Original Article

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Physiotherapy Section

Development, Validation and Pilot Testing of a Multidimensional Rehabilitation Protocol for Autonomic, Vasomotor and Cognitive Symptoms in Postmenopausal Women: A Two Phasic Feasibility Study

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ABSTRACT

Introduction: Nearly 87.7% of postmenopausal women experience autonomic, vasomotor, cognitive and psychological symptoms. These symptoms not only lower a woman's quality of life but also have a significant impact on her daily activities. Menopausal Hormone Therapy (MHT) is their most common management which comes with risk of breast cancer and deep vein thrombosis. So there is an urgent need for non pharmacological treatment alternatives.

Aim: To develop, validate and assess effectiveness of a multidimensional rehabilitation protocol for autonomic, vasomotor and cognitive symptoms in postmenopausal women.

Materials and Methods: This two Phasic feasibility study was conducted at Department of Physiotherapy, Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Mullana, Ambala, Haryana, India, between December 2023 to February 2025. A 45-50 minute rehabilitation protocol was developed which comprises of warm up, resistive, cognitive and cool down exercises. Then Delphi survey was conducted to evaluate the essentiality and relevance of the developed protocol by multidisciplinary experts and finally Content Validity Index (CVI) of protocol and its content/items was calculated. 12 postmenopausal women of age≥ 45 received the rehabilitation protocol for three days/week for four weeks. Pre-post treatment evaluations were done for postmenopausal symptoms by Menopause Rating Scale (MRS), autonomic symptoms by Composite Autonomic Symptom Score 31 (COMPASS31) and Hot Flash-Related daily Interference Scale (HFRDIS) while cognition assessed on Montreal Cognitive Assessment Scale (MoCA).

Results: Seven experts responded, evaluated and suggested modifications. Item-level CVI of each item was between 0.86-1 whereas Scale-level CVI by was found to be 0.93 which were above the satisfactory level. The results after protocol was administered showed significant improvements in various domains of MRS- symptom severity decreased from median scores 30 (27.25–31.75) at baseline to 18 (16.00–21.50) post-intervention, COMPASS31 scores exhibited a notable decline from 64 (55.25–66.00) to 52 (47.25–54.75), HFRDIS from 62 (54.00–65.50) to 43 (39.25–47.75) and MoCA scores improved from 21 (20.00–22.75) to 25 (23.25–25.75) post-intervention.

Conclusion: This multidimensional rehabilitation protocol is valid and effective in improving cognition and symptom severity of postmenopausal women and in future may serve as a adjunct to pharmaceuticals.

Keywords: Cognition, Hot flashes, Menopause, Quality of life

INTRODUCTION

Menopause is a natural aging process that shows the end of the reproductive stage and generally occurs between the age of 45 and 55 years [1,2]. Despite being a physiological phenomenon, menopause is frequently accompanied with symptoms that can significantly lower a woman's quality of life and have a significant impact on her daily activities [2].

Nearly, 87.7% of postmenopausal women experience symptoms like vasomotor (89.32%), sleep disturbances (66.72%), autonomic nervous system disorders (50%), mood changes, anxiety (49.80%), depressive symptoms (58.69%), cognitive changes (70%), urogenital symptoms (98.46%), fatigue, limb paraesthesia and joint pain (57.66%) [1,3,4]. The depletion of Estradiol hormone in postmenopausal women is mainly responsible for Autonomic Nervous System alterations [2].

The classic symptoms of menopause are hot flashes and night sweats (collectively known as Vasomotor symptoms), affects about 75% of women. It is caused due to the reduced activity of central opioids after menopause. Evidence suggests that it can result in sleep disturbance, low mood, depressive symptoms, less productivity and concentration in women having moderate to severe episodes of Vasomotor Symptoms (VMS) [3].

Cognitive complaints are more frequently reported in postmenopause. In comparison to perimenopausal and premenopausal women, postmenopausal women have decreased verbal memory, working memory and executive function along with reduced frontal cortical volume. Depletion of oestrogen impairs normal cognitive functioning because it regulates neurogenesis and synaptic plasticity and interacts with neurotransmitter systems [5,6].

