PROTOCOL PAPER

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High-intensity interval training versus hatha yoga for postmenopausal females on obesity, sarcopenia, dynapenia, lower limb alignment: study protocol for RCT

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Abstract

Introduction. Menopause is a challenging stage of a woman's life, with increased occurrences of musculoskeletal issues and obesity that need to be tackled early and effectively. Less is known about the effect of HIIT & hatha yoga on musculoskeletal parameters in post-menopausal females. Both exercise approaches differ and are comparable in many ways. Thus, the objective of the study is to determine and compare the effects of 12 weeks of HIIT and yoga training protocols in postmenopausal females with central adiposity, sarcopenia, dynapenia, and knee alignment. The present research article presents a study protocol comparing yoga and HIIT protocols prescribed for postmenopausal females.

Methods. This is an open-label, randomised, parallel-armed, assessor-blinded clinical trial that will be conducted on 160 postmenopausal females between 46 and 70 years randomly assigned to either the HIIT or yoga group. The intervention will be in the form of group therapy for 5 sessions per week for 12 weeks. The outcomes include sarcopenia by lean muscle mass using a bioelectric impedance analyser, a radiological measure of the Hip-Knee-Ankle angle, and the perceived stress scale and 36-item short form questionnaires assessed twice (pre & post). The outcomes, including gait speed, hand grip strength, waist circumference, and body mass index, will be assessed at pre, post-4th week, post-8th week, and post-12th week.

Discussion. The study outcomes will provide confirmatory evidence on the effects of Hatha yoga and HIIT exercise training protocols in managing menopausal weight gain, musculoskeletal issues (sarcopenia and knee malalignment), physical and functional capacity, as well as mental health in postmenopausal females.

Key words: ageing, exercise, high-intensity intermittent, menopause, alternative therapy

Introduction

Menopause is strongly associated with the increased occurrence of several non-communicable diseases or comorbidities posing numerous health issues in a woman's life compared to peer-aged males and reproductive-age females, thereby imposing a great burden on individual, financial, and healthcare delivery [1, 2]. The average age of menopause in Indian females is 46.2 years, which is earlier than their Western counterparts (51 years) [3].

Sarcopenia, dynapenia, and central adiposity are the three health-related factors that become evident from middle age and more severe as age advances [4]. Sarcopenia is defined as the loss of total body muscle mass while being replaced with fat mass. Dynapenia is a loss of muscle strength, as assessed by the palmar grip strength [5]. The prevalence of sarcopenia and dynapenia is higher in Indians than in their Western counterparts [6]. Central adiposity type of fat redistribution occurs after menopause, while in the reproductive age group, a female's fat is predominantly distributed at the hips and thighs [7]. All these factors pose increased risks of adverse health outcomes when occurring independently or together [8, 9]. The Asian Working Group for Sarcopenia (AWGS) has given diagnostic criteria cut-offs for the Asian population for the diagnosis of sarcopenia [5].

Another issue that affects this ageing female population is the change in angular alignment in the lower limbs, predominantly in the knee joints (varus or valgus) either due to central obesity or imbalances in muscles, which may further lead to arthritis-like inflammatory processes that need to be addressed [10, 11]. This can be accurately diagnosed by long-axis frontal plane radiography of the weight-bearing lower limbs by marking and measuring the coronal hip-knee-ankle angles (HKA) [12]. The correlation between obesity and increased adduction moment and joint loading in the knees that occur with ageing in elderly males and females due to coronal HKA angles has been well established in the literature [13]. Existing literature suggests an effective correction of the kinematics of the knee and hip as well as adduction moment in the frontal plane during dynamic loading conditions with 12 weeks of a structured exercise program, including strengthening or proprioceptive exercises [14–16]. However, there is a paucity of literature, where a gold standard assessment of alignment such as the HKA angle measured on X-ray is considered, to understand the efficacy of weight loss on correction of the lower limb alignment.

Physical exercise and proper nutrition are the best combinations of treatments to deal with these musculoskeletal issues [17, 18]. Several forms of exercise have been studied for their effectiveness in the prevention and management

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of musculoskeletal health risks in elderly females, with the majority of studies having intervened with either resistance or aerobic exercise protocols [19, 20]. Extensive literature exists on the role of aerobic and resistance training protocols in the above-stated conditions [21, 22]. The recent recommendations by the American College of Sports Medicine prescribe Moderate Intensity Continuous Training (MICT) for weight and fat mass with 150–250 minutes per week for prevention or >250 minutes of workout for weight reduction [20].

