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Intelligent depression tracking

Submission date	Recruitment status	[ ] Prospectively registered
19/12/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/12/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/12/2023	Mental and Behavioural Disorders	[ ] 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

Protocol serial number
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 Quy Court, Colliers Lane, Stow-cum-Quy, 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).

Primary study design
Observational

Study design
Observational longitudinal online study

Study type(s)
Diagnostic, Screening

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(s)
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).

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex

All

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
United Kingdom

England

Australia

Canada

Ireland

New Zealand

United States of America

Study participating centre

thymia
International House, 64 Nile St
London
United Kingdom
N1 7SR

Sponsor information

Organisation
Thymia Limited

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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 Goria, 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