

BARRERAS PARA LA REALIZACIÓN DE LA ACTIVIDAD FÍSICA EN POBLACIÓN CON DEPRESIÓN. PROTOCOLO DE UN ESTUDIO OBSERVACIONAL

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RESUMEN

Introducción: La depresión es una condición común que afecta la calidad de vida y el funcionamiento psicosocial. A nivel global, su prevalencia se estima en un 6%, con impactos sociales y económicos significativos. El ejercicio es cada vez más reconocido como un tratamiento viable para la depresión leve a moderada debido a sus beneficios biológicos y psicosociales. Sin embargo, desafíos como la falta de motivación, la fatiga y la ansiedad social suelen dificultar la adherencia. Este estudio tiene como objetivo identificar las barreras para la actividad física y evaluar la capacidad funcional de pacientes con depresión, proporcionando información para mejorar las intervenciones basadas en ejercicio.

Métodos: Se llevará a cabo un estudio transversal observacional remoto utilizando Cognito Forms y Microsoft Teams. Los participantes tendrán entre 18 y 65 años y diagnóstico clínico de depresión o distimia. Completarán cuestionarios validados como el PHQ-9, GPAQ, MPAM-R, PSQI y SEQRE. La capacidad funcional será evaluada de forma remota mediante el 30s Sit-to-Stand (30s-STSS) con instrucciones estandarizadas.

Análisis estadístico: Se emplearán estadísticas descriptivas para resumir medidas de tendencia central y dispersión, y modelos de beta regresión para examinar relaciones entre síntomas depresivos, autoeficacia, motivos de actividad física y capacidad funcional. Análisis secundarios explorarán diferencias entre niveles de síntomas depresivos y correlaciones entre las variables.

Ética y difusión: El estudio cumple con las normativas éticas y leyes de protección de datos. Los resultados serán compartidos a través de canales académicos y públicos para informar prácticas y políticas de salud mental relacionadas con el ejercicio.

Palabras clave: Trastornos mentales; Depresión; Ejercicio; Actividad física; Barreras.

BARRIERS TO ENGAGEMENT IN PHYSICAL ACTIVITY AMONG POPULATIONS WITH DEPRESSION. OBSERVATIONAL STUDY PROTOCOL

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ABSTRACT

Introduction: Depression is a common condition that impairs quality of life and psychosocial functioning. Globally, its prevalence is estimated at 6%, with significant social and economic impacts. Exercise is increasingly recognized as a viable treatment for mild to moderate depression due to its biological and psychosocial benefits. However, challenges such as lack of motivation, fatigue, and social anxiety often hinder adherence. This study aims to identify barriers to physical activity and evaluate the functional capacity of patients with depression, providing insights to enhance exercise-based interventions.

Methods: A remote cross-sectional observational study will be conducted using Cognito forms and Microsoft Teams. Participants aged 18–65 years with a clinical diagnosis of depression or dysthymia will complete validated questionnaires, including the PHQ-9, GPAQ, MPAM-R, PSQI, and SEQRE. Functional capacity will be assessed remotely using the 30-second Sit-to-Stand Test (30s-STST) with standardized instructions provided.

Analysis: Descriptive statistics will summarize measures of central tendency and dispersion, and beta regression models will examine relationships between depressive symptoms, self-efficacy, motives for physical activity, and functional capacity. Secondary analyses will explore variable differences across depression severity levels and correlations among key measures.

Ethics and Dissemination: The study complies with ethical guidelines and data protection laws. Findings will be shared through academic and public channels to inform healthcare practices and policies related to exercise in mental health.

Keywords: Mental disorders; Depression; Exercise; Physical activities; Barriers

INTRODUCTION

Depression is a common condition that reduces quality of life and limits psychosocial functioning (Malhi, Mann, 2018). The World Health Organization (WHO) ranked this mood disorder as the third leading cause of disease burden worldwide, and it is predicted to rise to the first position by 2030 (Malhi, Mann, 2018). The prevalence across countries is estimated to be around 6%. Studies show a similar recurrence of depression in both high-income and low-income countries, indicating that this condition is neither solely a result of poverty nor exclusively linked to the modern lifestyle of first-world countries (Malhi, Mann, 2018).

