

## Protocol

# The effects of promoting mentally active sedentary behaviour and physical activity on depressive symptoms: a randomized controlled trial

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## ABSTRACT

**Background:** Depressive symptoms are linked to poorer health and higher mortality, partly due to non-communicable diseases. While sedentary behavior contributes to these outcomes, its impact may depend on cognitive engagement. Evidence from interventions replacing passive sedentary activities with active or physical alternatives remains limited. Objectives were to evaluate the effects of an intervention replacing mentally passive sedentary behaviors with mentally active sedentary behaviors, light physical activity, or moderate-to-vigorous physical activity on depressive symptoms in adults with subclinical depression.

**Methods:** This single-center, parallel-group, randomized controlled trial will randomly allocate eligible participants (1:1) to either the intervention or control arm. The intervention group will engage in a 4-month goal-setting program designed to substitute mentally passive sedentary behaviors with mentally active sedentary behaviors, light physical activity, or moderate-to-vigorous physical activity. The control group will attend 4-month individual sessions and receive general guidance based on physical activity recommendations. Depressive symptoms (primary outcome), differentiated sedentary behaviors and physical activity levels, quality of life, body composition, and functional capacity will be evaluated at baseline and after the 4-month intervention. Data will be analyzed using an intention-to-treat approach to maintain randomization integrity, and per-protocol percentage changes will be compared using independent t-tests. All analyses will be conducted by a blinded researcher.

**Conclusions:** This trial could yield new insights into the benefits of replacing mentally passive sedentary behaviors with mentally active alternatives, light physical activity, or moderate-to-vigorous physical activity for alleviating depressive symptoms in adults with mild to moderate depression.

**Trial Registration:** This study is registered at ClinicalTrials.gov (identifier NCT07007234).

**Keywords:** Lifestyle, Mental disorders, Depression, Physical activity

## INTRODUCTION

Major depressive disorder constitutes a major public health concern worldwide. It is a highly prevalent disorder, affecting over 5% of global population per year.<sup>1,2</sup> A major risk factor for major depressive disorder is subclinical depressive symptoms.<sup>3</sup> Subclinical depression refers to the presence of depressive symptoms that do not meet the full diagnostic criteria for a depressive disorder.<sup>4</sup> Evidence indicates that individuals with subclinical depression have a twofold increased risk of developing major depressive disorder compared to the general population.<sup>5</sup>

Individuals with major depressive disorder have an increased risk of premature mortality in comparison with the general population, but this association is also observed among those with subclinical depression.<sup>6-10</sup> The excess mortality is not solely explained by the increased risk commonly of causes observed in this population such as suicide and other injuries, but also by communicable and non-communicable diseases (NCDs).<sup>7,11,12</sup> Among the NCDs, cardiovascular diseases are the leading causes of early death in individuals with mental disorders and subclinical depression.<sup>7,10</sup>

Frontline therapeutic interventions for subclinical depression typically include pharmacotherapy and psychotherapy.<sup>13,14</sup> Although helpful, the efficacy of these treatments is not optimal for all people, requiring additional interventions and these interventions do not target the heightened poor physical health.<sup>15-18</sup> Moreover, current clinical guidelines do not provide treatment recommendations for patients with subclinical forms of depression.<sup>19</sup> Lifestyle-based interventions, including reducing sedentary behavior and promoting physical activity, may be potential non-pharmacological approaches for managing individuals with subclinical forms of depression. Indeed, recent reviews underscore the potential benefits of lifestyle-based interventions in both primary prevention and clinical treatment across a spectrum of mental disorders.<sup>20-23</sup>

Sedentary behavior refers to any waking behavior characterized by an energy expenditure  $\leq 1.5$  metabolic equivalents (METs) while in a sitting, reclining, or lying posture.<sup>24</sup> Although epidemiological data indicate that sedentary behavior is independently associated with various adverse health outcomes (e.g., cardiovascular disease, type 2 diabetes, metabolic syndrome, obesity, anxiety, and depression), emerging evidence suggests that not all types of sedentary behavior are equally detrimental.<sup>25-31</sup> Specifically, sedentary behaviors involving minimal cognitive effort, referred as mentally passive sedentary behaviors (e.g., napping, listening to music, watching television), appear to have higher negative effects on health outcomes compared to sedentary behaviors that require higher cognitive engagement, named as mentally active sedentary behaviors, including activities such as work-related tasks that demand sustained attention and greater mental effort.<sup>32-34</sup> Conversely,

substantial evidence indicates a significant association between physical activity and depression, suggesting that enhancing physical activity levels may contribute to a reduction in depressive symptoms.<sup>35-38</sup> In this context, it is reasonable to speculate that replacing mentally passive sedentary behaviors with any form of physical activity (e.g., light, moderate, or vigorous) may lead to improved health outcomes since that physical activity is an independent protective factor associated with various health outcomes, including mental disorders.<sup>39,40</sup>

