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Research Protocol

Physiotherapy Section

Devising and Testing a Comprehensive Physiotherapy Protocol to Improve Muscle Strength, Mass, Function and Quality of Life in Type 2 Diabetic Postmenopausal Women: A Research Protocol

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ABSTRACT

Introduction: Type 2 Diabetes Mellitus (T2DM) is a chronic metabolic condition that can pose significant challenges for postmenopausal women, particularly in terms of their physical capabilities and overall wellbeing and they are at five times more risk of experiencing a reduction in muscle strength and mass comparison to non diabetic postmenopausal women. It poses significant health risks and requires proper management to prevent complications.

Need of the study: Previous literature indicates that postmenopausal women with T2DM undergo transitions such as ageing, inadequate nutrition, sedentary lifestyle, hormonal change, insulin resistance and chronic inflammation, leading to a decrease in muscle strength and mass. Consistent physical activities, such as aerobic exercise and resistance training, have been found to improve these transitions in type 2 diabetic postmenopausal women. Therefore, there is a need to design a comprehensive physiotherapy protocol for evidence-based exercises.

Aim: To design and test a comprehensive physiotherapy protocol for muscle strength, mass, function and Quality of Life (QoL) in T2DM postmenopausal women.

Materials and Methods: The study will be conducted in MM Super Specialty Hospital, Ambala, Haryana, from November 2024 to June 2026. This Delphi study will be followed by a randomised controlled trial and will be divided into two phases. The first phase includes the formulation and validation of a comprehensive physiotherapy protocol. The second phase includes testing the efficacy of the protocol by conducting a randomised controlled trial on type 2 diabetic postmenopausal. Outcome measures include body composition analyser (InBody 270), back-leg-chest dynamometer, hand-held dynamometer and SarQoL questionnaire (both English and Hindi versions), which will be assessed before intervention and after six weeks of intervention. Content validation will be determined according to the Content Validity Index (CVI) values. Statistical analysis will be done by the Wilcoxon signed-rank test/paired t-test and Mann-Whitney U test/independent t-test. The significance level will be set at p-value <0.05.

Keywords: Diabetes mellitus, Postmenopause, Resistance training

INTRODUCTION

Postmenopause is the phase when menstruation permanently ceases for 12 consecutive months. It mainly occurs after 50 years of age, but sometimes, early postmenopause also occurs [1,2]. In comparison to Western women, Indian women have early menopause, around the age of 46.2 years [2], and the range may also vary from 41.9 to 49.4 years [3]. The Follicle-Stimulating Hormone (FSH) level elevated in this period exceeds approximately 40 IU/L, which leads to an increased probability of experiencing vasomotor symptoms [4,5]. Postmenopause bears an elevated risk of developing heart disease and osteoporosis [6]. The oestrogen level decreases during and after menopause leading to insulin resistance, increasing the risk of developing T2DM. During this state, there is insufficient production of insulin by the pancreas and insulin resistance to meet the body's demands. That is why blood sugar levels elevate and cause hyperglycaemia [7,8].

The progression of T2DM in postmenopausal women is due to hormonal changes, metabolic syndrome, weight gain, poor dietary choices and lifestyle factors [9]. Globally, the prevalence of T2DM varies amongst postmenopausal women and is influenced by factors such as lifestyle, age, ethnicity and access to healthcare [10]. According to an International Diabetes Federation (IDA) prevalence study in 2021 worldwide, globally around 536.6 million people aged between 20-79 years had diabetes; however, specific data on the T2DM prevalence solely in postmenopausal is not available globally [10,11]. There is an interrelation between muscle strength, mass, physical function and Qol in Type 2 diabetic postmenopausal women [12]. There is a decrease in insulin sensitivity and an increase in insulin resistance accompanying sarcopenia [13,14]. Decreased muscle strength and impaired physical function lead to a reduction in mobility and day-to-daily activities [13]. So, overall QoL in type 2 diabetic postmenopausal women can be negatively impacted by these factors [12]. A good diet and proper physical activity can significantly reduce such risks [9]. Therefore, for reducing the chances of T2DM in postmenopausal women, maintaining a healthy weight, involvement in consistent physical activity, following a balanced diet and monitoring blood sugar levels are very important [15]. Diabetes could be managed by Healthcare experts on considering these factors for developing treatment strategies and endorsing exercise to augment wellbeing [12].

Interventions such as lifestyle modifications, aerobic exercise and resistance training have been shown to improve muscle strength, mass, physical function and QoL in this population [12]. There is a need to develop an extensive physiotherapy treatment protocol that addresses decline in muscle strength, mass, physical function and QoL in postmenopausal women. So, this study is planned to design a comprehensive physiotherapy protocol and determine its

effectiveness on muscle strength, mass, functional ability and QoL in type 2 diabetic postmenopausal.