The most effective treatment is MHT. But MHT can increase the risk diseases like breast cancer, deep vein thrombosis especially in older women adding on to their economic and financial burden therefore it is not suitable treatment option for women [7]. So there is a need for non pharmacological treatment alternatives [3]. Studies have shown that resistance training and aerobics are useful in improving autonomic functioning and vasomotor symptoms [3,8]. However, there is no rehabilitation protocol that addresses all types of symptoms (cognitive, autonomic and vasomotor) together in Postmenopausal women to improve their well-being. The objective of the study was to construct and validate a rehabilitation exercise protocol and to investigate its efficacy among postmenopausal

females. Therefore, the study aimed to generate, validate a multidimensional rehabilitation protocol and find out its effectiveness in improving cognitive, autonomic and vasomotor symptoms in Postmenopausal women.

MATERIALS AND METHODS

The present two Phasic feasibility study was conducted at the Department of Physiotherapy, Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Mullana, Ambala, Haryana, India, a tertiary care super-speciality teaching hospital between December 2023 to February 2025 and was approved by the Institutional Ethical Committee with reference number IEC- 2798 and have a clinical trial registry number: CTRI/2024/07/071291. Study comprised of two phases: 1) Protocol design and Validation; 2) Pilot testing of the protocol. postmenopausal Females between the ages of 45-60 were approached regarding the study from Gynaecology Department and screened according to the assessment performa. On the basis of inclusion and exclusion criteria 12 females were recruited. After which, the written consent was obtained from all the participants before the study commenced.

Sample size: A total of 12 samples were recruited on the basis of criterion based purposive sampling for the pilot study based on the inclusion and exclusion criteria [9].

Inclusion criteria:

- Age 45-60 years;
- Menopause ≥1 year;
- Females experiencing menopausal symptoms as evaluated using MRS [3];
- Females who understand English language [3].

Exclusion criteria:

- Females on hormonal replacement therapy and lipid lowering drugs;
- Any metabolic disorders like diabetes, hypothyroidism etc.,
- Any other hormonal disorder;
- Any neurological disorder;
- Any acute or chronic musculoskeletal inflammatory condition;
- Diagnosed psychological illness like depression, anxiety or sleep disorder;
- Any recent gynaecological surgery; and
- Hypertension {Systolic Blood Pressure (SBP)>160 mmHg, Diastolic Blood Pressure (DBP) >100} or taking anti-hypertensive drugs [3].

Study Procedure

Protocol designing was performed in a three step procedure: A) Content and domain specification; B) Item generation; and C) Protocol construction. Items in the protocol were obtained after thorough review of literature retrieved from databases like PubMed, ResearchGate and Google scholar. Publications that evaluated physiology, exercise and/or physical activity in the postmenopausal population were identified and three major areas to focus on were found i.e., cognitive, vasomotor and autonomic symptoms. Studies were again explored for exercises and rehabilitation of the above symptoms in postmenopausal females. Finally, three major exercises were identified: aerobics, resistive and cognitive training. After numerous discussions with all three authors, a 45-50 minute protocol was constructed with following exercises:

1. Warm up using aerobics exercises of moderate intensity with Heart Rate (HR) = 70% of Maximum HR, where maximum HR was obtained by using formula (220-Age). The HR of all participants was monitored using a digital pulse oximeter wore by them throughout the warm up.
2. Resistance training targeting major muscles given with 10-15 repetitions of 1 set for first two weeks and 10-15 repetitions of two sets for next two weeks.The exercises were progressed gradually based on participant tolerance. Aerobic intensity was maintained at 50% of maximum HR, while resistance training progressed from one set to two sets after two weeks following the principle of gradual overload [10];
3. Cognitive training with one set of each exercise;
4. Cool down including stretching and relaxation exercises. Stretching exercises will be done with 20 seconds hold.

