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Protocol for a Hybrid Type III Implementation-Effectiveness Trial of an Online Psychotherapy Program for Preventing Mental Health Problems Among Healthcare Professionals in the Andalusian Health System

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Abstract

Background: Healthcare professionals are at high risk of developing mental health disorders due to the stress they experience. Therefore, it is essential to offer evidence-based psychotherapeutic interventions to reduce their stress and improve their well-being. This protocol presents a Hybrid Type III study that evaluates the feasibility, acceptability, and sustainability of an online psychotherapy program—MINDxYOU—targeted at healthcare workers. In the context of growing demand for accessible and effective psychological interventions for health professionals, this study aims to test an implementation strategy that facilitates the integration of an evidence-based intervention into routine clinical practice.

Methods/Design: This research adopts a Hybrid Type III effectiveness-implementation design, primarily focusing on evaluating implementation strategies in real-world settings while simultaneously collecting data on clinical effectiveness. The study will be conducted in two phases: Phase 1: A pilot study (N=30) at the Regional University Hospital of Málaga. Phase 2: A larger-scale implementation (N=100) within the Andalusian Public Health System (SAS), targeting healthcare professionals providing direct care in hospital and primary care settings. Implementation outcomes to be evaluated include feasibility, acceptability, and sustainability.

Discussion: This implementation study aims to provide a framework for addressing barriers and enhancing facilitators for the integration of online interventions into healthcare practice. The ultimate goal is to bridge the gap between research and clinical practice, thereby contributing to the reduction of stress among healthcare professionals.

1. Background

Healthcare professionals face a series of stressors inherent to the highly demanding nature of their work, which can negatively impact their psychological well-being and physical health. Stress in these professionals is associated with increased emotional exhaustion, fatigue, and a decline in the quality of care provided to patients. The constant pressure to make quick and accurate decisions, high workload, intense emotions from interacting with critically ill patients, and confronting death and suffering can lead to disorders such as anxiety, depression, and burnout.

Despite growing awareness of the importance of supporting healthcare workers' mental health, traditional stress management interventions such as face-to-face therapy are often inaccessible or unfeasible for these professionals, who have limited time for self-care. There is thus an urgent need for solutions that are not only effective but also accessible and adaptable to the daily realities of these workers.

Various mindfulness-based interventions have shown effectiveness in reducing stress, but most require in-person participation. Digital mindfulness-based interventions—especially unguided ones—have gained attention for their flexibility and potential to be used conveniently by healthcare workers. One major challenge in psychological interventions is the gap between research and practice. Even when proven effective, interventions can take years to be implemented in real-world settings. Implementation science seeks to address this gap by studying barriers and facilitators to adopting new interventions in clinical environments.

MINDxYOU is an online psychotherapy program that integrates strategies such as mindfulness, compassion, acceptance, and spirituality to improve mental health among healthcare professionals. While previous studies have demonstrated its efficacy under controlled conditions, its implementation in real clinical settings requires a thorough evaluation of feasibility, acceptability, and sustainability. Identifying the barriers and facilitators that influence its adoption and continued use is key to ensuring successful integration into the healthcare system.

This study uses a Hybrid Type III design, allowing for simultaneous evaluation of implementation strategies and clinical outcomes. Unlike trials focused solely on efficacy, this approach prioritizes the analysis of factors influencing the program's acceptability and sustainability within health services. Specifically, the study will assess healthcare professionals' willingness to use MINDxYOU, their satisfaction with the platform, and the feasibility of incorporating it into daily clinical practice.

2. Research Question and Applicability

What is the feasibility, acceptability, and sustainability of implementing the MINDxYOU program in real healthcare settings, and what is its impact on reducing stress and improving the well-being of healthcare professionals?

This study has high applicability in mental health, particularly in healthcare systems experiencing high stress levels. Its integration into public health institutions could facilitate access to evidence-based interventions aimed at improving the well-being of healthcare professionals. Moreover, its findings will help optimize the implementation of digital therapies, identify barriers and facilitators, and extrapolate its use to other high-stress sectors. Evaluating its sustainability will support broader dissemination and adaptation to different contexts, ensuring long-term impact.

