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STOP - Successful treatment of paranoia

Submission date 24/06/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [X] Individual participant data [X] Record updated in last year
Registration date 03/08/2021	**Overall study status** Completed	
Last Edited 06/01/2026	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Paranoia is linked to several mental health conditions, including psychosis. Estimates suggest that 3.5% of people will get a psychotic disorder at some point in their lives. Psychosis is one of the most disabling mental health conditions. It leads to distress and impairment in work, family and social functioning. Recent advances in thinking suggest that treatments might be more effective if they focus on one particular symptom at a time and try to treat that rather than trying to treat the whole disorder in one go. This study proposes to develop and test a mobile app version of a new therapy for paranoia called CBM-pa. CBM-pa is a self-administered psychological therapy that has been developed by combining basic research on biases in paranoia with established techniques that can change these biases. CBM-pa is computerised and involves reading text that could be interpreted in a paranoid way (such as the stare of a stranger which could reflect harmful intentions). The therapy encourages readers to make the alternative interpretation (such as the stare reflecting harmless curiosity) by using word tasks and questions. A six-session version has been developed and a feasibility study has been completed with promising results. In year 1 of this study, we will develop CBM-pa into a more accessible and engaging 12-session app for mobile phones, called STOP: Successful Treatment of Paranoia, by adding 6 newly created sessions. In years 2-4 we will give patients STOP alongside their usual treatment and compare this with a control condition where patients simply read text in the mobile app instead. The study uses a randomised controlled design and patients are recruited from two different UK sites. We aim to identify how many sessions of STOP are best to give and will measure how many sessions produce enough change in paranoid symptoms to be clinically useful. We will take measurements at 6-, 12-, 18- and 24-weeks post-randomisation. Obtaining this longer-term follow-up data will show us whether any beneficial effects of STOP are lasting.

Who can participate?
Adults (aged 18 or over) diagnosed as suffering from clinically significant persecutory or paranoid symptoms for at least one month.

What does the study involve?
Participants will be randomly allocated to receive TAU plus either 6 or 12 weekly sessions of STOP, or TAU plus active text reading control. Participants will be asked to complete in-app assessments on target mechanism, clinical symptoms, mood changes and recovery. All participants are followed up in-person or online at 6-, 12-, 18- and 24-weeks post-randomisation.

What are the possible benefits and risks of participating?
Participants will take part in addition to receiving TAU.

Possible benefits of participation include a reduction in distressing paranoid symptoms. Feasibility data suggest there might be additional, smaller benefits for comorbid anxiety and depression, and improved resilience to stress. User-endorsed recovery measures will be used to capture any wider, daily functioning benefits. Providing easier access to treatment without additional therapist demand should reduce the overall cost of care.

There is a possibility that reading potentially paranoia-inducing material could cause distress. We now have data from the feasibility trial (variety of mood measures pre-post each session) showing that participants' immediate mood was either unaffected or slightly improved after each session. Nevertheless, we will assume the therapy might still evoke stress and will address this, as previously, by measuring mood within the app and offering contact with a relevant team member if scores above an agreed threshold are reached.

Where is the study run from?
1. King's College London (UK)
2. University of Bath (UK)

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

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof Jenny Yiend, jenny.yiend@kcl.ac.uk

Contact information

Type(s)
Scientific

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Prof Jenny Yiend

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Type(s)
Public

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Integrated Research Application System (IRAS)
303876

Study information

Scientific Title
STOP - Successful Treatment of Paranoia: Replacing harmful paranoid thoughts with better alternatives

Acronym
STOP

Study objectives
Twelve sessions of STOP will significantly reduce self-reported paranoid symptoms on our primary outcome compared to a 12-session active text reading control at 24 weeks post-randomisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 14/01/2022, London-Stanmore Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)20 7104 8064; stanmore.rec@hra.nhs.uk), ref: 21/LO/0896
2. No objection 19/07/2022, Medicines and Healthcare products Regulatory Agency (MHRA, 10 South Colonnade, Canary Wharf, London, E14 4PU, UK), ref: CI/2022/0033/GB

Primary study design

Interventional

Study design
Multicentre interventional double-blinded superiority randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Personality disorder - paranoia

Interventions
Current intervention as of 24/08/2022:
This study proposes to develop and test a mobile app version (STOP) of a new intervention for paranoia called CBM-pa. CBM-pa is a self-administered psychological therapy that has been developed by combining basic research on biases in paranoia with established techniques that can change these biases.

We will randomise 273 stabilised outpatients with persistent distressing paranoid symptoms to one of three study arms. Randomisation will be conducted by King's Clinical Trials Unit (CTU). Assignment to intervention or control is automatic within the app, upon entry of a uniquely generated participant code from the CTU.

Those in the intervention arms (groups 1 and 2) will receive treatment as usual (TAU) plus either 6 or 12 weekly sessions of STOP, respectively. Treatment As Usual will include standard care and may include pharmacotherapy and/or psychological therapies. Using a mobile app, participants will complete 40 training items per session whereby they have to read text inviting paranoid interpretations, then complete missing words and answer questions in a way that encourages more helpful beliefs about themselves and others. Each session should take approximately 40 minutes to complete, depending on reading speed.

