

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

Submission date 17/08/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/08/2022	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/12/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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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Contact information

Type(s)

Public, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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, Switzerland; +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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s))

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)

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

99 years

Sex

All

Total final enrolment

0

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

ETH Zurich

Weinbergstrasse 56/58

Zurich

Switzerland

8006

Sponsor information

Organisation

ETH Zurich

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

Individual participant data (IPD) sharing plan**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?
Protocol article		22/06/2023	23/06/2023	Yes	No

Participant information sheet			19/08/2022	No	Yes
Participant information sheet			19/08/2022	No	Yes
Participant information sheet			19/08/2022	No	Yes
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