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Exploring the safety and practicality of strobe light therapy for depression

Submission date
18/02/2025

Recruitment status
No longer recruiting

Registration date
01/05/2025

Overall study status
Completed

Last Edited
28/02/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] 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 a year. There are about 1.24 million people with depression in England and this is projected to rise to 1.45 million by 2026. Current treatments for depression can be divided into antidepressants (pharmacological) and talking therapies (psychotherapy). These treatments can be effective, but they have drawbacks. Taking antidepressants is often associated with problematic side effects; they take time to work (4 to 6 weeks) and do not work for everyone. Psychotherapy also takes time (12 to 20 weeks) and is costly and difficult to implement at scale because of barriers to accessing treatment and a shortage of trained therapists. Recently, there has been renewed interest in the potential for psychedelic drugs to treat depression. However, psychedelic therapy is unproven, is difficult to implement due to legal constraints, and is inaccessible to many. With the current mental health crisis, there is an urgent need for new effective and accessible treatments for depression.
This project will test the potential of stroboscopic light to treat mild to severe forms of depression, with the aim of developing a treatment that is easy to administer, has minimal side effects and is cost-effective relative to other treatment options.
Perhaps surprisingly, stroboscopic light experienced on closed eyes typically causes vivid visual experiences (e.g., colours, geometric patterns, movement, complex scenes), as well as, for some people, powerful emotional responses. These types of experience show some similarities to those reported during psychedelics. Recently, we completed a large-scale public art-science experience called Dreamachine (https://dreamachine.world/) which enabled nearly 40,000 people to safely have these types of stroboscopic experiences. The vast majority reported that Dreamachine was a highly enjoyable and positive experience. Many people, without prompting, said it helped alleviate their depression, anxiety, and related mental states. These anecdotal but numerous reports of mental health benefits are consistent with several other lines of evidence suggesting that using stroboscopic light may help alleviate depression.
This study is an early-phase investigation to systematically evaluate the safety and tolerability of stroboscopic light exposure in individuals with major depressive disorder (MDD). Participants will undergo 11 short sessions using differing stroboscopic parameters of increasing subjective intensity to determine the parameters that elicit engaging but comfortable experiences. If successful, this study will provide critical preliminary data supporting the future development of a novel, non-pharmacological, accessible, and scalable stroboscopic intervention for depression.

Who can participate?
Adults aged 18 years and over with depression

What does the study involve?
All stroboscopic stimulation will be delivered using a CE-certified commercial stroboscope, roXiva RX1. Participants will undergo 11 stroboscopic sessions of increasing subjective 'intensity', following a fixed order, each lasting 2 minutes. The first 10 sessions are divided into four 30-second sections to test incremental changes in parameters. Initial sections are designed to induce minimal effects, with subsequent sections using a staircase method to gradually increase the intensity of the stroboscopic experience. The final session (session 11) will contain a combination of all tested parameters. After each 2-minute session, participants will be asked whether they had any side effects; if they select no, they will not be asked any further information regarding the tolerability of the current session. If participants indicate that they experienced adverse effects, they will be presented with a list of symptoms to select the frequency at which each symptom occurred. Any reported side effects will then be rated on a 10-point scale. Participants will also report their overall experience on a 0-100 sliding scale, asking the participant to report how engaging, pleasurable, overall uncomfortable, and sleepy each session was. After each round of questions, participants will have an opportunity to share their thoughts on the session and also have a break. After the administration of all sessions and questionnaires, participants will be debriefed; this will be the end of the testing session.

What are the possible benefits and risks of participating?
To compensate participants for their time and effort, they will receive either 4 SONA credits per hour or £10 per hour. Additionally, the knowledge gained from this study may inform future treatment options for depression as well as being of general theoretical interest. Although there is no direct benefit to participants, in participating in the study participants will know that they have made a valuable contribution to these objectives.
The topics involved in this study may be more sensitive to some than others. A small number of questions about psychological symptoms involve asking about low mood and suicidal thoughts. If participants feel that answering any of these questions will impact negatively on their wellbeing or cause significant lasting distress, they are advised not to take part.
Mental health support resources are provided to (potential) participants. If researchers have concerns about participants' wellbeing, the project Co-I Clinical Psychologist James Stone will provide support to the participants to minimise any mental health risks.
Although most people have been exposed to strobe lights at some point in their lives, flashing lights may, in extremely rare cases, induce seizures in susceptible individuals, or may cause anxiety and discomfort and in some people migraines. Potential participants with a sensitivity to bright lights, frequent migraines or risk factors for seizures are advised not to take part in this experiment and will be excluded from participation during pre-screening.