REVIEW OF LITERATURE

Postmenopausal women with T2DM exhibit an elevated risk for cardiovascular complications, including stroke and heart disease, as well as bone health concerns such as osteoporosis [16]. Additionally, this population faces an increased likelihood of experiencing other diabetes-related complications and may suffer from psychological and emotional challenges [8]. Numerous studies have investigated the effects of various exercise modalities on muscle function and mass. Research conducted by Machado PG et al., and Martins FM et al., indicates that structured exercise programmes, particularly those incorporating moderate to high-intensity workouts, can enhance body composition, metabolic function, muscle strength, muscle mass, reduction in inflammation and glycaemic control [17,18]. Furthermore, a study by Jeon YK et al., demonstrated that the combination of resistance training and aerobic exercise correlated with improved muscle mass and enhanced insulin sensitivity [13]. Research by Bello M et al., established the long-term benefits of community-based exercise programmes on bone mineral density, contributing to improved muscle strength and overall health [19]. The forthcoming study is designed to be comprehensive, aiming to create a protocol that addresses multiple components of care rather than focusing exclusively on a singular therapeutic approach. Findings by Walankar P et al., showed that the implementation of core stability exercises significantly reduces the risk of falls among postmenopausal women with T2DM and facilitates improvements in balance and overall mobility [20]. Additional research has revealed the efficacy of core stability exercises in enhancing physical function, balance and QoL. Moreover, studies conducted by Maillard F et al., and Lesser IA et al., have demonstrated that tailored High-Intensity Interval Training (HIIT) effectively reduces visceral fat, thereby mitigating the risk of diabetes-related complications [21,22]. Metabolic regulation is positively influenced by structured aerobic exercise, as explained by Lagacé JC et al., underscoring the necessity for individualised exercise interventions to optimise health benefits [23].

The accumulated evidence highlights the importance of targeted interventions for this demographic. This comprehensive approach is vital for the effective management of both diabetes and menopausal challenges, ultimately enhancing the health and overall wellbeing of postmenopausal women with T2DM. This study emphasises adherence to American College of Sports Medicine (ACSM) guidelines to ensure that the proposed protocol is founded on established recommendations. While prior research has focused on various exercise regimens including aerobic training, functional training, HIIT, dance-based programmes and resistance training, none have concentrated on the development and validation of a comprehensive physiotherapy protocol specifically tailored to this population. Consequently, the current study is distinctive in its methodological approach to developing physiotherapy interventions for postmenopausal women with T2DM, thereby enhancing its applicability within clinical settings. The present study aims to design a comprehensive physiotherapy protocol and determine its effectiveness on muscle strength, mass, functional ability and QoL in T2DM postmenopausal women.

Primary Objectives

a) Formulation of a comprehensive physiotherapy protocol for the treatment of postmenopausal women with T2DM, concerning ACSM guidelines [12].

b) To determine the content validity of the developed protocol as a treatment for postmenopausal women with T2DM.

Secondary objectives: To check the efficacy of the protocol on muscle mass, strength, function and QoL in postmenopausal women with T2DM.

Null hypothesis: There will be no significant effect of the developed comprehensive physiotherapy protocol on muscle mass, strength, function and QoL in postmenopausal women with T2DM.

Alternate hypothesis: There will be a significant effect of the developed comprehensive physiotherapy protocol on muscle mass, strength, function and QoL in postmenopausal women with T2DM.

MATERIALS AND METHODS

This Delphi study will be followed by a randomised controlled trial, which will take place at the orthopaedic physiotherapy research laboratory and the outpatient department of a tertiary care super speciality hospital over a two-year period, from November 2024 to June 2026. Type 2 diabetic postmenopausal women attending the outpatient department will be approached with the proposal for the study. Ethical clearance has been obtained from the ethical committee of the institute (MMDU/IEC/3010), and the trial is registered in Clinical Trial Registry-India with CTRI number (CTRI/2024/11/076159). The study will adhere to the Declaration of Helsinki (2013) and the Indian Council of Medical Research's National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017) [24].

Procedure

The study consists of two concomitant phases:

In the first phase, a comprehensive physiotherapy protocol will be formulated for the treatment of type 2 diabetic postmenopausal women, concerning the ACSM guidelines [12]. This will be achieved by following the steps described in [Table/Fig-1].

Steps of the first phase.
1. The comprehensive physiotherapy protocol will be formed in accordance with the ACSM guidelines.
2. The content within the developed physiotherapy protocol will be validated by the experts. A panel of 10 experts in the relevant field will be formed, which includes 4 Physiotherapists, 3 Obstetrics and Gynaecology and 3 Medicine professors with at least 10 years of experience.
3. The validated final physiotherapy protocol will be further used for the second phase of the study.

[Table/Fig-1]: Steps of the first phase.

