Proposed Clinical Study USA & Brazil

DepressiStim Neurostimulation & Depression Study

ClinicalTrials.gov Identifier:

Recruitment Status :
First Posted
Last Update Posted :

Sponsor:
Leonhardt Ventures LLC

Collaborator:
DepressiStim

Information provided by (Responsible Party): Leonhardt Ventures LLC & DepressiStim LTP

Study Details

Study Description

Brief Summary:
Examine the safety and effectiveness of the DepressiStim Cranial Electrotherapy Stimulator Device on Major Depressive Disorder using two 20-minute per day treatment sessions over eight weeks.

Condition or disease	Intervention/treatment
Major Depressive Disorder	Device: DepressiStim Cranial Electrotherapy Stimulator Devic

Study Design

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	100 participants
Allocation:	Randomized
Intervention Model:	Crossover Assignment
Intervention Model Description:	This is a fully remote trial where participants engage at hom data, including proof of identity via government ID will be rev enrollment. Participants will be randomized into an immediate or delaye active DepressiStim device limited to Level 2 output even if device for the full 8 weeks.
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcom
Masking Description:	This is a fully remote trial. Participants will be randomized in participant is in the placebo or control arm. Participants will be unblinded at week 4 at the crossover.
Primary Purpose:	Treatment
Official Title:	Neurostimulation & Depression Study
Actual Study Start Date :	August 24, 2021
Estimated Primary Completion Date :	March 30, 2022
Estimated Study Completion Date :	November 30, 2022

Resource links provided by the National Library of Medicine

MedlinePlus Genetics related topics: Depression

U.S. FDA Resources

Arms and Interventions

Arm
Experimental: Immediate Treatment Arm The immediate treatment arm participants will be shipped an active DepressiStim device lim raises the dial beyond that. The participant will remain with the active device for the full 8 wee
Sham Comparator: Delayed Treatment Arm In the delayed treatment arm, the participants will receive a sham device that looks exactly th seconds. At week 4, sham arm participants will be unblinded and shipped an active device (li raises the dial beyond that). The delayed arm participants will continue with active devices fo

Outcome Measures

Primary Outcome Measures :

1. Change in Beck Depression Inventory Score Baseline vs week 4 [Time Frame: Week 4]

   Change in depression symptoms from baseline to treatment week 4 in immediate versus delayed arm. Lower scores show improvement in depression symptoms.

Secondary Outcome Measures :

1. Systematic Assessment for Treatment Emergent Events (SAFTEE) at week 8 [Time Frame: Week 8]

   assessment at week tolerability, safety and adherence at week 8

2. Change in Patient Health Questionnaire - 8 (PHQ-8) Score Baseline vs week 4 [Time Frame: Week 4]

   Change in self reported depression self assessed at baseline and week 4. Lower scores in the PHQ-8 show improvement in depression symptoms

3. Change in Patient Health Questionnaire - 8 (PHQ-8) Score Baseline vs week 2

[Time Frame: Week 2]

Change in self reported depression self assessed at baseline and week 2. Lower scores in the PHQ-8 show improvement in depression symptoms.

4. Change in Beck Depression Inventory Score Delay Arm Week 4 to Week 8
   [Time Frame: Week 8]

   Participants will self assess at point of receiving active device at crossover for the remaining 4 weeks of the trial. Lower scores show improvement in depression symptoms.

5. Change in Hamilton Depression Score Baseline vs week 4 [Time Frame: Week 4]

   Participants will be assessed by a tele-psychiatrist at baseline and week 4. Lower scores show improvement in depression symptoms.

6. Change in Hamilton Depression Score Baseline vs week 2 [Time Frame: Week 2]

   Participants will be assessed by a tele-psychiatrist at baseline and week 2. Lower scores show improvement in depression symptoms.

Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and to join a study. To learn more about this study, you or your doctor may contact the study resea For general information, Learn About Clinical Studies.

Ages Eligible for Study:	21 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion criteria:

- Age greater than or equal to 21
- US resident
- Can receive packages to their home via UPS/Fedex/USPS
- Major Depressive Disorder
- PHQ-8 Score greater than 10 (show some signs of mild to moderate depression)
- PHQ-8 Score less than 20 (given remote study serious depressed should be excluded)
- Read/write English
- have not contemplated suicide in the past year
- not been institutionalized for mental health issues.
- not currently experiencing problems with alcohol or drug abuse
- can commit to not drinking alcohol 4 hours before bedtime for the duration of the study
- can commit to two (2) 20 minute sessions per day for 8 weeks
- has not used a brain stimulation treatment in one year
- no suspected or known history of heart disease
- no pacemaker
- not under medical supervision for other serious medical condition
- not taking opioids
- is a resident of states in which we have licensed medical professionals

Contacts and Locations

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number):

Locations

United States and Brazil

Remote Virtual Trial

Sponsors and Collaborators

Leonhardt Ventures LLC

DepressiStim

Study Documents (Full-Text)

To be Provided

More Information

Responsible Party: Leonhardt Ventures LLC
ClinicalTrials.gov Identifier:
Other Study ID Numbers:
First Posted:
Last Update Posted:
Last Verified:

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: Yes

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	Yes
Product Manufactured in and Exported from the U.S.:	No

Additional relevant MeSH terms:
Depressive Disorder
Depressive Disorder, Major
Mood Disorders