Study Protocol

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Effectiveness of behavioral activation for depression treatment in medical students: Study protocol for a quasi-experimental design

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Abstract

Introduction: Depression is a frequent mood disorder among medical students that can lead to multiple negative consequences at individual and social level (such as academic achievement and interpersonal conflicts) as well as patient care performance. Therefore, the need of depression decreasing treatments in medical students is important. This study is designed to evaluate the effectiveness of the Behavioral Activation Treatment for Depression in a sample of Mexican medical students.

Methods: This study will be performed under a quasi-experimental design to verify the effectiveness of the Behavioral Activation Treatment for Depression to reduce depressive symptoms in medical students from two public universities in northwestern Mexico. The participants will be assessed with the Center for Epidemiologic Studies Depression Scale, the Depression Anxiety Stress Scales, the Pittsburgh Sleep Quality Index, and the Plutchik Suicide Risk Scale. In addition to the psychometric assessment, there will be an electroencephalogram evaluation using the EMOTIV (v 1.1) device.

Results: A pre-post intervention of 10 Behavioral Activation Treatment for Depression sessions will be implemented. The results of the effectiveness of the Behavioral Activation Treatment for Depression will be analyzed in five measures at pre-post intervention and two follow-ups of 3 and 6 months.

Conclusions: This study looks for evidence regarding the efficacy and feasibility of the Behavioral Activation Treatment for Depression in a sample of medical students from two public universities in Mexico with high levels of depression along with stress and anxiety.

Keywords

Mental health/psychiatry, depression, medical students, electroencephalogram, behavioral activation treatment for depression

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Introduction

Depression is a worldwide common mental disorder,[1] characterized by somatic and cognitive symptoms. Some basic symptoms for its diagnosis are during at least 2-week period, the person experienced most of the day and nearly every day, depressed mood, loss of interest, or pleasure in activities once enjoyed, decrease or increase in appetite, insomnia or hypersomnia, loss of energy, and difficulty concentrating.[2] This mental disorder has a high comorbidity with anxiety,[3] and it is related to suicidal behavior.[4]

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Other consequences are the presence of pain,[5] impaired memory function,[6] higher risk of cardiovascular disease,[7] as well as an increased risk of suffering dementia in late stages,[8] and at its worst, depression can lead to suicide.[1]

The way to evaluate patients with depression and how severely affected they are, has been done with the use of guides to the diagnosis of mental disorders, and psychometric tests, such as the Beck Depression Inventory.[9] However this could be considered a subjective measure, therefore, objective and direct measures are needed. There is wide evidence of the consequences of depression in Electroencephalogram (EEG) biomarkers, most of them are focused on differences in band power signals and asymmetry of the brain activity especially on alpha bands in frontal and left central cortex.[10]

Depression not only affects an individual and the family context, but also represents a public health problem, having an economic and social impact.[11] Estimates of the burden of the disease place depression as a leading cause of disability worldwide, in Mexico this mental disorder is placed in the fifth health problem that causes disability.[12]

Depression is associated with a relationship between behavior and the environment. The understanding of contingent relationships is central to behavioral models of depression, in which the main hypothesis is that a reinforcement must maintain the behavior.[13] The maintenance of depressive behavior results from a combination between the reinforcement of those behaviors and a lack of reinforcement to positive or healthy behaviors, thus it is assumed that people's behavior generates an insufficient degree of reinforcement to maintain them.[13]

Depression has been studied in different population groups, among the most affected are young people. College students have a higher proportion in suffering from this disorder compared to the general population,[14] especially among medical students. In a meta-analysis that included studies of these groups, a high proportion of depression and suicidal ideation has been observed. In comparison by region, the prevalence in North America was 30.3%, while 26.8% in South America. In México, a study done by Joffre-Velazquez et al. to determine the presence of depressive symptoms in 251 students of the School of Medicine at the Autonomous University of Tamaulipas, found a similar prevalence, 26.9% and 27.2% of the students from the first and fourth academic years, respectively, presented depressive symptomatology.[15] The most common risk factor for depressive symptoms is the stress generated by training demands such as the workload and the responsibilities that increased during the training phase.[16,17] Depression and anxiety can lead to school dropouts, work deficiencies, and degradation of social relationships.[18] In the medical practice, these disorders may cause a loss of interest in work and poor quality delivered in the treatment of patients.[19]

Diverse psychological treatments have shown evidence in reducing depressive symptomatology, but the Cognitive Behavior Therapy (CBT) is the treatment that counts with higher empirical evidence regarding its effectiveness.[20] However, there is available data that just the behavioral elements of the CBT could produce similar results.[21] Jacobson et al.[22] founded that only the behavioral components of CBT for depression had an efficacy equal to the CBT, and concluded that Behavioral Activation Treatment for Depression (BATD) is a more parsimonious treatment than CBT.