High-intensity interval training (HIIT) is a repeated set of high-intensity exercise efforts followed by rest intervals comprising lower-intensity efforts [23]. HIIT is an efficient exercise training method for managing diabetes mellitus [24], obesity blood inflammatory biomarkers [25], dyslipidemia [26], fat loss [27], and cardiometabolic disease [23] in all ages and sexes [28]. Compared to MICT, HIIT has the advantage of lesser time requirement while having similar or better improvements in terms of a decrease in fat mass and improved cardiovascular health [24]. In a scoping review on HIIT as a potential exercise intervention, the authors suggested that there are not enough studies looking into HIIT in elderly people with sarcopenia, and therefore additional interventional trials in this population are required [29].

Yoga is an ancient form of physical exercise and behavioural discipline of Indian origin. It involves being in static physical postures (Hatha yoga) or dynamic transitions (Vinyasa yoga) along with breathing control [30]. Recently, yoga has gained popularity globally, with a growing body of evidence stating effectiveness of yoga for treating various health and lifestyle conditions in Western countries as well. Yoga is a very effective strategy of moderate-intensity exercises for obesity [31], lipid markers [32], muscle strength [33], and metabolic syndrome [34]. One review reveals a single multicity prospective trial for the effect of yoga programs on Asian and African older females with sarcopenia, revealing yoga an effective preventive strategy on gait and fitness in the elderly [35].

Yoga and HIIT are comparable in many ways, based on various characteristics. While yoga involves physical poses, concentration, and deep breathing that is performed at a slow-to-moderate pace and intensity, HIIT involves relatively short bursts of vigorous activity performed at a high relative workload corresponding to ≥ 90% of $VO_{2\,max}$ [36]. Yoga provides aerobic effects [37] while HIIT provides both aerobic and anaerobic changes [38]. Further, HIIT has been compared with moderate-intensity training and other traditional exercise forms (Pilates, power yoga) for obesity and other patient populations [39, 40]. Yoga too has been compared to traditional aerobic exercises on mental and physical health outcomes [41–43].

Although evidence exists for the effects of HIIT in different patient populations, its potential effects on parameters that determine musculoskeletal health and physical function capacity are not known. The impact of yoga on issues related to ageing, such as falls, osteopenia, weight management, women's health, and stress, has been well-established in the literature. However, there is limited literature on the effect of yoga on other parameters of musculoskeletal health, such as sarcopenia, dynapenia, physical performance, and lower limb alignment in post-menopausal females. In addition, it would be interesting to explore more on the effects of 12 weeks of generalised forms of exercises on changes in the knee alignments employing a gold standard assessment method such as the HKA angle on X-ray rather than assessing the dynamic frontal plane angle to understand if the corrective effects are of any preventive importance for osteoarthritis (OA) of the knee or are only relevant at the muscular level. Further, there is a paucity of trials in postmenopausal women's health issues as well as health-related conditions of the elderly or the ageing population where HIIT and hatha yoga are compared.

Considering all this, the objective of the study will be to determine and compare the effects of 12 weeks of HIIT and Hatha yoga training on top of a prescribed standard diet chart on body composition, abdominal adiposity, knee joint alignment, muscle strength, functional capacity, perceived level of stress, and health-related quality of life in postmenopausal females with central adiposity, sarcopenia, and dynapenia.

Subjects and methods

The study protocol is reported using the SPIRIT reporting guidelines for protocol studies [44] (Appendix 1). For better reporting of the trial, CONSORT-2010 Statement: extension to pilot studies and feasibility trials guidelines have been referred to (Figure 1).

Trial design

This is an open-label, randomised, parallel-armed, assessor-blinded clinical trial with random allocation of study participants to two study groups. The trial will be undertaken in the community setting and in retirement homes of Belagavi city.

Participants

Participants will be post-menopausal females fulfilling the following criteria: Aged 46 to 70 years; waist circumference ≥ 80 cm [45]; palmar grip strength of the dominant hand: ≤ 18 kgs in 60–70 years and ≤ 23kgs in 46–60 years [46]; 4-metre gait speed of < 0.8m/s; not involved in any form of regular (regularity defined by at least 3 days per week) physical exercises (yoga/aerobic exercises/gym, etc.) in the most recent three months; and willing to comply with the prescribed diet and exercises for 3 months. Participants will be excluded if they have/are: associated comorbid conditions such as uncontrolled diabetes mellitus (DM) and/or hypertension according to their blood report or a physician's report in the most recent three months; known cases of cardiovascular surgeries/Ischemic heart disease; history of neurological or cerebrovascular disease; diagnosed case of polyarthritis, physical disability or severe joint degenerative condition such as osteoarthritis, spondyloarthropathies; cancer survivor or known case of cancer; diagnosed case of thyroid disease; currently on any weight loss program or medication; any fracture/dislocation or bone/joint surgery within the past year; any major surgical history including surgery on the abdomen/lower limb(s)/spine in the most recent year; known case of severe osteoporosis; history of total joint replacement; medications that affect body fat mass (e.g.: steroids, hormonal therapy); any other medical/surgical/neurological condition that prevents them from participating in the exercise; affected joint mobility due to any cause that affects performing the exercise; any contraindication to the application of a Bioelectrical Impedance Analyzer (BIA) such as a hearing aid, pacemaker, metal implant, kidney disorder, dialysis, diarrhoea, etc.; inability to comprehend commands.