Those in the control arm (group 3) will receive TAU plus active control, which involves 12 weekly sessions of in-app text reading. The active control condition is identical in trial procedure to the intervention but the content omits the active ingredient: resolution of an emotionally ambiguous situation in a benign/non-paranoid manner. Instead control participants read and respond to neutral, factual material.

Follow-up assessments, comprising primary and all secondary outcomes, will be researcher-administered and conducted at baseline, 6-, 12-, 18- and 24-weeks post-randomisation in purpose designed interview rooms or online. Treatment acceptability will be measured once, post treatment, using Ben-Zeev's scale; transient mood change across each session (Paranoid, Anxious, Sad, Friendly) will be measured using Visual Analogue Scales (VAS) pre-post each weekly session; and adverse or unwanted effects of the intervention will be measured at the 12-week follow-up using the Negative Effects Questionnaire (NEQ).

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Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 24/08/2022:
Paranoid symptoms are measured using the Paranoia Scale (PS) at 24 weeks (T4) post-randomisation follow-up.

Previous primary outcome measure:
Paranoid symptoms are measured using the Paranoia Scale (PS) at baseline (T0), 6 (T1), 12 (T2), 18 (T3) and 24 weeks (T4) post-randomisation follow ups.

Key secondary outcome(s)
Current secondary outcome measures as of 24/08/2022:
1. Target mechanism (interpretation bias) is measured at baseline (T0), 6 (T1), 12 (T2), 18 (T3), and 24 weeks (T4) post-randomisation using:
1.1. Similarity Rating Test (SRT)
1.2. Scrambled Sentences Task (SST)
2. Clinical symptoms are measured using:
2.1. Paranoia Scale (PS) at baseline (T0), 6 (T1), 12 (T2), and 18 weeks (T3) post-randomisation
2.2. Green Paranoid Thoughts Scale - Revised (R-GPTS) at baseline (T0), 6 (T1), 12 (T2), 18 (T3), and 24 weeks (T4) post-randomisation
2.3. Positive and Negative Symptom Schedule (PANSS) item 6 only at baseline (T0), 6 (T1), 12 (T2), 18 (T3), and 24 weeks (T4) post-randomisation
3. Other symptoms are measured at baseline (T0), 6 (T1), 12 (T2), 18 (T3), and 24 weeks (T4) post-

randomisation using:
3.1. Hospital Anxiety and Depression Scale (HADS)
3.2. Paranoia Worries Questionnaire (PWQ)
4. Recovery is measured at baseline (T0), 6 (T1), 12 (T2), 18 (T3), and 24 weeks (T4) post-randomisation using:
4.1. Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)
4.2. Questionnaire about the Process of Recovery (QPR)
4.3. Recovering Quality of Life (ReQoL)

Previous secondary outcome measures:
1. Target mechanism (interpretation bias) is measured at baseline (T0), 6 (T1), 12 (T2), 18 (T3) and 24 weeks (T4) post-randomisation using:
1.1. Similarity Rating Test (SRT)
1.2. Scrambled Sentences Task (SST)
2. Paranoid symptoms are measured at baseline (T0), 6 (T1), 12 (T2), 18 (T3) and 24 weeks (T4) post-randomisation using:
2.1. Green Paranoid Thoughts Scale (GPTS)
2.2. Peter's Delusions Inventory (PDI)
2.3. Positive and Negative Symptom Schedule (PANSS) - item 6 only
3. Other symptoms are measured using the Hospital Anxiety and Depression Scale (HADS) and Paranoia Worries Questionnaire (PWQ) at baseline (T0), 6 (T1), 12 (T2), 18 (T3) and 24 weeks (T4) post-randomisation
4. Recovery is measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) and Questionnaire about the Process of Recovery (QPR) at baseline (T0), 6 (T1), 12 (T2), 18 (T3) and 24 weeks (T4) post-randomisation

Completion date
16/12/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 24/08/2022:
1. Any clinical diagnosis featuring clinically significant persecutory or paranoid symptoms, present for at least the preceding month. This will be operationalised as a score of 3 ("mild") or more on the paranoia item (item 6) of the Positive and Negative Syndrome Scale (PANSS).
2. Displaying an interpretation bias ≥2 on the 8-item screening version of the Similarity Ratings Task (SRT). The screening score has a range of +3 (strong positive bias) to −3 (strong paranoid bias).
3. If on psychotropic medication, then stable on medication for at least the last 3 months and expected to be so for the study duration
4. Aged ≥18 years
5. Capacity to consent

