sessions will focus on whatever is of most concern to the participant at the time. Those in the second group continue to receive their treatment as usual, with no additional therapy from the research team. Participants in both groups will meet with a researcher for an initial assessment (which involves discussing current mental health difficulties and completing some questionnaires), and complete follow up assessments after 6 months and 12 months to repeat the initial questionnaires. Family members

will also be asked to complete some questionnaires at the initial assessment, 6 month follow up and 12 month follow up assessment. Finally, a selection of those who take part are interviewed about their experiences in the study to help the research team decide whether a larger study should take place to explore the research further.

What are the possible benefits and risks of participating?
It is hoped that the combined individual and family therapy will be beneficial to those who are offered it but this cannot be guaranteed, and not everyone will be offered the therapy as part of the trial. This means there may be no direct benefits for those taking part in the study although many people find being involved in research to be a positive experience. There are no risks involved with taking part in the study. It is possible that some people may find talking about their mental health and their experiences distressing, however plenty of opportunities will be provided to discuss any concerns and participants can choose not to continue with the study if they wish.

Where is the study run from?
1. Greater Manchester West Mental Health NHS Foundation Trust (UK)
2. Bolton Early Intervention in Psychosis Team (UK)
3. Salford Early Intervention in Psychosis Team (UK)
4. Trafford Early Intervention in Psychosis Team (UK)

When is the study starting and how long is it expected to run for?
March 2016 to April 2019

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

Who is the main contact?
1. Dr Heather Law (public)
2. Professor Paul French (scientific)

Contact information

Type(s)
Public

Contact name
Dr Heather Law

ORCID ID
http://orcid.org/0000-0002-1889-9179

Contact details
Greater Manchester West Mental Health NHS Foundation Trust
Psychosis Research Unit-Rico House
Harrop House
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Type(s)
Scientific

Contact name
Prof Paul French

Contact details
Greater Manchester West Mental Health NHS Foundation Trust
Psychosis Research Unit-Rico House
Harrop House
Bury New Road
Prestwich
Manchester
United Kingdom
M33 7FT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
30981

Study information

Scientific Title
Combined individual and family therapy in comparison to treatment as usual for people at risk of psychosis: A feasibility study

Acronym
IF-CBT Trial

Study objectives
The aim of this study is to investigate whether a combined individual and family intervention is an acceptable, feasible and potentially effective treatment option for people with an At Risk Mental State (ARMS) for psychosis compared to standard treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester East Research Ethics Committee, 26/05/2016, ref: 16/NW/0278

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

Primary study design
Interventional

Secondary study design
Randomised controlled 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
Specialty: Mental Health, Primary sub-specialty: Psychosis; UKCRC code/ Disease: Mental Health/ Organic, including symptomatic, mental disorders

Interventions
Participants are randomised to one of two groups using a secure telephone randomisation system in a 1:1 ratio.

Combined individual and family therapy: Participants will be offered a combined individual and family Cognitive Behavioural Therapy plus their usual treatment. A maximum of 25 individual therapy sessions will be available (usually one per week) lasting up to an hour, over a 6 month period. Therapy sessions will focus on whatever is of most concern to the participant at the time. Alongside this, 4-6 sessions of Cognitive Behavioural Therapy with key family members or family support members will be available. These sessions will focus on making sense of experiences, communication styles, problem solving and goal setting.

Usual treatment alone: Participants in this study arm will not be offered any additional treatment from the study. They will continue with routine care or 'treatment as usual' from their care team or GP.

All participants will meet with a researcher for a follow up assessment at 6 months and 12 months after randomisation.

Intervention Type
Other

Primary outcome measure
Transition to psychosis as defined by the Comprehensive Assessment of At Risk Mental States at baseline, 6 and 12 months.

Secondary outcome measures
1. Time use is measured using the time use survey at baseline, 6 and 12 months
2. Depression is measured using the Beck Depression Inventory at baseline, 6 and 12 months
3. Social anxiety is measured using the Social Interaction Anxiety Scale at baseline, 6 and 12 months

4. Use of formal and informal health and social care is measure using the adapted EPQ at baseline, 6 and 12 months
5. Health status is measured using the EQ-5D at baseline, 6 and 12 months

Overall study start date
01/03/2016

Completion date
01/04/2019

Eligibility

Key inclusion criteria
1. Aged 16-35
2. Screen positive on the Comprehensive Assessment of At Risk Mental States (CAARMS) for an At Risk Mental State
3. Be living with at least one member of their family
4. Help seeking

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 76; UK Sample Size: 76

Key exclusion criteria
1. Current or previous receipt of anti-psychotic drugs
2. Moderate to severe learning disability
3. Organic impairment
4. Insufficient fluency in English
5. Significant risk to self or others

Date of first enrolment
27/06/2016

Date of final enrolment
27/01/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Greater Manchester West Mental Health NHS Foundation Trust
Psychosis Research Unit
Rico House
Harrop House
Bury New Road
Prestwich
Manchester
United Kingdom
M33 7FT

Study participating centre
Bolton Early Intervention in Psychosis Team
Bentley House
Viking Works
Weston Street
Bolton
United Kingdom
BL3 2RX

Study participating centre
Salford Early Intervention in Psychosis Team
Broadwalk Centre
51 Belvedere Road
Salford
United Kingdom
M6 5EJ

Study participating centre
Trafford Early Intervention in Psychosis Team
Crossgate House
Cross Street
Sale
United Kingdom
M33 7FT

Sponsor information

Organisation

Greater Manchester West Mental Health NHS Foundation Trust

Sponsor details
Research and Development
Harrop House
Bury New Road
Prestwich
Manchester
England
United Kingdom
M25 3BL
+44 161 358 0594
Kathryn.harney@gmw.nhs.uk

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
The main aims of the feasibility study, to inform a definitive study, will be delivered via descriptive data and analysis of data after the last follow-up assessment (post 01/04/2019). This will include reporting data in line with the CONSORT 2010 Statement. There will also be additional reporting of qualitative data. These findings will be written up for publication in high

impact peer-reviewed journals. Additionally, findings will be presented at national and international conferences, as well as service user/voluntary sector organisations and networks and their newsletters and websites. Service-users involved in the study will be encouraged to participate in dissemination.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/02/2021	25/05/2021	Yes	No
HRA research summary			28/06/2023	No	No