Diverse studies have corroborated the effectiveness of the BATD, some meta-analysis has compared this model with waiting list groups, placebo, conventional treatment, cognitive therapy, and pharmacological treatment in cases with severe depression, and the results indicated that the BATD is an effective treatment for depression.[23,24] Other studies have also concluded that the BATD could be a viable option for the treatment of mild to moderate depression.[25]

In the BATD, the patient monitors his or her emotions and daily activities, as a behavioral element. It seeks to increase the number of pleasant activities and to increase interactions with the environment.[26] Thus, it considers positive reinforcement as the main intervention strategy.

In addition, in a study comparing the efficacy of BATD with CBT and Antidepressant Medication (ADM) in adults with major depressive disorder, results showed that the efficacy of BATD is comparable to ADM and more effective than CBT. It is considered that one of the factors that makes BATD more effective than CBT is that BATD focuses on the modification of avoidance behaviors in intrapersonal and interpersonal difficulties; also in this treatment people learn to identify avoidance patterns by responding with activation behaviors.[24]

Due to the high prevalence of depression worldwide, it is required to use brief evidence-based interventions that can allow effective attention to the current demand. The BATD is an easy-to-implement therapeutic model with solid research support.[27]

Even though BATD has been proved to be effective in treating depression in different contexts and diagnosis in Latin American countries,[13,27] there is no available evidence of its effectiveness in Mexican population, especially among Medical students.

This study aims primarily to assess the effectiveness of the BATD on depression symptoms in a medical student sample, observed by the changes in the psychometrics, and the alpha waves in the EEG measures (Asymmetry and band power differences) after receiving the BATD. The objectives are the following: (1) to examine the correlations between the symptoms at pre and post treatment through psychometrics validated tests and (2) to examine the effects of the BATD in psychometric and EEG measures in a follow-up phase at 3 and 6 months in a medical student sample of two public universities of Mexico. The hypotheses of this study establish that after the participants received the BATD a significant decrease ($p < 0.01$) in depression and anxiety symptoms; as well as a significant increase in the sleep

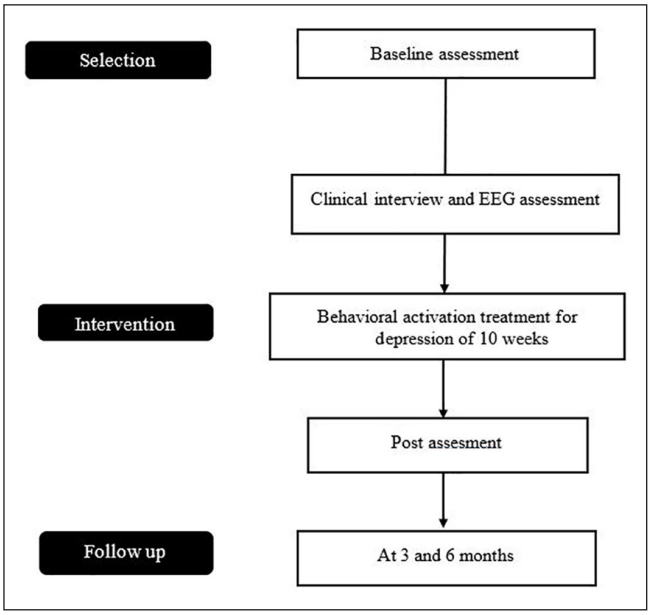

Figure 1. Process flow of the behavioral activation treatment for depression.

quality of the participants; and an increase in the alpha rhythm will occur.

Methods

Study design

This pilot study is designed as a within-subjects clinical trial. Therefore, this intervention will be implemented in a highly vulnerable population with a widely observed affected mental health, and a need for psychological treatment. Unfortunately, there are a limited number of psychologists at the universities; consequently, a comparison group and randomization will not be possible.

This trial will be performed approximately through 1.5 years, divided in 3 periods of 6 months each. In the first period, the medical students at both universities will be evaluated in order to identify possible candidates and also during this time, the therapists that will implement the treatment will be trained in the BATD. In the second period, the treatment will be implemented. In the third period, the two follow-ups of 3 and 6 months will be conducted and the results will be analyzed. Each participant will follow the same evaluation and intervention process described in Figure 1.

