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Brief talking therapies on wards

Submission date	Recruitment status	[X] Prospectively registered
19/08/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/08/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/11/2020	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Inpatient psychiatric care is a scarce resource, yet large numbers of patients are being re-admitted to hospital care. This study will investigate the possibility of running a trial of a brief talking therapy for people with distressing psychotic symptoms receiving inpatient care following a mental health crisis.

Who can participate?
Adults (aged at least 18) that are inpatients in a psychiatric ward.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 (intervention) receive the talking (mindfulness-based crisis interventions) therapy. Those in group 2 (control) receive a control therapy (social activity therapy). Information is gathered on how many people are re-admitted to hospital 6 months later.Participants also fill out some questionnaires asking about their symptoms, emotions and recovery. Questionnaire data is collected at the beginning and end of therapy, and 3 and 6 months after people are discharged from hospital. Participants and staff involved in the study are also invited to give feedback on the study in an interview or focus group. This may help plan a larger future study to find out whether this simple intervention can help people with psychosis stay out of hospital for longer following a crisis.

What are the possible benefits and risks of participating?
Both therapies are likely to have some benefit. However, this will vary from person to person. Talking therapies can sometimes involve talking about feelings, thoughts or experiences which may be upsetting at times. This is a completely normal part of therapy and the trial therapist is very experienced in keeping this to a level which is manageable. Participants can always stop a therapy session or indeed to stop therapy altogether if they do not wish to carry on.

Where is the study run from?
King’s College London, Institute Of Psychiatry (UK)

When is the study starting and how long is it expected to run for?
October 2015 to July 2017

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

Who is the main contact?
Dr Pamela Jacobsen

Contact information

Type(s)
Public

Contact name
Dr Pamela Jacobsen

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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19490

Study information

Scientific Title
Mindfulness-based crisis interventions (MBCI) for psychosis within acute inpatient psychiatric settings: a feasibility randomised controlled trial

Acronym
amBITION

Study objectives
This study aims to investigate the feasibility of conducting a trial of a brief talking therapy for people with distressing psychotic symptoms receiving inpatient care following a mental health crisis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Camberwell St Giles Research Ethics Committee, 15/LO/1338

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Topic: Mental Health; Subtopic: Psychosis; Disease: Psychosis

Interventions
1. Control therapy - SAT, Social Activity Therapy (SAT) is a brief intervention (1-5 sessions) which involves helping the client to identify activities they enjoy, and carrying these out with the therapist on the ward.;
2. Talking therapy - MBCI, Mindfulness-Based Crisis Interventions (MBCI) is a brief therapy (1-5 sessions) focussing on developing a shared understanding of what has brought the person into crisis, and introducing other ways of coping with future distressing experiences using mindfulness-based techniques.; Follow Up Length: 6 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Primary outcome measure
Feasibility/acceptability; Timepoint(s): At trial end (incl. recruitment rate/retention)

Secondary outcome measures
1. Pilot clinical/symptom measures; Timepoint(s): Baseline, Post-therapy, 3 month follow-up, 6 month follow-up
2. Pilot outcome data on re-admission rates; Timepoint(s): 3 and 6 month follow-up
3. Self-ratings of Psychotic Symptoms
4. Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ)

5. Depression, anxiety and stress scales (DASS-21)
6. Southampton Mindfulness Questionnaire (SMQ)
7. Questionnaire about the Process of Recovery (QPR)

Overall study start date
01/01/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Aged 18 or above
2. Current psychiatric inpatient on a working-age adult ward
3. Diagnosis of schizophrenia-spectrum disorder or psychotic symptoms in the context of an affective disorder (International Statistical Classification of Diseases and Related Health Problems, Tenth edition [ICD-10], F2039)
4. Reports at least one current distressing positive psychotic symptom
5. Able to give informed consent to participate in trial, as assessed by consultant psychiatrist /responsible clinician
6. Willing and able to engage in psychological therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60; Description: This is a feasibility randomised controlled trial (RCT) with 2 arms (experimental and control therapy). 60 patients will be recruited to the trial, 30 in each arm.

Total final enrolment
50

Key exclusion criteria
1. Established diagnosis of learning disability, or major cognitive impairment arising from any underlying medical condition (e.g. head injury, neurological disorder) resulting in significant functional impairment
2. Unable to engage in a talking therapy in English, or to complete simple written questionnaires in English
3. Primary diagnosis of substance misuse

4. Does not report any current distressing psychotic symptoms
5. Lacks capacity to consent to participation in research trial
6. Unable to take part in individual therapy due to risk of aggression/violence
7. Mental state precludes possibility of engaging in a talking therapy, e.g. significant thought disorder

Date of first enrolment
01/10/2015

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
Institute Of Psychiatry
16 De Crespigny Park
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London

Sponsor details
Room 1.8
Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 4UL

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
1. Submission of trial protocol to BMC Psychiatry (peer reviewed open access journal)
2. Poster presentation of trial protocol at World Congress of Behavioural and Cognitive Therapies (June 2016)
3. Paper presentation of trial outcomes at British Association for Behavioural and Cognitive Psychotherapies
4. Paper submission of quantitative/qualitative outcomes to clinical psychology/psychiatry peer-reviewed journal
5. Dissemination at a local level to NHS services and via service user and charity networks

Updated 07/09/2018:
The main trial paper is currently being prepared for submission to a peer-reviewed journal, with publication expected by July 2019.

Intention to publish date
01/07/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the Chief Investigator Dr Pamela Jacobsen. Anonymised data will be shared in accordance with participant consent and ethical approval for the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2016		Yes	No
Basic results		06/09/2018	07/09/2018	No	No
Results article	results	29/04/2020	25/11/2020	Yes	No
HRA research summary			28/06/2023	No	No