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Cognitive Bias Modification for Paranoia

Submission date
25/04/2016

Recruitment status
No longer recruiting

Registration date
12/05/2016

Overall study status
Completed

Last Edited
10/07/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Paranoia is associated with a range of mental health conditions, including psychosis, and the most common form of psychotic delusion, persecutory delusions. Persecutory delusions are common in a range of disorders and present in 10-15% of the general population. Patients with the most common diagnosis (Schizophrenia) are estimated to occupy a quarter of all psychiatric hospital beds, account for one half of all psychiatric admissions and cost England £11.8 every year. The Schizophrenia Commission reported patients have to battle for services, suffer considerable distress, low self-confidence and loss of control. Employment rates are low (8%) and many patients suffer stigma and discrimination. A significant number of patients continue to experience distressing symptoms despite treatment (i.e.pharmacotherapy). The Commission report NICE-recommended psychological treatment for psychosis, Cognitive Behavioural Therapy (CBT), is received by only 1 in 10 of those who could benefit. This study is looking at a new treatment (or intervention) called Cognitive Bias Modification for Paranoia (CBM-pa). CBM-pa involves participants reading stories on a computer screen, completing missing words and answering questions about each story in a way that encourages more helpful beliefs about themselves and others. This study is investigating whether CBM-pa is an effective treatment for people suffering from delusional paranoid beliefs.

Who can participate?
Adults (aged 18-65) diagnosed as suffering from clinically significant persecutory or paranoid symptoms for at least one month.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 receive CBM-pa. The sessions take place once a week for a total of six weeks. CBM-pa consists of 40 scenarios in each session for a total of 240 different scenarios. The exercises are interactive; for each CBM-pa scenario, participants have to read three lines on a computer screen, completing missing words and answer questions about each scenario in a way that encourages more helpful beliefs about themselves and others. Participants in group 2 are assigned as the control group. They also attend sessions once a week over six weeks. The experience is identical, but content given is missing the active ingredient: resolution of an ambiguous situation in a benign/non-paranoid manner. Instead control participants read and respond to factual material. All participants are followed up though the post and/or phone calls one month and again three months after the study is complete.

What are the possible benefits and risks of participating?
Participants take part in addition to receiving treatment-as-usual. However, the therapy might evoke stress in those presenting paranoia. To address this, the participant's mood is routinely assessed before leaving and follow-up contact with a clinical psychologist offered, if needed. Participants are fully informed about what the study involves both in writing and verbally. Any undue distress occurring during a procedure is reported to the Chief Investigator and Consultant Clinical Psychologist at that time, allowing accurate monitoring to take place and provide support as necessary. Any clinically significant issues that arise from these questions are addressed by reference to the patients' psychiatrist or main clinician in charge of their care. This is always done with the patient's permission and is only breached in the rare instance criminal activity is disclosed. For patients recruited through self-referral route, if any clinically significant issues arise during the interview then verbal consent is obtained from the patient to pass onto the responsible GP. If participants refuse to consent to GP contact they are referred to senior clinicians part of the team. The experimental procedure used in this study is modelled on a history of similar investigations in clinical depression and anxiety where even in these samples similar CBM techniques have not produced an increased susceptibility to anxiety or depression.

Where is the study run from?
1. King's College London (UK)
2. South London and Maudsley NHS Foundation Trust (Maudsley Hospital) (UK)

When is the study starting and how long is it expected to run for?
November 2015 to November 2018

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

Who is the main contact?
Dr Jenny Yiend

Contact information

Type(s)
Public

Contact name
Dr Jenny Yiend

Contact details
King's College London
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SE5 8AF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20719

Study information

Scientific Title
Cognitive Bias Modification for Paranoia: a randomised controlled trial

Study objectives
The study hypothesis is that the biases which Cognitive Bias Modification for Paranoia (CBM-pa) manipulates are a maintaining mechanism for patients' delusional paranoid beliefs. Reducing these biases should reduce paranoid beliefs and associated distress.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - City Road & Hampstead Research Ethics Committee, 26/02/2016, ref: 16/LO/0071

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Personality disorder - paranoia

Interventions
There will be two sets of material and the participants will be randomly assigned to one or the other group. CBM-pa consists of 40 scenarios in each session (six weekly sessions), for a total of 240 different scenarios. The exercises involved will be interactive; for each CBM-pa scenario, participants will have to read three lines on a computer screen, completing missing words and

answer questions about each scenario in a way that encourages more helpful beliefs about themselves and others.
In the computerised text-reading control condition participants will have exactly the same process, but will read a different scenario. The experience is identical, but content omits the active ingredient: resolution of an ambiguous situation in a benign/non-paranoid manner. Instead control participants read and respond to factual material.