A study involving 43,863 adults observed over 13 years demonstrated that replacing 30 minutes per day of mentally passive sedentary behavior with equivalent durations of mentally active sedentary activities, light physical activity, or moderate-to-vigorous physical activity reduces the risk of incident depression.<sup>41</sup> While these findings provide significant insights, the cross-sectional design employed in these studies precludes establishing cause-and-effect relationships. Therefore, these results should be interpreted with caution. Although emergent evidence indicates that different types of sedentary behavior may differently affect health outcomes, randomized clinical trials are still required to elucidate the potential benefits of an intervention to replace mentally passive sedentary behaviors with mentally active sedentary behaviors, light physical activity or moderate-to-vigorous activity on depressive symptoms in individuals with mild to severe symptoms of depression.

### Objectives and hypothesis

The main purpose of this study is to investigate the effects of an intervention aimed at replacing mentally passive sedentary behaviors with mentally active sedentary behaviors, light physical activity, or moderate-to-vigorous activity on subclinical depression.

Our hypothesis is that replacing mentally passive with mentally active sedentary behaviors, light physical activity, or moderate-to-vigorous activity will result in lower depressive symptoms compared to those receiving a control intervention consisting of general instructions related to World Health Organization (WHO) guidelines for physical activity.

## METHODS

### Trial design

This study consists of a single-center, parallel-group, randomized controlled trial. Eligible participants are randomly assigned in a 1:1 ratio by a blind researcher to one of the two study arms using specific software (<https://www.randomizer.org>): intervention or control. All outcome measures are assessed at baseline (pre) and following 4-month experimental period (post). This study is described according to the standard protocol items: recommendations for interventional trials (SPIRIT) checklist. The findings of this study will be reported

following the consolidated standards of reporting trials (CONSORT) guidelines (Figure 1). The current study is registered at ClinicalTrials.gov (identifier NCT07007234).

### ***Trial setting***

The study is being conducted at Santo Amaro University. Experimental visits occur at the Nutrition Assessment Laboratory at the Unisa Research Center (URC). Participant recruitment began in June 2025 and is expected to continue until July 2026. In case the number of participants does not meet the estimated sample size, we will submit a request for an extension of the recruitment deadline.

### ***Eligibility criteria***

Inclusion criteria are following: individuals aged over 17 years showing mild to severe symptoms of depression (i.e., Beck's depressive inventory scored >14). Exclusion criteria are the following: incapacity to read and sign the informed consent form; physical disabilities (e.g., amputees, wheelchair users) and blind and/or deaf people; cancer in the past 5 years; inability to perform the physical tests; and prior diagnosis of muscle degenerative disease (e.g., myopathies, amyotrophic lateral sclerosis).

### ***Recruitment***

Participants are recruited through the community outreach program at Santo Amaro University. Also, we are announcing the study on social media (i.e., Instagram, Facebook and university blog) inviting potential candidates to attend the university for initial screening.

### ***Research ethics approval***

This study is conducted in line with the principles of the Declaration of Helsinki, and it was approved by the local Ethics Committee (Ethics Committee Approval Number: CAEE - 69886123.8.0000.0081; approval numbers: 6.231.001).

### ***Consent***

All participants are informed about the aims and risks of the research and shall sign an informed consent about the risks and benefits associated with their participation in the study.

