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Assessing the safety, tolerability, and feasibility of a stroboscopic intervention protocol in people with depression

Submission date
07/07/2025

Recruitment status
No longer recruiting

Registration date
16/07/2025

Overall study status
Ongoing

Last Edited
14/07/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims

Depressive disorders cost the UK over £27 billion annually. Approximately 1.24 million people in England currently live with depression, a figure projected to rise to 1.45 million by 2026. Existing treatments fall into two main categories: antidepressants (pharmacological) and talking therapies (psychotherapy). While both can be effective, they have notable limitations. Antidepressants are often associated with problematic side effects, can take 4–6 weeks to take effect, and are not effective for everyone. Psychotherapy typically requires 12–20 weeks and is expensive and difficult to scale due to therapist shortages and access barriers.

Recently, there has been renewed interest in the use of psychedelic therapies for depression. However, these approaches remain unproven, legally restricted, and largely inaccessible. Given the ongoing mental health crisis, there is an urgent need for safe, effective, and scalable alternatives.

This study will investigate the potential of stroboscopic light stimulation as a novel treatment for mild to severe depression. The aim is to develop an intervention that is easy to administer, well-tolerated, cost-effective, and minimally reliant on pharmaceuticals.

Surprisingly, when experienced with closed eyes, stroboscopic light typically induces vivid visual phenomena such as colours, geometric patterns, motion, and even complex scenes, alongside, for many, strong emotional responses. These effects resemble those associated with psychedelic experiences. In our recent large-scale public art-science installation, Dreamachine (https://dreamachine.world/), nearly 40,000 people safely underwent stroboscopic experiences. The overwhelming majority reported these as highly enjoyable and positive, and many, without prompting, noted a reduction in symptoms of depression, anxiety, and other negative mental states. These reports, while anecdotal, align with emerging evidence suggesting that stroboscopic stimulation may have therapeutic benefits for depression.

This early-phase study will systematically evaluate the safety, tolerability, and feasibility of stroboscopic light exposure in individuals with major depressive disorder (MDD). Participants will be allocated to either an intervention or control condition and attend four weekly 30-minute sessions. The intervention and control protocols are matched in total light exposure but differ in the intensity of visual hallucinations they produce. Throughout the study, we will assess tolerability, subjective experience, retention, mood, and well-being. If successful, the findings

will provide critical preliminary data to support the future development of a non-pharmacological, scalable intervention for depression.

Who can participate?
Adults aged 18 years or over who are currently experiencing depression

What does the study involve?
Stroboscopic stimulation will be delivered using a CE-certified commercial stroboscope (roXiva RX1). Participants will attend four weekly 30-minute sessions and be randomly assigned to either the intervention or control group. The two conditions differ only in the intensity of visual hallucinations elicited by the strobe sequences.
All participants will complete the same set of measures. Before the first session, participants will report their expectations about the intervention and complete validated measures of depressive symptoms and affect. After each session, they will complete questionnaires assessing tolerability, visual hallucinations, altered states of consciousness, and mood. Additional online questionnaires measuring depressive symptoms will be sent on days 1, 3 and 5 after each session. From the second session onwards, participants will also report any side effects experienced in the previous week.
This approach will allow us to assess tolerability across repeated exposures, identify any emerging side effects, and evaluate the overall feasibility of the intervention for people with depression. It will also provide exploratory data on changes in mood, affect, and subjective experience throughout the course of the study.

What are the possible benefits and risks of participating?
Participants will receive compensation for their time: either 4 SONA credits per hour or £10 per hour. Although there may be no direct benefit to individuals, participants will contribute to advancing our understanding of new treatment approaches for depression.
Some questionnaires include sensitive items about low mood and suicidal thoughts. If participants feel these may adversely affect their well-being, they are advised not to take part. Mental health support resources will be provided, and if researchers have concerns about a participant's well-being, clinical psychologist Dr James Stone (Co-Investigator) will provide appropriate support.
Strobe lights are commonly encountered in everyday life, but in rare cases they may induce seizures in individuals with photosensitivity, or cause anxiety, discomfort, or migraines. Individuals with a history of light sensitivity, frequent migraines, or seizure risk factors will be excluded during pre-screening and are advised not to take part.

