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Metacognitive therapy for those at high risk of developing psychosis

Submission date
16/11/2018

Recruitment status
No longer recruiting

Registration date
06/02/2019

Overall study status
Completed

Last Edited
04/02/2020

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
Individuals who are assessed as being at high risk of developing psychosis have mental health problems which affect their behaviour, thinking and perception, as well as a person's ability to socialise, work and carry out the tasks of daily life. Common difficulties are unusual or overvalued beliefs (e.g. paranoia) and perceptual experiences (e.g. hallucinations such as hearing voices). Developing effective interventions for preventing such individuals from experiencing a first episode of psychosis have been an important focus of research in the last decade. Psychological treatment in the form of cognitive therapy (a talking therapy) is currently indicated however, access and resource issues are still a limitation for delivering this within the NHS. Developing treatments which are aimed at important areas of change and at a range of psychological difficulties seen within this population could lead to better and more efficient treatments. Evidence suggests that metacognitive therapy (MCT) can provide a useful alternative to CBT. MCT is a talking therapy based on a metacognitive model of emotional disorders with an evidence base for treating mental health difficulties such as generalised anxiety disorder, social anxiety, depression and PTSD, all of which are highly present in the specified research population. MCT is often a shorter treatment than traditional CBT, requiring 6-8 sessions for symptom improvement. We have already conducted a pilot study of 12 sessions of MCT for individuals with established psychosis showing positive results for patients' psychotic experiences. Applying a similar approach allows for a shorter treatment than is currently offered, thereby affording personal, social and economic benefits. This study provides an opportunity to investigate the acceptability of this treatment with individuals at high risk of developing psychosis allowing for the evaluation of such an approach in producing symptom relief and recovery.

Who can participate?
Young people at high risk of developing psychosis who meet At Risk Mental State (ARMS) criteria and are being seen in one of the participating sites Early Detection and Intervention Teams (EDIT) are eligible to participate.

What does the study involve?
All participants who are willing and eligible to participate are offered 12 session of Metacognitive Therapy (MCT) delivered in flexible locations and times.

What are the possible benefits and risks of participating?
Some participants may find completing some of the assessments distressing. In order to minimise this, participants will be offered choice regarding the length of the assessments, including the option of breaks and completing the assessments across multiple sessions. We have a standardised protocol for managing distress that has been developed with the Psychosis Research Unit Service User Reference Group. The participant will be able to freely withdraw from the study at any point, which will also be clear on the consent form and this will not affect their statutory care. In order to reduce any inconvenience caused to the participant, all of the assessments will be completed in a non-stigmatising and convenient location of the participants' choice (e.g. their home, their GP surgery or a community venue).

Participants that are randomly allocated to MCT will have the benefit of receiving a brief and non-invasive intervention that has been found to have enduring effects, without a lengthy waiting list. If the therapy is successful then this means the participant may experience an important and meaningful improvement in their difficulties. This would be with the aim of learning a series of skills which they can continue to apply throughout their life to reduce the chances of the problems returning. Additionally, all participants will be allowed the chance to discuss their difficulties in assessments at more frequent time points that could be offered in normal standard care. The assessments will be completed in non-stigmatising and convenient locations, of the participants choosing. For participants that are not receiving MCT, having regular assessments is considered a potential benefit given that it presents an enhancement from routine care as psychotic like experiences will be monitored more regularly.

Where is the study run from?
The study is being run from Greater Manchester Mental Health NHS Foundation Trust. We aim to recruit 10 participants to run the case series.

When is the study starting and how long is it expected to run for?
The trial is expected to run from June 2013 for approximately 18-24 months.

