

Intelligent depression tracking

Submission date 19/12/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/12/2023	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/12/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The thymia AI depression model is a cross-sectional model trained on data from shift workers and patients with depression. Earlier versions of the model were published at doi: 10.21437/Interspeech.2022-10393 and doi: 10.21437/Interspeech.2023-1709. Now, in its newest and most updated version, it can be validated on an entirely new sample to establish its generalisability. For fairness, model performance will also be tested on different demographic and minority groups.

Who can participate?

All participants aged 18 years old and over who for the depression group have a diagnosis of major depression disorder (MDD) and healthy volunteers for the control group

What does the study involve?

For this study, participants will take part in a series of short online activities, some of which will be repeated at regular intervals (three times a week) for 3 months/12 weeks. The activities can be completed on the thymia platform via the participant's laptop or smart device from home but must be completed on the same device each time and on a stable wifi connection. Activities include demographics and context questionnaires (capturing confounders), proprietary games that record facial expressions and speech (not used in the present study), and standard clinical (screening) questionnaires that investigate patient health and generalised anxiety disorder.

What are the possible benefits and risks of participating?

Participants will be learning about longitudinal research participation and helping research on a future tool that might improve the assessment of mental health. They are paid £2.25 per session. Some questionnaire questions may cause discomfort because they prompt introspection or because they are personal.

Where is the study run from?

thymia Limited (UK) using Prolific for online participant recruitment (a widely used participant platform with one of the highest data quality reputations)

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

July 2021 to March 2024

Who is funding the study?
Innovate UK (Biomedical Catalyst 10050419) & thymia Limited (UK)

Who is the main contact?
Dr. Alexandra Georgescu, alexandra@thymia.ai

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Alexandra-Livia Georgescu

ORCID ID

<https://orcid.org/0000-0003-1929-5673>

Contact details

International House

64 Nile Street

London

United Kingdom

N1 7SR

+44 (0)7533848443

alexandra@thymia.ai

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IDEPT 1

Study information

Scientific Title

Intelligent DEpression Tracking (I-DEPT) - A novel, longitudinal and multi-modal machine learning framework for quantifying depression symptoms

Acronym

I-DEPT

Study objectives

The AI model will achieve at least >75% AUC and >75% sensitivity and specificity compared to PHQ-8 scores at a cutoff threshold of 10 in an independent depression sample. For fairness, we will test model performance on different demographic and minority groups.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 06/08/2021, The Association of Research Managers and Administrators (7 Quay Court, Colliers Lane, Stow-cum-Quay, Cambridge, CB25 9AU, United Kingdom; +44 (0) 131 380 0066; enquiries@arma.ac.uk), ref: None available

The study is covered by ethics approval via two previous umbrella applications, reviewed by an independent research ethics expert working under the auspices of the Association of Research Managers and Administrators on 6th August 2021 (depression study on Prolific online platform) and 3rd November 2022 (longitudinal study on Prolific online platform).

Study design

Observational longitudinal online study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Home

Study type(s)

Diagnostic, Screening

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

Depressive symptoms, including anxiety (as a highly common comorbidity) and other mental and/or chronic physical health comorbidities (other than respiratory)

Interventions

This study is an observational, longitudinal, online study recruiting people with and without depression symptoms and participants who don't (as a control group). Note that participants who experience depressive symptoms may have anxiety (as a highly common comorbidity) and other mental and/or chronic physical health comorbidities (other than respiratory).

For this study, participants will take part in a series of short online activities (sessions last 15 minutes), some of which will be repeated three times a week (Tuesdays, Thursdays and Saturdays) for 12 weeks. The activities can be completed on the thymia platform via the

participant's laptop or smart device from home but must be completed on the same device each time and on a stable wifi connection. The activities are designed to collect observational data (not as an intervention).

The activities can be split into the following four categories:

1. Thymia research activities or short games, part of the current version of the thymia AI tool. These are proprietary speech-eliciting tasks (prolonging vowel sounds, describing pictures, reading paragraphs of text, answering questions out loud) and the thymia version of the n-Back game (with a 1-Back and a 2-Back);
2. Thymia research questionnaires will be used to gather more context and information to further develop the thymia AI model [not part of the current clinical trial]. These include a tiredness questionnaire and the current state questionnaire. Our demographics questionnaire will be important in describing the sample and a user engagement questionnaire will be instrumental in gathering feedback.
3. Standardised, validated questionnaires (i.e. widely used questionnaires). These are the mood questionnaire Patient Health Questionnaire PHQ-8 (a shortened version of the PHQ-9 that excludes questions on suicidality and self-harm), the anxiety questionnaire Generalised Anxiety Disorder GAD-7.
4. Other/Custom questionnaires that are of clinical use and part of the clinical standard procedure like the medication adherence questionnaire, are inspired by questions that clinicians typically ask during appointments and are used to further characterise the sample.

