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Mental imagery (pictures in the "mind's eye") psychological talking therapy for psychosis - 2

Submission date
10/05/2022

Recruitment status
No longer recruiting

Registration date
14/06/2022

Overall study status
Completed

Last Edited
04/06/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[X] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Schizophrenia is a severe mental health condition, for example, where individuals hear distressing voices other people cannot hear (e.g. auditory hallucinations) and/or have distressing unusual beliefs that others do not share (delusions). They also report negative core beliefs (e.g., “I am vulnerable; I am a failure; Others are hostile”) and unwanted intrusive mental images (that are in the “mind’s eye” and other senses) which may be maintaining factors for psychotic symptoms.
One of the best interventions for psychosis is Cognitive Behavioural Therapy (CBT), which is recommended by the UK National Institute for Health and Care Excellence (NICE). Sadly, the first generation of CBT for Psychosis (adapted from CBT for emotional disorders) has a small effect size, and there is a need to refine and improve it. Imagery approaches are almost completely absent from multiple CBT for Psychosis therapy manuals. Empirical studies consistently demonstrate that imagery has a more powerful impact on emotion than verbal cognition. Therefore, we anticipate using an imagery focused approach to target images and schemas will result in a reduction in psychotic symptoms.
We wish to undertake a feasibility randomised controlled trial of an imagery-focused therapy called iMAPS-2, which targets negative images and negative core beliefs (schemas). Our research aims to improve the current treatments for people with psychosis. We wish to explore a psychological therapy (i.e. iMAPS-2) where the therapist and client specifically work with distressing “mental imagery” (e.g., “pictures in the mind’s eye, sounds in the mind’s ear”), and negative beliefs, which are often reported but rarely treated. Moreover, the project will tell us if we may be able to run a definitive randomised controlled clinical trial.

Who can participate?
Service-users under the care of Early Intervention (EI) in Psychosis and Community Mental Health Teams within Pennine Care NHS Foundation Trust who experience psychosis and distressing mental imagery can participate.

What does the study involve?
Participants will be randomly allocated to either the iMAPS-2 treatment arm or treatment as usual (TAU). Those receiving the iMAPS-2 intervention will be offered up to 12 sessions of an imagery-focused psychological therapy.

Qualitative aspect of the study:
Participants who are randomised into the iMAPS-2 treatment arm and receive > 4 weeks intervention will be invited to take part in a qualitative interview about their experience of the therapy.
Clinicians who have had experience of referring at least one participant to the iMAPS-2 trial will be invited to take part in a qualitative interview about their experience of the process.

What are the possible benefits and risks of participating?
Possible benefits to participation may include feelings of satisfaction and achievement at being involved in trial research that leads to improved psychological therapy effectiveness for people living with distressing psychosis. Moreover, individuals receiving iMAPS-2 interventions may also experience improvement in their ability to cope with and manage symptoms of psychosis.
This study does not involve any known physical risks or harm to participants or the researchers. However, talking about personal experiences and feelings may be difficult and can cause emotional upset. The protocol for assessing and reporting risks and the distress protocol for the current study will be followed in such cases.

Where is the study run from?
Pennine Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2021 to June 2024

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

Who is the main contact?
Dr Christopher Taylor (chrisdjtaylor@nhs.net)

Study website
https://www.researchinpsychosis.com/imaps2

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
309409

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 309409, NIHR 203507, CPMS 52560

Study information

Scientific Title
iMAgery focused therapy for PSychosis-2 (iMAPS-2): A feasibility randomised controlled trial

Acronym
iMAPS-2

Study objectives
1. What number and percentage of eligible patients/service users consent to the trial (recruitment)?
2. What is the level of engagement with adherence to the iMAPS intervention (therapy sessions attendance measures; therapist fidelity)?
3. What completion and data quality rates can be achieved (data completion and retention of participants)?
4. What estimates of effect sizes (if any) are present (acknowledging this is a feasibility trial)?
5. What are service users' views regarding i) acceptability of participating in the trial, ii) the outcomes measures collected, including their acceptability and the ranking of the potential primary outcome measures for the definitive trial, and iii) acceptability of receiving iMAPS therapy (including adherence to intervention protocol)?
6. What is the estimated sample size for a fully powered trial to evaluate the effectiveness of iMAPS (relative to usual care)?
7. What is the range of services used by participants and which are likely to be key cost drivers to consider for the main trial?
8. What is the range of health benefits and are they covered by the EQ-5L health status questionnaire?