Recruitment

Participants will be invited and informed about the study interventions through flyers/pamphlets, advertisements in regional newspapers, and screening camps conducted at the community level. Interested participants will be screened for eligibility and the study will be explained in detail.

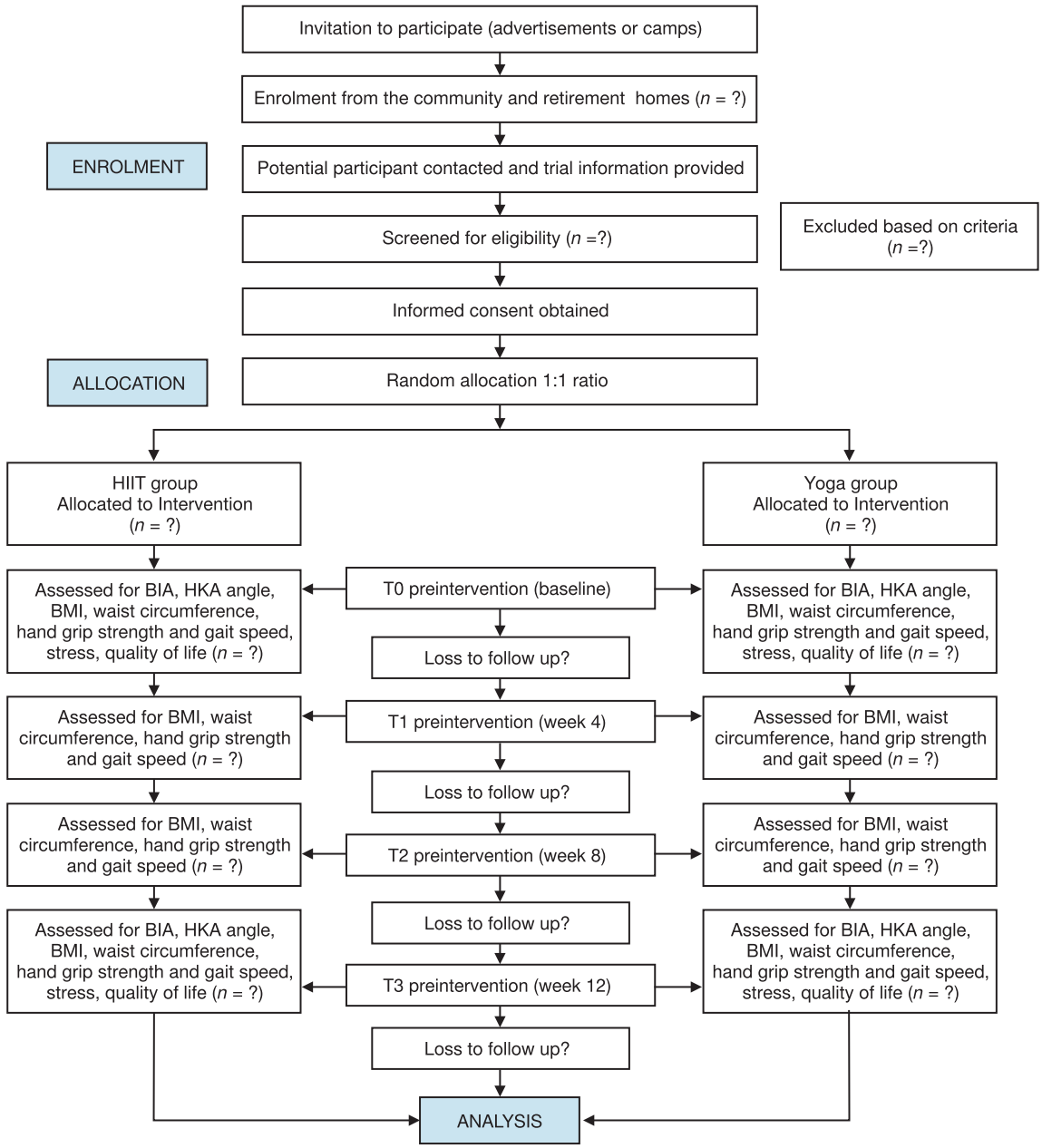

Figure 1. CONSORT flow diagram (SPIRIT guidelines)