Where is the study run from?
Sussex Centre for Consciousness Science, University of Sussex (UK)

When is the study starting and how long is it expected to run for?
June 2025 to March 2026

Who is funding the study?
Medical Research Council (MRC), through the Developmental Pathway Funding Scheme (DPFS) [APP34051]

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
WP2

Study information

Scientific Title
Assessing the safety, tolerability, and feasibility of a stroboscopic intervention in mild to severe forms of major depressive disorder

Study objectives
1. Stroboscopic light stimulation is safe and well-tolerated in individuals with mild to severe Major Depressive Disorder (MDD).
2. A 4-week stroboscopic intervention protocol, with weekly 30-minute stroboscopic stimulation sessions, is feasible in people with MDD.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/06/2025, Sciences & Technology C-REC (University of Sussex, Brighton, BN1 9RH, United Kingdom; +44 (0)1273 877492; crecscitec@sussex.ac.uk), ref: ER/LK344/4

Study design
Single-centre interventional double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Depression

Interventions
Stratification
Participants will be assigned to either an intervention or control condition. Stratification will be based on current psychoactive drug treatment (none vs medication) and their baseline depressive symptom severity, as measured by the PHQ-9 (5–16: mild to moderate; 17–27: moderate to severe). Participants will be unaware that two different conditions exist, and testing researchers will be blinded to participants' group allocation. Stratification will be done through a Python script which assigns participants one of 10 random stroboscopic session names (5 control, 5 intervention). This assigned session will be administered to the participant throughout the study; the testing researchers are blinded to which session names belong to which condition.
Participants' IDs, assigned stroboscopic session names, and conditions are saved to a file and will be periodically checked by a researcher who is not testing. Unblinding of the participants during debriefing is automated and does not require the researcher's unblinding until after the end of all data collection.

Overall Structure of the Intervention
All participants will attend four weekly testing sessions (60-90 minutes each), either taking part in the stroboscopic intervention (30 minutes) or the control condition (30 minutes). During the light sessions, participants will sit in front of a commercial strobe light with their eyes closed. The light sessions will not reach more than a luminance value of ~2700 lux, with a ±5% maximum between-condition deviation. Stimulation frequencies range between 3.75 and 15 Hz, with a duty cycle range of 25 to 75%. Half of the stroboscopic device will deliver dynamic stroboscopic stimulation, while the other half remains at a constant 60 Hz "wash light" with a duty cycle of 50% (perceived as constant). To effectively eliminate stroboscopically induced visual experiences in the control condition, a luminance ratio of 10:1 (wash:strobe) is applied; both conditions apply the same total luminance over time but produce minimal to moderate visual experiences. In the intervention condition, this ratio is reversed, with the wash light being 1 /10th the brightness of the strobe light, leading to engaging visual experiences.
The primary outcomes of the study are critical data on the safety, tolerability, and feasibility (as measured by overall retention rate) of the stroboscopic intervention in individuals with major depressive disorder (MDD). In addition, measures of depressive symptoms and well-being will be administered throughout the study to assess the potential therapeutic effects of repeated stroboscopic light exposure. Finally, to capture participants' session-specific experiences, we will administer measures of altered states of consciousness, visual hallucinations, and general experiential responses during the stroboscopic sessions.

Participants will take part in the four stroboscopic sessions at the University of Sussex. A soundproof booth in the testing room allows for participant privacy. The testing researcher will be outside to monitor the participants and respond to any needs during the experiments. All questionnaires will be administered through Qualtrics.