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 09/05/2022, Yorkshire and The Humber Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8134; leedswest.rec@hra.nhs.uk), ref: 22/YH/0091

Study design
Feasibility outcome assessor blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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
Schizophrenia, schizotypal and delusional disorders

Interventions
iMAPS-2 involves novel change techniques including imagery re-scripting (imaging an image or memory and changing the ending to change the meaning) of past events, imagery re-scripting of flash-forwards, working with nightmares and creating positive imagery. Other techniques used to work with negative core beliefs and images are i) learning that pushing images away makes them come back stronger (image suppression and responding differently), ii) testing beliefs about images and schemas (behavioural experiments), iii) changing (manipulation) of images and iv) working with upsetting memories. The use of the “Safe Place” image, as the first introduction to imagery work, ensures that patients have a personalised strategy to reduce any distress experienced. There are clear distress protocols developed and agreed in advance with patients (including managing dissociation) before the imagery sessions begin (after a careful assessment and formulation).

iMAPS-2
Participants allocated to the intervention arm will receive 12 sessions of an individualised iMAPS-2 intervention over a 12-week therapy phase. Each session will last between 60 and 80 minutes and will be video recorded for fidelity monitoring purposes ,with informed written consent.

Comparator: Treatment As Usual (TAU)
Treatment As Usual will involve interventions offered by an early intervention service or a community mental health team (fortnightly/monthly visits from social worker, mental health nurse, outpatient psychiatry reviews quarterly, medication, routine CBT). The study would not seek to restrict access in routine care to CBT. We will record during the trial by asking participants and by reviewing their clinical record and record any service users in the usual care

arm of the trial who receive routine CBT or other psychological intervention. However, we know there are still significant barriers to NHS therapy. The 2020 English NCAP Psychosis National Audit collected data on access to CBT, defining a course of CBT as receiving just one session of therapy, (rather than the min. 16 sessions recommended by NICE). Even with this low threshold, only 49% of service users had this offer in EI. Secondary care services have historically had even poorer commissioner investment.

Ancillary & Post-trial Care
The iMAPS-2 therapy is designed to be a stand-alone psychological therapy. Participants who wish to access further psychological assessment and therapy will be signposted to accessing this via the local NHS clinical services which they are eligible to be referred to.

Allocation and randomisation
Participants will be allocated in a 2:1 ratio to one of two arms within the RCT; usual care or iMAPS intervention plus usual care using blocks of random (but relatively short) length, stratifying by being a service user/patient under the care of a Community Mental Health Team or an Early Intervention Psychosis Team Health Teams (CMHT).
Randomisation will be performed by Sealed Envelope, an online central randomisation service. The randomisation list will be generated by a statistician independent from the study team and held by Sealed Envelope. Delegated staff at sites with access to the online randomisation service will have to confirm the eligibility criteria before they enter the stratification information and being permitted to randomised.

Intervention Type
Behavioural

Primary outcome measure
Feasibility assessed after completion of 0, 16- and 28-weeks battery assessment follow ups by calculating:
1. Recruitment rate: number of participants consented into the trial and randomised. This will also include number of referrals per month; source of recruitment; number of patients (potential) participants contacted; number of participants screened for eligibility; number of screened patients who are found to eligible, reasons for non-eligibility or withdrawal of interest – where potential participants are happy to share these reasons).
2. Therapy engagement: i) Number of therapy sessions attended, ii) % of participants who drop out of therapy, iii) % of participants who did not receive treatment allocated.
3. Therapist adherence to therapy protocols and supervision protocols. This will include assessing therapist fidelity against the Cognitive Therapy Rating Scale Revised (CTS-R) or the Cognitive Therapy Rating Scale for Psychosis (CTS-Psy)
4. Therapy safety: number of Serious Adverse Events (SAEs) and Adverse Events (AEs)
5. Retention rates and Blinding Breaks

Secondary outcome measures
Measured at baseline, 16 and 28 weeks:
1. Schema (Brief Core Schema Scales; Fowler, Freeman, Smith, Kuipers, Bebbington, Bashforth, et al., 2006)
2. Imagery characteristics (VAS/MIPQ; Taylor et al., 2019, PIQ; Taylor et al., 2022)
3. Psychosis (Psychotic Symptom Rating Scales; PSYRATS; Haddock et al., 1999, PANSS; Kay et al. 1987; QPR; Law et al., 2014)
4. Trauma (TALE; Carr et al., 2018, ITQ; Cloitre et al., 2018)
5. Basic Emotions Scale (Power, 2006)

