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What are the effects of training on thought processes and symptoms in persons with depression?

Submission date
04/11/2021

Recruitment status
No longer recruiting

Registration date
24/11/2021

Overall study status
Completed

Last Edited
12/12/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Depression and anxiety are the most common mental disorders and major causes of disability. However, psychological and psychiatric treatments are not very effective and the effects do not last. It is being recognised that the mechanisms of depression and anxiety are made up of a complex set of interactions between memory, thought processes, emotion, behaviour, and physical symptoms.
This study aims to gather data from persons with depression or anxiety before and after going through some different therapy approaches, in order to assess those approaches.

Who can participate?
Adults over 18 years, with Major Depressive Disorder (MDD) or Generalized Anxiety Disorder (GAD), or healthy volunteers for the control group.

What does the study involve?
Participants will be randomly allocated to receive either the active therapy for 4 weeks or placebo.

What are the possible benefits and risks of participating?
Participants included in groups with a clinical diagnosis, after completing participation in the study, will be able to enter the usual psychotherapeutic process free of charge, provided by the Psychological Support and Service Center of the University of Maia, regardless of the need arising from participation in the study.
No risks.

Where is the study run from?
Instituto Superior da Maia (Portugal)

When is the study starting and how long is it expected to run for?
July 2020 to December 2023

Who is funding the study?
Fundação para a Ciência e a Tecnologia (Portugal)

Who is the main contact?
Daniel Castro, dcastro@ismai.pt

Contact information

Type(s)
Scientific

Contact name
Mr Daniel Castro

ORCID ID
https://orcid.org/0000-0003-4602-7404

Contact details
Avenida Carlos Oliveira Campos – Castêlo da Maia
Maia
Portugal
4475-690
+351 229 866 000
dcastro@ismai.pt

Additional identifiers

Protocol serial number
SFRH/BD/148884/2019

Study information

Scientific Title
Effects of cognitive control training plus bias modification for depressed and anxious patients in comparison with a placebo group

Acronym
CogNet

Study objectives
Aim 1: Develop an integrated cognitive model for depression and anxiety.
Hypothesis 1: Interactions between cognitive processes, emotion regulation, and symptoms will differ between the MDD group, the GAD group, and HA participants group.

Aim 2: Explore the specific interactions and changes in these interactions that occur in the network of interactions during CBM plus CCT.
Hypothesis 2: In the network of the MDD group and the GAD group in CBM plus CCT condition more interactions will change during the intervention in comparison with the control groups.
Hypothesis 3: Across all 3 groups (i.e., MDD, GAD, HA) CBM interventions and CCT will be associated with the respective cognitive processes which they aim to change. CBM for

interpretation will be associated with the measure of interpretation biases (i.e., Scrambled Sentences Test). CBM for attention will be associated with the measure of attentional bias (i.e., dot-probe). CCT will be associated with the working memory capacity measure (i.e., 2 n-back).
Hypothesis 4: Changes in memory biases interactions will occur in the CBM plus CCT groups due to indirect effects of the CBM and CCT interventions but not in the control groups.
Hypothesis 5: CBM plus CCT will have an increase in the number of interactions between emotion regulation strategies in comparison with control groups.

Aim 3: Test the assumptions of network theory of psychopathology.
Hypothesis 6: Network density will decrease in the CBM plus CCT groups independently of the disorder.
Hypothesis 7: Central constituents of the network will predict CBM plus CCT intervention outcome.
Hypothesis 8: Network properties will differ across the 3 groups (i.e., MDD, GAD, HA)

Aim 4: Test the efficacy of CBM plus CCT protocol in the reduction of depressive and anxious symptoms.
Hypothesis 9: CBM plus CCT will reduce symptoms of depression and anxiety in comparison to controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/07/2020, Faculty of Psychology and Educational Sciences, Ethics Committee (Rua Alfredo Allen, 4200-135, Porto, Portugal; +351 226 079 725; comissao_etica@fpce.up.pt), ref: 2020_06-7b

Primary study design
Interventional

Study design
Three-armed double-blinded randomized controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Major depressive disorder, generalized anxiety disorder

Interventions
This study is a three-armed, double-blinded randomized control trial that, to assess the mechanisms of change, compares the efficacy of cognitive control training and bias modification in Major Depression Disorder (MDD), Generalized Anxiety (GAD), and a group of healthy adults (HA).

