

# Brief talking therapies on wards

<b>Submission date</b> 19/08/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/11/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## 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

**ORCID ID**  
<http://orcid.org/0000-0001-8847-7775>

**Contact details**  
King's College London  
Institute Of Psychiatry  
16 De Crespigny Park  
London  
United Kingdom  
SE5 8AF

## 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**

## 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?
<a href="#">Protocol article</a>	protocol	01/12/2016		Yes	No
<a href="#">Basic results</a>	results	06/09/2018	07/09/2018	No	No
<a href="#">Results article</a>		29/04/2020	25/11/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No