In Spain, the prevalence of depression is estimated to be 4.73%, generating an economic burden of approximately €6,145,000 in direct and indirect costs (Vieta et al., 2021). Additionally, the annual incidence rate in Spain is 7–8 cases per 1,000 persons per year, and it is twice as common among women than among men, highlighting a significant gender gap (Malhi, Mann, 2018; Vieta et al., 2021).

Nowadays, several treatments are available for depression. The most evidence-based approaches include psychotherapy (e.g., cognitive-behavioral therapy [1++], behavioral activation [1++], interpersonal therapy [1+], and mindfulness-based cognitive therapy [1+]) and pharmacotherapy, which is recommended primarily for severe depression cases and may also be considered for moderate cases under certain circumstances, as per the National Institute for Health and Care Excellence (NICE) guidelines (Fonseca Pedrero et al., 2021; National Institute for Health and Care Excellence (NICE), 2022).

In addition, exercise has emerged as a potential treatment that interacts with various aspects of depression (Singh et al., 2023). At a biological level, exercise has been shown to increase hippocampal volume, reduce cortisol levels, and modify other biomarkers potentially linked to depression (Beserra et al., 2018; Gujral et al., 2017). From a psychosocial perspective, it can improve mood, self-esteem, self-efficacy, and reduce social isolation, rumination, and negative thoughts (Craft, 2005; Craft, Perna, 2004; Singh et al., 2005).

Although exercise proves to be a useful tool for the treatment of patients with mild to moderate depression, it presents serious limitations (Fabiano et al., 2024). These include lack of motivation, fatigue, fear of movement, social anxiety, and economic difficulties. As a result, patients often struggle to adhere to exercise programs and achieve their goals (Fabiano et al., 2024).

Therefore, this study aims to gather information on the perceived barriers and limiting factors that hinder engagement in physical activity among patients with depression. The ultimate goal is to enhance the understanding of these challenges and provide insights that can improve the design and implementation of exercise-based interventions for this population.

To achieve this, the primary objective of the study is to identify the perceived barriers to engaging in physical activity among patients with depression and assess their functional capacity based on the severity of symptoms. These barriers may include psychological, social, or behavioral factors that limit participation in exercise, regardless of whether the individual has received a formal prescription for physical activity.

As a secondary objective, the study aims to examine how motivational-affective factors and cognitive-evaluative aspects relate to the functional capacity of these patients.

METHODS

Study design and Participants

An observational cross-sectional study using a convenience non-probabilistic sample strategy will be conducted in an online format using Cognito forms and Microsoft Teams.

To participate in the study, participants will have to fulfill the following inclusion criteria: a depression or dysthymia diagnosis based on ICD-11 or DSM-5TR criteria by their referring physician and an age between 18 and 65 years old. Subjects will be excluded from the study if they are pregnant women, have presence of comorbidities such as neurological signs; systemic rheumatoid diseases (including fibromyalgia), central nervous system disease, presence of severe cognitive impairment,

schizophrenia, psychotic or bipolar spectrum disorders.

The procedures of this study underwent an evaluation of the Ethics Committee of Centro Superior de Estudios Universitarios La Salle and was approved with the registry number CSEULS-PI-012/2024.

Variables and Instruments

Sociodemographic data

The following sociodemographic data will be collected through an initial questionnaire: age, sex, height, weight, academic level, depression and other diagnostics, medication (type and dosage), social and employment status. Body Mass Index (BMI) will be calculated with the granted height and weight information.

Depressive symptoms

Depressive symptoms will be measured using the Patient Health Questionnaire-9 (PHQ-9), a valid and reliable instrument. It is a self-administered questionnaire with 9 items. The items are rated on a 4-point Likert scale ranging from 0 to 3, with total scores ranging from 0 to 27. Higher scores indicate greater severity of the symptoms. (Diez-Quevedo et al., 2001)

Physical activity

The levels of physical activity will be assessed using the Spanish version of the Global Physical Activity Questionnaire (GPAQ). This instrument has demonstrated acceptable validity and psychometric properties for measuring physical activity (PA) levels through METs. The questionnaire consists of 16 items distributed across three domains: work-related physical activity, transport-related physical activity, and recreational physical activity. It categorizes PA levels over the past week into high, moderate, and low (Armstrong, Bull, 2006).