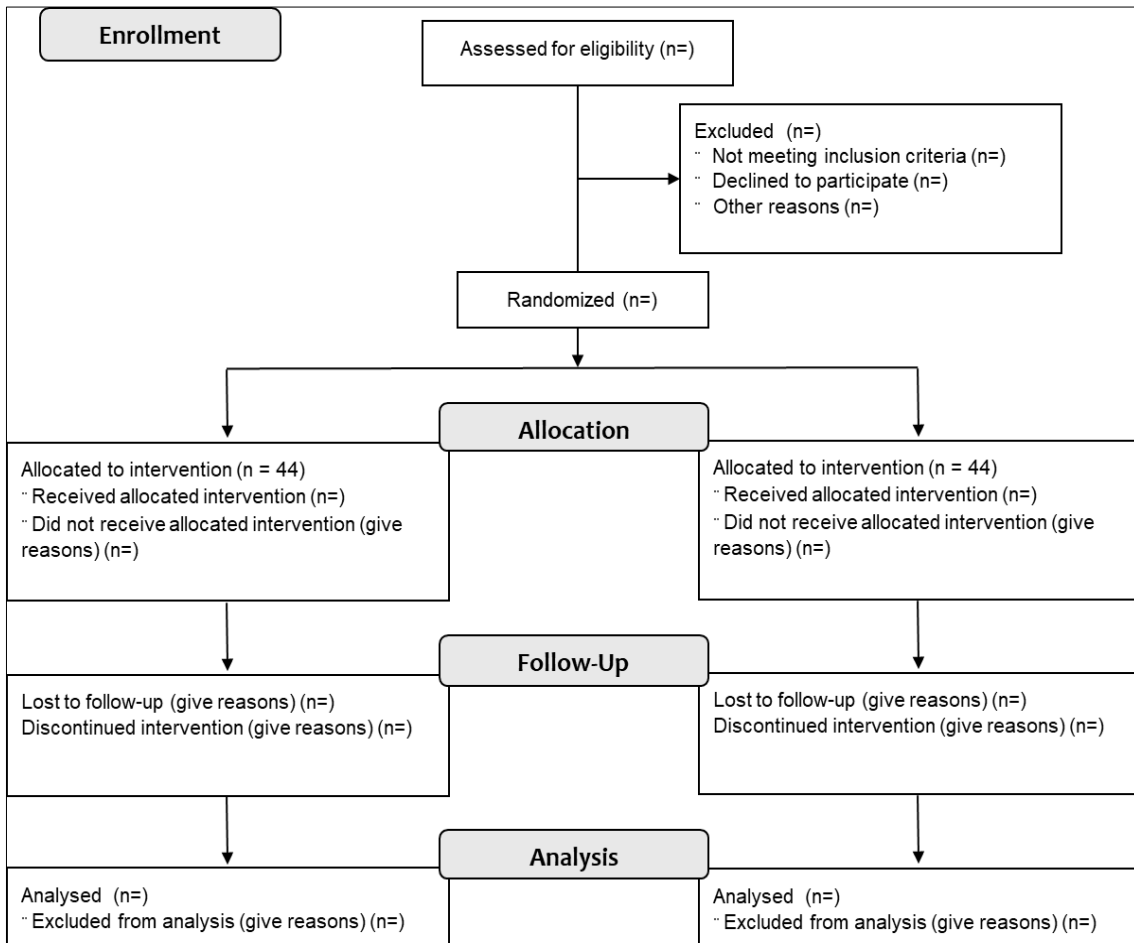
### ***Intervention and comparator***

The intervention group consists in a 4-month goal-setting intervention aimed at replacing mentally passive sedentary behaviors with mentally active sedentary behaviors, light physical activity, or moderate-to-vigorous activity. The intervention protocol was adapted to prior study in which the main aimed was testing the feasibility and efficacy of a personalized intervention focused on replacing sedentary