Participants, after the initial screening, are assigned according to diagnosis to the MDD, GAD, or HA group. Then, participants, of each group, are randomized (randomizeR package for R) into an active condition (cognitive control training plus bias modification intervention) or placebo condition. Intervention starts with a baseline assessment followed by 2 weeks of cognitive control training with 2 sessions per week and another 2 weeks for bias modification intervention

also with 2 sessions per week. Modification interventions for memory bias, will not be used as these intervention strategies have only recently been proposed (LeMoult & Gotlib, 2019) and it has been suggested that memory bias might be effectively changed through interventions targeting interpretation bias (Everaert et al., 2013, 2014).

The initial screening session will be done by an experienced clinical psychologist to establish the diagnosis. To this end, the Structured Clinical Interview for DSM-5 (SCID-5; First et al., 2015), will be used, as well as, the Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001) and the Generalized Anxiety Disorder-7 (GAD-7; Spitzer et al., 2006).

In the baseline assessment, all participants will complete the PHQ-9 (Kroenke et al., 2001), GAD-7 (Spitzer et al., 2006), and the Regulation Emotion System Survey (RESS; De France & Hollenstein, 2017). This will be followed, in the same session, by an assessment of attentional bias, interpretation bias, memory bias, and working memory. Attentional biases will be assessed with the Dot-probe task as proposed by (Disner et al., 2017). The Scrambled Sentences Test (SST; Wenzlaff & Bates, 1998) will be used to assess interpretational biases. Memory biases will be assessed with the Self-Referent Encoding Task (SRET; (Derry & Kuiper, 1981)) and the working memory with the N-back task (Haatveit et al., 2010).

In the following 4 weeks, in each session, all the participants will be asked to complete all the baseline assessments. In addition to this, for the first 2 weeks, participants in the active condition group will be submitted to a cognitive control intervention, namely, Adaptive Paced Serial Addition Task (APASAT; Siegle et al., 2007). Participants in the placebo group, during these 2 weeks will perform a control version of APASAT (Hoorelbeke et al., 2015).
The last 2 weeks of intervention participants in the active condition will be submitted to two cognitive bias modification interventions, namely, a modified Dot-Probe task (Hsu et al., 2018) for attentional biases modification, and the Word Fragments Completion task (WFC; Joormann et al., 2015) for interpretational biases modification. In the placebo condition participants will perform a neutral training condition of the same tasks (see section 2.6. Interventions)

In the follow-up session, one week after the intervention, the assessments will be the same as those used in the baseline assessment for all participants.

Intervention Type
Behavioural

Primary outcome(s)
1. Depression symptoms are measured with the Patient Health Questionnaire-9, in all groups and conditions, in the screening, baseline, intervention, and follow-up stages to assess the development of depressive symptoms.
2. Anxiety symptoms is measured using the Generalize Anxiety Disorder-7 in all the sessions and in all groups and conditions.
3. Attentional bias is measured using a Dot-Probe Task in the baseline, intervention, and follow-up stages.
4. Interpretation bias is measured with the Scrambled Sentences Test at baseline, intervention, and follow-up stages.
5. Working memory is measured with the N-back task at baseline, during intervention and follow-up stages.

Key secondary outcome(s)

1. Emotion regulation strategies are measured with the Regulation Emotion System Survey at baseline, during intervention and follow-up stages.
2. Memory bias is measured with the Self-Referent Encoding Task at baseline, during intervention and follow-up.