3. Hypotheses

1. Primary hypothesis (implementation): Implementing the MINDxYOU program in healthcare settings will be feasible, acceptable, and sustainable among healthcare professionals.

2. Secondary hypothesis (clinical effectiveness): Participants using the program will experience a significant reduction in perceived stress, anxiety, and depressive symptoms compared to baseline.

3. Adherence hypothesis: Program usage and participant satisfaction will be positively associated with perceived ease of use and perceived effectiveness of the intervention.

4. Barriers and facilitators hypothesis: Factors such as work overload and lack of time may hinder program adoption, while accessibility and the flexibility of the online format will facilitate its integration into the routines of healthcare professionals.

4. Objectives

Primary Objective:

To evaluate the feasibility, acceptability, and sustainability of implementing the MINDxYOU program in real-world healthcare settings.

Secondary Objective:

To assess clinical outcomes of the intervention, including its effects on perceived stress, anxiety levels, and depression symptoms among healthcare professionals.

5. Methodology

5.1 Study Design

This study will adopt a Hybrid Type III effectiveness-implementation design, which combines the evaluation of implementation processes with the observation of the clinical outcomes of the intervention. This type of design primarily focuses on implementation strategies (feasibility, acceptability, and sustainability), while clinical outcomes are assessed in a naturalistic way without randomization at the patient level (Proctor et al., 2011).

Study phases:

- Phase 1 – Pilot study (N=30): An initial pilot study will be conducted at the Regional University Hospital of Málaga with a group of healthcare professionals. The program's acceptability will be assessed through surveys and interviews, and its use within the clinical setting will be observed. - Phase 2 – Expanded study (N=100): In this phase, the program will be implemented at scale within the Andalusian Health Service (SAS), including a broader sample of healthcare professionals from hospitals and primary care centers.

5.2 Participants

The study sample will consist of healthcare professionals working in clinical settings (hospitals and primary care centers) within the Andalusian Health Service (SAS). Participants may include doctors, nurses, nursing assistants, social workers, physiotherapists, psychologists, ambulance technicians, and healthcare students.

5.3 Inclusion and Exclusion Criteria

Inclusion criteria:

(1) Being a current healthcare professional (2) Aged between 18 and 70 years (3) Ability to understand Spanish (4) Digital literacy and access to a smartphone, tablet, or computer with internet access (5) Continuity in the same workplace for at least 6 months (6) Signing the informed consent form

Exclusion criteria: (1) Diagnosis of severe mental illness (2) Suicidal ideation (3) Substance abuse or related disorders

5.4 Variables and Measures

Main variables (implementation): In line with the Consolidated Framework for Implementation Research (CFIR), Proctor et al. (2011), and Hermes et al. (2019), this study will evaluate the following implementation outcomes: feasibility, acceptability, and sustainability. Additionally, focus groups will be conducted with key stakeholders at each center after the intervention (post-treatment) to qualitatively assess implementation domains.

Feasibility:
Defined as the extent to which a new treatment can be successfully used or carried out in a specific setting. Feasibility will be assessed through passive data collected by the online platform, such as frequency of use. The Feasibility of Intervention Measure (FIM) (Weiner et al., 2017), consisting of 4 items, will also be used. This scale has shown good psychometric properties with high internal consistency (α = 0.85–0.91) and test-retest reliability coefficients (r = 0.73–0.88).

Acceptability:
Defined as the perception among stakeholders that the intervention is satisfactory or useful. It will be assessed using: - System Usability Scale (SUS) (Bangor et al., 2008): A 10-item questionnaire measuring usability, qualitatively linked to intervention quality and acceptability. The Spanish version has demonstrated good internal consistency (α = 0.81)

(Sevilla-González et al., 2020). - Internet-based Client Satisfaction Questionnaire (CSQ-I) (Boß et al., 2016): An 8-item, 4-point Likert scale questionnaire measuring overall satisfaction.