Motives for Physical Activity

The motives for engaging in physical activity will be measured using the Motives for Physical Activity Measure-Revised (MPAM-R), a valid and reliable tool. This instrument assesses five distinct motivational factors: enjoyment, appearance, social, fitness, and competence, each representing a specific reason individuals might choose to engage in physical activity. (Moreno Murcia et al., 2007)

The scale consists of 28 items distributed among the five factors. Responses are recorded on a 7-point

Likert scale, ranging from 1 ("not at all true for me") to 7 ("very true for me"). Higher scores in each factor indicate a stronger motivation related to that specific domain. (Moreno Murcia et al., 2007)

Sleep quality

Sleep quality is another variable affected in patients with depression. It will be measured using the Spanish version of the Pittsburgh Sleep Quality Index (PSQI), a valid tool for assessing sleep quality ($\alpha = 0.76$) (Favela Ramírez et al., 2022). The PSQI consists of 10 items scored from 0 to 7, with lower scores showing better sleep quality (Buysse et al., 1989).

Self-Efficacy to regulate exercise

This variable will be measured using the Self-Efficacy Questionnaire to Regulate Exercise (SEQRE), adapted into Spanish. It is a valid and reliable tool ($\alpha = 0.84$) consisting of 7 items. On this scale, participants rate how confident they feel about their ability to maintain a regular exercise routine (three or more times per week). Each item is rated on a scale from 0 ("I cannot do it at all") to 100 ("I am very confident I can do it") (Vega, Lomeli, 2020).

Lower Limb Strength

The 30 second Sit to Stand (30s-STs) is a validated test used to assess lower limb strength and functional performance. Adapted for remote use, this test is conducted via videoconference, where the clinician provides detailed explanations of the protocol and instructions to ensure the participant's full understanding (Bowman et al., 2023).

A sturdy, armless chair is positioned, preferably against a wall and centered within the camera's field of view for maximum visibility. Participants are instructed to cross their arms over their chest and perform as many sit-to-stand cycles as possible within 30 seconds. At the end of the test, the Rate of perceived exertion (0–10) will be evaluated (Bowman et al., 2023).

This adapted approach ensures the reliability of results while enabling the test to be conducted safely in a remote setting (Bowman et al., 2023).

Procedure

The entire evaluation procedure will be carried out remotely. The participants will receive two links in advance. The first will be a link for the Questionnaires in Cognito Forms and the second to the Microsoft

Teams platform. Microsoft Teams will be used to address participants' questions and conduct the 30-second Chair to Stand Test. The call will not be recorded.

Before beginning the questionnaire, the study will be explained in detail, and any questions regarding it or the informed consent, which will be signed electronically, will be addressed.

Once the Informed consent is signed and sociodemographic data has been collected, the questionnaires will be completed in the following order: PHQ-9, GPAQ, MPAM-R, Pittsburgh Scale and the SEQRE.

After the Questionnaires the 30s-STs will be assessed remotely.

Sample size calculation

To determine the sample size a pilot study with 30 subjects ($n=30$) will be conducted. This pilot study will enable us to estimate the effect size and variance of the variables of interest, which will then be used to accurately calculate the number of participants needed for the main study. A level of significance of $\alpha = 0,05$ and a statistical power of 80% ($1-\beta = 0.80$) will be established. Since it is a cross-sectional design, no dropouts are anticipated. These parameters will ensure that the sample is adequate to detect significant associations between depressive symptomatology (PHQ-9), self-efficacy (SEQRE), motives for physical activity (MPAM-R), and functional capacity (30s-STs).

Statistical analysis

All statistical analyses will be performed using R Software in the R Studio environment (RStudio, PBC, Boston, MA, USA). Descriptive analyses will be conducted to summarize demographic and clinical characteristics of participants like age, sex, height, weight, BMI, academic level, depression and other diagnostics, medication (type and dosage), social and employment status. Categorical variables will be summarized with frequencies and percentages. Continuous variables will be summarized with mean, standard deviation, medians, quartiles 1 and 3, minimum and maximum.

