A brief imagery intervention for future-oriented mental images

Submission date	Recruitment status	Prospectively registered		
27/04/2023	No longer recruiting	☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
02/05/2023		[X] Results		
Last Edited	Condition category	Individual participant data		
31/05/2023	Mental and Behavioural Disorders			

Plain English summary of protocol

Background and study aims

It is common for people to feel anxious, suspicious, or threatened. These feelings are often experienced alongside threatening verbal thoughts and/or threatening mental images. Mental images often evoke greater emotional responses compared to verbal thoughts. Treatments targeting specific symptoms can be highly successful, for example, some studies have found that interventions using imagery-based strategies are effective when treating mental images. This study aims to plan to develop a brief imagery-based intervention targeting mental images, which are not related to past life events to reduce the distress that they cause. The study team aims to assess the acceptability of the intervention and to investigate whether it will lead to a reduction in feelings of anxiety, suspiciousness, and threat. Results from this study will determine whether or not this new treatment seems promising, and whether further studies are justified.

Who can participate?

Adults who have experienced distress through hearing voices and/or paranoia, and who also experience distressing mental images

What does the study involve?

Participation will involve completing an assessment interview either via Microsoft Teams or telephone. This session will involve discussing the aims of the intervention and completing baseline questionnaires. The questionnaires will ask you about your experiences of mood, general anxiety, thoughts of suspiciousness and threat, and mental images. The mental images will be briefly discussed and participants will be provided with an overview of the intervention.

Following this, participants will begin the brief imagery-based intervention, which will consist of four hourly sessions with the project lead, a trainee clinical psychologist who has received training in this approach. The first session will consist of providing participants with an understanding of what distressing mental images are and why imagery-based techniques are helpful when working with distressing mental images. Then an image to work on will be identified and a brief questionnaire will be completed.

In the second session, the details of your chosen mental image will be mapped out to better understand what has maintained it. You will again be asked to complete a brief questionnaire.

In the third session, the participant will start practising various techniques to increase the control of their mental images and complete a brief questionnaire.

In the fourth session, the learning will be summarised and there will be time to think about how the techniques can be applied to other distressing mental images that you may have, as well as complete a brief questionnaire. The participant will be invited back a week later to complete a follow-up interview where they will be asked to share feedback on their experience of completing the intervention. They will also be asked to repeat the baseline questionnaires which were completed at the initial assessment session. It is a good clinical practice to record sessions, which the trainee clinical psychologist will be able to share and discuss in supervision. Supervision will take place on a weekly basis and all recordings will be permanently deleted once they have been discussed. Recordings will not be transcribed. It can be specified on the consent form, whether participants consent to this or not. The trainee clinical psychologist will take notes throughout their participation.

What are the possible benefits and risks of participating?

It is hoped that participation will help reduce the experience of distressing mental images. It is also hoped that the findings will inform a larger-scale study that will eventually contribute to NHS services using the intervention in treating distressing mental images. Some of the questionnaire measures and content of the sessions may evoke difficult emotions. Participants will be provided with contact details of services and third-party organisations that will be able to offer support and guidance if they experience further distress. They can withdraw from the study at any point. If the capacity to consent is lost during the study, identifiable data will be retained.

Where is the study run from?

This study is being conducted as part of the project lead, Nithura Sivarajah's, PhD thesis, University of Oxford (UK)

When is the study starting and how long is it expected to run from? February 2021 to March 2023

Who is funding the study?
The University of Oxford Clinical Psychology Doctorate Programme (UK)

Who is the main contact? Nithura Sivarajah, nithura.sivarajah@oxfordhealth.nhs.uk (UK)

Contact information

Type(s)

Scientific

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Type(s)

Principal Investigator

Contact name

Prof Craig Steel

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Additional identifiers

EudraCT/CTIS number

Nil Known

IRAS number

306129

ClinicalTrials.gov number

Secondary identifying numbers

IRAS 306129

Study information

Scientific Title

Brief imagery-based metacognitive intervention for flashforwards in psychosis: a fixed baseline case series

Acronvm

IBMI FOR FLASHFORWARDS

Study objectives

The intervention would:

- 1. Be acceptable and feasible to deliver
- 2. Lead to improvements in measures of mental imagery characteristics (vividness, conviction, control, distress, and frequency), anxiety, depression, persecutory delusions, and schema beliefs 3. Change will be maintained at a one-week follow-up

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/12/2022, North of Scotland Research Ethics Service (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224558458; gram.nosres@nhs.scot), ref: 22/NS/0084

Study design

Mixed methods fixed-baseline case-series design non-controlled non-randomized single-centre study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Internet/virtual

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

Persecutory delusions in psychosis

Interventions

A novel four-session imagery-based metacognitive intervention was developed as part of the study. All participants received the intervention.

All sessions will be delivered online via Microsoft Teams and all questionnaires and forms will be completed using Microsoft Forms. Supervision sessions were also delivered via Microsoft Teams. All recruitment and research sessions took place via Microsoft Teams.

