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Positive Memory Training for the treatment of depression in schizophrenia

Submission date	Recruitment status	[X] Prospectively registered
13/03/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/03/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/05/2021	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

Schizophrenia is a mental illness which occurs in around 1 in 100 people. About half will also suffer from depression, and around 1 in 20 will commit suicide. The NHS spends over £2 billion a year on the treatment of schizophrenia. Medication does not work well for everyone, and a lot of service users prefer talking therapies. Several studies have shown that psychological therapies work, and can help to save the NHS money by keeping people out of hospital. Unfortunately, current psychological therapies for schizophrenia are quite long (at least 6 months) and do not specifically target the treatment of depression. Our research team has developed a new psychological intervention to meet this need. It is relatively short-term (3 months) and is very structured. This makes it easy to train NHS staff to be able to deliver it. There have been encouraging results with this new therapy in previous studies. Given the potential benefit to patients diagnosed with schizophrenia, it is important to test whether this intervention will work for them. We plan to conduct a study to find out whether this treatment is effective and good value for money in treating depression in this group of patients.

Who can participate?

Individuals diagnosed with schizophrenia/schizo-affective disorder can participate.

What does the study involve?

Individuals who give consent and are eligible are allocated into one of two groups: either 'treatment as usual' or 'treatment as usual plus 3 months of positive memory training'. We will assess people at several times during the study. We will also develop a measure to use with people when they finish the study, to check whether they found it acceptable. We will compare the level of depression within the two groups in order to see whether those who received the treatment became less depressed than those who did not.

What are the possible benefits and risks of participating?

Those allocated to receive positive memory training may benefit from enhanced self-esteem and improved mood. There are no known risks associated with taking part in this study.

Where is the study run from?
Berkshire Healthcare Foundation Trust (UK) and Southern NHS Foundation Trust (UK) in collaboration with the University of Reading (UK).

When is the study starting and how long is it expected to run for?
Recruitment will commence in April 2014 for a period of 19 months, with follow-up assessments lasting a further 9 months.

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

Who is the main contact?
Dr Craig Steel
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15976

Study information

Scientific Title
Positive Memory Training for the treatment of depression in schizophrenia: a randomised controlled trial

Acronym
PoMeT

Study objectives
The main hypothesis to be tested is that Positive Memory Training (PoMeT), delivered to patients with co-morbid schizophrenia and depression, in addition to standard psychiatric care will result in a reduced level of depressed symptomatology. The subsidiary hypothesis is that reduction in the symptoms of depression will mediate a reduction in psychotic symptomatology and service use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13SC0634; First MREC approval date 13/02/2014

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

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

Interventions
Individuals who give consent and are eligible for the study will undergo an assessment at the start and 3 months, 6 months and 9 months after the first assessment. After the initial assessment, participants are allocated into one of two groups: either 'treatment as usual' or 'treatment as usual plus 3 months of positive memory training'. Those who receive positive memory training will have access to 8-12 one-hour sessions of the intervention within a 3-month period. The intervention trains people to increase their accessibility to feelings of positive self-esteem, initially within sessions and then in their day to day lives.

Intervention Type
Other

Phase

Phase III

Primary outcome measure
Depression: self-report, assessed through the Beck Depression Inventory-II at 3, 6 and 9 months

Secondary outcome measures
1. Schizophrenia symptoms (0, 3 and 9 months only). Assessed by clinical interview using the Positive and Negative Symptom Scale (PANSS).
2. Mood and Quality of Life. Assessed using the Generalised Anxiety Disorder Assessment (GAD7), the Work and Social Adjustment scale and the Warwick-Edinburgh Mental Well-Being Scale.
3. Self-Esteem. Measured using the Rosenberg self-esteem scale.
4. Mental Imagery (0, 3 and 9 months only). . Assessed using the Spontaneous Use of Imagery Scale.
5. Therapy Satisfaction (end of treatment only). Assessed using the newly developed measure.
6. Level of Service Use and Costs. Using a version of the Client Service Receipt Inventory (CSRI) which has been adapted for use in the current study and termed the Health Economic Questionnaire (0, 3 and 9 months).
7. Generic health-related quality of life and broader well-being of patients. EuroQol EQ-5D-5L, ICECAP-A and OxCAP-MH (0, 3, 6, 9 months).
8. Generic health-related quality of life and broader well-being of primary carers. EuroQol EQ-5D-5L and Carer Experiences Scale (CES) (0 and 9 months).

Overall study start date
01/04/2014

Completion date
01/10/2016

Eligibility

Key inclusion criteria
Participants will be included if:
1. They consent and have a current DSM-IV diagnosis of schizophrenia or schizo-affective disorder
2. Present with symptoms consistent with at least a mild level of depression, as indicated by a score of 14 or above on the BDI-II
3. They will be aged between 18 and 65
4. They will be able to read and write in English to a level required to participate in a talking therapy
5. Have a fixed abode: Operationalised as having a current address (including B&B or open access hostel)
6. Evidence (e.g., from key worker) indicating that the person is more likely than not to have a reliable address throughout the 12 months study duration

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment
100

Key exclusion criteria
Not be suffering from an organic disorder which is associated with psychotic symptoms or have a learning disability.

Date of first enrolment
01/04/2014

Date of final enrolment
01/11/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Reading
Reading
United Kingdom
RG6 6AL

Sponsor information

Organisation
Berkshire Healthcare Foundation Trust (UK)

Sponsor details
Fitzwilliam House
Skimped Hill Lane
Berkshire
Bracknell

England
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RG12 1BQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t542436

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0712-28021

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?
Protocol article	protocol	14/04/2015		Yes	No
Results article		01/12/2020	10/05/2021	Yes	No