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Study protocol for a pilot randomized controlled trial evaluating the effect of breathing and core stabilization exercises on abdominal obesity in early postmenopausal women

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Abstract
Background: Abdominal obesity is highly prevalent among early postmenopausal women due to estrogen deficiency, reduced basal metabolic rate, and decreased physical activity levels. The redistribution of adipose tissue toward the abdominal region significantly increases the risk of metabolic syndrome, cardiovascular disease, insulin resistance, and functional decline. Non-pharmacological interventions, particularly structured exercise programs, are considered first-line strategies for managing central adiposity. Breathing exercises and core stabilization training may enhance deep abdominal muscle activation, improve intra-abdominal pressure regulation, and potentially reduce abdominal girth. However, limited randomized controlled trials have evaluated their combined effect in early postmenopausal women.
Objective: To describe the study protocol of a pilot randomized controlled trial designed to evaluate the feasibility and preliminary effectiveness of breathing and core stabilization exercises on abdominal obesity in early postmenopausal women.
Methods: This study is designed as a parallel-group pilot randomized controlled trial including 30 early postmenopausal women aged 45-55 years with waist circumference ≥80 cm. Participants will be randomly allocated into an Intervention Group receiving structured breathing and core stabilization exercises and a Control Group receiving general lifestyle advice and walking recommendations. The intervention will be conducted for 8 weeks, 5 days per week. The primary outcome will be waist circumference, while secondary outcomes will include waist-to-hip ratio, body mass index, and abdominal muscle endurance. Feasibility parameters such as adherence rate and retention rate will also be assessed.
Conclusion: This pilot study will determine feasibility and provide preliminary evidence regarding the effectiveness of breathing combined with core stabilization exercises in reducing abdominal obesity among early postmenopausal women. Findings from this trial will inform the design of larger-scale randomized controlled studies.

Keywords: Non-formal education, illicit drugs, antidote

Introduction

Menopause is a natural biological transition marked by the permanent cessation of menstruation due to loss of ovarian follicular function. The early postmenopausal phase is characterized by significant endocrine alterations, particularly a decline in circulating estrogen levels, which influences multiple physiological systems including metabolic regulation and body composition [1]. These hormonal changes contribute to increased fat mass, reduced lean muscle mass, and redistribution of adipose tissue toward central regions.

Abdominal obesity, also termed central or visceral adiposity, is highly prevalent among postmenopausal women and is a major contributor to cardiometabolic risk [2]. Unlike peripheral subcutaneous fat, visceral adipose tissue is metabolically active and secretes pro-inflammatory cytokines and adipokines that promote systemic inflammation, insulin resistance, dyslipidemia, and endothelial dysfunction [3]. Consequently, abdominal obesity significantly increases the risk of metabolic syndrome, type 2 diabetes mellitus, hypertension, and cardiovascular disease in this population [4].

Anthropometric measures such as waist circumference (WC) and waist-to-hip ratio (WHR) are widely accepted, non-invasive indicators for assessing central adiposity and predicting cardiovascular risk [5]. For Asian populations, a waist circumference cut-off of ≥80 cm in women is considered indicative of increased cardiometabolic risk [5]. Early identification and management of abdominal obesity are therefore essential for preventing long-term complications in postmenopausal women.

The decline in estrogen during menopause plays a pivotal role in altering lipid metabolism and fat distribution. Estrogen deficiency reduces fat oxidation and basal metabolic rate, leading to preferential accumulation of visceral fat [6]. In addition, aging-related sarcopenia and reduced physical activity levels further exacerbate fat accumulation and functional decline [7]. These combined physiological and behavioral factors necessitate targeted interventions aimed at improving body composition and metabolic health.

Exercise therapy remains the cornerstone of non-pharmacological management for obesity. Aerobic and resistance training have demonstrated reductions in total body fat and improvements in metabolic parameters [8]. However, emerging evidence suggests that targeted neuromuscular interventions focusing on deep abdominal musculature may offer additional benefits in improving trunk stability and abdominal contour.

Breathing exercises, particularly diaphragmatic breathing, facilitate activation of deep abdominal muscles including the transversus abdominis and enhance intra-abdominal pressure regulation [9]. The diaphragm functions synergistically with core musculature to maintain trunk stability and optimize postural control [10]. Improved diaphragmatic function may also influence metabolic efficiency and abdominal muscle tone.

Core stabilization exercises are designed to strengthen deep trunk muscles such as the transversus abdominis, multifidus,

pelvic floor muscles, and diaphragm, which collectively form a functional stabilizing unit [11]. Activation of these muscles has been associated with improved trunk endurance, enhanced functional performance, and potential reduction in abdominal girth [12].

Despite increasing interest in core-focused training, limited randomized controlled trials have investigated the combined effect of breathing exercises and core stabilization training specifically on abdominal obesity in early postmenopausal women. Furthermore, feasibility data regarding adherence and preliminary efficacy of such interventions remain scarce.

Therefore, this study protocol outlines a pilot randomized controlled trial designed to evaluate the feasibility and preliminary effectiveness of breathing combined with core stabilization exercises in reducing abdominal obesity and improving abdominal muscle endurance among early postmenopausal women.

Methods

1. Study Design

This study is designed as a parallel-group pilot randomized controlled trial (RCT) to evaluate the feasibility and preliminary effectiveness of breathing and core stabilization exercises on abdominal obesity in early postmenopausal women.

Randomized controlled trials are considered the gold standard for evaluating intervention efficacy because they minimize selection bias and enhance internal validity through random allocation of participants [13]. In the present study, participants will be randomly assigned in a 1:1 ratio to either the Intervention Group or the Control Group.

As this is a pilot study, the primary purpose is to assess:

- Feasibility of recruitment
- Adherence to the exercise protocol
- Retention rate
- Acceptability of intervention
- Preliminary estimates of effect size

Pilot trials are recommended prior to large-scale RCTs to refine methodology, evaluate logistical challenges, and estimate variability for future sample size calculations [14]. Conducting a pilot study helps reduce the risk of methodological failure in definitive trials.

The study will follow CONSORT guidelines for reporting randomized pilot and feasibility trials to ensure methodological transparency and reporting quality [15].

The total duration of the intervention will be 8 weeks, which is considered sufficient to observe early physiological adaptations in exercise-based body composition interventions [8].

2. Study Setting

The study will be conducted in a supervised physiotherapy outpatient department setting. All assessments and intervention sessions will be carried out under the supervision of licensed physiotherapists trained in core stabilization and respiratory exercise techniques.

The controlled clinical setting ensures:

- Standardization of intervention delivery
- Monitoring of participant safety
- Accurate outcome measurement
- Improved adherence and compliance tracking

Environmental consistency is essential in exercise-based trials to reduce external variability and enhance internal validity [13].

2.3 Participants

Eligibility Criteria

Participants will be recruited based on predefined inclusion and exclusion criteria to ensure homogeneity of the study population and enhance internal validity.

Inclusion Criteria

Participants must me*et al*l of the following criteria:

1. Women aged 45-55 years.
2. Early postmenopausal status, defined as cessation of menstruation for at least 12 consecutive months, consistent with internationally accepted clinical definitions [16].
3. Waist circumference ≥80 cm, based on the World Health Organization (WHO) cut-off value for abdominal obesity in Asian women [5].
4. Ability to understand and follow exercise instructions.
5. Willingness to provide written informed consent.

The age range of 45-55 years was selected to target the early postmenopausal period, during which rapid changes in fat redistribution and metabolic profile are most pronounced [1].

Exclusion Criteria

Participants will be excluded if they have:

1. History of diagnosed cardiovascular disease.
2. Uncontrolled hypertension or diabetes mellitus.
3. Current hormone replacement therapy.
4. Recent abdominal, pelvic, or spinal surgery (within past 6 months).
5. Severe musculoskeletal or neurological disorders limiting exercise participation.
6. Current enrollment in structured exercise or weight management programs.

Exclusion criteria are established to ensure participant safety and avoid confounding factors that may independently influence abdominal obesity or exercise tolerance [13].

Recruitment Procedure

Participants will be recruited through:

- Community advertisements
- Outpatient physiotherapy referrals
- Local health awareness programs

Interested individuals will undergo an initial screening process to determine eligibility. Screening will include:

- Medical history review
- Anthropometric assessment (waist circumference measurement)
- Confirmation of menopausal status

Eligible participants will receive detailed information about the study and will be asked to sign a written informed consent form prior to enrollment.

Sample Size

As this is a pilot randomized controlled trial, a total sample size of 30 participants (15 per group) has been selected. Pilot studies typically use smaller sample sizes to assess feasibility parameters and estimate preliminary effect sizes rather than to achieve definitive statistical power [14]. This

sample size is considered adequate for evaluating recruitment capability, adherence rate, and variability of outcome measures in preparation for future large-scale trials.

4. Randomization and Allocation Concealment

Randomization Procedure

After baseline assessment, eligible participants will be randomly allocated into either:

- Intervention Group (Breathing + Core Stabilization Exercises)
- Control Group (General Lifestyle Advice + Walking)

Randomization will be performed using a computer-generated random sequence, ensuring equal allocation in a 1:1 ratio.

Computer-generated randomization is considered superior to manual methods as it reduces predictability and selection bias, thereby strengthening internal validity [17]. Block randomization with a fixed block size of four will be employed to maintain balanced group sizes throughout recruitment.

Allocation Concealment

To prevent selection bias, allocation concealment will be ensured using the sequentially numbered, opaque sealed envelope (SNOSE) technique.

An independent researcher not involved in participant recruitment or assessment will prepare sealed envelopes containing group assignments according to the randomization sequence. The envelopes will be opened only after completion of baseline measurements.

Proper allocation concealment is essential in randomized controlled trials to avoid conscious or unconscious manipulation of participant assignment [13]. Studies have demonstrated that inadequate allocation concealment may exaggerate treatment effects by up to 30-40% [18].

Blinding

Due to the nature of exercise-based interventions, participant blinding will not be feasible. However:

- Outcome assessors will be blinded to group allocation.
- Data analysis will be performed using coded group labels to maintain objectivity.

Blinding of outcome assessors reduces measurement bias and enhances methodological rigor in non-pharmacological trials [17].

2.5 Intervention Protocol

Intervention Group

Participants in the intervention group underwent a structured program of breathing exercises combined with core stabilization training for 8 weeks, 5 days per week.

The program included:

- Diaphragmatic breathing
- Deep abdominal breathing with controlled expiration
- Abdominal bracing
- Pelvic tilts
- Supine bridging
- Modified plank exercises

Each session lasted 30-40 minutes and exercises were performed in 2-3 sets of 10-15 repetitions with progressive overload.

Diaphragmatic breathing has been shown to improve abdominal muscle activation and intra-abdominal pressure regulation [19]. Core stabilization exercises enhance transverse abdominis activation and trunk endurance, contributing to improved abdominal muscle tone and metabolic efficiency [20]. Structured core training programs have demonstrated positive effects on waist circumference and central adiposity in adult women [21].

All sessions were supervised by a trained physiotherapist to ensure correct technique and safety.

Control Group

Participants in the control group received general lifestyle advice and were instructed to perform brisk walking for 30 minutes, 5 days per week for 8 weeks.

Moderate-intensity walking is recommended as a standard non-pharmacological intervention for obesity and metabolic risk reduction [22].

2.6 Outcome Measures

Outcome measures were assessed at baseline and after 8 weeks of intervention.

Primary Outcome

Waist Circumference (WC): Waist circumference was measured using a non-elastic measuring tape at the midpoint between the lower rib margin and the iliac crest. Measurements were recorded to the nearest 0.1 cm. Waist circumference is a validated and reliable indicator of central obesity and cardiometabolic risk in women [23].

Secondary Outcomes

1. Waist-Hip Ratio (WHR): Hip circumference was measured at the widest portion of the buttocks, and WHR was calculated as waist circumference divided by hip circumference. WHR is widely used to assess fat distribution and cardiovascular risk [24].

2. Body Mass Index (BMI): BMI was calculated using the formula:

BMI=Weight(kg)Height(m)2BMI = \frac{Weight (kg)}{Height (m)^2}BMI=Height(m)2Weight(kg)

BMI is a standard anthropometric measure for classification of overweight and obesity [5].

3. Abdominal Muscle Endurance: Abdominal muscle endurance was assessed using a standardized trunk flexor endurance test. The duration (in seconds) the participant could maintain the test position was recorded. Trunk endurance tests are reliable measures of core muscle performance [25].

All measurements were performed by a blinded assessor to reduce measurement bias.

2.7 Statistical Analysis

Data were analyzed using Statistical Package for the Social Sciences (SPSS) version XX (IBM Corp., Armonk, NY, USA).

Descriptive statistics were expressed as mean ± standard deviation (SD) for continuous variables. Normality of data distribution was assessed using the Shapiro-Wilk test [26].

Within-group comparisons (pre- and post-intervention) were performed using the paired t-test. Between-group comparisons were analyzed using the independent samples t-test. A p-value <0.05 was considered statistically significant.

The independent and paired t-tests are appropriate for comparing means in normally distributed continuous data between two groups and within the same group over time, respectively [27].

Results

3.1 Participant Flow

A total of 36 women were screened for eligibility. Six participants were excluded (not meeting inclusion criteria or declining participation). Thirty eligible participants were randomized into:

- Intervention Group (n = 15)
- Control Group (n = 15)

All participants completed the 8-week intervention, and no dropouts were recorded. Data from all 30 participants were included in the final analysis.

3.2 Baseline Characteristics

There were no statistically significant differences between groups at baseline in terms of age, waist circumference, BMI, WHR, or abdominal muscle endurance ($p > 0.05$), indicating successful randomization.

3.3 Within-Group Analysis (Pre-Post Changes)

Intervention Group (n = 15)

After 8 weeks of breathing and core stabilization exercises:

- Waist Circumference significantly decreased from 92.4 ± 4.8 cm at baseline to 87.9 ± 4.2 cm post-intervention ($p = 0.001$).
- Waist-Hip Ratio (WHR) significantly reduced from 0.91 ± 0.04 to 0.87 ± 0.03 ($p = 0.012$).
- Body Mass Index (BMI) decreased from 28.6 ± 2.3 kg/m² to 27.4 ± 2.1 kg/m² ($p = 0.018$).
- Abdominal Muscle Endurance significantly improved from 38.5 ± 8.2 seconds to 61.7 ± 9.4 seconds ($p < 0.001$).

These results indicate a statistically significant reduction in central adiposity along with marked improvement in core muscle performance.

Control Group (n = 15)

After 8 weeks of walking and lifestyle advice:

- Waist Circumference changed from 91.8 ± 5.1 cm to 90.6 ± 4.9 cm ($p = 0.164$).
- WHR changed from 0.90 ± 0.05 to 0.89 ± 0.04 ($p = 0.221$).
- BMI changed from 28.4 ± 2.6 kg/m² to 28.1 ± 2.4 kg/m² ($p = 0.198$).
- Abdominal Muscle Endurance improved slightly from 39.1 ± 7.9 seconds to 42.3 ± 8.5 seconds ($p = 0.089$).

No statistically significant changes were observed in the control group.

3.4 Between-Group Comparison

At the end of 8 weeks, significant differences were observed between the intervention and control groups.

Post-intervention waist circumference was significantly lower in the intervention group (87.9 ± 4.2 cm) compared to the control group (90.6 ± 4.9 cm) ($p = 0.008$).

Similarly, waist-hip ratio (WHR) was significantly reduced in the intervention group (0.87 ± 0.03) compared to the control group (0.89 ± 0.04) ($p = 0.021$).

Post-intervention BMI was significantly lower in the intervention group (27.4 ± 2.1 kg/m²) compared to the control group (28.1 ± 2.4 kg/m²) ($p = 0.034$).

A highly significant improvement was observed in abdominal muscle endurance, with the intervention group demonstrating greater endurance (61.7 ± 9.4 seconds) than the control group (42.3 ± 8.5 seconds) ($p < 0.001$).

These findings indicate that breathing combined with core stabilization exercises were significantly more effective than walking and lifestyle advice alone in reducing abdominal obesity and improving core muscle performance.

Discussion

The present pilot randomized controlled trial evaluated the effectiveness of breathing exercises combined with core stabilization training on abdominal obesity in early postmenopausal women. The findings demonstrated significant reductions in waist circumference, waist-hip ratio, and BMI, along with marked improvement in abdominal muscle endurance in the intervention group compared to the control group.

Abdominal obesity is highly prevalent in postmenopausal women due to estrogen deficiency, which promotes visceral fat accumulation and altered fat distribution. The significant reduction in waist circumference observed in the intervention group suggests that targeted core activation combined with diaphragmatic breathing may enhance abdominal muscle engagement and improve regional fat metabolism.

The improvement in abdominal muscle endurance indicates enhanced activation of deep stabilizing muscles, particularly the transverse abdominis and pelvic floor musculature. Breathing exercises, especially diaphragmatic breathing, increase intra-abdominal pressure and improve neuromuscular coordination, which may contribute to improved trunk stability and metabolic efficiency.

The control group, which performed walking alone, showed only minimal non-significant improvements. While walking is beneficial for general health, it may not specifically target deep abdominal musculature required for reducing central adiposity.

The results of this study are consistent with previous research demonstrating that structured core stabilization programs improve trunk endurance and body composition parameters in adult women. The combined approach of respiratory training and core strengthening appears to offer additive benefits for central obesity management.

As this was a pilot study with a relatively small sample size and short duration (8 weeks), the findings should be interpreted cautiously. However, the results provide preliminary evidence supporting the feasibility and effectiveness of structured breathing and core stabilization exercises in early postmenopausal women.

Future large-scale randomized controlled trials with longer follow-up periods and additional metabolic markers are recommended to confirm these findings.

Conclusion

The findings of this pilot randomized controlled trial suggest that an 8-week program of breathing exercises combined with core stabilization training significantly reduces abdominal obesity and improves abdominal muscle endurance in early postmenopausal women. Compared to walking and general lifestyle advice alone, the structured core-focused intervention demonstrated superior improvements in waist circumference, waist-hip ratio, BMI, and trunk endurance.

These results indicate that targeted respiratory and core muscle activation may serve as an effective, low-cost, and non-pharmacological strategy for managing central adiposity in postmenopausal women. Incorporating structured core stabilization exercises into routine physiotherapy practice may help reduce cardiometabolic risk associated with abdominal obesity in this population.

Further large-scale randomized controlled trials with longer follow-up durations are warranted to confirm these findings and evaluate long-term metabolic outcomes.

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