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Turning the curse into a blessing: using mindfulness to reduce suspiciousness and paranoia in individuals with personality characteristics and experiences related to psychosis

Submission date
24/05/2019

Recruitment status
No longer recruiting

Registration date
29/05/2019

Overall study status
Completed

Last Edited
04/07/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aim
Schizotypy refers to a set of personality traits characteristic of schizophrenia found in the general population. Schizotypy is comprised of positive, negative and disorganised factors, reflecting the symptom dimensions of schizophrenia. Positive schizotypy (magical thinking, unusual perceptual experiences, ideas of reference and suspiciousness/paranoia) has recently emerged as a significant predictor of schizophrenia-spectrum disorders, with suspiciousness /paranoia thought to be the strongest predictor of subsequent psychosis.

However, this emergent status as a psychosis risk factor is only one side of the coin, since positive schizotypy has also been linked to creativity, presenting both: psychosis risk and creative potential.
This link is thought to be underlined by a more open sensory information processing style; leading theorists have argued that schizophrenia may result in part from an inability to filter information. Yet, having a more open information processing style (i.e., less filtering) has also been linked to creativity and originality of thought. Antipsychotic medication, currently the main psychosis-prevention strategy, is known to dampen down more open processing in people either with or vulnerable to schizophrenia, potentially reducing conditions promoting creativity in these individuals. Alternative interventions are needed that are efficacious in reducing psychosis risk factors, whilst preserving decreased information filtering thought to promote creativity.

Mindfulness training is one such alternative preventative intervention. Mindfulness is a present-moment receptive awareness, promoting openness, non-judgement, and non-reactivity towards experience. Mindfulness has previously been found to favourably change the relationship with distressing thoughts and images in people with psychotic experiences, including paranoid thoughts, and has been found to reduce paranoia in healthy individuals after a short course of training. Notably, past research has demonstrated that expert meditators have lower levels of

suspiciousness/paranoia (compared with meditation-naïve healthy individuals), yet also demonstrate decreased sensory information filtering. This indicates that decreased sensory information filtering and suspiciousness/paranoia are dissociable with mindfulness practice.

The aim of the current study is to examine the feasibility, acceptability and impact of an online mindfulness-based intervention for reducing suspiciousness/paranoia in individuals with high positive schizotypy, without interfering with more open sensory information processing style thought to support heightened creativity in these individuals.

Who can participate?
Healthy volunteers from the general population (aged 18-65) who are high in both positive schizotypy and suspiciousness/paranoia, as assessed by an online screening survey, will be invited to take part.

What does the study involve?
Participants will be randomly allocated to either a mindfulness-based intervention (MBI) group or active control group. The MBI will consist of daily 'Headspace' 10-minute guided mindfulness meditations, delivered via the Headspace online mobile app. Participants in the active control group be asked to complete 10-minute daily reflective journaling, also via an online mobile app. The trial will last for 40 days (10 minutes of homework activity per day). Participants will be asked to attend the lab prior to and after the intervention for baseline and post-assessment, as well as an online assessment at home after the initial 10-days of their respective programme. Participants in the mindfulness-based intervention will also be interviewed about their experience upon completion.

What are the possible benefits and risks of participating?
This study received full ethical approval as a low-risk study. No risks are anticipated as a result of participation. All participants are free to withdraw from the study at any point. Participants will be offered the opportunity to discuss any questions or concerns they may have during their involvement in the study and will be signposted to relevant sources of information/help should they have any concerns about suspiciousness/paranoia.
Possible benefits will be a reduction in suspiciousness/paranoia and associated factors (e.g., depression, anxiety, worry). All participants will be remunerated for their participation in this study and may find the homework activity they are given enjoyable. Participants in both groups will also be provided with a gifted subscription to Headspace after the post-intervention lab assessment.

Where is the study run from?
All testing will take place at the Institute of Psychiatry, Psychology and Neuroscience, King's College London, UK.

When is the study starting and how long is it expected to run for?
The study will begin in May 2019 and is expected to run until October 2020.

Who is funding the study?
This research is funded by Mental Health Research UK (MHRUK and the Fieldrose Charitable Trust) and the European Mind and Life Institute.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RE11806

Study information

Scientific Title
Turning the curse into a blessing: using mindfulness to reduce suspiciousness and paranoia in individuals with high positive schizotypy

Study objectives
The current study aims to examine the feasibility, acceptability and impact of an online mindfulness-based intervention for reducing suspiciousness/paranoia in individuals with high positive schizotypy, whilst preserving conditions thought to promote creativity in these individuals.
It is hypothesised that, following a mindfulness-based intervention, suspiciousness and paranoia will be reduced in individuals with high positive schizotypy compared to an active control, whilst sensory information filtering style (thought to underlie heightened creativity in these individuals) will be preserved. The study will also explore underlying mechanisms through which mindfulness may reduce suspiciousness/paranoia in individuals with high positive schizotypy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/03/2018, Psychiatry, Nursing and Midwifery Research Ethics Subcommittees (PNM RESC, King's College London, Room 4.16/ 4.16A Waterloo Bridge Wing, Franklin Wilkins Building, Waterloo Road, London, SE1 9NH; 020 7848 4077; pnm@kcl.ac.uk), ref: LRS-17/18-5604.