Sustainability:
Assessed through ongoing monitoring of platform usage (access and participation logs) and semi-structured interviews to determine the integration of the program into users' daily routines.

Secondary variables (clinical): - Perceived Stress Scale (PSS) (Cohen et al., 1983): 10 items rated on a 5-point Likert scale assessing unpredictability, uncontrollability, and overload during the past month. Scores range from 0 to 40, with higher scores indicating higher perceived stress. The Spanish version has good psychometric properties ($\alpha = 0.81$; test-retest reliability $r = 0.77$). - Patient Health Questionnaire-9 (PHQ-9) (Kroenke et al., 2001): 9-item self-report scale assessing severity of depressive symptoms. The Spanish version demonstrates comparable diagnostic validity with 88% sensitivity and specificity. - Generalized Anxiety Disorder-7 (GAD-7) (Spitzer et al., 2006): 7-item self-report scale assessing anxiety over the past two weeks. Total scores range from 0 to 21; higher scores indicate more severe symptoms. The Spanish version has shown good psychometric properties (García-Campayo et al., 2010).

5.5 Sample Size

For the pilot study, a sensitivity analysis was conducted using a paired samples t-test, assuming a moderate effect size (Cohen's $dz = 0.46$), 95% confidence level ($\alpha = 0.05$), and 80% statistical power. The required sample size was determined to be $N = 30$. For the full study, the same analysis was applied with a smaller effect size (Cohen's $dz = 0.25$), resulting in a required sample size of $N = 100$.

5.6 Procedure

Recruitment strategies will include posters and brochures in hospitals and primary care centers, as well as presentations in group sessions with healthcare professionals, including those attending occupational stress consultations. Email invitations will include a brief explanation of the study and a web link to the platform. Participants will be required to submit signed informed consent electronically. Eligibility will be verified, and those meeting inclusion criteria will be formally enrolled. Participants will receive a welcome email with platform login credentials. Instructions on how to use the platform will be provided in the welcome module.

Participants will be assessed on all study variables every 8 weeks. Usability (SUS) will be assessed after completing Modules 1 and 4. Platform usage will be tracked (logins, completed modules, submitted tasks).

5.7 Evidence-Based Program

MINDxYOU is a self-guided online intervention based on third-wave psychotherapies, including mindfulness, compassion, acceptance, and spirituality. It consists of four modules

and includes videos, readings, guided audio exercises, and downloadable resources to integrate practices into daily healthy habits (e.g., physical activity, sleep, diet, socialization).

The program starts with a welcome module where participants share their stress factors and receive motivational feedback to encourage adherence. Each module includes explanatory videos, key content, and practical exercises. Participants are encouraged to complete each module over two weeks. Module 1 focuses on applying mindfulness and compassion to healthy lifestyle areas. The program lasts approximately 8 weeks.

A recent study showed significant reductions in perceived stress among participants who completed at least three of the four modules. Improvements were also noted in depression, anxiety, somatization, resilience, self-compassion, and some mindfulness facets (López-Del-Hoyo et al., 2025).

6. Data Analysis

For the implementation analysis, outcomes will be assessed following the framework by Hermes et al. (2019) and Proctor et al. (2011). Passive data will include objective usage metrics (e.g., logins, frequency of use, completed modules, tasks submitted). Quantitative data from questionnaires will be analyzed using appropriate statistical methods, while qualitative data will be gathered through stakeholder interviews.

For the clinical analysis, variables will be described using mean and 95% confidence intervals for normally distributed quantitative variables, or medians and interquartile range for non-normally distributed data. Effectiveness variables (stress, anxiety, and depression) will be compared using paired-samples t-tests.

7. Ethics and Dissemination

All procedures will follow the Declaration of Helsinki (1964 and subsequent amendments; latest version adopted at the 64th WMA General Assembly, Fortaleza, Brazil). Signed informed consent will be obtained from all participants, who will not receive any financial compensation. Participants will be informed about study procedures, potential risks, and their right to withdraw at any time.