The content validation of the protocol was later done by Delphi survey method via a group of experts and Content validation Index was obtained [11,12]. The above mentioned protocol was validated by seven experts with an average experience of 9.5 years in working with postmenopausal women. Five experts were Master of Physiotherapy (MPT) in (Obstetrics and Gynaecology) (Obs and Gynae) and two were Associate Professor in Obstetrics and Gynaecology Department with an M.Ch degree. The experts suggested only one modification i.e., to decrease the intensity of aerobic training from 70% of the maximum HR to 50% of the maximum HR. The final modified protocol is given in [Table/Fig-1].

Intervention	Exercises	Intensity	Duration
Warm up with aerobic training	Cycling treadmill	moderate intensity, SpO_2/ HR = 50% of Maximum Heart Rate (HR)	10 min
Resistance training	Arm curls, cross body reach, shoulder front raises, banded dumbbell T row, Abdominal crunches, dynamic quadriceps, hamstring curls, calf raises	10-15 repetitions for first two weeks 10-15 repetitions of 2 sets for next two weeks	15 min
Cognitive training	Trail making Digit span Stroop test Games like elephant memory, shapes and colour, jigjaw puzzles.	1 set of each exercise	15 min
Cool down session	Stretching exercises Relaxation exercises	Stretching exercise will be done with 20 seconds hold	10 min

[Table/Fig-1]: Multidimensional rehabilitation protocol for postmenopausal women.
SpO2: Saturation of Peripheral Oxygen

Outcome measures: The outcome measures used for the assessment were Menopause Rating Scale (MRS), Composite Autonomic Symptom Score 31 (COMPASS31), Hot Flash-Related daily Interference Scale (HFRDIS) and Montreal Cognitive Assessment (MoCA). The assessments were taken at baseline and after 28 days or 4 weeks.The assessor took all the assessments and was not blinded.

Menopause Rating Scale (MRS): The MRS is an internationally accepted tool developed in the 1990s to assess the severity of menopausal symptoms and their impact on quality of life. It includes 11 symptoms, each scored from 0 (none) to 4 (severe) effects. It shows good reliability, with internal consistency (0.6-0.9) and test-retest reliability (0.8–0.96) across various regions. Higher the score, more severe will be the symptom [13].

Composite Autonomic Symptom Score 31: The COMPASS 31 (Composite Autonomic Symptom Score 31) is a structured, self-administered questionnaire designed to assess the severity and distribution of autonomic symptoms across multiple domains. It contains 31 items and responses are weighted and aggregated into a total score ranging from 0 to 100, with higher scores

indicating greater autonomic symptom burden. COMPASS 31 has demonstrated strong internal consistency, with Cronbach's alpha values ranging from 0.74 to 0.93 across different subdomains, indicating strong reliability [14].

Hot Flash-Related daily Interference Scale: It is a 10-item scale measuring the degree hot flashes interfere with nine daily activities; the tenth item measures the degree hot flashes interfere with overall quality of life. This tool was designed to measure the impact of hot flashes on overall quality of life. Higher scores indicate higher interference due to hot flashes and thus, greater impact on quality of life [15].

Montreal Cognitive Assessment (MoCA): The MoCA evaluates multiple cognitive domains including attention, executive functioning, memory, language, visuo-spatial abilities, abstraction, calculation and orientation. Total score is 30, with a score of 26 or higher generally indicating normal cognitive function. The internal consistency of the MoCA, typically ranges between 0.83-0.89 indicating strong reliability [16].

STATISTICAL ANALYSIS

The statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 20.0 software. The normality was assessed by Shapiro-Wilk test and analysis of baseline-post intervention scores was done by using Wilcoxon-signed Rank test.

RESULTS

The Item-level CVI (I-CVI) of each item was found to be between 0.86 and one whereas the Scale level CVI (S-CVI) by average method was found to be 0.93 which was above the satisfactory level. The demographic characteristics of participants and the baseline outcome measures are presented in [Table/Fig-2]. The results showed statistically significant improvement in all the outcome measures post intervention and are represented in median scores and interquertile range (25%-75%). The Menopause Rating Scale showed a marked reduction in symptom severity, with the median score with Interquartile Range (IQR) decreasing from 30 (27.25-31.75) at baseline to 18 (16.00-21.50) post-intervention with p-value=0.002, indicating 40% reduction of menopausal symptoms.