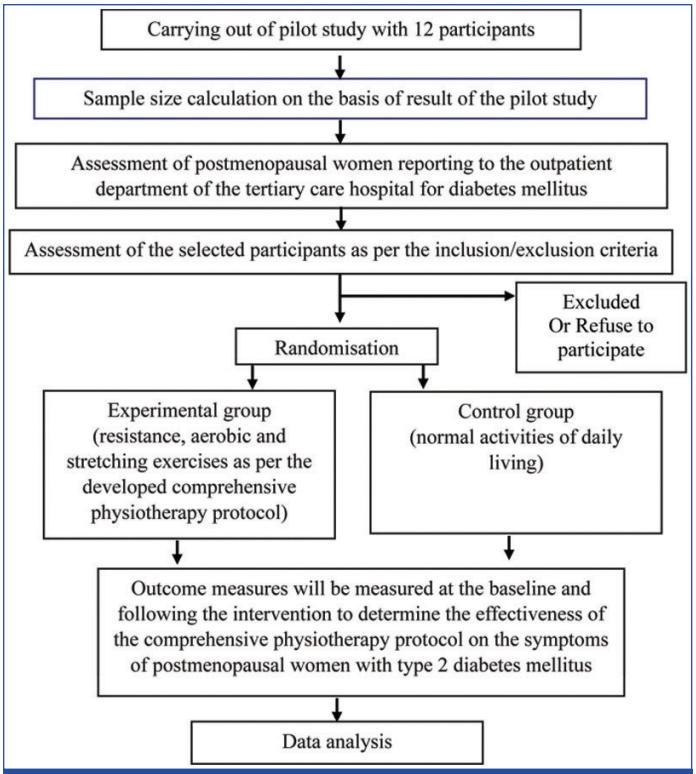
The comprehensive physiotherapy protocol will include two program protocols, which include supervised and home program protocols. Supervised includes resistance training for the major groups of muscle and aerobic training, while the home protocol will includes stretching exercises and walking. Both also include warm-up and cool-down phases. The nature and parameters of these exercises will be confirmed with the final advancement of the treatment protocol.

The second phase will consist of the development of a prospective two-group pretest-post-test study to check the efficacy of the protocol on muscle strength, mass, function, and QoL in type 2 diabetic postmenopausal women.

Each participant will be treated with the interventions from the developed protocol. Following six weeks of treatment, the postintervention assessment for the outcome measures will be done. The acquired data will then be analysed. A detailed procedure is explained in [Table/Fig-2].

Inclusion criteria: Females aged ≥45 years, with an absence of menstruation for a minimum of 12 consecutive months and females diagnosed with T2DM for at least one year, based on the American Diabetes Association (ADA) criteria will be included in the study [12].

Exclusion criteria: Patients with history of alcoholism, uncontrolled blood pressure, existing myopathies, arthropathies, or diagnosed neuropathies, thromboembolic or gastrointestinal conditions, cardiovascular diseases, infectious diseases, cancer, medical contraindications for intense physical activity, painful joints, or if they are undertaking hormonal replacement therapy will be excluded from the study.



[Table/Fig-2]: Study flowchart (second phase).

Sample size estimation: Sample size estimation is performed using the statistical software G*Power. The significance level is set at 0.05, and the study's power is set at 80% (β=0.8), with an anticipated effect size of 1.1, calculated based on a pilot study involving 12 patients. After the calculations, the required sample size was determined to be 36 participants (including a 20% dropout rate), meaning there will be 18 participants per group. If the patient agrees to participate, then the primary research therapist will assess the patient for the eligibility criteria. If the eligibility criteria are met, then the therapist will provide an information sheet to the patients that explains the study procedure and treatment protocol, as well as the risks and benefits of the intervention, in a language which is easily understandable to them. Then, written informed consent in their preferred language will be acquired. Each participant will then be evaluated for the demographic details and outcome measures.

Outcome Measures

The standardised procedure will be followed for the outcome measures used, which include body composition analyser (InBody 270) by InBody India Pvt Ltd, used for measuring skeletal muscle mass, weight and percentage of body fat.

Back-leg-chest dynamometer by Medilab: it is a device used to measure the strength of the back, legs and chest muscles. It typically features an adjustable chain to accommodate different heights and force application points.

Jamar Hydraulic Hand-held Dynamometer from Medilab will be used for evaluating the grip strength.

The SarQoL (Sarcopenia & QoL) Questionnaire is designed to measure the QoL in patients with sarcopenia, a condition characterised by the loss of muscle mass and function, typically affecting older adults. The questionnaire is self-administered and consists of 55 items organised into 22 questions. It takes approximately 10 minutes to complete. The SarQoL Questionnaire covers various aspects of life affected by sarcopenia, including physical capabilities, pain, daily activities and overall wellbeing [25].

STATISTICAL ANALYSIS

Data will be analysed using statistical software {Statistical Package for the Social Sciences (SPSS) version 20. SPSS Inc., Chicago, IL, USA}. CVI will be determined for content validation. As the sample size is less than 50, the Shapiro-Wilk test will be used to establish normality. Mean±standard deviation will be used for reporting descriptive statistics if the data follows the normal distribution; if not, the data will be expressed as the median and interquartile range. Depending on the distribution and nature of the data, either the Wilcoxon signed-rank test or paired t-test will be used to compare the pre- and postintervention scores within the group, while the independent t-test or Mann-Whitney U-test for between-group analysis. The level of significance will be set at 0.05.

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