Study population

This study will be carried out in the following two public universities in the northwest of México:

1. The Psychology Laboratory in the School of Medicine and Psychology at the Autonomous University of Baja California, where clinical trials have previously been conducted. This laboratory has appropriate environmental conditions such as light, space, and sound isolation. The students will be selected from a sample pool, taking into consideration a published study in 2019 that states that an average of 757 students were enrolled in 2017 from the Faculty of Medicine and Psychology.[28]
2. Institute of Biomedical Sciences of the Autonomous University of Ciudad Juarez, which has similar facilities for care, and is used to provide psychotherapeutic care. In this case, the students will be selected from a sample pool of 1238 students from the School of Medicine enrolled in the academic semester of August–December 2019.

Table 1. Inclusion and exclusion criteria.

Inclusion criteria
1. The participants must be medical students of Tijuana or Ciudad Juarez
2. Man or woman aged 18–60 years diagnosed in the clinical interview with a mild to moderate depression
3. The participants that scored with low scores of suicidal ideations in the instruments described in this article
4. Give full informed consent to participate in the study
Exclusion criteria:
1. Any participant who is currently using drugs
2. Participants currently in psychological and/or pharmacological treatment
3. Recent suicide attempt (3 months or less ago)
4. Refuse to sign the informed consent
5. Other relevant reasons determined by the clinician

Participant selection, recruitment, and retention

The participants must fulfill the following inclusion criteria (further information of the exclusion criteria could be found in Table 1).

This intervention will be aimed at students with depressive symptoms, which were previously evaluated using the Center for Epidemiologic Studies Depression Scale (CES-D), considering a cut-off score of 16 and above. Afterwards, a psychological interview will be conducted taking as reference the Diagnostic Manual of Mental Disorders criteria.[2] To fill in the scales and the interview, all the participants will be provided with information and an informed consent form that could be retrieved from Clinical Trials (ID: NCT04069182).

An advertising campaign will be carried out through social networks and printed information within the facilities of the medical school at the Autonomous University of Baja California and the Autonomous University of Ciudad Juarez. In the advertisement, medical students will be invited to answer the evaluation through a direct link to the scales contained in a Google Drive form. This modality will allow

Table 2. Behavioral activation sessions planned for 10 sessions.

Session	Content
1	Depression and psychoeducation treatment, introduction of daily monitoring, and homework assignment
2	Homework review, assess the model understanding, presentation of Vital Areas, Values and Activities form, and homework assignment
3	Task reviews, introduction of the selection form and hierarchy of activities, and task assignments
4	Homework review, introduction to activity planning, and homework assignment
5	Task reviews, introduction of agreements, and task assignments
6 to 9	Task reviews, review of the material worked throughout the sessions, and task assignments
10	Daily monitoring with activity planning. End of the treatment

students to answer the scales anonymously. The estimated time to answer the form is approximately 20 min. The scales, advertisement, interviews, and the treatment will be delivered in Spanish.

According to the limited resources related to available spaces and available therapists (four in Tijuana and four in Juarez), as well as the limited period of time, the sample size of this study could not be statistically calculated as with sample size calculations. Hence, a convenience sample will be selected for this quasi-experimental design and first pilot study implementing the BATD in medical students in Mexico. It will include a non-probabilistic sample, and a comparison group will not be available.

The total number of medical students to be included in this sample is 20 participants, 10 participants in each city. This criterion is based on the minimum sample size accepted for experimental and quasi-experimental designs per group required for one-sided hypothesis that is 15 participants.[29,30]

Intervention

The BATD is based on a protocol created by Maero and Quintero,[27] which take up behavioral principles of reinforcement, punishment, molding, and attenuation. The authors propose a brief behavioral activation treatment of 10 sessions in face-to-face format where different forms are used to record as daily monitoring, activity planning, description of values, and establish support networks to reduce depressive symptoms. The treatment is structured, therefore, as the sessions progress, patients are increasingly involved in more activities in different areas of their lives that serve as positive reinforcers, resulting in a decrease of depressive symptoms.[25] The 10 sessions of the BATD protocol are applied in a structured manner, in an approximate 50 min each (see Table 2).

