



Mini Review

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Exploring Mind-Body Physical Activity for Menopausal Women: the PALAR Project Protocol

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Abstract

Introduction: Menopause is characterized by the cessation of the menstrual cycle, occurring naturally as a part of aging. However, menopause can also result from other health conditions such as premature ovarian failure, surgery, or certain medical treatments. The transition through menopause is often associated with a range of physical and psychological symptoms, which can significantly impact quality of life. Mind-body physical activities have shown promise in alleviating these symptoms and promoting overall well-being.

Methods: We will conduct a prospective mixed-methods study involving women aged 50 and above to explore the effects of mind-body physical activity on menopausal symptoms and quality of life. The study will include both quantitative and qualitative approaches to gather comprehensive data. Quantitative measures will assess changes in physical health, psychological well-being, and menopausal symptoms. Qualitative interviews will explore participants' experiences and perceptions of the intervention. The study protocol has received ethical approval from the University of Zululand Research Ethics Committee (UZREC171110-031 Dept.2021/11).

Dissemination: Findings from this study will be disseminated through academic journals, conference presentations, and community health forums to inform healthcare providers and stakeholders about the potential benefits of mind-body physical activities for menopausal women.

Keywords: Menopause, Mind-body physical activity, Quality of life, Mixed-methods study, Women's health

Introduction

Menopause, defined as the permanent cessation of menstruation resulting from the loss of ovarian follicular activity, marks a significant transitional phase in a woman's life, usually occurring

around the age of 50 [1]. This transition is characterized by hormonal fluctuations, particularly decreases in estrogen and progesterone levels, leading to a wide array of physiological and psychological symptoms that can profoundly impact a woman's quality of life [2].



Physiologically, menopausal women often experience vasomotor symptoms such as hot flashes and night sweats, as well as urogenital symptoms like vaginal dryness and urinary incontinence. These symptoms can lead to discomfort and distress, impacting daily activities and sleep quality [3]. Additionally, the decline in estrogen levels is associated with long-term health risks, including osteoporosis, cardiovascular diseases, and metabolic syndrome, increasing the likelihood of fractures, heart disease, and diabetes in postmenopausal women [4]. Psychologically, menopause can be accompanied by mood swings, depression, anxiety, and cognitive disturbances. These symptoms are not only distressing but can also exacerbate pre-existing mental health conditions or contribute to the onset of new ones [5]. The psychological impact of menopause is often influenced by cultural, social, and individual factors. For instance, cultural attitudes towards aging and menopause can significantly affect how women perceive and cope with menopausal symptoms. In some cultures, menopause is viewed positively as a transition to a respected elder status, while in others, it is stigmatized, leading to feelings of shame and decreased self-worth [6].

Given the complex interplay of biological, psychological, and social factors, it is essential to adopt a holistic approach to understanding and addressing the health impacts of menopause. Integrative health practices, particularly those that combine physical and mental well-being strategies, have shown promise in managing menopausal symptoms. Mind-body physical activities such as yoga, tai chi, and meditation have been found to alleviate both physiological and psychological symptoms, promoting overall well-being [7]. The healthy lifestyles project' interventions through physical activity and lifestyle modification in menopausal women in rural communities at King Cetshwayo District is designed to explore the effectiveness of mind-body physical activities in improving the health and well-being of menopausal women. The Project focuses on menopausal women in rural communities, who may have limited access to healthcare services and resources for managing menopausal symptoms.

By implementing and evaluating community-centered intervention strategies, the Healthy Lifestyles Project aims to provide evidence-based recommendations for promoting healthy living among menopausal women. This prospective mixed-methods study will involve women aged 50 and above, utilizing both quantitative and qualitative approaches to gather comprehensive data. Quantitative measures will assess changes in physical health, psychological well-being, and menopausal symptoms, while qualitative interviews will explore participants' experiences and perceptions of the interventions. The study's findings will be disseminated through academic journals, conference presentations, and community health forums to inform healthcare providers and stakeholders about the potential benefits of mind-body physical activities for menopausal women. The holistic nature of the Healthy Lifestyle Project aligns with the growing recognition of the need for integrative health approaches in managing menopause. By focusing on both physical and mental health, the project aims to address the multifaceted impacts of menopause and improve the overall quality of life for menopausal women. The emphasis on community-centered strat-

egies also highlights the importance of accessible and culturally sensitive interventions that can be tailored to the specific needs of women in different contexts.