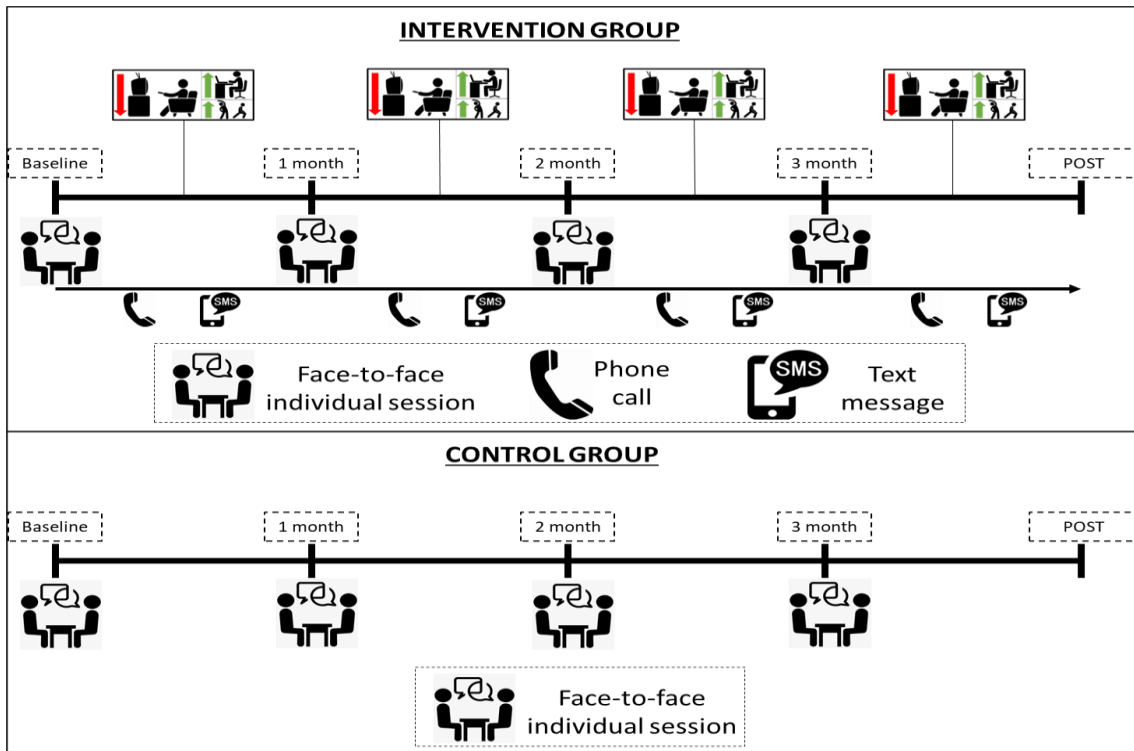
time with light-intensity physical activity in patients with rheumatoid arthritis.<sup>42</sup>

Overall, the intervention protocol consists of 4 face-to-face monthly individual sessions, lasting ~15-30 minutes. A trained researcher carefully evaluate the data obtained from the self-reported sedentary behavior assessment using the longitudinal aging study Amsterdam - sedentary behavior questionnaire (LASA-SBQ) in order to identify the duration (in hours and minutes) that participants spend in mentally passive sedentary behaviors, such as napping, listening to music, watching television, sitting and talking (with or without using a smartphone), or attending church or the theater. Subsequently, the researcher explains the potential negative impacts of mentally passive sedentary behaviors on health outcomes and emphasizes the importance of replacing them with other activities, including light, moderate, or vigorous physical activities (e.g., slow walking, climbing stairs, or gardening). Then, the researcher proposes the intervention in which the participant should choose at least 3 goals to replace mentally passive sedentary behaviors with mentally active sedentary behaviors, light physical activity, or moderate-to-vigorous activity in each one of the following domains: transport, leisure/social activities and exercise. For instance, if a participant spends two hours watching television, the researcher may suggest replacing at least 30 minutes of this mentally passive sedentary behavior with a light physical activity, such as stretching or light walking. This approach is applied individually to each participant based on the LASA assessment results. During follow-up visits, participants should complete the LASA-SBQ questionnaire again to allow researchers to determine whether the goals have been met and to make any necessary adjustments to the intervention such as increasing the duration, frequency, or intensity of the selected goal. Patients receive supportive phone calls and/or text messages on a weekly basis to check the compliance with the goals. Two times a week, home-based online supervised exercise training is offered to the intervention group to allow an increase in moderate-to-vigorous physical activity. Also, compliance is also verified during the individual meetings; if a given goal has been reported to be not achievable, this may be replaced with another one. Control group also participate in 4-month face-to-face monthly individual sessions during the experimental period, lasting ~15-30 minutes, however they receive general instructions related to WHO guidelines for physical activity.

At the end of the study, each participant will be asked about the feasibility, barriers, and facilitators related to adherence to intervention to replace mentally passive sedentary behaviors with light physical activity or moderate-to-vigorous activity throughout the experimental period. Any adverse events will be documented including feelings of general fatigue, soft tissue soreness and injury or illness. Attendance will be recorded to ensure compliance with the protocol. Figure 2 detail overall design of each group.