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

When is the study starting and how long is it expected to run for?
February 2025 to April 2025

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

Who is the main contact?
Dr David Schwartzman, D.Schwartzman@sussex.ac.uk

Study website
https://www.sussex.ac.uk/research/centres/sussex-centre-for-consciousness-science/index

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr David Schwartzman

ORCID ID
http://orcid.org/0000-0002-3779-396X

Contact details
University of Sussex
Sussex House
Falmer
Brighton
United Kingdom
BN1 9RH
+44 (0)7709918923
D.Schwartzman@sussex.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

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

Study objectives
1. Evaluate the safety and tolerability of exposure to stroboscopic light in major depressive disorder (MDD)
2. Collect critical data on the stroboscopic parameters that reliably elicit tolerable, comfortable and engaging experiences and the (control) parameters that cause minimal stroboscopic experiences

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/02/2025, Sciences & Technology C-REC at the University of Sussex (University of Sussex, Brighton, BN1 9RH, United Kingdom; +44 (0)1273 877492; crecscitec@sussex.ac.uk), ref: ER/LK344/4

Study design
Single-arm safety and tolerability study (with dose escalation)

Primary study design
Other

Secondary study design

Study setting(s)
Laboratory, University/medical school/dental school

Study type(s)
Safety

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
Depression

Interventions
This tolerability study will not have a control condition.

Participants will complete an online safety questionnaire for pre-screening to minimise the risk of seizures from strobe light and screen for depression. Participants will be invited into the laboratory for testing, completing 11 2-minute strobe sessions with increasing subjective 'intensity', following a fixed order.

The first 10 sessions are divided into four 30-second sections to test incremental changes in parameters: luminance, stimulation frequency, rapid frequency changes, and duty cycles. The 11th session is a dynamic combination of all the tested parameters in the first 10 sessions.

After each session, participants indicate whether they experienced negative side effects, if they select no, they will not be asked any further information regarding the tolerability of the current session. If participants indicate that they experienced adverse effects, they will be presented with a list of symptoms from the Visual Discomfort Questionnaire to select the frequency at which each symptom occurred (Vinkers et al., 2024). Any reported side effect will then be rated on a 10-point scale, which will be referred to as the tolerability score or symptom discomfort score, the scale ranges from 0 (no symptom discomfort) to 10 (worst possible symptom

discomfort), with 3 indicating mild symptom discomfort, 5 moderate symptom discomfort, and >7 severe symptom discomfort. Any report of a scorer >7 will result in that parameter's testing being stopped immediately to avoid further discomfort.

Participants will also report their overall experience on a 0-100 sliding scale via Qualtrics, asking the participant to report how engaging, pleasurable, overall uncomfortable, and sleepy each session was.

After each round of questions, participants will have an opportunity to share their thoughts on the session and also have a break.

To ensure that the experimental procedure has not inadvertently increased participants' depressive symptoms, participants will fill out the M3VAS change and the PHQ-9 again at the end of the testing session.

After the administration of all sessions and questionnaires, participants will be debriefed; this will be the end of the testing session.

Intervention Type
Device

Pharmaceutical study type(s)
Dose response

Phase
Phase 0

Drug/device/biological/vaccine name(s)
Stroboscope

Primary outcome measure
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.
2. Tolerability measured on a 10-point scale ranging from no discomfort (0) to severe discomfort (10) after each 2-minute strobe session, assessing each 30-second section. Outcome: Identify a range of stroboscopic parameter settings with an upper 80% confidence limit of the mean tolerability score is <7 (mild to moderate) across all minor side effects.

Secondary outcome measures
1. Type and frequency of side effects measured using the Visual Discomfort Questionnaire after each 2-minute strobe session
2. Feasibility estimated through participant recruitment numbers over the duration of the study
3. Arousal, enjoyment, overall discomfort and engagement as reported through single visual analogue scale items (scale 0-100) following each 2-minute strobe session

Overall study start date
02/02/2025

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Willingness to take part in the study
3. PHQ-9 score indicative of mild to severe depression (score of 5-27)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
32

Key exclusion criteria
1. Positive response to any question on the safety screening protocol (see attached)
2. PHQ-9 scores are above the thresholds indicative of mild depression (score of 5-27)
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

Date of first enrolment
05/02/2025

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sussex Centre for Consciousness Science
University of Sussex
Falmer
Brighton
United Kingdom
BN1 9RH

Sponsor information

Organisation
University of Sussex

Sponsor details
Research & Enterprise Services
Brighton
England
United Kingdom
BN1 9RH
+44 (0)1273 878798
researchsponsorship@sussex.ac.uk

Sponsor type
University/education

Website
https://www.sussex.ac.uk/?utm_source=google&utm_medium=cpc&utm_campaign=aip-uos-2024-ug-su-dig-brd&utm_term=university%20of%20sussex&utm_content={adgroup}&gad_source=1&gclid=CjwKCAiAzba9BhBhEiwA7glbao6u-bGTNVXBAEkPH2kiinj1oDObj6lO6nKyviNADYTHh2MQvV9wuxoCWC8QAvD_BwE

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

Publication and dissemination plan
Peer-reviewed journals (ideally open-access) and public dissemination via UoS/SCCS.

Intention to publish date
01/03/2026

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. Anonymous data can be requested from the project PI, Dr David Schwartzman (D.schwartzman@sussex.ac.uk). The data includes validated measures of depressive symptomatology: PHQ-9 BDI-II and M3VAS change scores; Tolerability or symptom discomfort score for the stroboscopic parameters described in the protocol; and overallexperience scores for each session on a 0-100 sliding scale reflecting how engaging, pleasurable, overall uncomfortable, and sleepy each session was.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			28/02/2025	No	No