This brief and structured psychosocial approach is focused on relieving depression and relapses; it is directly focused on exercising behavior modification. The premise is based on the fact that people's problems and their responses to them, reduces the ability to experience positive environmental rewards. The treatment focuses on helping patients to systematically increase contact with their life's reward sources and solve their problems through procedures that focus on activation and the processes that inhibit it, such as escape, avoidance behaviors, and ruminant thoughts.[26]

Conducive to improve the adherence, if the patients have difficulties to assist to their weekly session, the session will be rescheduled for the next week, in case that the patient does not notify to reschedule his or her appointment, the therapist will call or send an email to inquiry about the patient's clinical condition and to reschedule to ensure ethical criteria.

In order to implement BATD, four therapists will be located in each institution for the application of the treatment. The therapists will be qualified psychologists, who must have skills and experience in evaluation, interview, and psychotherapy. In addition, at an interpersonal level, they must show empathy, commitment and follow the professional ethical criteria.

Once chosen, the therapists will receive training in the BATD in 2-hour sessions, twice a week for 1 month. The sessions will be taught through videoconferences by a certified expert in the BATD, who has a long experience in clinical intervention as a trainer in clinical context. Furthermore, all participants will receive training materials (slides, audio recordings, and PDF files) to review at any moment.

In addition, the therapists will be included in a weekly videoconference supervisory program that will take place on the same dates of the intervention, this program is divided into 1-hour sessions during treatment, where therapists have the opportunity to present their cases and to receive feedback by the group.

Participants will be allowed to withdraw at any point in the study, however, they must explain their reasons to the therapist or researchers in charge to provide them alternatives for their mental health care. Patients' withdrawals will be registered and analyzed for future improvements of the study.

Patients participating in the study will be recruited on a voluntary basis, so they will not receive an incentive beyond the benefits of treatment. Other circumstances in which treatment could be finished are the following: not attending three consecutive sessions, not being able to contact the patient when trying to reschedule a session, when there is no remission of depressive symptoms after having fulfilled the established sessions, and if the treatment is not being effective for a patient in particular.

Assessments

Participant assessments consist of four self-reported scales and a neurological evaluation of EEG. The primary outcome

will be depression symptoms measured by the CES-D and the EEG,; secondary outcomes will be stress, anxiety, sleep quality, and suicide risk values. The measurements will be applied in the initial phase of the treatment, at the end of treatment and at the follow-up (3 and 6 months).

1. *Center for Epidemiologic Studies Depression Scale.* The depression levels will be assessed by the CES-D, a self-report scale that evaluates depression symptoms within the previous 2 weeks. This scale consists in 20 questions and contains 4 possible answers as follows: rarely or never (less than 1 day), sometime or rarely (1–2 days), occasionally or a good part of the time (3-4 days), and most of the time (5–7 days).[31] This instrument has been constantly used in mental health research and its psychometric properties prove to be a valid scale among different populations like young people (Cronbach's alpha of 0.83) and adults (Cronbach's alpha of 0.84).[26]
2. *Depression, Anxiety and Stress Scale* (*DASS*-21). The DASS-21 is a self-report scale that evaluates the subscales of depression, anxiety, and stress within the past week. Each subscale contains seven questions with four possible answers (0–3) as follows: does not apply to me (0), applied to me in some degree, or some of the time (1), applied to me in a considerable degree or a good part of time (2), applied to me a lot or most of the time (3). All the scores must be multiplied by two to obtain the final score, where each subscale has a cut-off scores for each severity condition (normal, moderate, severe), cut-off for moderate levels are 14–20 for depression, 10–14 for anxiety, and 19–25 for stress, where any score above is considerate as severe or extremely severe.[32] This scale has been validated in Hispanic population obtaining high reliability for global ($\alpha = 0.96$) and for each subscale; depression ($\alpha = 0.93$), anxiety ($\alpha = 0.86$), and stress ($\alpha = 0.91$).[33]
3. *Pittsburgh Sleep Quality Index* (*PSQI*). The quality of sleep scores will be assessed using the PSQI, this instrument evaluates the patterns of sleep quality, which differentiates people who have a poor sleep quality from those who have a good sleep quality of sleep; for this purpose, seven areas are evaluated, where the ranges of responses range from 0 to 3 with a total sum that goes from 0 to 60, where the cut-off point is a score of 5, indicating a poor sleep quality.[34] The evaluation in the Mexican population has shown solid reliability criteria ($\alpha = 0.78$).[35]
4. *Plutchik Suicide Risk Scale* (*PSRS*). The PSRS is a questionnaire where suicide risk is assessed. The questions are posed dichotomously (yes/no), where the history of suicide attempts, suicidal ideation, and suicide plans is considered. On this scale, a cut-off point of >6 is established that differentiates people at risk from those who are not at risk of committing suicide.[36] The properties of this scale have shown good reliability ($\alpha = 0.74$), based on these findings, it is established that it is an appropriate questionnaire to assess suicide risk.[37] This scale has been used in previous studies with Mexican population.[38]
5. *Electroencephalogram EMOTIV EPOC+*.[39] A supplementary neuropsychological measure of EEG will be used to measure brain waves. To accomplish this measurement, this study will be using the EMOTIV (v 1.1), a 14-channel mobile EEG that allows measuring the electrical activity patterns of the brain. Neuropsychological measurements have been used to evaluate mental disorders, especially EEG tools, these devices are placed on the head allowing brain wave measurements created by postsynaptic action potentials that affect an electrical charge that is measured in different types of waves; alpha 8 Hz–13 Hz, beta $>$ 13 Hz, theta 4 Hz–8 Hz, and delta $<$ 4 Hz.[40] Through these physiological correlates, diverse mental disorders have been evaluated from brain wave patterns. Evaluations with EEG have proven useful for assessing disorders such as anxiety.[41] In the case of depression, alpha waves are evaluated, where a quantitatively lower difference is described in people with depression compared to people without depression.[42,43] As well as greater frontal alpha EEG asymmetry in mid-frontal and mid-lateral electrodes (F3/F4 and F7/F8) was observed in depressed patients.[44] Due to its usefulness, this physiological evaluation implementation is relevant, and it is effective at measuring neuropsychological correlates that identify depression in clinical contexts.