Randomisation

Eligible consenting participants will be randomly assigned to either HIIT or Yoga groups. As the study intervention will be in the form of group therapy, multiple groups of 10–12 participants will be created as per the geographical area of the city. The entire group will be randomly allocated to HIIT or Yoga groups by block randomisation with a 1:1 ratio.

Blinding

It will be a double-blinded study. An independent assessor and statistical data analyst will be blinded from the names of the groups by coding the study groups as A or B.

Study interventions

To maintain the quality of reporting of interventions: Template for Intervention Description and Replication (TIDieR) and Consensus on Exercise Reporting Template (CERT) guidelines/checklists are referred to (Appendix 2, 3) [47, 48].

After random allocation to two groups, participants will be invited group-wise on a specific date and time for a 2-hour orientation workshop and counselling. They will be informed about the preparation for the exercise sessions, including mats, footwear, clothing, etc.

HIIT group

The sessions will be conducted by a qualified physiotherapist. Participants will perform three supervised sessions of HIIT per week over 12 weeks. This program will consist of spot jogging/running for 30 seconds, maintaining pace at 70–90% of MHR, and interspersed with low-intensity active recovery, which includes walking for 120 seconds. The exercise intensity will be kept at 70–90% of the maximum heart rate (heart rate max = 208 – 0.7 × age) such that it will be an individualised approach [24, 26]. The detailed exercise protocol and progression are presented in Table 1.

Table 1. High-Intensity Interval Training exercise protocol

Variables	Week 1 to 4	Week 5 to 8	Week 8 to 12
Intensity	70% MHR	80% MHR	90% MHR
Level	Beginner	Beginner–Intermediate	Intermediate
Warm-up (type & time)	General mobility / stretches for all major joints (10 min)	General mobility exercises / stretches for all major joints (10 min)	General mobility exercises / stretches for all major joints (10 min)
Type of exercise	Spot jogging/running (repeated alternately)	Spot jogging/running (repeated alternately)	Spot jogging/running (repeated alternately)
Single exercise bout time	30 s	30 s	30 s
Exercise bouts (*n*)	6	8	10
Total exercise time	3 min	4 minutes	5 minutes
Recovery exercise type	Brisk walking (repeated alternately)	Brisk walking (repeated alternately)	Brisk walking (repeated alternately)
Single active recovery exercise time	120 s	120 s	120 s
Recovery bouts (*n*)	7	9	11
Total active recovery exercise time	14 min	18 min	22 min
Total exercise time	30–35 min	35–40 min	40–45 min
Cool down (type & time)	Stretching of major muscles and breathing exercises (10 min)	Stretching of major muscles and breathing exercises (10 min)	Stretching of major muscles and breathing exercises (10 min)
Supervised sessions/week	3	3	3
Home exercise sessions / week (Brisk walking)	2	2	2
Frequency	5 sessions per week	5 sessions per week	5 sessions per week

MHR – maximum heart rate

Table 2. Hatha Yoga exercise protocol

Variables	Week 1 to 4	Week 5 to 8	Week 8 to 12
Intensity	Beginner	Beginner–Intermediate	Intermediate
Warm-up (type & time)	General mobility / stretches exercises for all major joints (10 min)	General mobility exercises / stretches for all major joints (10 min)	General mobility exercises / stretches for all major joints (10 min)
Type of exercise	Basic asanas with suryanamaskaras	Basic asanas with suryanamaskaras	Basic asanas with suryanamaskaras
Repetitions	Asanas (any 2): 2 to 3 reps Suryanamaskara (3–6)	Asanas (any 2): 2 to 3 reps Suryanamaskara (7–12)	Asanas (any 2): 2 to 3 reps Suryanamaskara (13–20)
Cool down (type & time)	Savasana & pranayama (10 mins)	Savasana & pranayama (10 min)	Savasana & pranayama (10 min)
Total exercise time	50–60 min	50–60 min	50–60 min
Supervised sessions / week	3	3	3
Home exercise sessions / week (Brisk walking)	2	2	2
Frequency	5 sessions per week	5 sessions per week	5 sessions per week

Yoga group

A certified yoga trainer will conduct the yoga sessions. Participants will practise yoga for 1 hour including warm-up, Yoga poses (any 2 repeated 2–3 times progressing from simple to complex poses), Sun salutation (repetitions 6–20) incrementally, Pranayama, and cool down (Savasana) [31, 35]. Three supervised yoga sessions per week will be conducted for 12 weeks. Table 2 presents with comprehensive exercise prescription for the yoga group.

