

Slow wave entrainment using a smartwatch: a randomized crossover study

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
19/01/2026	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
30/01/2026	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
30/01/2026	Other	<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

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Additional identifiers

Study information

Scientific Title

Does slow wave entrainment with a smartwatch increase delta power and sleep quality in healthy adults compared to no intervention?

Study objectives

The goal of this study is to test whether rhythmic sound and vibrations from a smartwatch can increase the amplitude of slow brain waves during sleep and assess the effects on sleep quality in healthy adults. Previous research using sleep lab systems has demonstrated that rhythmic stimuli can increase slow brain waves; this research will test whether we can achieve the same results using a smartwatch app.

Ethics approval required

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Ethics approval(s)

approved 16/10/2023, MIT Committee on the Use of Humans as Experimental Subjects (COUHES) (Room E25-143B, 77 Massachusetts Ave, Cambridge, 02139, United States of America; +1 (0)617 253 6787; couhes@mit.edu), ref: 2309001115

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Blinded (masking used)

Control

Placebo

Assignment

Crossover

Purpose

Device feasibility

Study type(s)

Health condition(s) or problem(s) studied

Sleep quality in healthy adults

Interventions

Active conditions: Slow wave entrainment using a smartwatch.

Placebo condition: Participant wears smartwatch but no entrainment is performed.

Crossover study where both participants receive placebo on one night and active stimulation on the other night.

Intervention Type

Drug/Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Slow wave entrainment

Primary outcome(s)

1. Sleep delta power measured using home EEG at stimulation night of the experiment
2. Awake cognition measured using computerized adaptation of Trail Making Task B at day after the stimulation night and the day after the placebo night
3. Sleep disruption by stimulation measured using number of stimulation stops due to arousal at stimulation night of the experiment
4. Sleep quality measured using Leeds Sleep Quality Evaluation Questionnaire at day after the stimulation night and the day after the placebo night
5. Daily mood measured using Brunel Mood Scale at day after the stimulation night and the day after the placebo night

Key secondary outcome(s)

1. Percent of stimuli delivered in sleep stage N3 by the system measured using comparison of stimulation times to manual sleep stages from home EEG at stimulation night

Completion date

25/10/2024

Eligibility

Key inclusion criteria

Aged 18-120 years old

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

18 years

Upper age limit

120 years

Sex

All

Total final enrolment

93

Key exclusion criteria

Age less than 18 or above 120 years

Date of first enrolment

08/04/2024

Date of final enrolment

23/10/2024

Locations

Countries of recruitment

United States of America

Sponsor information

Organisation

Samsung Research America

Funder(s)

Funder type

Funder Name

Samsung Research America

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 publicly available repository (Open Science Framework, DOI not yet assigned) and on your project page at <https://www.media.mit.edu/projects/sleep-entrainment/overview/>

Non-identifiable data such as heart rate and motion data recorded by the watch and answers to questions about your sleep will be stored, used for future research studies, and may be shared with other researchers for future research studies without additional informed consent from you or your legally authorized representative. Your data might be shared with academic research

institutions, non-profit entities, and/or for-profit entities. Your data may also be made publicly available in research data repositories such as the Open Science Framework and shared with our research sponsor (Samsung). Non-identifiable data will be stored indefinitely.

Your data will be available for any research question, such as research aimed at understanding the development and causes of many diseases and conditions or the development of new scientific methods.

IPD sharing plan summary

Stored in publicly available repository