An overview of the metacognitive intervention:

Session 1: Psychoeducation and Identifying Target Flashforward delivered by final year trainee clinical psychologist (also qualified High-Intensity CBT therapist), Nithura Sivarajah and supervised by Craig Steel

- 1. Discuss verbal thoughts versus mental imagery in relation to emotions.
- 2. Discuss brain activity and findings from neuroimaging studies.
- 3. The brain cannot tell the difference between imagined events and real events which explains the strong emotional reactions.
- 4. Use examples to explain the difficulties and power of mental images versus real situations. This could include participants hearing real music versus imagining hearing music, participants seeing specific facial expressions such as an angry face versus imagining seeing an angry face and imagining taking a penalty versus taking a penalty.
- 5. Explain that control over images can impact distress caused by the images.
- 6. Using positive images to evoke happy and safe feelings.
- 7. You can learn to change images, and the brain will react as if it is happening, even if it's not real, and the mood can change.
- 8. Identify target flashforward
- 9. Complete the Mental Imagery in Psychosis Questionnaire (MIPQ)

Session 2: Microformulation delivered by Nithura Sivarajah and supervised by Craig Steel

- 1. Discuss the central role of control.
- 2. Complete microformulation
- 3. Complete MIPQ

Session 3: Metacognitive Techniques delivered by Nithura Sivarajah and supervised by Craig Steel

1. Examples of attention techniques

Attention training

Switching techniques

2. Examples of imagery manipulation techniques

Imagining popping the image like a balloon

Imagining smashing the image like glass

Imagining shrinking the image or blowing it up

Imagining the image on a TV and switching channels

Imagining the image being on the radio and turning down the volume/switching it off

Imagining changing the colour of the image

Imagining the image looking funny

Imagining putting the image in a bottle and throwing it into the sea

Session 4: Ending delivered by Nithura Sivarajah and supervised by Craig Steel

- 1. Recall/summarise and reflect on the learning.
- 2. Plan how to continue to implement the techniques in the future and explore how to widen their application (e.g., how to use them for other mental images).

Follow Up: Delivered by Nithura Sivarajah and supervised by Craig Steel

- 1. Complete the qualitative feedback survey
- 2. Repeat baseline questionnaires
- 3. Complete MIPQ

Intervention Type

Behavioural

Primary outcome measure

Acceptability and feasibility measured by attendance rates of the sessions in the case series. A Microsoft Teams grid was created to note down attendance after each session, and safety in relation to experiences of adverse events. A record was kept on any reported experiences of any risk to self, to or from others, e.g., episodes of deliberate self-harm, hospitalizations, losses, relapses or any other traumatic experiences, measured through verbal feedback and qualitative feedback measured at the final session, the follow-up session, using a bespoke qualitative measure.

Secondary outcome measures

- 1. Reliable change index and clinical statistical change measured using scoring from the following scales at assessment (baseline) and follow-up:
- 1.1. Generalised Anxiety Disorder Assessment (GAD-7)
- 1.2. Patient Health Questionnaire-9 (PHQ-9)
- 1.3. The Persecutory and Deservedness Scale (PaDS)
- 1.4. Brief Core Schema Scale (BCSS)
- 2. Imagery characteristics measured using an adapted Mental Imagery in Psychosis Questionnaire (MIPQ), participants rated MIPQ scores at every session. These were evaluated using visual analysis and Tau-U calculator.

Overall study start date

25/02/2021

Completion date

31/03/2023

Eligibility

Key inclusion criteria

- 1. Aged 18-65 years old
- 2. Primary reported experiences of psychosis supplemented by diagnostic criteria for schizophrenia and schizoaffective disorder from the ICD-11
- 3. Identifys a distressing flashforward image related to a persecutory delusion
- 4. Has sufficient understanding of the English language
- 5. Has the capacity to give consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

8-9

Total final enrolment

8

Key exclusion criteria

- 1. Signs and diagnosis of learning disabilities
- 2. Endorsement of suicidal intent
- 3. Current alcohol or substance dependence
- 4. Documented or suspected neurological or general medical condition that might be responsible for the psychotic manifestation.

Date of first enrolment

15/12/2022

Date of final enrolment

17/02/2023

Locations

Countries of recruitment

England

United Kingdom

Study participating centre John Sharich House

Southern Health NHS Foundation Trst Slade Site, Horspath Driftway Headington Oxford United Kingdom OX3 7JH

Study participating centre

Early Intervention In Psychosis (pharm)

Prospect Park Hospital Honey End Lane Reading United Kingdom RG30 4EJ

Sponsor information

Organisation

Oxford Health NHS Foundation Trust

Sponsor details

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+44 (0)1865 901 000
Natalia.Jastrzebska@oxfordhealth.nhs.uk

Sponsor type

Hospital/treatment centre

Website

http://www.oxfordhealth.nhs.uk/

ROR

https://ror.org/04c8bjx39

Funder(s)

Funder type

University/education

Funder Name

University of Oxford

Results and Publications

Publication and dissemination plan

The study will be submitted as a partial fulfilment of Nithura Sivarajah's thesis for the Doctorate in Clinical Psychology Programme at the University of Oxford. It is also planned the study will be published in a peer-reviewed psychology journal.

Intention to publish date

30/07/2023

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication. All information and data will be stored on a password-protected Oxford Health NHS Foundation Trust laptop.

IPD sharing plan summary

Stored in non-publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			31/05/2023	No	No
HRA research summary			26/07/2023	No	No