

# A small scale randomised trial of a computer-based pre-Cognitive Behavioural Therapy 'informed choice' intervention to improve uptake and implementation of CBT for psychosis

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<b>Registration date</b> 02/08/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/11/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Psychosis affects over 600,000 people in the UK, many of whom have recurring persistent symptoms, despite medication. Symptoms include beliefs that people are conspiring against you (persecutory delusions) or hearing voices that are critical, abusive or command you to do unpleasant or harmful things (auditory hallucinations). The distress caused and the impact on day-to-day function can lead to hospitalisation and poor quality of life. Currently Cognitive Behavioural Therapy for psychosis (CBTp) is the only recommended individual talking therapy. CBTp can help people manage these distressing experiences leading to improved recovery and quality of life. However, 94% of NHS Trusts struggle to deliver it and fewer than 10% of patients receive it because of barriers like lack of knowledge about what CBTp is and does, pessimism about whether it works, strong medical beliefs, and a lack of hope and confidence in the ability to cope and change. A pre-CBT informed choice intervention has been developed to promote better, more informed, and more empowered offers and uptake of CBTp. The aim of this study is to test the draft pre-CBT informed choice intervention in a small-scale study.

### Who can participate?

Service users with psychosis aged 16-65, and clinicians who work with people with psychosis in the NHS, from sites in London and Sussex

### What does the study involve?

Each group (service users or clinicians) is randomly allocated to one of two groups. One group receives the digital pre-CBT 'informed choice' intervention, presented in a one-hour introductory session and made available to the participant for the subsequent month. The package includes basic information, interactive elements, animated stories and downloadable handouts. The other group use the CBT section of the NHS choices website, which is presented in a similar introductory session for up to one hour and provided as a printed handout for future reference. The trialists assess how easy it is to recruit, consent and retain people in the study up to the one month follow-up. The use of the new digital pre-CBT informed choice intervention is explored

both through data obtained on page views on the website, and through a questionnaire and interviews with 6 service users and 6 clinicians who have used the intervention in Sussex and London. The interviews further explore feedback on the form and content of the digital intervention materials, including the acceptability of the materials and their use. The effect of the intervention on the likelihood of offering/referring CBTp (clinician) or taking up CBTp (service user) is measured. All participants complete a set of questionnaires before they look at the intervention packages, immediately after their introductory session, and at the one month follow up. Additional questionnaires measure attitudes towards CBT for psychosis, illness perceptions, attitudes towards CBTp within the NHS (clinicians only), psychological wellbeing (service users only) and empowerment. CBT-related activities in the preceding month are also collected at the start of the study and at one month follow-up, based on both interview and case notes.

What are the possible benefits and risks of participating?

It is anticipated that the intervention will be feasible, and that clinicians and service users will be more empowered, more knowledgeable and as a result more positive towards offering or taking up CBTp. There is a risk of disappointment if a service user or clinician is randomly allocated to receive the comparison intervention rather than the new informed choice intervention. However, this risk is mitigated by ensuring that those participants who are allocated to the comparison intervention are also provided with one month's access to the new information package at the end of the study. There is also risk of fatigue due to completion of a number of questionnaires, and distress when sensitive topics of wellbeing, health perceptions, empowerment and treatment are discussed.

Where is the study run from?

Sussex Partnership NHS Foundation Trust (UK)  
South London and Maudsley NHS Foundation Trust (UK)

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

March 2015 to June 2018

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Kathryn Greenwood  
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## Contact information

### Type(s)

Scientific

### Contact name

Dr Kathryn Greenwood

### Contact details

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## **Additional identifiers**

### **Protocol serial number**

NIHR ref: PB-PG-0213-30125

## **Study information**

### **Scientific Title**

A feasibility pilot RCT of a pre-Cognitive Behavioural Therapy (CBT) digital 'informed choice' intervention to improve attitudes towards uptake and implementation of CBT for psychosis

### **Acronym**

The U&I study RCT

### **Study objectives**

Is a pre-CBT for psychosis 'informed choice' intervention to improve knowledge, beliefs and behaviours of clinicians and service-users feasible to be implemented in the NHS?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

London-Dulwich Ethics committee, 17/03/2017, ref: 15/LO/0041

### **Study design**

Multi-centre interventional longitudinal randomized control trial

### **Primary study design**

Interventional

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

Psychosis

### **Interventions**

Stratified block randomisation and varying block size, randomized by group (clinician or service user), and site (London or Sussex):

Intervention: pre-Cognitive Behaviour Therapy (CBT) digital 'informed choice' intervention, presented during a manualised one hour introductory session with one month access  
Control: CBT section of the NHS choices website presented in an equivalent session of up to one hour with printed summary sheet provided as a handout

## **Intervention Type**

Mixed

## **Primary outcome(s)**

1. Likelihood of offering/referring or taking CBT, measured by a single Likert scale (0-10) immediately post intervention and at one month follow-up
2. Feasibility of recruitment within the NHS (numbers recruited, consented) during the trial recruitment period August 2017- January 2018
3. Feasibility of use of the package in the NHS, measured using qualitative interviews with thematic analysis of 6 service users and 6 clinicians (3 each in Sussex and London) who have used the package; and evaluation form and activity data on use of the package, during the follow-up period September 2017 - February 2018

## **Key secondary outcome(s)**

1. Knowledge and attitudes towards CBTp, measured using new questionnaires developed and validated with service users and clinicians during phase 1a and b of the current study, immediately post intervention and at one month follow-up
2. Illness perceptions, measured using the adapted illness perceptions questionnaire, immediately post intervention and at one month follow-up
3. Attitudes and Behaviours towards CBTp implementation, measured using the NOMAD tool (clinicians only), immediately post intervention and at one month follow-up
4. Psychological wellbeing, measured using the CHOICE short-form measure of psychological wellbeing (service users only) immediately post intervention and at one month follow-up
5. Empowerment, measured using Rogers' Empowerment scale, immediately post intervention and at one month follow-up
6. CBT-related activities in the preceding month, based on both interview and case notes screen, collected at baseline and at one month follow-up

## **Completion date**

30/06/2018

## **Eligibility**

### **Key inclusion criteria**

1. Service users with a current psychotic disorder diagnosis (F20-F29 ICD-10 diagnoses) as evidenced by their clinical notes and/or discussion with lead psychiatric professional.
2. NHS clinicians who work with psychosis service users
3. Age 16-65
4. Some level of ambivalence towards CBT for psychosis as identified by likelihood of referring, taking up CBTp on a Likert rating scale

### **Participant type(s)**

Mixed

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Insufficient grasp of the English language to enable questionnaire completion
2. Cognitive impairment or learning disability which precludes engagement with the study materials

**Date of first enrolment**

03/08/2017

**Date of final enrolment**

30/04/2018

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Sussex Partnership NHS Foundation Trust**

United Kingdom

BN13 3EP

**Study participating centre**

**South London and Maudsley NHS Foundation Trust**

United Kingdom

BR3 3BX

## **Sponsor information**

**Organisation**

Sussex Partnership NHS Foundation Trust

**ROR**

<https://ror.org/05fmrjg27>

# 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

## Individual participant data (IPD) sharing plan

Initial pilot data will not be made available as the trialists do not have consent for this level of data sharing. The plan is to use the data to support progression to a full RCT. Data will be stored electronically within Sussex Partnership NHS Foundation Trust according to ethical procedures.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	20/11/2018		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No