The scenarios will be different for both the groups and as yet it is not known if there will be of any benefit to participants. If at the end of the study one procedure is found to be more helpful than the other in relieving paranoia, then anyone NOT allocated to that procedure will be offered the opportunity to receive it. Participants will receive postal/telephone 1 and 3 month follow-up. Remote follow-up is preferred to reduce costs and minimise attrition. All participants will be reimbursed for completing assessments (only), and will be given £10 for each of the 6 research assessments they attend. We will conduct this study following CONSORT guidelines. The King's Clinical Trials Unit will conduct double-blind randomisation. CBM-pa is self-administered, allowing researchers to be blind to condition. Control and intervention are procedurally identical and previous studies' debriefing indicates participants cannot correctly guess their assigned condition. Here, participants and researchers will be asked to guess assigned condition to evaluate double-blinding. Minimisation will be piloted on key participant characteristics (gender, severity of baseline paranoia, cognitive bias).

Intervention Type
Other

Primary outcome measure
1. Paranoid beliefs, measured using the Ambiguous passages task at baseline T0, six weekly sessions (Ti), end of treatment (T1), one month (T2) and three months follow-ups (T3)
2. Paranoid symptoms, measured using the Positive and Negative Symptoms Scale (item 6 only) at baseline T0, six weekly sessions (Ti), end of treatment (T1), one month (T2) and three months follow-up (T3)
3. Vulnerability to stress measured using the visual analogue score (VAS) at end of treatment (T1), pre and post a virtual reality assessment (VR)

Secondary outcome measures
1. Paranoid beliefs, measured using the Scrambled sentences task and the Cognitive Flexibility Scale at baseline T0 and end of treatment (T1).
2. Paranoid symptoms, measured using the Paranoia Scale, Paranoid Thoughts Scale, Peter’s Delusions Inventory, at baseline T0 and end of treatment (T1).
3. Vulnerability to stress measured using the laughter task at end of treatment (T1).

Overall study start date
30/11/2015

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Any diagnosis featuring clinically significant persecutory or paranoid symptoms, present for at least the preceding month

2. Above threshold (>2 on item 6) on the paranoia item of the Positive and Negative Symptoms Scale
3. Displaying a baseline interpretation bias, as measured by the 'Scrambled Sentences Task'
4. Stable on medication for at least the last 3 mths and expected to be so for study duration
5. Age 18-65
6. Capacity to consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
62

Key exclusion criteria
1. Severe cognitive impairment
2. Illiteracy
3. Major physical illness (cancer, heart disease, stroke)
4. Major substance or alcohol misuse
5. Currently receiving, or soon due to receive, a psychological intervention targeting the same psychological mechanisms as CBM-pa (paranoid beliefs), or having done so in the last 3 months

Date of first enrolment
14/04/2016

Date of final enrolment
09/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
Institute of Psychiatry, Psychology & Neuroscience
De Crespigny Park
London
United Kingdom
SE5 8AF

Study participating centre
South London and Maudsley NHS Foundation Trust
Maudsley Hospital
Denmark Hill
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation
Guy's Campus, King's College London

Sponsor details
c/o Mr Keith Brennan
Room 1.8 Hodgkin Building
-
United Kingdom
-

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0220mzb33

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 study website (http://bryonycrane.wix.com/cbm-pa) will substantially aid dissemination (including 'easy read' versions, reviewed by service-users) and enable participants to update on progress whenever they choose. Locally, NHS Trust newsletters will feature results. The trialists will present at service-user in Research Forum (SURF). National organisations will provide further vehicles for dissemination (e.g. MHRN, SANE; Rethink Mental Illness; McPin). The Institute of Psychiatry, Psychology & Neuroscience holds frequent national and international events (e.g. Trust and CAG workshops) for dissemination which the trialists will utilise. International dissemination will include high impact open-access peer-review publication (e.g. top specialist journal Clinical Psychological Science) throughout the duration of the study (2015-2018) and international conferences (e.g. WCBCT).

Intention to publish date
30/11/2019

Individual participant data (IPD) sharing plan

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?
Protocol article	protocol	29/06/2017		Yes	No
Results article	qualitative results	23/07/2019	25/07/2019	Yes	No
Results article	results	01/01/2021	13/08/2020	Yes	No
Results article	questionnaire evaluation results	01/05/2021	12/05/2021	Yes	No
HRA research summary			28/06/2023	No	No

Results article	feasibility, effects, dose-response and primary outcomes for future trials	22/06 /2022	10/07 /2024	Yes	No