Diet

A certified nutritionist will prepare the diet program. A printed diet program booklet in regional and English languages will be provided to study the participants to follow for 12 weeks.

The diet chart comprises a high-protein, low-fat, fat-carbohydrate diet along with a timely menu with portion sizes. The preintervention diet that the participant followed will be noted, total calories calculated and a deficit of 600 calories will be prescribed with an individualised approach.

Relevant concomitant care

Both interventions will begin with a warm-up and end with a cool-down. Home exercise for both groups will include brisk walking as per the individual's own capacity for 30–40 minutes to be performed on the two alternative days each week on which study intervention is not scheduled. Intervention for HIIT and Yoga will be conducted in a large exercise hall (Tables 1, 2). Participants will be told to refrain from any medications, other forms of exercise, or diets for weight loss until the study is completed. They will also receive a list of permitted/prohibited eateries.

Adherence to interventions

The participants will be provided a comprehensive log diary to mark their daily compliance with the exercise and diet during the study period, which will be reviewed every two weeks and feedback given. Also, the investigator will ensure adherence to reminder messages.

Criteria for dropout

– Participant misses more than 12 (20%) of the total 60 exercise sessions
– Participant misses any two of the three follow-up evaluations/assessments
– Participant is unwilling or unable to continue the exercise for any personal or medical reasons
– During the study period, the participant has any medical emergency or their existing comorbid conditions worsen

Criteria for protocol modifications/discontinuation

The protocol will be amended or modified only in the case of any adverse event noted or practical difficulty faced during the conduct of the trial. Should there be any modifications, information will be provided to the Research Ethical Committee for the amendments and permission sought.

Data collection procedures

The outcome assessments will be carried out by a qualified physiotherapist who will be blinded from the group allocation. Demographic characteristics such as age, diet, comorbidities, age of menopause, etc., will be noted (Figure 2).

Primary outcomes

Waist circumference: Waist circumference will be measured in centimetres using a non-stretch fibre tape with participants in a standing position. The measurement will be taken at 1 cm above the umbilicus in complete expiration to ensure reliable measures. Decimals will be rounded off to the nearest 1 cm [49]. The waist circumference will be measured at preintervention (T0), and at the end of the 4th (T1), 8th (T2), and 12th (T3) weeks post-intervention.

Secondary outcomes

Criteria for diagnosing sarcopenia: Sarcopenia will be determined by the cutoffs given by AWGS criteria as follows: low Appendicular Skeletal Muscle Index by BIA with ≤ 5.7 kg/m^2 for females; diminished muscle mass along with reduced mus-

	Enrolment	Allocation	Post allocation			Closeout
TIMEPOINT	**$-t_1$**	**0**	**T_0/Baseline**	**T_1/Week 4**	**T_2/Week 8**	**T_3/Week 12**
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
HIIT			X	X	X	X
Yoga			X	X	X	X
ASSESSMENTS:						
Waist circumference	X		X	X	X	X
Hand grip strength	X		X	X	X	X
Gait speed	X		X	X	X	X
Body impedance analysis			X			X
Body mass index			X	X	X	X
Hip-knee-ankle angle			X			X
SF-36			X			X
Perceived stress score			X			X

HIIT – high-intensity interval training, SF-36 – 36-Item Short Form Survey

Figure 2. Schematic diagram of schedule of enrolment, interventions, and assessments (participant timeline)

cle strength [Females ≤ 18 kgs] or physical performance by 6 m or 4 m walk test with < 1.0 m/s or < 0.8 m/s, respectively. The appendicular skeletal muscle index (ASMI) is calculated using the formula [5]:

$$\text{ASMI (kg/m}^2\text{)} = \frac{\text{lean body mass of arms + lean body mass of legs (kg)}}{\text{height (m}^2\text{)}}$$

Total Fat and muscle mass using a Bioelectrical Impedance analyser (BIA)

BIA measurement will be performed after overnight fasting of 8 hours [50]. The contraindications for the use of BIA that may cause interference with the readings will be checked for. An Actofit Body Analyzer Pro Max (Actofit Wearables, China) will be used, connected to a smartphone via Bluetooth with the ActoFit Health software application installed (https://play.google.com/store/apps/details?id=com.actofitSmartScale). After entering basic details, the participants are made to stand barefoot on the machine. The machine then analyses various body composition parameters, including fat mass, lean muscle mass, skeletal mass arms and legs, and body fat %. The report is generated in pdf format, initially stored in the connected smartphone and transferred to the electronic database (Figure 1). The BIA outcome will be assessed at pre-intervention (T0), and 12 weeks (T3) post-intervention.

The body mass index (BMI) will be calculated by the BIA based on the height entered into the machine, which will be measured at pre-intervention (T0) and at the end of the 4th (T1), 8th (T2), and 12th (T3) weeks post-intervention, and noted in the unit of kg/m^2.

Hand grip strength (HGS) to measure dynapenia: A Jamar hand dynamometer (reliability is [3,1] = 0.98 and validity [ICC (2, K) = 0.99]) (Manufacturer: Sammons Preston Rolyan, UK. Model no.0205010) will be used to assess HGS. Participants will be made to sit on a chair with an erect back (without an armrest) with the feet well supported on the floor. They will be positioned with the dominant side shoulder adducted, elbow flexed at a right angle, forearm in the mid-prone position, and wrist in 25–30° dorsiflexion. The individual will be told to press the handle of the dynamometer with a maximum-effort isometric contraction. The better of two readings will be considered for analysis with a 1-minute break between the trials to rule out fatigue [5]. This outcome will be measured at pre-intervention (T0) and at the end of the 4th (T1), 8th (T2), and 12th (T3) weeks post-intervention.

Gait Speed by 4-metre Walk test: AWGS 2019 recommends measuring the gait speed by the time taken to walk 4 metres (m) at a normal pace as a measure of physical performance [5]. Using a carpenter's measuring tape, a 4 m walking path with no obstacles will be marked with adhesive black tape. The participants will be instructed to walk at their usual speed from the start to the endpoint and the time taken to complete the 4 m course will be noted. The speed will then be calculated by dividing the distance as a constant (4 m) by the time taken (seconds). A gait speed of ≤ 0.8m/s is considered affected [51]. The average of two trials will be considered for analysis. The outcome will be measured at pre-intervention (T0) and at the end the of 4th (T1), 8th (T2), and 12th (T3) weeks post-intervention.

Lower limb alignment by Hip-knee-ankle angle (HKA angle)

The HKA angle is defined as the angle between the mechanical axes of the femur and tibia, measured by a full-length lower limb radiograph. This is the best estimate of mechanical alignment. The X-ray measurements will be taken by a qualified radiology technician. Participants will undergo full-length lower limb radiographs in a weight-bearing position without footwear, with the tibial tubercles/patella facing forwards. A single exposure anteroposterior radiograph will be obtained using a 51 × 14 inch graduated grid cassette. The two images of the X-ray will be stitched together into a single film image from the pelvis to the bilateral feet with the help of software. The angle marking will be done by the principal investigator to maintain reliability, who will be trained to mark the angle by a radiologist [12]. The HKA will be noted for both sides in units of degrees at pre-intervention (T0), and 12 weeks (T3) post-intervention.

The HKA angle will be marked as per the reference article. The mechanical axis of the femur (FM) will be drawn from the centre of the head of the femur to the centre of the femoral intercondylar point. The mechanical axis of the tibia (TM) will be drawn from the tibial interspinous point to the tibial midplafond. By extending both the FM and TM lines, the angle formed at the point of their intersection is the HKA angle [12]. The angle will be measured by software. For the knee in neutral alignment, the HKA angle is approximately 1–1.5° varus. However, in healthy individuals, the HKA can vary between 1° valgus and 3.2°varus [52].

Secondary/patient-reported functional outcomes: These outcomes will be assessed at pre-intervention (T0), and 12 weeks (T3) post-intervention, where the participants will be provided with printed questionnaires in their regional language. If the participant is illiterate, it will be read out and filled in. The below-mentioned two questionnaires will be translated and back-translated into the required regional languages for the participants who are not conversant in the English language.

36-Item short form health survey: The 36-item short form survey (SF-36) is a standard, reliable, and valid instrument for evaluating Health-Related Quality of Life (HRQOL) in the elderly and adult population. It is a 36-item questionnaire that measures eight parameters of health status with scores from 0 to 100. Higher scores indicate better health status and a mean score of 50 is considered a normative value [53].

Perceived Stress Scale: This is a classic stress assessment instrument that helps to measure individual stress levels. This is a self-administered questionnaire where the questions are asked about one's feelings in the last month. Individual scores on the PSS can range from 0 to 40, with higher scores indicating higher perceived stress [35].

Sample size

The required sample size was calculated based on a previous study considering the waist circumference outcome parameter [18, 24]. The expected mean difference ($x_1 - x_2$) was assumed as 3.6 = *d*. The *SD* values were S1 = 9.8 (Yoga) and S2 = 4.6 (HIIT). With these available values and assumptions, the following formula was applied: $n = 2S^2(Z_{1-\alpha} + Z_{1-\beta})^2 / (x_1 - x_2)^2$, where S = S1 + S2/2 = 7.1, $Z_{1-\alpha}$= 1.96 at 5% α error, $Z_{1-\beta}$ = 1.037 at 85% power, $d = x_1 - x_2 = 3.65$. Hence, the sample size was calculated as 68 in each group. Considering a 20% dropout rate (with the formula n / 1-*d*, where d is the percent dropout) the net total sample resulted in 80 participants in each study group [54].

Safety monitoring

All participants will provide physical fitness approval to participate in the protocol from their family physician. The ex-

pected adverse events will be any joint inflammatory signs or swellings, injuries, light-headedness, chest discomfort, etc. during the exercise session. Should any such adverse event occur, the Ethical Review Committee will be informed, and the participant will be dropped and referred for further investigations and management.

Data management

The data will be fed into MS Excel and tabulated in an Excel spreadsheet, ensuring anonymity. These records will be stored securely with access only to the principal investigator. The intervention groups will be named A & B to keep the statistician blinded. The data will not be shared with anyone without coding or de-identification of participants.

Statistical methods

Statistical analysis will be performed with the SPSS software version 28.0 (SPSS, Inc. Chicago, IL, USA) Descriptive and inferential statistical analysis will be carried out for the collected data. Quantitative variables will be presented as means and standard deviations. Test for normality of distribution will be conducted, based on which, parametric (*Z* test and/or ANCOVA) or non-parametric (Mann–Whitney *U* test or the Wilcoxon signed-rank test) tests will be performed. The primary effect analysis will be by the intention-to-treat principle. A probability value of less than 0.05 will be considered statistically significant.

Ethical approval

The research related to human use has complied with all the relevant national regulations and institutional policies, has followed the tenets of the Declaration of Helsinki, and has been approved by the KLE Academy of Higher Education and Research ethical committee for human subjects for Ph.D. research ref. no. KAHER/EC/21-22/018.

Informed consent

Each participant will be required to sign a written consent form for the study. The patient information sheets and informed consent forms will be given in English and regional languages. If a participant is illiterate, the form will be read out to the participant in their regional language, and a thumb impression will be taken with the witness' signature.

Confidentiality

All information collected from this research project about participants will be kept confidential. A coded form of the group data will be made available in scientific publications/presentations. The data will be stored electronically and password protected. The authors will ensure that the names of the participants will not be published, and due efforts will be made to conceal their identities should their photographs be published.

Discussion

Women's health is a national priority rather than a personal priority. Menopause is a difficult phase in a female's life, associated with numerous challenging health issues that need to be tackled with effective strategies. An editorial suggests obesity, sarcopenia, and osteoporosis may be an interlinked triad in postmenopausal females and stresses the importance of identifying those with the triad and managing them with a well-tailored energy-restricted, high-protein diet and a resistance exercise program [4].

Physical exercise is a crucial non-pharmacological approach to promote health in the context of the ageing population, thereby preventing secondary health complications. The literature review suggests a prescription of resistance training, aerobic training, or a combination of both for the prevention or treatment of sarcopenia [15].

Considering the different nature of exercises of HIIT and Yoga, their effect may vary. HIIT is intense and alternated with active rest periods, while yoga is moderately intense with a uniform, continuous pace. The time-saving nature of HIIT, while being as effective as traditional methods, makes this training more preferred in today's era. HIIT is predominantly a dynamic exercise form, while yoga involves static and dynamic postures. However, HIIT requires strong motivation due to the high level of exertion it poses, whereas yogic postures may be felt as complex or difficult to attain. HIIT involves performing simple exercises such as brisk walking, running, jogging, or similar dynamic exercises, while yoga involves attaining and maintaining yogic postures.

Further, HIIT has been compared with MICT and other traditional exercise forms for obesity and other patient populations, indicating equal effects for both [39]. Yoga has also been compared to traditional aerobic exercises on mental and physical health outcomes, with results suggesting yoga is either equally effective or superior to traditional exercise forms [40, 41]. A literature search resulted in a study conducted on male school students comparing Pilates, power yoga, and HIIT on muscle endurance, with results suggesting HIIT to be better than the other two [42]. Another study compared the feasibility of Bikram yoga (intense yoga) with HIIT in females (20–50 years) with persistent pain, with conclusions stating both to be equally effective [43]. The outcomes of the current trial will provide insight as to what intensity and form of exercise will be effective in bringing about changes in muscle mass, muscle strength, physical functional capacity, and other obesity-related parameters.