**Figure 1: Consolidated standards of reporting trials (CONSORT) flow diagram.**



**Figure 2: Overall design of each experimental group.**

### **Goals domains and explanation**

Goals will be separated into the following domains.

#### *Transport*

It consists of replacing mentally passive sedentary behavior decreasing sedentary time during transportation (e.g., park further away from your destination except when carrying heavy weight, or alight from the bus a stop before or after your destination);

#### *Leisure/social activities*

It consists of replacing mentally passive sedentary behavior with any leisure activity (e.g., stand up during advert breaks when watching television walk with your dog at least twice a week);

#### *Exercise*

It consists of replacing mentally passive sedentary behavior with any exercise or sports (e.g., supervised exercise, playing any sports);

#### *Active mentally sedentary behaviors*

It consists of replacing mentally passive sedentary behavior with any active mentally sedentary behaviors such as reading, praying, using the computer and administrative activities.

### **Face-to-face individual sessions aims and structure**

Face-to-face individual sessions will be conducted monthly. During the first visit, the researcher will explain the potential negative impacts of mentally passive sedentary behaviors on health outcomes and emphasize the importance of replacing these behaviors with more beneficial activities. Based on the LASA results, the researcher will then propose an individualized intervention in which each participant will select at least three goals aimed at replacing mentally passive sedentary behaviors with mentally active sedentary behaviors, light physical activity, or moderate-to-vigorous physical activity. Participants will be encouraged to actively choose their own goals, while the researcher will provide guidance to ensure that the selected goals are realistic and feasible within the participant's daily routine.

During the subsequent sessions (2nd to 4th sessions), the LASA-SBQ questionnaire will be re-administered to allow the researcher to determine whether the participant is meeting the predetermined goals. Participants adhering to the goals will be encouraged to maintain their routine. If not, the researcher will discuss other ways of overcoming the reported barriers; if a barrier is unresolved, the participant will be guided in selecting a new goal.

### **Outcomes**

#### *Depressive symptoms (primary outcome)*

The depressive symptoms will be assessed by Beck's depressive inventory (BDI), which is composed by 21 multiple-choice statements, each with four possible answers (0-3).<sup>43</sup> The final score ranges from 0 to 63 points, with higher scores being indicative of higher symptoms of depression. The BDI is a validated tool for the Brazilian population.<sup>44</sup>

#### *Self-reported and objective physical inactivity and sedentary behavior assessment*

Physical activity will be assessed using the international physical activity questionnaire-long form (IPAQ).<sup>45</sup> In brief, the participants will be requested to report the time spent walking, and in moderate and vigorous intensity physical activity, with a minimal duration of 10 minutes in the past 7 days for each following domains: leisure-time; transport; household, and occupational. Time spent on each activity will be calculated as the number of days multiplied by the number of hours reported. Sedentary behavior will be assessed using the questionnaire LASA-SBQ.<sup>46</sup> The LASA-SBQ consists of ten questions to estimate sedentary behavior in various daily situations such as nap activities [napping], reading, praying or listening to music, watching television, using computers, hobbies, administrative activities, to talk, transport, and going to church or the theater. This instrument allows us to calculate the time spent in hours and minutes on a typical weekday (i.e., Monday to Friday) and typical weekend day (i.e., weekend). Examples of mentally passive sedentary behaviors are nap activities [napping], listening to music, watching television, talking using or not a smartphone when sitting, going to church or the theater. Conversely, reading, praying, using the computer and administrative activities will be considered as active mentally sedentary behaviors.

Objective measures of physical activity levels and sedentary behavior will be assessed using ActiGraph GT3X® accelerometers (ActiGraph, Pensacola, Florida, USA). Participants will be instructed to wear the accelerometer for 7 consecutive days during waking hours, except when bathing. All participants will be required to accumulate at least ten hours of valid activity recordings per day for at least five days. The accelerometer will be worn on an elastic belt at the waistline on the right side of the hip. To accurately register when the device will be worn and removed, patients kept a daily log. Data will be exported from the device in 60-s epochs, using ActiLife software (ActiGraph, Pensacola, v.6., Florida, USA). Non-wear periods will be defined as intervals of at least 60 min of zero activity counts, assuming a tolerance of no more than two minutes of counts between 0 and 100. Freedson cut-points will be used to define epochs as follows: sedentary time (<100 counts/min), light-intensity physical activity (≥100 to <1952 counts/min), and moderate to

vigorous physical activity ( $\geq 1952$  counts/min).<sup>47</sup> Sedentary behavior and physical activity levels data will be presented as min/day.