Measures Administered Before First Strobe Session
At the beginning of the study, participants will fill out a combination of the Treatment Expectation Questionnaire (TEX-Q) and the Stanford Expectations of Treatment Scale (SETS) to

assess their expectations about the stroboscopic intervention. To capture baseline information about the participant's depressive symptomology, they will complete the Beck Depression Inventory-II (BDI-II), the self-report Montgomery-Åsberg Depression Rating Scale (MADRS-S), and the Beck Anxiety Inventory (BAI).

Before each Stroboscopic Session
Participants will be asked whether there have been any changes to the treatment of their depression, alongside being asked to provide a description of any changes in their depressive symptoms. To assess potential side effects associated with completing multiple strobe sessions, they will complete the self-rated global measure of Frequency, Intensity, and Burden of Side Effects Rating (FIBSER).
To provide session-specific information about participants' depressive symptomology and general well-being, they will complete the Maudsley 3-item Depression Visual Analogue Scale (M3VAS), Patient Health Questionnaire 9 (PHQ-9), and the Scale of Positive and Negative Experience (SPANE).

Immediately after each Stroboscopic Session
To assess tolerability, participants will indicate whether they experienced any side effects during the session; if they select no, they will not be asked for any further information regarding the tolerability of the session. If participants report any side effects, they will be asked to select relevant symptoms from a list based on the Visual Discomfort Questionnaire and indicate the frequency with which each symptom occurred. Any reported side effects will then be rated on a 10-point scale, which will be referred to as the tolerability score or symptom discomfort score. This scale ranges from 0 (no symptom discomfort) to 10 (worst possible symptom discomfort), with 3 indicating mild symptom discomfort, 5 as moderate symptom discomfort, and >7 as severe symptom discomfort. Any report of a score above 7 will result in the participant’s exclusion from the experiment, and they will not be tested further.
To capture participants' stroboscopic experiences, they will complete the 6-Dimension Visual Hallucination Questionnaire and the 42 items of the original 94-item 5D-Altered States of Consciousness Ratings Scale, which pertain to its 11 subdimensional factors.
The Maudsley 3-item Depression Visual Analogue Scale – change (M3VAS-Change), PHQ-9, and the SPANE will be administered to assess changes in well-being and depressive symptoms since before the stroboscopic session.
Participants will also report their overall experience on visual analogue scales ranging from 0-100, indicating how engaging, pleasurable, uncomfortable, and sleep-inducing each session was. They will also be given the opportunity to provide written feedback about their experience.

SMS Questionnaires
Following sessions 1, 2, and 3, participants will be asked to complete a follow-up questionnaire, including the M3VAS-Change, PHQ-9, and SPANE, at 1, 3, and 5 days after each session. Participants will receive an SMS containing a link to this Qualtrics questionnaire.

After the Fourth (Final) Stroboscopic Session
After the final strobe session, participants will complete the same measures as they did after sessions 1, 2 and 3; additionally, they will also complete the pre-test questionnaires (BDI-II, BAI, and MADRS-S). At the end of the fourth testing session, participants will be compensated for their participation.
After session four, participants will receive a single follow-up questionnaire via SMS, sent one week after their final stroboscopic session. This questionnaire will include the M3VAS-Change, PHQ-9, SPANE, and FIBSER to capture any side effects. Lastly, participants will be debriefed about the aims of the study and which group they were in.

Monitoring Well-being and Suicidality
Throughout the study, at each testing session, participants will be asked whether their depressive symptoms have worsened, with particular attention to suicidality. Should the testing researchers identify any cause for concern, the principal investigator and clinical lead will take the appropriate steps to ensure the participant receives the necessary support.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
roXiva RX1

Primary outcome(s)
1. Safety, defined as no severe adverse reactions as a direct result of stroboscopic stimulation, defined as a reaction that results in death, is life-threatening or requires hospitalisation. This information will be collected throughout the study.
2. Tolerability measured on a 10-point scale, ranging from no discomfort (0) to severe discomfort (10) after each 30-minute strobe session, assessing each 30-second section. Outcome: Mean tolerability scores <7.
3. Tolerability Index total (TI): number of participants experiencing an event (side effect) /number of patients discontinuing the study due to any event. Outcome: TI >35. Calculated following the completion of the study.
4. Recruitment: Recruited participants are defined as those who attended at least one session. Retained participants are those who completed all stroboscopic testing sessions. Outcome: Recruit 84 participants within 18 months (≥80% recruitment rate acceptable) and retain at least 80% of those recruited at treatment completion at 18 months.

