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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

Submission date
02/08/2017

Recruitment status
No longer recruiting

Registration date
02/08/2017

Overall study status
Completed

Last Edited
22/11/2018

Condition category
Mental and Behavioural Disorders

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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)

Other

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
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 measure
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

Secondary outcome measures
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

Overall study start date
08/03/2015

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

Age group
Adult

Sex
Both

Target number of participants
80

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
England

United Kingdom

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

Sponsor details
Sussex Education Centre
Millview Hospital Site
Nevill Avenue
Hove
England
United Kingdom
BN3 7HZ

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
The protocol and analysis plan will be published prior to the end of the study in June 2018.

Newsletters will be circulated by letter/e-mail and local websites to inform participants of study outcomes. A results 'launch' will be organised to which all participants and stakeholders will be invited. A series of talks and workshops will be open to service-users, families, health professionals, commissioners, GP's and newly formed communities of practice led by service directors and managers. SURF and peer researchers will deliver talks and provide guidance on reaching out to service-users. Results will be presented from different perspectives (service user, clinician, trainer) and to a range of audiences (e.g. ISPSS/Tigger service-user conference, Hearing Voices Network). Locally, the results will be presented at SPRiG seminars and the R&D conference. Mental health charities will be contacted regarding publication in journals such as 'One in Four' and locally, on service-users websites, like 'Sussex Voice'. The study team will present findings at regional and national psychological therapies meetings and international psychosis conferences. The main study papers will be published in Open Access formats so they are accessible free of charge. Questionnaires will be available on key websites (PRP, EYE, SPRiG). Significant publications are envisaged at each phase and to appropriate audiences (e.g. Behaviour Research and Therapy, Implementation Science, British Journal of Psychiatry). The aim is to submit all publications within one year of the end of the study in June 2019.

Intention to publish date
30/06/2019

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?
Protocol article	protocol	20/11/2018		Yes	No
HRA research summary			28/06/2023	No	No