Who is funding the study?
Self-funded

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
811 (GMW, R&D)

Study information

Scientific Title
MetaCognitive Therapy for those meeting At Risk Mental State criteria: a pilot study

Acronym
MCT for ARMS

Study objectives
The primary objective of this research is to investigate the feasibility and acceptability of metacognitive therapy for individuals assessed as being at high risk of developing psychosis. The objectives are:
1. To assess recruitment rate, quality of data collection and follow-up
2. To provide a final check of the protocol in order to test its integrity to ensure all procedures are in place prior to progressing to the next phase
3. To provide data from which a sample size can be calculated
4. To examine the appropriateness, feasibility and acceptability of the intervention and measures
5. To clarify training and supervision needs for delivering this intervention prior to the commencement of a randomised trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Greater Manchester West Research Ethics Committee, 17/12/2013, 13/NW/0238

Study design
Interventional open pilot trial

Primary study design
Interventional

Secondary study design
Open pilot trial

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
At Risk Mental State (at risk of psychosis)

Interventions
The MCT intervention consisted of 12 sessions over a period of 12 weeks following baseline assessment, and followed the treatment manual developed by Wells (Wells, 2011). For the purpose of this study, the metacognitive model of generalised anxiety disorder (Wells, 1995) was adapted for use with UHR individuals, in a similar way to the therapy previously described for people with a diagnosis of schizophrenia (Hutton, Morrison, Wardle & Wells, 2014; Morrison et al., 2014). The metacognitive model asserts that psychological distress results from extended processing in response to negative cognitions (comprising thoughts, images, voices etc). Examples of extended processing include worry, rumination and unhelpful thought control strategies, collectively termed as the CAS (Wells & 209 Matthews, 1996). MCT aims to reduce the CAS by ameliorating thought control strategies and modifying metacognitive beliefs, which contribute to worry, rumination and distress. The MCT intervention consisted of:
1. Assessment of metacognitive strategies in response to cognitions and elicitation of metacognitive beliefs
2. Socialisation to the metacognitive model
3. Model-based formulation of difficulties
4. Practice of detached mindfulness alongside postponement of thought control strategies
5. Evaluation and modification of positive and negative metacognitive beliefs
6. Attention training.

Intervention Type
Other

Primary outcome measure
1. Recruitment, measured by number of referrals and number consenting at the baseline
2. Retention, measured by percentage follow-up and questionnaire response rates after 3 and 6 months

Secondary outcome measures
All measures were administered at the end of treatments (3 months post baseline) and at a 6 month follow-up:
1. At risk symptoms (psychotic-like experiences), assessed using the Comprehensive Assessment of At Risk Mental States (CAARMS)
2. Anxiety and depression, assessed using the Hospital Anxiety and Depression Scale (HADS)
3. Metacogntions, assessed using the Metacognitions Questionnaire 30 (MCQ30)
4. Hypothetical interpretations of voices, assessed using the Interpretation of Voices Inventory (IVI)

5. Beliefs about paranoia, assessed using the Beliefs About Paranoia Scale (BAPS)
6. Worry, assessed using the Anxious Thoughts Inventory
7. Cognitive attention, assessed using the The Cognitive Attention Syndrome Scale (CAS1)

Overall study start date
11/06/2013

Completion date
30/10/2015

Eligibility

Key inclusion criteria
1. Have an identified case manager
2. In contact with mental health services
3. Meet entry criteria for an Early Detection and Intervention Team (for those at high risk of developing psychosis) operationally defined using the CAARMS
4. Judged by their clinician/case manager to be clinically stable for at least the previous 4 weeks

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10

Total final enrolment
10

Key exclusion criteria
1. Moderate to severe learning disability
2. Evidence of clear organic neurological impairment (e.g., head injury or dementia)
3. Non-English speaking in so far as this would prevent the use of standardised assessment instruments
4. Inpatient/acute care required immediately prior to or during baseline assessment
5. Taking prescribed antipsychotic medication
6. Absence of case management
7. Primary diagnosis of substance dependency

Date of first enrolment
06/03/2014

Date of final enrolment
15/04/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Bury New Road, Prestwich
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Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal in 2018.

Intention to publish date
01/03/2019

Individual participant data (IPD) sharing plan
The 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	17/01/2020	04/02/2020	Yes	No
HRA research summary			28/06/2023	No	No