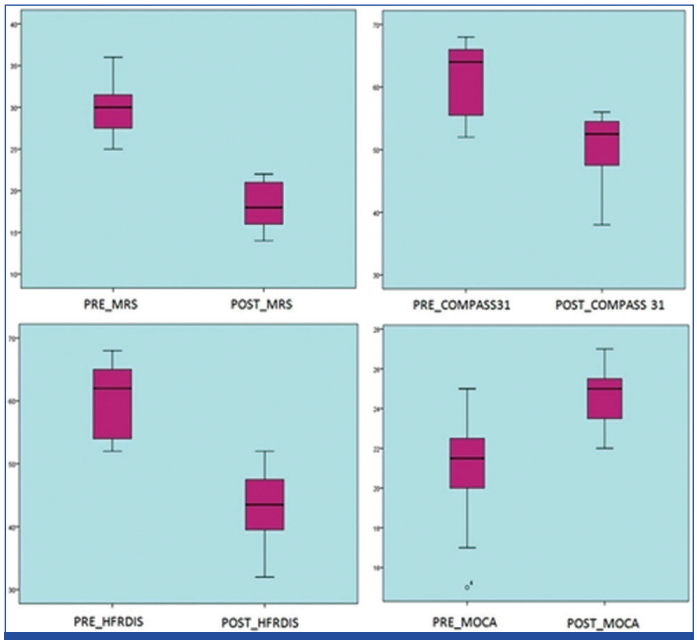
Demographic characteristics	Mean±SD
Age (years)	53.00±2.79
Height (cm)	163.33±4.92
Weight (kg)	65.08±4.27
BMI	25.33±1.58
Menarche age (years)	15.50±1.16
Menopause age (years)	50.75±2.05
Duration of menopause (years)	2.25±1.13

[Table/Fig-2]: Demographic characteristics of all participants (n=12).

The COMPASS-31, which evaluates autonomic symptom burden, exhibited a notable decline of 18.75% in scores from 64 (55.25-66.00) to 52 (47.25-54.75), reflecting improved autonomic regulation. The HFRDIS scores also decreased from 62 (54.00-65.50) to 43 (39.25-47.75), suggesting improvement in vasomotor symptoms. The HFRDIS score showed an approximately 30.6% reduction following the intervention. Cognitive function as assessed on MoCA, also showed a significant improvement in the scores with the median score increasing from 21 (20.00-22.75) at baseline to 25 (23.25-25.75) post-intervention (p=0.002), indicating enhancement in global cognitive abilities such as memory, attention and executive function with 19% symptom reduction [Table/Fig-3,4]. The effect size for menopause rating scale found to be 0.886, for COMPASS-31 the effect size was 0.890 whereas for HFRDIS and MoCA was found to be 0.883 and 0.896, respectively.

S. No.	Variables	Median (IQR)	Min-Max	p-value
1	Pre_MRS	30 (27.25-31.75)	25-36	0.002*
2	Post_MRS	18 (16.00-21.50)	14-22	
3	Pre_COMPASS31	64 (55.25-66.00)	52-68	0.002*
4	Post_COMPASS31	52 (47.25-54.75)	38-56	
5	Pre_HFRDIS	62 (54.00-65.50)	52-68	0.002*
6	Post_HFRDIS	43 (39.25-47.75)	32-52	
7	Pre_MoCA	21 (20.00-22.75)	15-25	0.002*
8	Post_MoCA	25 (23.25-25.75)	22-27	

[Table/Fig-3]: Comparison of variables at baseline and after 4 weeks of intervention (Wilcoxon-signed Rank test).
*significant p-value, # Wilcoxon-signed Rank test
PRE: Pre-intervention scores; POST: Post-intervention scores; MRS: Menopause Rating scale; COMPASS31: Composite Autonomic Symptom Score 31; HFRDIS: Hot Flash-related daily interference scale, MoCA: Montreal cognitive assessment



[Table/Fig-4]: Box-plot representation of pre-post comparison of all outcome measures.
PRE: Pre-intervention scores; POST: Post-intervention scores; MRS: Menopause Rating scale; COMPASS31: Composite Autonomic Symptom Score 31; HFRDIS: Hot Flash-related daily interference scale, MoCA: Montreal cognitive assessment

DISCUSSION

This study was aimed to construct and validate a rehabilitation exercise protocol for postmenopausal females and to investigate its efficacy among them.