The EEG performs measurements in the following four lobes: for the frontal lobe, it has electrodes in the areas AF3, AF4, F7, F8, F3, F4, FC5, and FC6; in temporal, T7 and T8; in parietal, P7 and P8; and in the occipital, O1, O2. As for the resolution of the signals, it uses sequential sampling at a rate of 128 samples per second at 14 bits that measures beta, alpha, gamma, and theta activity. In addition, it has a bandwidth of 0.2 Hz–43 Hz. EEG records are obtained under two conditions of 3 min each, (1) eyes closed and (2) eyes open. In this study, the alpha waves (8–13 Hz) will be evaluated,[45] due to the fact that are important indicators in the assessment of depression in depressive patients, in which low levels of alpha waves have been found, so it is suggested that there is a difference between depressive patients and non-depressive patients with regard to the levels of alpha waves.

Statistical analysis plan

The data obtained from the participants will be captured in the Statistical Package for Social Sciences (SPSS), to execute statistical tests according to the research objectives. For

this, normality tests of the variables will be performed, comparisons between the means of the pre-post measurements and in the follow-up evaluations will be calculated with Student's *t*-test for paired samples considering a small sample size.[46] In addition, to meet the secondary objectives, Pearson's correlation coefficients will be obtained to assess the relationship between the self-report scales. The correlation and *t*-test statistics of the self-report scales will be estimated with a 99% reliability limit. In addition, effect size (Cohen's *d*) tests will be calculated, where the pre-post intervention and follow-up evaluations will be compared, where an effect of $d=0.80$ based on psychological treatments is expected.[47]

Managing participant safety

All participants will sign and accept the informed consent to answer the psychometric scales and be measured by the EEG device. The informed consent will explain the scales administration, the aims of the study, and the possibility to enroll into a BATD treatment.

Participants that indicate serious mental disorders, high depression symptoms, suicidal ideation, or suicidal behavior through the scales or at the clinic interview, will be channeled to corresponding mental health institutions with specialized treatment.

The bioethics committee of the Autonomous University of Baja California will be allowed to monitor the entire study process from its approval to the follow-up. The university and the founding organization request a progress of this study every 6 months, and when the results are collected.

Data participant safety

The management of the participant's confidentiality is fundamental to the study. The interview data collected in written formats will be assigned to a locked locker. Each participant will have a code for privacy purposes. In addition, all collaborators will sign a document where they accept the total personal confidentiality of the patient. Only for the researchers in charge of both universities will have access to all the information contained. Data such as assessments in paper, signed consents, and digital assessments will be deleted after a period of 5 years. In case that during this period of time an auditory is requested by the university or the funding source, or at the moment of the results being delivered to be published and are requested by a journal. The identity of the participants will not be unveiled to any of these organisms.