#### *Quality of life assessment*

Quality of life will be assessed using the World Health Organization quality of life assessment (WHOQOL-BREF).<sup>48</sup> This questionnaire contains 26 items: the first assesses overall quality of life, the second evaluates satisfaction with personal health, and the remaining questions are grouped into four domains - physical health, psychological health, social relationships, and environment. This instrument was validated for the Portuguese language and it has been used for both healthy and clinical populations.<sup>49-52</sup>

Score ranges from 0 to 100 points; higher scores are indicative of higher quality of life. Individuals scoring below 50 points in each domain will be classified as having a poor quality of life in that domain.

#### *Body weight and composition*

Body weight will be assessed on a calibrated digital scale (Filizola, PL 200 kg, SP, BR) and height will be evaluated with the aid of a stadiometer (Sanny, ES2060, SP, BR), from which BMI will be calculated. Body composition (fat mass and fat-free mass) will be assessed using 4-point bioelectrical impedance device (hands and feet) (OMRON HBF - 514, Omron Healthcare Brasil, SP, BR).

#### *Functionality*

Functionality will be measured by the timed-stands test and the timed-up-and-go test.<sup>53,54</sup> The timed-stands test evaluates the maximum number of stands that an individual can perform from a standard-height armless-chair (i.e., 45 cm), whereas the timed-up-and-go test registers the minimal time (in seconds) that each individual requires to rise from a standard chair, walk to a line on the floor three meters away, turn around, and sit down again. Two attempts will be allowed for each test. All tests will be conducted by the same investigator to avoid bias.

#### *Sample size*

Sample size was determined with the aid of a G-Power software (version 3.1.2 – Universitat Kiel, Germany) package. Because there was a lack of data available for sample size determination based on the main outcome, the sample size calculation was conducted by inputting  $\alpha$  error (0.05), power ( $1 - \beta$  error=0.95), and an arbitrary, conservative effect size (Hedges'  $g=0.40$  [moderate effect]) considering moderate between-group effect size (intervention versus control) for depressive symptoms. Calculations were based on an ANOVA with repeated measures (within-between interactions), and the total sample size was determined to be 84 participants.

#### *Statistical methods*

Data will be presented as mean $\pm$ standard deviation (SD), estimated mean difference between groups (EMD) at post (only in the presence of group x time interaction), 95% confidence interval (95% CI), unless otherwise indicated. Data will be analyzed using an intention-to-treat (ITT) approach to preserve the integrity of randomization. Dependent variables will be analyzed by a mixed model analysis for repeated measures, using group (intervention versus control) and time (pre and post) as fixed factors, and subjects as random factors.

In case of group x time interaction, post-hoc tests with Tukey's adjustment will be performed for multiple comparisons. In case of normality assumptions are not met, we will employ a generalized estimating equations (GEE) for the analysis. GEE is a robust statistical method suitable for repeated measures or correlated data that does not require normally distributed residuals. It allows for modeling dependent variables of various types (continuous, binary, or count) while accounting for within-subject correlations and providing population-level estimates of intervention effects, making it particularly appropriate for ITT analyses. Significance level was set at  $p \leq 0.05$ . Analyses will be done in statistical environment R (version 3.5.3; R Core Team 2020).

#### *Data collection and management*

Participant identities will be anonymized using ID numbers. All collected data will be securely stored and managed in an online spreadsheet. All informed consent and forms will be securely stored in a locked cabinet located in a restricted-access office at the university. Only study team members will have access to the office. Data records will be maintained for at least 5 years after the publication of results.

#### *Trial monitoring*

The principal investigator will have overall responsibility for the oversight and conduct of the study. Study team members will be responsible for collecting data and administering the intervention and, in case of any issues, they must promptly report them to the principal investigator.