6. Working alliance (WAI-Client/WAI-Therapist; Hatcher & Gillaspy, 2006)
7. EQ-5D 5L, a NICE recommended health measure utilised for QALY estimate and the ReQoL-10 for feasibility of economic analysis.
8. Health economic data, using an adapted version of the Economic Patient Questionnaire (Davies, Lewis and Jones, 2007) which includes questions from the Client Service Receipt Inventory (CSRI).
9. NHS service use measured by inpatient admission, outpatient visits, A&E, primary, community and social care use.
10. Mental health & functioning (BAI; Beck et al., 1988, CDS; Addington et al., 1993, WEMWBS; Tennant et al., 2007, PSP; Morosini et al., 2000)

Overall study start date
15/11/2021

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Meeting criteria for a schizophrenia-spectrum diagnosis (ICD-10 codes F20, F22, F23, F25, F28, F29; ICD-11 codes F20, F22, F23, F25, F28, F29; ICD-11 codes 6A20, 6A21, 6A23, 6A24, 6A2Y, 6A2Z) AND Score of 3 Mild or above on P1 Delusions or P3 Hallucinations on Positive and Negative Syndrome Scales (PANSS), OR
a criterion level of positive symptoms severity indicated by a score of > 3 (mild symptom present) on the delusions (P1), hallucinations (P3), grandiosity (P5) or suspiciousness (P6) items of the PANSS in the previous week (this is usually the operational criteria to under the care of early intervention psychosis team) And/or the psychosis transition criteria of the CAARMS
2. Aged 18 years and above
3. Identifying a distressing image (Rated 50% distressing or above) related to the psychotic experience scoring 3 or above on PANSS. The participant will self-report the image as distressing (e.g., Have you had a distressing image over the past month? Yes/No What would you rate the distress over the past month from 0-100?).
4. Capacity to give informed consent,
5. Under the care of an NHS mental health team the study is recruiting from
6. With a keyworker/access to a duty team worker.

Qualitative study:
1. Capacity to provide informed consent for interviews
2. Consent to have interviews recorded
3. Participation in iMAPS-2, with at least 4 weeks involvement in iMAPS-2 post randomisation
4. Sufficient English language proficiency to take part in qualitative interviews or agreement to the use of an interpreter

Clinician referrers qualitative Study:
1. Consent to have interviews digitally recorded
2. Experience of referring at least one service user to the iMAPS-2 Study

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45

Total final enrolment
45

Key exclusion criteria
1. Primary diagnosis of alcohol, substance misuse disorder, or bipolar disorder (affective psychosis)
2. Secondary presenting difficulties such as severe addiction, acute suicidal risk, dementia, neurological disorder.
3. Developmental disability (moderate to severe learning difficulty)
4. Acquired brain injury/organic syndrome
5. Currently participating in physical or mental health treatment studies or receiving psychological therapy
6. Unable to complete the measures in written English (due to assessment battery psychometric validation in English)
7. In forensic settings
8. Unmanageable level of risk of violence to researchers or clinicians (harassment behaviour – stalking).

Date of first enrolment
14/06/2022

Date of final enrolment
11/09/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
United Kingdom
OL6 7SR

Sponsor information

Organisation
Pennine Care NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.penninecare.nhs.uk/

ROR
https://ror.org/03t59pc95

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The key output will be an imagery-focused therapy for people with psychosis, feasible to deliver in NHS settings, ready for testing in a definitive clinical trial. We plan to disseminate our findings via peer reviewed publications, presentations, reports on websites, etc.

The findings will be widely disseminated to all relevant stakeholders, including patients, mental health staff, NHS managers, service commissioners and the general public. All participants will be asked if they want to receive details of the study findings and if they consent a lay summary will be emailed or posted to them. All Publications will acknowledge the contribution of the NIHR, NHS and the host NHS Trust.

Intention to publish date
30/11/2025

Individual participant data (IPD) sharing plan
At the discretion of the Chief Investigator and team, anonymised data will be made available upon reasonable request, which must include a protocol and statistical analysis plan and not be in conflict with the research team's planned publication strategy and after we have completed our publication strategy, consistent with our data sharing policy.
chrisdjtaylor@nhs.net

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 1.0	03/06/2024	04/06/2024	No	No