Discussion

This pilot study will implement the BATD in a sample of medical students of two Public Mexican Universities. This is the first study that will implement this treatment in a vulnerable sample suffering from depression symptoms which affected their daily activities, and that will be carried out in Mexico. In addition to this, it has been observed that medical students have a high proportion of 27%–30% of depression and 11% of suicidal ideation.[48,49]

It is also consistent with the needs of Latin American countries, where there are difficulties in creating empirical evidence on the efficacy and efficiency of psychotherapeutic treatments. Furthermore, it is expected that this study will play an important role in the dissemination of clinical psychology in a population with particular sociocultural characteristics where depression is an important mental health problem that affects a large number of people in the country.[12] It is also expected that the support for effectiveness of this study will have an important impact, since it adapts to a health care system where the means to address this problem are insufficient.[50] This study will provide evidence regarding the effectiveness of Behavioral Activation Treatments in educational institutions. The evidence that will be obtained from this study can support its application in similar environments, since it is a short-lived treatment, easy to implement, and effective.

Dropping out is one of the difficulties that treatment can face due to the lack of openness to psychological treatments and the constant changes in the class schedules of students, however, this is expected to decrease with the controls applied and previously explained such as follow-up with the patient in case of missing sessions and willing to reschedule sessions adjusted to the available time of the patient.

Several limitations of this study should be mentioned. The reason for carrying out a quasi-experiment implies that the results are not contrasted with a control group or waiting list, the choice of this design was due to the ethical implications of providing psychological treatment to all the patients with depressive symptoms. Despite this reason, the research would be strengthened if a comparison group would be used, for example, by contrasting it with another model of psychotherapeutic intervention. Also, it would be ideal to test the effectiveness of the BATD through a Randomized Controlled Trial, where the participants can be randomly assigned to at least one of two groups and to have a control group to compare the effectiveness of the results of the BATD. However, this is not possible to implement at this study due to the lack of the necessary resources such as a higher number of psychologists to implement the treatment to different groups and more available spaces. Another important limitation is the small sample of 20 participants. It would be ideal to have a higher sample to generalize the results of the effectiveness of the BATD in medical students in México, however, since this is a pilot study, this could be implemented in future studies. Another limitation to consider in this study is to count only with medical students of two universities in the north of México, specifically both in the border cities between Mexico and United States, therefore the results, although relevant for research, would be stronger if a broader sample of students of different universities in México are included, specifically in the center and south of Mexico, where the socioeconomic status and circumstances are different from

the north. Finally, although this study is specifically directed at medical students due to the high stress levels that they experiment due to their training, it would be relevant to compare the effectiveness of the BATD with other university students with high levels of pressure, or even with medics already working in private or clinical hospitals.

Regardless of these limitations, it is expected that this pilot study will provide evidence to implement in a broader sample the BATD to decrease the high prevalence of depression in the general population.

Conclusion

This will be the first study implementing the Behavioral Activation Therapy for Depression in medical students of Northwest Mexico, specifically in two cities at the border of Mexico and the United States. The effectiveness of the intervention will be measured with objective measures such as EEG and widely validated and reliable psychometric instruments. If positive results are found, the BATD could be implemented in more universities and other vulnerable populations with a high risk of suffering depression.

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Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval

This research protocol has been reviewed by the Bioethics committee of the Faculty of Medicine and Psychology of the Autonomous University of Baja California (approved in May 2019, with the number 714 / 2019-1). The approval was delivered to Dr Alejandro Domínguez Rodríguez, main researcher and responsible for this project. This study is also registered within Clinical.Trails.gov (NCT04069182). The name of trial registry is Behavioral Activation Therapy for Medical Students with Symptoms of Depression in Two Cities of Mexico.

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Informed consent

All participants will sign and accept the informed consent to answer the psychometric scales and be measured by the EEG device. The informed consent will explain the scales administration, the aims of the study and the possibility to enroll into a BATD treatment. To fill in the scales and the interview, all the participants will be provided with information and an informed consent form that could be retrieved from Clinical Trials (ID: NCT04069182).

Trial registration

This study is also registered within Clinical.Trails.gov (NCT04069182). The name of trial registry is Behavioral Activation Therapy for Medical Students with Symptoms of Depression in Two Cities of Mexico.

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Supplemental material

Supplemental material for this article is available online in NCT04069182.

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