Major protocol modifications (e.g., changes in eligibility, outcomes, analysis) must be approved by ethics committees. Data confidentiality will comply with Spanish Organic Law 3/2018 on Data Protection and Digital Rights, aligned with the EU GDPR. A specific plan will be implemented to ensure maximum data security, using two separate systems and databases: one for personal data and one for clinical data, hosted on separate servers.

Study results will be published in peer-reviewed biomedical journals and presented at national and international conferences. Reporting will adhere to the StaRI (Standards for Reporting Implementation Studies) statement (Pinnock et al., 2017).

8. Study Timeline

ACTIVITY 1: Implementation Study (2025–2026) 1.1 Pilot study at Regional University Hospital of Málaga1.2 Implementation within the Andalusian Health Service (SAS): - Intervention delivery, coordination meetings with healthcare staff- Participant recruitment and online treatment administration- Post-treatment protocol evaluation, platform maintenance, technical support- Collection of acceptability and appropriateness data, focus groups with professionals and managers

ACTIVITY 2: Data Analysis and Interpretation (2026–2027) - Research team meetings; quantitative and qualitative data analysis- Final report preparation

ACTIVITY 3: Dissemination and Exploitation of Results (2027) - Preparation of manuscripts; dissemination through professional events, health agencies, social media, and media outreach

9. Funding and Resources

This project is supported by a 3-year Junior Postdoctoral contract funded by the Andalusian Government (CSyC 2024 – Postdoctoral Grants, Ref: RHJ-0043-2024). The study is based at the Research Unit of the Mental Health Clinical Management Unit at the Regional University Hospital of Málaga, part of the Biomedical Research Institute of Málaga (IBIMA), which provides the infrastructure required for conducting the research. Resources from the Mental Health UGC will cover costs such as software licenses.

Personnel: Junior Postdoctoral Researcher (36 months) – €125,514Technical: Moodle license – €2,000 annually

10. Study Limitations and Strengths

This study's strengths include its innovative implementation focus, accessible online format, evidence-based design, and applicability across various healthcare environments. However, limitations include possible low adherence, lack of a control group, variability in participation, and dependence on technology. Its potential integration into the public health system makes it a valuable resource for supporting healthcare workers' mental health, reducing demand on mental health services, and improving patient care quality.

11. Discussion

This implementation study of the MINDxYOU program provides key insights into the feasibility, acceptability, and sustainability of a digital mental health intervention for healthcare professionals. Findings will evaluate how mindfulness-, compassion-, and acceptance-based strategies can be effectively integrated into real clinical settings (Bauer & Kirchner, 2020).

A key strength of this study lies in its implementation science approach, addressing both barriers and facilitators of adoption in the Andalusian Health Service. Identifying these factors is essential for designing strategies that support the sustainable and scalable use of

MINDxYOU. The Hybrid Type III design advances implementation science by simultaneously assessing clinical effectiveness and contextual influences (Proctor et al., 2011).

Preliminary evidence suggests MINDxYOU can significantly reduce perceived stress and improve healthcare professionals' psychological well-being (López-Del-Hoyo et al., 2025). However, real-world implementation may face challenges, including adherence and acceptance by participants. Results will be essential to evaluate the program's feasibility in busy clinical workflows.

Digital platforms for mental health gained rapid acceptance during the COVID-19 pandemic, representing a paradigm shift in healthcare delivery. Still, questions remain about their long-term quality, accessibility, and effectiveness. This study includes usability and acceptability metrics to empirically evaluate healthcare professionals' engagement and identify factors that could enhance implementation (Bangor et al., 2008).

From a clinical perspective, results may help bridge the gap between research and care, supporting routine use of evidence-based interventions. Findings can inform program adaptations and scalability for other high-stress populations. Ultimately, improving healthcare workers' mental health may also enhance patient care quality. Effective implementation strategies could guide future digital health interventions, benefiting both the workforce and the healthcare system as a whole.