Completion date
01/12/2023

Eligibility

Key inclusion criteria
1. Over 18 years old.
2. Be fluent in Portuguese.
3. Normal or corrected normal vision.
4. Meet the criteria for Major Depressive Disorder or Generalized Anxiety Disorder for inclusion in the clinical groups. In turn, for the inclusion in the Healthy Adults group participants must not have any psychological diagnose.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Meet the criteria for substance abuse, bipolar disorder, and any psychotic disorder or symptoms.
2. Active suicidal ideation or a previous suicide attempt.

Date of first enrolment
01/04/2022

Date of final enrolment
01/08/2023

Locations

Countries of recruitment
Portugal

Study participating centre
Centro de Apoio e Serviço Psicológico da Universidade da Maia
Av. Carlos de Oliveira Campos, 4475-690
Maia
Portugal
4475-690

Sponsor information

Organisation
Instituto Superior da Maia

ROR
https://ror.org/04f761z39

Funder(s)

Funder type
Government

Funder Name
Fundação para a Ciência e a Tecnologia

Alternative Name(s)
Portuguese Science and Technology Foundation, Foundation for Science and Technology, Fundacao para a Ciencia e a Tecnologia, The Foundation for Science and Technology (FCT), FCT

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Portugal

Results and Publications

Individual participant data (IPD) sharing plan

The use of the data collected in the study will only be carried out after signing a free, specific, informed and explicit consent, filled in by the participants who express an interest in participating. Informed consent to participate in research will be in accordance with Law 67/98 of 26 October and the Declaration of Helsinki of the World Medical Association (Helsinki 1964; Tokyo 1975; Venice 1983; Hong Kong 1989; Somerset West 1996, Edinburgh 2000; Washington 2002 , Tokyo 2004, Seoul 2008, Fortress 2013).
Participants will be informed and clarified about the nature of confidentiality and its ethical and legal limitations (2.8 of the Code of Ethics of Portuguese Psychologists). Failure to maintain confidentiality will only be justified when it is considered that there is a situation of danger for the participant or for third parties who may seriously threaten their physical or mental integrity - danger to life, danger of significant damage, or any other form of ill-treatment. The information collected and the respective procedures will comply with Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016. In case of accidental discoveries, during the project, of danger to life, danger of significant damage, or any other form of ill-treatment of the participant, he/she will be referred to specialized follow-up services and removed from the present study.
No data will be collected regarding name, address, personal contacts, ancestry, descent, religious, political, philosophical or other opinions. The personal data processed within the scope of the project will be aligned with the objectives of the study and will be exclusively limited to what is strictly necessary for the fulfillment of these objectives, namely, sociodemographic data (age, gender, education, marital status, professional status), and relative to cognitive processes and patterns of emotion regulation, as well as symptomatology.
The procedures for processing and storing the data collected under the project will involve the construction of an electronic database. The anonymization process will be guaranteed by the absence of registration and collection of identifying data from the participants (e.g., name), so that the data collected cannot be attributed to a specific person, thus guaranteeing its confidentiality.
The data collected, including those collected through questionnaires, as well as age and gender, marital status, education, professional status, medication and psychiatric diagnosis/s will be made available to the research team without any identifying element. For this, an alphanumeric code will be created for each participant, safeguarding anonymity. These data will be stored in a computer, protected by an access code/password, on a computer located in the laboratory of the Human Development and Psychology Research Unit (UNIDEP) of the University Institute of Maia, in accordance with the appropriate ethical and deontological procedures. The final database, with anonymized content, will be kept in an open repository of online scientific data. The repository used will be the Open Science Framework (www.osf.io) and only variables relevant to the study will be available and never data that can identify the participants. In case of exclusion of the participants, these elements will be eliminated.
Study participants have the right to transparency and information on the processing of their personal data, notification of any rectification in the process of processing them, opposition, not subject to automated decisions and the disclosure of the results of this study. The processing and protection of personal data complies with the limits and conditions established in Deliberation No. 1704/2015, of the CNPD, applicable to the processing of personal data carried out within the scope of research studies, and is based on the Ethical and Deontological Principles of the Code of Ethics and Deontology of the Portuguese Psychologists Association.

IPD sharing plan summary