All adverse events will be documented in accordance with regulatory requirements and reported to the principal investigator and the institutional review board within the required timelines. The principal investigator will submit continuing review reports, protocol amendments, and any unanticipated issues involving risk to participants to the institutional review board as required.

This oversight framework is designed to ensure the integrity of the study and the protection of all participants involved.

**Table 1: Participant timeline.**

Time points	Trial period					
	Enrollment		Post-randomization			Close-out
	0 to pre	Pre	t <sub>1</sub>	t <sub>2</sub>	t <sub>3</sub>	Post
<b>Enrollment</b>						
Eligibility screen	X					
Informed consent	X					
Randomization		X				
<b>Intervention/comparator</b>						
Intervention <sup>c</sup>		X				X
Comparator <sup>d</sup>		X				X
<b>Assessments</b>						
Depressive symptoms (primary outcome)		X				X
Self-reported physical inactivity assessment		X				X
Self-reported sedentary behavior assessment		X	X	X	X	X
Objective physical inactivity assessment		X				X
Objective sedentary behavior assessment		X				X
Quality of life assessment		X				X
Body weight and composition		X				X
Functionality		X				X

PRE: Baseline assessments; t<sub>1,2,3</sub>: face-to-face individual sessions; POST: 4-month following experimental period assessments; c: the intervention group will participate in a 4-month goal-setting program designed to replace mentally passive sedentary behaviors with mentally active sedentary behaviors, light physical activity, or moderate-to-vigorous physical activity; d: the control group will participate in monthly, face-to-face individual sessions over a 4-month period to receive general instructions based on the WHO guidelines for physical activity

### Dissemination policy

The results of this study will be shared through publications in peer-reviewed journals, as well as through abstracts and poster presentations at national and international conferences.

## DISCUSSION

This single-center, parallel-group, randomized controlled trial will investigate the effects of an intervention aimed at replacing mentally passive sedentary behaviors with mentally active sedentary behaviors, light physical activity, or moderate-to-vigorous activity on subclinical depression. Our a priori hypothesis is that replacing mentally passive with mentally active sedentary behaviors, light physical activity, or moderate-to-vigorous activity will result in lower depressive symptoms compared to those receiving a control intervention consisting of general instructions related to WHO guidelines for physical activity. This theoretical assumption is supported by studies showing that not all types of sedentary behavior are equally detrimental to health outcomes such as depressive symptoms.<sup>25-31</sup> However, it is important to note that this assumption is based on observational studies rather than clinical trials, which limits the strength of the inferences that can be made about the potential benefits of replacing mentally passive sedentary behavior with physical activity for reducing depressive symptoms. Furthermore, distinguishing between types of sedentary behaviors and understanding their specific impacts on depression symptoms can lead to more effective clinical practices,

tailored interventions, improved risk assessment, and enhanced long-term management of depression.

The strengths of this study include its randomized controlled design, which enables the investigation of the effects of replacing mentally passive sedentary behaviors with either mentally active sedentary behaviors, light physical activity, or moderate-to-vigorous physical activity compared to a standard care intervention aligned with WHO physical activity guidelines. The study also employs a robust combination of objective and indirect measures to assess both sedentary behavior and physical activity, enhancing the accuracy and depth of behavioral assessment. This approach will significantly refine our understanding of how different types of sedentary behavior impact depressive symptoms. Additionally, the study evaluates a personalized intervention with potential for implementation in real-world.

This study has some potential barriers, including a potential high withdrawal rate and difficulty replacing mentally passive sedentary behaviors with either mentally active sedentary behaviors, light physical activity, or moderate-to-vigorous physical activity. To address these challenges, research staff will work closely with participants to ensure they fully understand the study procedures and objectives, as greater participant engagement is associated with increased motivation to complete the study. In addition, staff will maintain regular contact with participants and offer flexible scheduling for face-to-face individual sessions and visits for assessment.

## CONCLUSION

This study has the potential to contribute novel evidence on the effects to replace mentally passive sedentary behaviors with mentally active sedentary behaviors, light physical activity, or moderate-to-vigorous activity on depressive symptoms in individuals with mild to severe depression. Our findings may support the design of evidence-based interventions that focus on specific sedentary behaviors to prevent or reduce the progression of depressive symptoms.

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*Conflict of interest:* None declared

*Ethical approval:* The study was approved by the Institutional Ethics Committee

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