The Menopause Rating Scale showed a marked reduction in symptom severity, indicating a significant reduction of menopausal symptoms. Guevara et al., highlights the importance of exercise and physical activity for women, especially during the menopausal stage. It emphasises that consistent physical activity is an essential therapeutic intervention that can greatly enhance postmenopausal women's health outcomes and reduces the symptoms. According to the authors, women who are physically inactive may have a significant risk of developing metabolic syndrome, cardiovascular diseases as well as experiencing worsening menopausal symptoms. The findings suggest that both aerobic and strength training exercises can effectively counteract the adverse effects associated with menopause, such as chronic inflammation and muscle loss, thereby enhancing overall quality of life [17]. Meta-analysis done by Khalafi M et al., in 2021 revealed that exercise training had a beneficial impact on inflammation during post-menopause by considerably lowering levels of Tumour Necrosis Factor-alpha (TNF-α), C-Reactive Protein (CRP), and Interleukin-6 (IL-6) while raising adiponectin levels [18].

A study published in 2020 by Rohini NS et al., suggested that ageing and menopause are associated with altered adipose

tissue metabolism, which leads to a greater build-up of body fat. Changes in the central nervous system, the body temperature and sympathetic nerve activity after the onset of menopause are because of adipokines. Adverse alterations in adipokines and inflammatory markers are closely associated with increased visceral adiposity. Increase in visceral body fat leads to an imbalance in autonomic nervous system functioning, along with sympathetic activation [19].

The COMPASS-31, which evaluates autonomic symptom burden, exhibited a notable decline in scores, reflecting improved autonomic regulation. A systematic review with meta-analysis is done by Sánchez-Delgado JC et al., in 2023 explored the effects of physical activity on cardiovascular autonomic modulation on postmenopausal population highlights that exercise can enhance cardiovascular health, as shown by improvements in Blood Pressure Variability (BPV) and HR Variability (HRV) indices [20]. The improvements seen in the present study are similar to the ones seen in a study by Earnest CP et al., where after six months of moderate intensity exercise training HRV of postmenopausal women improved [21]. Another study on induced postmenopausal rats also proved that combination training of resistive and aerobic training improved baroreflex sensitivity and HRV [22]. These improvements can be attributed to both aerobic and resistive exercises. As aerobic training enhances parasympathetic (vagal) activity and decreases sympathetic dominance by enhancing the heart's ability to slow down and respond flexibly to physiological demands. Thereby, reducing resting HR and improving HRV, whereas resistive exercises works by improving parasympathetic modulation, reducing adiposity and sympathovagal imbalance enhancing venous return [21,22].

Hot flushes and sweating, both symptoms are very common among postmenopausal women. It is believed that activities of central opioids are involved in vasomotor symptoms. After menopause these central opioids such as dynorphin and beta-endorphin are decreased but it can be reversed by physical exercise and large musculature activation. The local regulation of blood flow to the skin or a change in autonomic haemodynamic control may be the cause of these climacteric vasomotor symptoms. Improvements in HFRDIS has been supported by study done by Bailey TG et al., where a 16-week moderate intensity exercise protocol improved hot flushes in 21 postmenopausal women by attenuating the physiological markers of hot flushes- reduced sweating and vasodilatation. Moreover, aerobic training also reduces core temperature, enhances thermoregulatory sensitivity of sweating and skin blood flow and increased cerebral blood flow processes that help mitigate hot flushes [23].

