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On a journey to feel a little better. Or BEDDA.

Submission date	Recruitment status	[X] Prospectively registered
17/08/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/08/2022	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/08/2024	Mental and Behavioural Disorders	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In this study, we aim to improve the detection and prevention of subclinical depression in an individual who has not previously met the full criteria for major depression and who currently experiences depressive symptoms. Detection and prevention can offer help before the subclinical depression becomes a full-blown depressive episode. Improving this detection and prevention is important because more and more people are suffering from subclinical and clinical depression.

Who can participate?
Healthy individuals who are at least 18 years old and over with residency in Switzerland

What does the study involve?
This study aims to improve the prevention of depression in students and the general public by developing digital biomarkers and a digital intervention called BEDDA. Participants interact with the digital health app for 30 sessions. To receive compensation, participants must complete these 30 sessions in 45 days or less. The digital health app called BEDDA consists of a conversational agent (i.e., chatbot), a gamified slow-paced breathing training, and actionable advice integrable into everyday life.

What are the possible benefits and risks of participating?
Potential benefits include a reduction in symptoms of depression and anxiety and a stress reduction. Participants will learn a slow-paced breathing technique that may help them to calm down in stressful situations. To the best of our knowledge, the different components of BEDDA have not been associated with any health risks. For individuals excluded due to the severity of symptoms, we will provide information on how to find help from mental health services.

Where is the study run from?
Center for Digital Health Interventions (ETH Zurich) (Switzerland)

When is the study starting and how long is it expected to run for?
February 2021 to February 2026

Who is funding the study?
1. CSS health insurance (public health insurance Switzerland)
2. Center for Digital Health Interventions (ETH Zurich) (Switzerland)

Who is the main contact?
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Study website
https://www.bedda.me

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EK 2022-N-31

Study information

Scientific Title
Development of a digital biomarker and intervention for subclinical depression: Study protocol for a longitudinal waitlist control study

Acronym
BEDDA

Study objectives
Due to the substantial number of voice features, formulating a hypothesis for investigating digital biomarkers for subclinical depression is difficult. However, related work reported differences in voice features depending on the severity of depression (Cummins et al., 2015; Low et al., 2020). Certain features (such as fundamental frequency, jitter, shimmer) extracted from voice and breathing should correlate higher with symptoms and severity of depression than other features (e.g., first and second formant variability), as this difference has been reported in Low et al. (2020). Similarly, we cannot predict feature importance for more elaborated machine learning models. For reported classification accuracy or predictive accuracy of existing work, we refer to the publications from Cummins et al. (2015) and Low et al. (2020).

Regarding the investigation of efficacy, we can formulate the hypothesis. We hypothesize that the intervention group using the slow-paced breathing training "Breeze" will show significant improvements in symptoms and severity of depression compared to a waitlist control.

Cummins, N., Scherer, S., Krajewski, J., Schnieder, S., Epps, J., & Quatieri, T. F. (2015). A review of depression and suicide risk assessment using speech analysis. In Speech Communication (Vol. 71, pp. 10–49). Elsevier B.V. https://doi.org/10.1016/j.specom.2015.03.004

Low, D. M., Bentley, K. H., & Ghosh, S. S. (2020). Automated assessment of psychiatric disorders using speech: A systematic review. In Laryngoscope Investigative Otolaryngology (Vol. 5, Issue 1, pp. 96–116). John Wiley and Sons Inc. https://doi.org/10.1002/lio2.354

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/06/2022, ETH Zurich Ethics Commission (ETH Zurich Prof. Dr. Detlef Günther, HG F 57, Rämistrasse 101, 8092 Zurich, Switerland; +41 44 63 28572; ethics@sl.ethz.ch), ref: EK 2022-N-31

Study design
Single-centre interventional double-blinded waitlist-controlled field study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Prevention of depression

Interventions
Participants will be allocated using a computer algorithm script (Python) to either waitlist control or intervention group. Participants in the intervention group will start the intervention while participants in the waitlist control group will wait until the intervention group has finished the intervention.

Participants will interact with the digital intervention BEDDA consisting of a scripted conversational agent, a slow-paced breathing training called Breeze, and actionable advice for different symptoms. The intervention comprises 30 daily interactions the participants must complete in less than 45 days.

Intervention Type
Behavioural

Primary outcome measure
1. Depression severity measured using the nine-question version of the Patient Health Questionnaire (PHQ-9) at baseline, after 14 interactions, and at the end of the intervention (after 30 interactions).
2. One of three randomly selected symptoms of depression (mood, agitation, anhedonia) measured using the Multidimensional Mood State Questionnaire (MDMQ) on a daily basis
3. Physiological (such as heart-rate-variability) and behavioral (such as physical activity) outcomes measured using a Garmin Smartwatch Fitness Tracker in a sub sample of 25% of the participants

Secondary outcome measures
Anxiety severity measured using the seven-question version of the General Anxiety Disorder questionnaire (GAD-7) and stress using the short version of the Trier Inventory for Chronic Stress at baseline, after 14 interactions, and at the end of the intervention (after 30 interactions)

Overall study start date
01/02/2021

Completion date
01/02/2026

Eligibility

Key inclusion criteria
1. Aged 18 years old and over
2. Residency in Switzerland
3. Understand of mid-level English or German (B1-B2)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

200

Key exclusion criteria
1. Current diagnosis with or in treatment for a mental health disease
2. Asthma, COPD, or any other lung or respiratory tract disease
3. Pregnancy
4. Scoring greater than 15 for symptom severity of depression and anxiety in the PHQ-9 and GAD-7 instruments, respectively
5. Positive response to the last question of the PHQ-9, accessing suicide ideation or self-harm

Date of first enrolment
17/10/2022

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
Switzerland

Study participating centre
Center for Digital Health Interventions
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Organisation
ETH Zurich

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Sponsor type
University/education

Website
https://www.ethz.ch/en.html

ROR
https://ror.org/05a28rw58

Funder(s)

Funder type
University/education

Funder Name
CSS Health Insurance

Funder Name
Eidgenössische Technische Hochschule Zürich

Alternative Name(s)
ETH Zurich, ETH Zürich, Federal Institute of Technology Zurich, ETH Zürich (Eidgenössische Technische Hochschule Zürich), Eidgenössische Technische Hochschule Zürich (Switzerland), Eidgenössische Technische Hochschule Zürich (ETH), ethzurich, ETH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/02/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			19/08/2022	No	Yes
Participant information sheet			19/08/2022	No	Yes
Participant information sheet			19/08/2022	No	Yes
Protocol article		22/06/2023	23/06/2023	Yes	No