The primary aim is to associate depressive symptoms (PHQ-9) with self-efficacy (SEQRE),

motives for physical activity (MPAM-R) and functional capacity (30s-STs). For this aim multiple beta regression model will be employed to examine the relationship between SEQRE, MPAM-R and 30s-STs with PHQ-9 scores. The scores will be standardized to values between 0 and 1 (Ferrari, Cribari-Neto, 2004). In the case of values reaching exactly 0 or 1 slight modifications will be made (e.g. 0.0001 and 0.9999) to fit within the bounds. To minimize potential bias, additional covariates—including age, sex, BMI, and comorbidities—will be included in the model to control for their possible confounding effects on the relationship between depressive symptoms and the primary predictors. Before running the beta-regression, the assumptions of models will be evaluated. Model diagnostics such as residual versus fitted plots, Cook's distance, leverage, and Q-Q plot measures will be evaluated to check for violations of assumptions.

As a secondary analysis the differences in both primary (SEQRE, MPAM-R and 30s-STs) and secondary variables (sleep quality, GPAQ) between the severity level of depressive symptoms proposed in the PHQ-9 (mild, moderate, moderately severe, severe) will be studied (Kroenke et al., 2001). For this aim a one-way analysis of variance (ANOVA) will be employed with the Bonferroni adjustment, together with a post-hoc analysis for pairwise comparisons. Before running the ANOVA, the model assumptions will be evaluated using Q-Q plots and scatterplots of residuals versus fitted values to check for normality, homoscedasticity, and residual behavior. If the assumptions are not met robust statistical methods, will be applied using the "WRS" and "WRS2" packages (Mair, Wilcox, 2020; Wilcox, 2021), specifically a robust one-way ANOVA for medians with 2000 bootstrap resamples.

Additionally, three Spearman correlation analysis will be included to evaluate the strength of association between PHQ-9, SEQRE and MPAM-R with the rest of the variables (Schober et al., 2018).

Limitations

The study has several limitations. First, a cross-sectional design does not establish causality relationship between variables. A non-probabilistic sample can limit the external validity of the findings

due to patients with less severe symptoms being more predisposed to participating in the study.

Another limitation is the usage of self-reported outcome measures that can present a floor and/or ceiling effect.

Furthermore, potential technological barriers may arise, as some participants may have limited access to a stable internet connection or lack technological literacy, which could impact their ability to complete the remote assessment accurately.

ETHICAL ASPECTS

From an ethical standpoint, no conflict of interest is reported by the researchers and participants.

The study will be conducted in accordance with the Spanish national legislation on data protection for volunteers, specifically the LOPD, and in adherence to the guidelines of the Helsinki Declaration. All participants will be informed in detail about the study and must provide their informed consent prior to participation through the Cognito Forms platform.

Only personal and health-related data provided by the participants will be collected in compliance with EU Regulation 2016/679 of the European Parliament and the Council of 27 of April 2016, concerning the protection of natural persons regarding the processing of personal data and the free movement of such data. Regarding data storage, the information will be pseudonymized by associating each participant with an alphanumeric code stored on an encrypted computer to prevent identification and ensure confidentiality. Moreover, only the main researcher of the study will have access to this data, while the rest of the research team will not have direct access to the information.

DISSEMINATION OF RESULTS

The findings of this study on barriers to engagement in physical activity of patients with depression will be communicated through academic and public channels to maximize reach and practical application. Results will be published in scientific journals and presented in mental health related conferences and seminars. Additionally, findings will be summarized in an accessible format with clinical

implications to support decision-making by healthcare professionals and influence health policies.

FRASES DESTACADAS

- Aunque el ejercicio haya resultado una herramienta útil para el tratamiento de pacientes con depresión leve a moderada, presenta varias limitaciones.
- Este estudio tiene como objetivo identificar las barreras para la actividad física y evaluar la capacidad funcional de pacientes con depresión, proporcionando información para mejorar las intervenciones basadas en ejercicio.

HIGHLIGHTS

- Although exercise proves to be a useful tool for the treatment of patients with mild to moderate depression, it presents serious limitations
- This study aims to identify barriers to physical activity and evaluate the functional capacity of patients with depression, providing insights to enhance exercise-based interventions.

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