Study design
Interventional experimental randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

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
High positive schizotypy and suspiciousness/paranoia in the general population.

Interventions
The study will implement a 40-day mindfulness-based online intervention. This will consist of guided mindfulness meditations to be completed by participants at home (10 minutes per day for 40 days), delivered via the online mindfulness app 'Headspace'.

The active control condition will consist of 40 days of reflective journaling. Participants will complete 10 minutes of journaling per day via a free online journaling app. Participants will be asked to reflect on and journal about their daily activities each day.

Participants will be randomised into the intervention or control group using a random, computer-generated number sequence.

Intervention Type
Behavioural

Primary outcome measure
The primary outcome measures will be suspiciousness/paranoia, assessed via self-report scales and an objective measure:
1.1 Fenigstein & Vanable's Paranoia Scale (FVPS).

1.2 Green et al Paranoid Thoughts Scale (GTPS)
1.3 The objective measure of paranoia will be a previously validated inter-personal Virtual Reality (VR) environment:

Participants will be asked to spend 5 minutes in an virtual reality everyday social environment (a pub). Participants will then complete the State Social Paranoia Scale following their exposure to the VR environment, and visual analogue scales (relating to how participants felt during their time in the virtual reality environment (e.g., how safe they felt in the VR environment)

All primary outcome measures will be administered at baseline (pre-intervention) and within 1 week following completion of the 40-day trial. The FVPS will also be administered after completion of the initial 10 days of the trial.

Secondary outcome measures
1. Anxiety, depression and stress as measured by the depression anxiety stress scale (DASS)
2. Worry, as assessed by the penn state worry questionnaire-past-week (PSWQ-PW)
3. Interpersonal sensitivity assessed by the interpersonal sensitivity measure (IPSM)
4. Compassion measured via the self-compassion scale short-form (SCS-SF). Visual analogue scales relating to how compassionate participants felt towards themselves and others within the virtual reality environment will also be used.
5. Mindfulness skill as measured by the five facet mindfulness questionnaire (FFMQ).
6. Schizotypal symptom-like experiences as measured by the schizotypal personality questionnaire
7. Subjective experience of creativity as measured by the experience of creativity questionnaire
8. Sensory information processing, indexed by acoustic startle response.

All above secondary measures will be administered at baseline and within 1 week following the completion of the 40-day trial. The DASS, PSWQ-PW, IPSM, SCS-SF and FFMQ will also be administered after the initial 10 days of the trial.

9. Subjective experience related to the MBI (e.g., ease of use, practicality, enjoyment, potential changes in experience of interpersonal interactions) will be assessed using semi-structured interviews, which will take place at the post-trial assessment visit (within 1 week following completion of the 40-day trial).
10. Engagement with daily homework activity will be tracked via the apps.
11. Retention will be tracked throughout the trial and feedback surveys will be given to participants who choose to discontinue involvement in the trial.

Overall study start date
01/10/2017

Completion date
16/10/2020

Eligibility

Key inclusion criteria
1. Scored high (at least +0.5 SD) on i) positive schizotypy and ii) scored high (at least +0.7 SD) on the suspiciousness/paranoia subscale of positive schizotypy, as measured by the Schizotypal Personality Questionnaire (administered via an online pre-screening survey).
2. Aged between 18-65.

3. Must be based in an area where they can attend the lab sessions (London, UK).
4. Have access to a smart device (phone or tablet) with access to the internet.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
The target overall sample for the trial is 40 participants (20 per group).

Total final enrolment
33

Key exclusion criteria
1. History or current diagnosis of a psychiatric conditions (e.g. psychosis)
2. History of or current drug/alcohol abuse
3. Photosensitive epilepsy
4. Hearing impairment
5. Engaging in regular formal mindfulness practice (at least 10 minutes per day, at least 4-5 days per week) for the past 3-4 months (including meditation, yoga, tai chi, or other)

Date of first enrolment
13/05/2019

Date of final enrolment
01/09/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
Institute of Psychiatry, Psychology and Neuroscience
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Organisation
Institute of Psychiatry, Psychology and Neuroscience

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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Charity

Funder Name
Mental Health Research UK

Alternative Name(s)
Mental Health Research in United Kingdom, MHRUK

Funding Body Type
Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Mind and Life Europe

Results and Publications

Publication and dissemination plan
The researchers plan to submit the study report for peer-reviewed publication at an appropriate academic journal.

Intention to publish date
28/02/2022

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/07/2024	04/07/2024	Yes	No