Methods

Aims and Objectives

This project aims to investigate the mental health impact of menopause by evaluating both the physiological and psychological aspects through several distinct work stream packages. The focus of this protocol is on Work Package (WP) 2, which consists of two components: WP2a and WP2b. The primary objective of WP2 is to comprehensively explore menopause across diverse populations globally and to further validate our novel menopause assessment tool known as the Menopause Rating). This tool was developed through a synthesis of existing research data, clinical expertise, and collaborative efforts as part of the broader women's health program, ELEMI.

Study Design

The Healthy Lifestyle Project employs a multifaceted approach where Work Package 2a (WP2a) utilizes a prospective mixed-methods study design aimed at gathering information using existing clinically validated questions. The administration of these questions will be followed by a study-specific topics guide developed to assess participant experience to further strengthen the understanding and evaluation of menopause. This mixed-methods approach allows for a comprehensive exploration of menopause, integrating quantitative data from validated questionnaires with qualitative insights gathered through participant experiences.

Data Collection

Participants will complete a series of validated questionnaires online, which encompass various aspects of their health and well-being. These questionnaires include the Hospital Anxiety and Depression Scale (HADS), Insomnia Severity Index Scale (ISIS), Menopause Rating Scale (MRS), Greene Climacteric Scale (GCS), Health-Related Quality of Life (HRQoL), Quebec Pain Disability Scale (QPDS), Marital Satisfaction Scale (MSS), and the Burnout Assessment Tool (BAT-12). These assessments will be conducted at two time points: baseline (day 1) and day 30 after obtaining informed consent. Additionally, a subset of participants will undergo qualitative interviews at day 60, using a predetermined topic guide. These interviews will be recorded and transcribed in full by local research teams. Early interviews will undergo review by the research team to evaluate the need for any modifications to the topic guides. The anticipated duration for each interview is approximately 45 minutes, though this may vary for individual participants. The transcripts will then be transcribed by the researchers, ensuring accuracy, before being de-identified and uploaded into NVivo software for data coding and retrieval. Following the completion of Work Package 2a, Work Package 2b will commence as a feasibility study, focusing on validating the assessment tool in a broader participant population.

Informed Consent

Informed consent will be obtained electronically using the Qualtrics XM platform for both WP2a and WP2b. Participants will

receive detailed information regarding the study before providing their consent. Once individuals deemed eligible agree to participate, they will be officially enrolled in the study. Participants will retain the option to withdraw from the study at any point before submitting their questionnaire. Compliance with the Protection of Personal Information Act 4 of 2013 (POPI Act) will be ensured throughout the process. However, once the questionnaire is submitted, it will not be feasible to identify and withdraw the participant's data unless they have previously provided contact details for such purposes. In such instances, any data collected with the participant's consent will be retained, but no further data will be gathered, and no additional research procedures will be conducted concerning that specific participant. Any request for the withdrawal of personal data will be handled in accordance with the Protection of Personal Information Act 4 of 2013 (POPI Act) and the University's policies and procedures.

Data Analysis

Quantitative data will be gathered through online questionnaires using the Qualtrics XM platform. Each participant will be assigned a study ID, ensuring the anonymity of their personal information. Data will then be extracted from the Qualtrics XM platform and imported into statistical software packages such as SPSS and STATA for graphical representation and analysis (Qualtrics, Provo, UT). The process of data collection and analysis will be intertwined. Should data saturation be achieved, the focus of interviews may shift to other groups to enable a more comprehensive exploration where appropriate. For WP2a, descriptive statistics will be presented for continuous variables, utilizing means (SD) or medians (IQR) as appropriate based on the data's distribution. For categorical data, statistics in the form of frequencies and proportions will be provided. Non-parametric techniques like the Kruskal-Wallis test and Mann-Whitney U-test will be employed in cases where data does not adhere to a normal distribution. Additionally, Chi-square or Fisher's exact test will be used for categorical variables to explore associations between demographic data and responses related to mental health and well-being. Pearson's correlation analysis will measure the strength of linear relationships between variables (IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp).

For WP2b, Pearson's correlation analysis will assess the strength of linear relationships between variables. The goodness-

of-fit of latent class models for categorical responses will be evaluated through Pearson and likelihood-ratio chi-squared tests. Following this, a factor model will be employed using confirmatory factor analysis with the Maximum Likelihood approach to explore the covariance fit of the tested factor models. Model selection will be based on Goodness-Of-Fit Indices (GOF), considering various indices for both absolute and relative fit [8-10].

Author's Contributions

MM HS BS and NL conceptualized and developed the Project as part of the Palar program. MM NL SN GM VE HS NL NN DA YS BS IS designed the statistical analysis plan. MM wrote the first draft of the protocol manuscript. All authors critically appraised and commented on the protocol manuscript. All authors read and approved the final manuscript.

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None.

Conflict of Interest

None.

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