Previous participant inclusion criteria:
1. Any clinical diagnosis featuring clinically significant persecutory or paranoid symptoms, present for at least the preceding month
2. Showing paranoid symptoms >/=3 on the paranoia item (item 6) of the Positive and Negative Symptoms Scale (PANSS)
3. Displaying an interpretation bias >/= 1 on the 8-item screening version of the Similarity Ratings Task (SRT). The screening score has a range of +3 (strong positive bias) to −3 (strong

paranoid bias)
4. If on psychotropic medication, then stable on medication for at least the last 3 months and expected to be so for the study duration
5. Age 18 - 65 years
6. Capacity to consent, assessed by clinician using the South London and Maudsley NHS Trust required standard protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
274

Key exclusion criteria
Current participant exclusion criteria as of 24/08/2022:
1. Severe cognitive impairment
2. Illiteracy or inability to understand written and spoken English for any other reason
3. Major physical illness (cancer, heart disease, stroke)
4. Major substance or alcohol misuse, assessed by the SCID-V screen
5. Currently receiving, or soon due to receive, a psychological intervention targeting the same psychological mechanism as STOP (i.e., paranoid belief change) or having done so in the last 3 months
6. Currently taking part in any other interventional research study
7. Scoring 7 (defined as ‘Extreme’) on item 6 of the PANSS
8. At high risk of suicide as indicated by the Columbia Suicide Severity Rating Scale (C-SSRS) - Screen Version

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2. Illiteracy
3. Major physical illness (cancer, heart disease, stroke)
4. Major substance or alcohol misuse, assessed by the SCID-V screen
5. Currently receiving, or soon due to receive, a psychological intervention targeting the same psychological mechanism as CBM-pa (paranoid beliefs) or having done so in the last3 months

Date of first enrolment

01/09/2022

Date of final enrolment
26/06/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
Institute of Psychiatry, Psychology & Neuroscience
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England
SE5 8AF

Study participating centre
University of Bath
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Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository.
The data generated by this study will be deposited with UK Data Archive, via the ReShare process. Our data will be discoverable via the UK Data Archive. To enhance the awareness of the data and access to it we will include links to the archive data deposit as follows: in all study publications; on the study website; on the MRC Gateway; on Open Science Framework. We will prepare a data sharing policy, in line with the data sharing principles of the referenced MRC policy which will be made available on the study website and UK Data Archive.

Types of data that will be shared:
Quantitative: baseline, 0, 6, 12, 18 & 24 week follow ups; pre- and post-intervention sessions mood trackers. Data generated are from:
i) Evaluation: semi-structured clinical interviews, self-report questionnaires (mood, personality, symptom, recovery measures), experimental tasks

When the data will become available/for how long:
Within the UK Data Archive system depositors can set an embargo on open access and restrict the type of users who can access the data. For this study we will apply a 12-month embargo to access from the end of the trial to allow the main outputs of the study to be accepted in the peer reviewed literature. Should the main findings be published sooner the embargo period will be correspondingly shortened. Data will be retained for a period of 20 years after project completion, in line with MCR and King's guidelines.

Access criteria for sharing data (with whom, for what type of analyses, by what mechanism):
We will ensure that the criteria and process governing access is transparent and in line with MRC policy. It will include independent oversight. Details will be made available on the study website and with the data deposit. This will vary according to the lifecycle stage of the study (active trial recruitment phase, PI led analysis, archiving stage).
As we anticipate only occasional requests for data access, we will follow MRC's suggested Model 2 for access decisions. In this model the PI is responsible for access decisions but draws on the

study team and/ or an independent advisor. All decisions are documented, and the advisor periodically reviews these and approves the study's access policy and procedures.

We will set access permissions within UK Data Archive, to allow for the implementation of the governance policy. New users would be asked to provide a written request for access with reference to MRC policy on research sharing which would then be considered according to the criteria and process outlined in the study policy on data access.
We will ensure that a data sharing agreement is written and signed by both parties as outlined in MRC guidance section 7. It will cover all the items listed in that section such as: new purpose for which the data will be used; conditions of use; appropriate acknowledgement of original funding source, etc.

Consent from participants/Data anonymisation:
The data will be suitable for sharing. Participants will be assigned an anonymised ID within the datasets. Although datasets will not include any direct identifiers(e.g., participant's name or contact details) they will include indirect identifiers (e.g., date of birth, gender, ethnicity and sensitive clinical diagnostic information). In combination with other information this could make it possible to re-identify an individual, albeit very unlikely. Therefore, we assume that these data will not be robustly anonymised and we will include a specific item in our informed consent procedures allowing participants to indicate whether they consent to data sharing via a national repository. The data deposit will be limited to those cases giving consent.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		02/12/2024	03/12/2024	Yes	No
Dataset	Under embargo until 31/12/2025		16/07/2025	No	No
HRA research summary			28/06/2023	No	No
Other publications	Protocol for embedded mixed methods process evaluation	22/12/2025	06/01/2026	Yes	No
Participant information sheet	Bath version 3.0	27/04/2022	24/08/2022	No	Yes
Participant information sheet	London version 3.0	27/04/2022	24/08/2022	No	Yes
Plain English results			16/07/2025	No	Yes
Statistical Analysis Plan	version 1.2		15/01/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes