ISRCTN90727704 https://doi.org/10.1186/ISRCTN90727704

Using an AI memory game to detect depression and anxiety in older Brazilians

Submission date	Recruitment status	[ ] Prospectively registered
09/11/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/11/2023	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/01/2025	Mental and Behavioural Disorders	

Plain English summary of protocol
Background and study aims:
The n-Back Task is a cognitive test that can help identify working memory dysfunction in people with depression and anxiety. Thymia Limited, a company that specializes in developing AI models for depression and anxiety symptoms, uses n-Back performance as a biomarker to help diagnose these conditions. In a pilot study, Thymia aims to investigate the accuracy of their models in screening and diagnosing depression and anxiety symptoms. They also aim to establish the transferability of their AI model's performance to the Lacos dataset, which represents an older Brazilian population. This dataset is distinct from the majority of Thymia's data, which were used to train the original model. The Thymia dataset includes over 6,000 participants from mainly the UK, US, Spain, and Indonesia, aged 18 to 80 with a mean of 35 years old.

Who can participate?
Participant must be:
- Over 50 years of age
- Receiving ongoing health support via a private healthcare route at Lacos Saude
- Normal or corrected-to-normal vision
- Normal or corrected hearing
- Able to read, understand, and sign the Informed Consent Form
- Access to a laptop, smartphone, tablet, or other device and able to use them
- Willingness to be recorded

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 (twice a week) for 6 months. 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 contexts questionnaires, proprietary games that record facial expressions and speech (not used in the present study), the n-Back activity of interest and standard clinical (screening) questionnaires: PHQ-8 (Patient Health Questionnaire), GAD-7 (Generalised Anxiety Disorder) and GDS (Geriatric Depression Scale).

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. If the answers the participants provide in the standardised validated questionnaires or the custom questionnaires that are clinical standard procedure show scores that are unusual, their clinician may request a call or an additional appointment with them, resulting in more personalised care.

Where is the study run from?
thymia Limited (UK)

When is the study starting and how long is it expected to run for?
August 2022 to December 2023

Who is funding the study?
thymia Limited (UK)
Lacos Saude (Brazil)

Who is the main contact?
Dr. Alexandra Georgescu
admin@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 7533848443
alexandra@thymia.ai

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
TL 1

Study information

Scientific Title
Transferability of n-back task biomarkers in ai mental health models to old-age Brazilian population

Acronym
TNB-AI

Study objectives
Primary: The AI model evaluation in the Brazilian population will achieve at least >70% AUC and >65% sensitivity and specificity in both depression and anxiety.
Secondary: There is a significant difference in terms of key N-back parameters between 2-Back and 1-Back (see secondary outcome measures) in the Brazilian sample which is comparable to the existing thymia n-Back dataset.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/08/2022, Association of Research Managers and Administrators (7 Quy Court, Colliers Lane, Stow-cum-Quy, CB25 9AU, United Kingdom; +44 (0) 131 380 0066; djcarpenter247@gmail.com), ref: The Thymia Virtual Clinic - A User Engagement Study

Study design
Single-centre observational study design

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 the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Depressive and anxiety symptoms screening in an elderly Brazilian population (service users of a private health care provider). They may have multiple physical health comorbidities.

Interventions
For this study, participants will take part in a series of short online activities, some of which will be repeated at regular intervals (twice a week) for 6 months. 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 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 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, 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. a 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, the geriatric depression scale GDS.
4. Other/Custom questionnaires that are of clinical use and part of the clinical standard procedure like the medication adherence questionnaire and the pain scale, which are inspired by questions that clinicians typically ask during appointments and are used to further characterise the sample.

Intervention Type
Other

Primary outcome measure
Measured using the thymia platform via the participant's laptop or smart device twice a week for 6 months:
1. Area Under the Curve (AUC), specificity and sensitivity of the AI models (depression and anxiety). These are standard machine learning evaluation metrics that will help establish the performance and accuracy of a model trained on a set of data can predict accurately in an entirely new set of data collected in a clinical and completely new context.
2. PHQ-8 and GAD-7 to measure anxiety and depression

Secondary outcome measures
Measured using the thymia platform via the participant's laptop or smart device twice a week for 6 months:
1. Average reaction time
2. Average omission errors
3. Average false positive rate (commission errors)
4. Average precision
5. Average recall from the n-Back game (1-Back and 2-Back)

Overall study start date
01/08/2022

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Over 50 years of age
2. Receiving ongoing health support via a private healthcare route at Lacos Saude
3. Normal or corrected-to-normal vision
4. Normal or corrected hearing
5. Able to read, understand, and sign the Informed Consent Form
6. Access to a laptop, smartphone, tablet, or other device and able to use them
7. Willingness to be recorded

Participant type(s)
Service user

Age group
Senior

Lower age limit
50 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
100

Total final enrolment
69

Key exclusion criteria
1. Under 50 years of age
2. Not receiving ongoing health support via a private healthcare route at Lacos Saude
3. No normal or corrected-to-normal vision
4. No normal or corrected hearing
5. Not able to read, understand, and sign the Informed Consent Form
6. No access to a laptop, smartphone, tablet, or other device and/or not able to use them
7. No willingness to be recorded

Date of first enrolment
11/01/2023

Date of final enrolment
30/11/2023

Locations

Countries of recruitment

Brazil

Study participating centre
Grupo Laços Saúde
R. dos Inválidos, 123 - Centro
Rio de Janeiro
Brazil
20231-045

Sponsor information

Organisation
thymia Limited

Sponsor details
International House, 64 Nile Street
London
England
United Kingdom
N1 7SR
+44 7776 181475
admin@thymia.ai

Sponsor type
Industry

Website
https://thymia.ai/

Funder(s)

Funder type
Industry

Funder Name
thymia Limited

Funder Name
Lacos Saude

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
31/01/2024

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.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/12/2024	27/01/2025	Yes	No