Key secondary outcome(s))
Exploratory analyses will examine the trajectories of affective symptom measures across the study period, from baseline (pre-session 1) to either post-session 4 or the week 5 follow-up, depending on the instrument:
1. Overall depressive symptom severity measured using the Patient Health Questionnaire-9 (PHQ-9), total score (0–27)
2. Sadness (depressed mood), anhedonia (loss of pleasure), and overall energy (psychomotor activity) measured using the Maudsley 3-item Visual Analogue Scale (M3VAS), each measured on a scale from 0-100.
3. The frequency of a broad range of Positive (SPANE-P, 6–30) and Negative Experiences (SPANE-N, 6–30) measured using the Scale of Positive and Negative Experience (SPANE)
4. Depressive symptom severity measured using the Beck Depression Inventory-II (BDI-II), total score (0–63)
5. Depressive symptom severity measured using the Montgomery–Åsberg Depression Rating Scale – Self-Report (MADRS-S), total score (0–54) for self-reported depressive symptoms
6. Anxiety severity measured using the Beck Anxiety Inventory (BAI), total score (0–63)

7. Treatment expectations measured using a combination of the Treatment Expectation Questionnaire (TEX-Q) and the Stanford Expectations of Treatment Scale (SETS)
8. Participants' overall experiences during each stroboscopic session measured using the Six-Dimensional Visual Hallucination Questionnaire (6D-VHQ) following each stroboscopic session

9. Participants' visual experiences during each stroboscopic session measured using the 11-factor Altered States of Consciousness rating scale (11-ASC)

Completion date
01/03/2026

Eligibility

Key inclusion criteria
1. Depression Patient Health Questionnaire-9 (PHQ-9) score of 4-27, reflecting mild to severe depression
2. >18 years of age
3. Willingness to take part in the study protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. Positive response to any question on the safety screening protocol (see attached)
2. PHQ-9 scores are below the thresholds indicative of any severity of depression (score of <5)
5. Currently pregnant
6. History of or current substance or drug abuse
7. History of or current diagnosis of psychosis; bipolar disorder; Parkinson's Disease; dementia; Alzheimer's disease
8. A history of traumatic brain injury (TBI)
9. Presence of certain eye disorders such as retinal blindness, cataracts, retinal diseases of the eye and glaucoma
10. Regular use of light therapy, including the use of light boxes, light visors and dawn simulation lamps (does not include the use of seasonal affective disorder [SAD] alarm clocks)
10. Depressive symptomology that displays a seasonal pattern

Date of first enrolment
09/05/2025

Date of final enrolment

30/09/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sussex Centre for Consciousness Science
University of Sussex
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Sponsor information

Organisation
University of Sussex

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Anonymised research data will be retained indefinitely; this is mentioned clearly in the consent form. This will allow data to be available for future research purposes and so that the results of this research project are open to investigation if needed. The results obtained from the research will be published in open-access publications, ensuring widespread availability and dissemination of the findings.

Anonymised data related to this study may also be uploaded onto the Open Science Framework website (https://osf.io/) for other
researchers to examine. The available dataset includes the following:

Validated measures of depressive symptomatology: PHQ-9, BDI-II, MADRS-S, M3VAS change scores, and BAI

Affect measure: SPANE

Treatment expectation measures: TEX-Q and SETS

Stroboscopic session experience measures: 6D-VHQ and 5D-ASC

Reported side-effects between sessions: FIBSER

Tolerability/symptom discomfort scores for the stroboscopic parameters used in the protocol

Overall experience ratings for each session (0–100 sliding scales of engagement, pleasure, discomfort, and sleepiness)

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes