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SlowMo trial: a digital therapy for people who fear harm from others

Submission date
30/01/2017

Recruitment status
No longer recruiting

Registration date
02/02/2017

Overall study status
Completed

Last Edited
18/03/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims

People often experience distressing worries about other people intentionally causing harm, also known as paranoia. Paranoia is one of the most common symptoms of severe mental health problems and is associated with marked distress and disruption to people's lives. Paranoia tends to be associated with certain thinking habits, called "fast thinking". Everybody thinks fast and this can be helpful in some situations. At other times, fast thinking may contribute to feeling more stressed than we need to be. SlowMo is a therapy service which has been developed by service users, designers, researchers and clinicians to support people to notice their upsetting worries and fast thinking habits, and then provides tips to help them slow down for a moment to notice new information and safer thoughts. The aim of this study is to find out whether SlowMo reduces paranoia. The study will also investigate how SlowMo works (do changes in fast thinking reduce worries about others) and whether differences in beliefs, memory, and motivation influence this.

Who can participate?

Adults who have had distressing paranoia for at least three months.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group take part in the SlowMo programme in addition to receiving usual care. This involves eight individual, face-to-face sessions with a trained therapist, which are supported by a website with interactive stories and games. The programme helps people to find out how fast thinking habits can contribute to upsetting thoughts, and try out tips to learn what helps them slow down their thinking and cope with worries. The first two sessions involve learning that worries about others and fast thinking are common, and developing an individualised understanding of the person's thoughts and thinking habits. The remaining six sessions deal with learning and trying out tips to slow down thoughts. Those in the second group receive usual care only, as they would if they weren't taking part in the study. At the start of the study and then after 12 and 24 weeks, participants complete a number of questionnaires to assess their paranoia and related symptoms as well as their mental wellbeing.

What are the possible benefits and risks of participating?
It is hoped that those receiving SlowMo will find it helpful. However, this cannot be guaranteed. Those who do not receive SlowMo will not be given a phone with the SlowMo app but will be reimbursed for their time. The information from all participants may help to support others with similar problems. If SlowMo is shown to work, then the plan would be for it to be more widely available in NHS services in the future. There are no anticipated risks involved with participating. However, as standard practice, the university sponsoring the research has insurance arrangements in place to provide for any harm arising from taking part if it were to occur. NHS indemnity (insurance) operates in respect of the therapy that is provided.

Where is the study run from?
1. South London and Maudsley NHS Foundation Trust (UK)
2. Oxford Health NHS Foundation Trust (UK)
3. Sussex Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2015 to August 2019

Who is funding the study?
Efficacy and Mechanism Evaluation Programme (UK)

Who is the main contact?
Dr Thomas Ward
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Study website
www.slowmotherapy.co.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number
206680

ClinicalTrials.gov number

Secondary identifying numbers
32154, IRAS 206680

Study information

Scientific Title
A randomised controlled trial to evaluate the outcomes and mechanisms of a novel digital reasoning intervention for persecutory delusions

Acronym
SlowMo

Study objectives
Research questions:
1. Is SlowMo efficacious in reducing paranoia severity over 24 weeks, when added to treatment as usual (TAU), in comparison to TAU alone?
2. Does SlowMo reduce paranoia severity by improving fast thinking (reducing belief inflexibility and jumping to conclusions)?
3. Do participant characteristics (i.e. their cognitive capacities, specifically working memory and thinking habits; and their symptoms, specifically negative symptoms) moderate the effects of the intervention?
4. Does outcome differ by adherence to the intervention and is adherence predicted by the participants' beliefs about their illness and about the intervention?
5. Does the SlowMo digital therapy platform have acceptable rates of usability, acceptability and adherence?
6. Does SlowMo reduce worry?

Study Hypotheses:
Primary hypotheses:
1. The intervention will reduce paranoia severity over 24 weeks.
2. Fast thinking (belief inflexibility and jumping to conclusions) will improve in response to the intervention.
3. Reductions in fast thinking will mediate positive change in paranoia severity.

Secondary hypotheses:
4. Poorer working memory and more severe negative symptoms will negatively moderate treatment effects.
5. Therapy adherence will moderate the effects of treatment on outcome and adherence will be predicted by beliefs about mental health problems.
6. Worry will not mediate reductions in paranoia severity

Ethics approval required
Old ethics approval format

Ethics approval(s)

Camberwell St Giles committee, 07/12/2016, ref: 16/LO/1862

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Paranoia

Interventions
Participants are randomised in a 1:1 ratio to one of two groups.

Intervention group: Participants receive the SlowMo intervention in addition to treatment as usual (TAU). SlowMo consists of eight individual, face-to-face sessions, delivered by trained therapists, assisted by a website with interactive stories and games. SlowMo supports people to find out how fast thinking habits can contribute to upsetting thoughts, and try out tips to learn what helps them slow down their thinking and cope with worries. Personalised session content is synchronised with a mobile app to support people to make use of strategies learnt in their daily life. The first two sessions involve learning that worries about others and fast thinking are common, and developing an individualised understanding of the person's thoughts and thinking habits. The concepts of 'thinking fast' and 'thinking slow' are introduced. It is explained that everyone thinks fast at times, and this can be helpful although at other times thinking fast can mean we feel worried when we do not need to be. Participants learn that thinking slow can be helpful in dealing with stress and worries about other people. This key principle frames the remaining 6 sessions where people are supported to find out about and try out tips to slow down for a moment, such as the impact of mood and past experiences on paranoia.

Control group: Participants receive treatment as usual only, which involves usual care with reference to best practice guidance, specifically NICE guidance on community mental health treatment for people with psychosis and the standards of community care required by the Care Quality Commission. Participation in the study will not alter usual treatment decisions about medication and additional psychosocial interventions which remain the responsibility of the clinical team.

For participants in both groups, assessments are undertaken at baseline, after treatment at 12 weeks, and at 24-week follow-up.

Intervention Type
Other

Primary outcome measure
Paranoia is assessed using the Green Paranoid Thoughts Scale (GPTS) at screening, baseline, 12 weeks and 24 weeks.

Secondary outcome measures
1. Frequency, severity and impact of delusional beliefs are assessed using The Psychotic Symptom Rating Scales (PSYRATS-delusions) at baseline, 12 weeks and 24 weeks
2. Positive symptoms are assessed using the Scales for Assessment of Positive Symptoms (SAPS) at baseline, 12 weeks and 24 weeks (N.B all items will be used at baseline but only the Persecutory delusions and ideas of reference items will be used at 12 and 24 weeks)
3. Belief flexibility (Possibility of being mistaken; PM) is assessed using the Maudsley Assessment of Delusional Beliefs (MADS); Wessely et al. (1993), at baseline, 12 weeks and 24 weeks
4. Belief flexibility (Presence of Alternative Explanations; AE) is assessed using Explanation for Experiences (Freeman et al., 2004) at baseline, 12 weeks and 24 weeks
5. The Jumping to conclusions (JTC) bias is assessed using the Beads Task in ratios 60:40 and 85: 15 at baseline, 12 weeks and 24 week
6. Negative symptoms are assessed using Brief Negative Symptom Scale (BNSS) at baseline
7. Beliefs about problems are assessed using Beliefs about Problems Questionnaire at baseline
8. Working memory is assessed using Letter Number Sequencing (from Wechsler Adult Intelligence Scale (WAIS IV) at baseline
9. Processing speed and set-shifting are assessed using the Trail Making Task- A&B at baseline
10. Reasoning about paranoia is assessed using the Thinking about Paranoia Scale (TAPS) at baseline, 12 weeks and 24 weeks
11. Current worry is assessed using the Penn State Worry Questionnaire at baseline, 12 weeks and 24 weeks
13. Beliefs about the self and others are assessed using Brief Core Schema Scales (BCSS) at baseline, 12 weeks and 24 weeks
14. Carer criticism is assessed using Perception of carer criticism (adapted from Hooley et al., 1989) at baseline
15. Mental well-being is assessed using The Warwick-Edinburgh Mental Well-being Scale (WEMWBS) at baseline, 12 weeks and 24 weeks
16. Quality of life is assessed using the Short Assessment of Quality of Life (MANSA) at baseline, 12 weeks and 24 weeks
17. Service use (including medication, bed and crisis team days, contact with criminal justice system) will be assessed using the Client Service Receipt Inventory at baseline and 24 weeks

Overall study start date
01/07/2015

Completion date
25/10/2019

Eligibility

Key inclusion criteria

1. Aged 18 years and over
2. Persistent (3+ months) distressing paranoia (as assessed using clinical interview (SCAN) and score >29 on Green Paranoid Thoughts Scale (GPTS), persecutory subscale)
3. Diagnosis of schizophrenia-spectrum psychosis (F20-29, ICD 10: Present State Examination, version 10)
4. Capacity to provide informed consent
5. Sufficient grasp of English to participate in informed consent process, assessments and interventions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 360; UK Sample Size: 360

Total final enrolment
362

Key exclusion criteria
1. Lacks capacity to consent
2. Profound visual and/ or hearing impairment
3. Insufficient comprehension of English
4. Inability to engage in the assessment procedure
5. Engagement in psychological therapy for paranoia
6. Primary diagnosis of substance abuse disorder, personality disorder, organic syndrome or learning disability

Date of first enrolment
01/05/2017

Date of final enrolment
14/05/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South London and Maudsley NHS Foundation Trust
Maudsley Hospital
Denmark Hill
London
United Kingdom
SE5 8AZ

Study participating centre
Oxford Health NHS Foundation Trust
4000 John Smith Drive
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Oxford
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OX4 2GX

Study participating centre
Sussex Partnership NHS Foundation Trust
Swandean
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United Kingdom
BN13 3EP

Sponsor information

Organisation
King's College London

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Sponsor type
University/education

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http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Organisation
South London and Maudsley NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.slam.nhs.uk/

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
Efficacy and Mechanism Evaluation Programme

Alternative Name(s)
NIHR Efficacy and Mechanism Evaluation Programme, EME

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Trial results will be disseminated through a series of publications in high-impact peer reviewed journals.

Intention to publish date
31/03/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Philippa Garety (philippa.garety@kcl.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/11/2017		Yes	No
Results article		01/07/2021	08/04/2021	Yes	No
Results article		01/07/2022	04/07/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/08/2021	18/03/2025	Yes	No