Another study by Berin E et al., revealed that 15-weeks resistance training program targeting major muscle groups reduced the frequency and severity of the vasomotor symptoms. The training regimen included eight exercises- leg curl, seated row, latissimus dorsi pull-down, leg extension, leg press and chest press, back lifts and crunches. Two exercises used body weight, while six exercises were done using seated resistance machines [3]. But the limitation of this strength training protocol was that one requires to go to gym for using equipment for doing the exercises and major drawback was that not every women is physically fit enough to carry out these heavy exercises strength. Whereas, the resistance exercises which we have added in the present protocol are safe and can be done in home as well.

Additionally, significant improvements were observed in cognitive domain post intervention, indicating enhancement in global cognitive abilities such as memory, attention and executive function. The results of the present study corroborates with a study by Ramadhana DR et al., who gave two week multi-component exercises that included resistive and aerobic exercises that improved executive function (e.g., inhibition, processing speed) as well as global cognitive scores in postmenopausal women [24]. This could be due to the fact that Aerobic training increase cerebral blood flow and reduce cerebro-vascular resistance, creating a physiological environment that supports oxygen and nutrient delivery to brain tissue thereby supporting synaptic health and resistive exercises stimulates production of neurotrophic factors {e.g., Brain-Derived Neurotrophic Factor (BDNF)}, which supports neuroplasticity and memory pathways [25].

According to Voelcker-Rehage C et al., motor fitness significantly correlated with both the executive control and perceptual speed tasks, whereas physical fitness was primarily related to the executive control process. These two types of fitness were found to be correlated with cognitive functioning [26]. The effects of aerobic training combined with at least one additional form of exercise, such as a mix of aerobic and resistance or multi-component exercise, are more pronounced on cognition [18-26]. Therefore based on this literature the authors formed their protocol such that it includes basic resistance training, simple cognitive exercises, stretching exercises, breathing exercises along with aerobic training. There protocol included cognitive exercises such as stroop, trail making and digit span because they are short, simple to administer in a clinical research setting, have strong psychometric support in adults and older populations and collectively target the specific cognitive domains most frequently affected during menopausal transition (attention/processing speed, working memory and executive control/inhibitory function) [24,27,28]. Various studies have shown improvement in physical fitness, body fat composition, global cognition, verbal memory after incorporating some other form of exercise be it physical training, breathing or computer-based cognitive training in the exercise session [26,29-32].

The study demonstrates that a structured multidimensional rehabilitation protocol can effectively reduce autonomic, vasomotor, cognitive and overall menopausal symptoms, offering a safe non pharmacological option for postmenopausal women. Clinically, it provides physiotherapists with a feasible, cost-effective intervention that can be easily implemented in routine OPD practice. The significant improvements observed suggest that such programs may also help lower long-term cardiovascular and cognitive risks. Future research should validate these findings in larger samples, explore long-term effects and integrate digital tools for better adherence. Further expansion of the protocol to women with co-morbidities and diverse populations can enhance its applicability and clinical utility.

The present study highlighted the potential of integrated, non pharmacological rehabilitation approaches in managing postmenopausal health concerns. To the best of the author's knowledge this rehabilitation protocol is the first which addresses to mitigate the most prevalent postmenopausal symptoms. It can be beneficial for women suffering from these symptoms in their daily lives. In future, studies with larger sample sizes and randomised controlled trials are needed to establish stronger evidence.

CONCLUSION(S)

The multidimensional rehabilitation protocol developed in the present study was found to be valid, feasible and effective in improving autonomic, vasomotor and cognitive symptoms in postmenopausal women, thereby fulfilling the primary aim of developing, validating and pilot-testing a comprehensive non pharmacological intervention. Its positive outcomes suggest that such a protocol can reduce reliance on pharmacological management and serve as a clinically meaningful approach for improving overall well-being in postmenopausal women.

Limitation(s)

The present study has a few limitations. Because the sample size was small, the results may not fully represent the wider postmenopausal population and the findings should be interpreted with caution. Since there was no control group, it is difficult to compare these improvements with natural recovery or other

treatment options. Additionally, the short follow-up period does not allow us to understand whether the benefits seen would last over a longer duration.

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