Standard machine learning evaluation metrics will help validate and establish the performance and accuracy of a model trained on a set of data that can predict accurately in an entirely new set of data (and demographic subsets thereof) collected in a new context.

Intervention Type

Behavioural

Primary outcome measure

Depression likelihood measured using machine learning across all timepoints (i.e. cross-sectional model, where the timepoints from the same participant are dependent. Importantly, we produce AUC, sensitivity, and specificity as quality metrics. These are standard machine learning evaluation metrics that will help validate and establish the performance and accuracy of a model trained on a set of data in predicting accurately an entirely new set of data collected in a new context (and demographic subsets thereof).

Secondary outcome measures

Depression scores measured using the Patient Health Questionnaire PHQ-8 every two weeks and for the analysis, the value of the PHQ-8 that is closest to each individual session (three times per week) will be used to label the data at each timepoint

Overall study start date

01/07/2021

Completion date

31/03/2024

Eligibility

Key inclusion criteria

1. 18 years old and over
2. Speak English as their first language
3. Willing to be video- and audio-recorded

Participant type(s)

Healthy volunteer, Patient

Age group

Mixed

Lower age limit

18 Years

Upper age limit

99 Years

Sex

Both

Target number of participants

500

Key exclusion criteria

Control group:

1. Neurological conditions, such as Parkinson's or seizure disorders like epilepsy
2. Neurodevelopmental conditions like ADHD or Autism
3. Mental health conditions like depression, anxiety or schizophrenia
4. Learning conditions, such as dyslexia or language difficulties
5. Respiratory disease
6. Never had visual problems (glasses are fine) or hearing problems

Depression group**:

1. Diagnosis of Major Depression Disorder
2. Neurological conditions, such as Parkinson's or seizure disorders like epilepsy
3. Neurodevelopmental conditions like ADHD or Autism
4. Mental health conditions other than depression and anxiety (this is due to high comorbidity of MDD and GAD)
5. Learning conditions, such as dyslexia or language difficulties
6. Respiratory disease
7. Never had visual problems (glasses are fine) or hearing problems

**To reach target numbers in the depression group, the eligibility criteria may be relaxed to include other mental health diagnoses (e.g. bipolar) and neurodevelopmental conditions (e.g. ADHD, Autism).

Date of first enrolment

01/04/2023

Date of final enrolment

31/03/2024

Locations

Countries of recruitment

Australia

Canada

England

Ireland

New Zealand

United Kingdom

United States of America

Study participating centre

thymia

International House, 64 Nile St

London

United Kingdom

N1 7SR

Sponsor information

Organisation

Thymia Limited

Sponsor details

International House, 64 Nile St

London

England

United Kingdom

N1 7SR

+44 (0)777 6181475

admin@thymia.ai

Sponsor type

Industry

Website

<https://thymia.ai/>

Funder(s)

Funder type

Government

Funder Name

Innovate UK

Alternative Name(s)

innovateuk

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The project's findings will be shared through multiple channels, categorised into two main groups: those targeting an academic audience and those aimed at the general public.

Academic Audiences: The research team intends to generate one publication in a high-impact, peer-reviewed journal specialising in mental health and machine learning. They also plan to present their results at relevant conferences within these fields. While the publications are expected to become available 6-12 months after the trial concludes, conference presentations may be completed during the trial itself.

General Public: To engage with the general public, the researchers will create a report tailored for this audience, which will be electronically accessible 6-12 months following the trial's completion, aligning with any scientific publications. This report will be shared with prominent clinical organisations. The report will also be disseminated through various social media and marketing channels.

Intention to publish date

30/11/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made generally publicly available due to licensing and IP considerations. However, we are open to partnering with research institutes and individual academics including pseudonymised data sharing upon request (at Dr Stefano Gorla, stefano@thymia.ai). Data is available for 8 years and consent of participants was given to share non-identifying data (i.e. not raw data) with other researchers in collaboration.

IPD sharing plan summary
Available on request