The impact of obesity on altering the lower limb alignment, especially in the ageing population, is a known fact [54]. The change in angular alignments may lead to arthritic changes at a later stage. A recent study demonstrated that a 12-week structured exercise program that aims at strengthening knee extensors and hip abductors and fostering control of the lower-limb alignment during dynamic loading conditions improved the ability to control the knee and hip frontal plane kinematics, although with smaller effect sizes [14]. There also have been positive effects of three months of proprioceptive exercise and weight loss intervention by diet on foot posture and loading as well as knee adduction moment and lower limb alignments in elderly and OA knee patients [15, 16].

The trial outcomes will help us determine whether weight reduction will have an impact on knee malalignment and prevention of arthritic changes, thereby exploring the role of exercise and weight loss. Any angular changes that are visible due to the intervention will be confirmatory as the HKA angle is currently accepted as the gold standard measure.

Menopause and ageing are also associated with affected quality of life, mood issues, difficulties in managing stress, etc. Yoga is considered best for managing stress and improving mood [55]. As there is evidence that shows the release of good hormones by exercising, HIIT may also show improvements in mental health parameters and quality of life [56]. Hence, the trial results will also help us determine the positive effects of exercising on reducing perceived stress levels and improving health-related quality of life.

To the best of the authors' knowledge, this will be the first study to explore the impact of weight loss on angular corrections in the lower extremities and to explore the impact of HIIT on Sarcopenia and dynapenia in post-menopausal females.

Limitations

This study poses a few limitations. The body composition parameters, such as fat and muscle mass, will be measured by BIA even though DEXA would be more valid. Due to its cost of assessment, BIA is considered. However, AWGS approves both BIA and DEXA for diagnosing sarcopenia. Maintaining a fixed and consistent timing of the day for follow-up assessments for body composition measures would pose a practical difficulty during the course of the study data collection. The questionnaires used for assessing perceived stress and quality of life were translated and back-translated into regional languages. However, verification of the translated versions through separate studies was not possible before their applications to study participants.

Expected outcomes

The outcomes of the trial will determine whether high-intensity exercise or the hatha yoga approach, which is a moderate-intensity exercise, is beneficial for musculoskeletal issues of ageing females, such as sarcopenia, dynapenia, and lower limb malalignment.

The literature confirms the role of exercise in preventing and treating sarcopenia and dynapenia. The ageing population in general, and postmenopausal females, approach healthcare providers to manage musculoskeletal issues. Thus, the study findings have the potential to reveal substantial information on the role of exercise and its beneficial effects on ageing women's health, which will be of interest to clinicians, exercise trainers, physiotherapists, yoga trainers, and rehabilitation professionals.

Trial status

Presently, trial status is open to recruitment, with 45% of recruitment completed. The enrolment is estimated to be completed in November 2023.

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Disclosure statement

The Radiology Department, Krsnaa Diagnostics Pvt. Ltd., KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi, India provided sponsoring for X-ray with 50% discounted charges for radiological films for assessment of lower limb alignment. The sponsor has and will have no input into the study conceptualisation, design, protocol writing, or manuscript writing. They also bear no interest in the results or outcomes of the study. They play no role in the decision of the authors to submit the report for publication. The authors acknowledge their support.

Conflict of interest

The radiology dept, Krsnaa Diagnostics Pvt. Ltd., KLES Dr. PK Hospital & MRC, Belagavi sponsored X-rays at a 50% discounted price. However, the funding body will have no input into the study conceptualisation, design, protocol writing, or the manuscript's writing. They also bear no interest in the results or outcomes of the study.

Dissemination policy

The study outcomes will be published in a peer-reviewed scientific journal. Authorship for publication will be based on contribution to the study completion from the phase of study idea, concept, and design until the phase of manuscript drafting and write-up.

Availability of data and materials

The trial data will be available on request to the study's Principal Investigator. At the end of the study data collection phase, the dataset will be shared on Mendeley Data, access to which will be given only to those who send requests.

Study sponsor and role

The Radiology Department, Krsnaa Diagnostics Pvt. Ltd., KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi, India provided sponsoring for X-ray with 50% discounted charges for radiological films for assessment of lower limb alignment. The sponsor has and will have no input into the study conceptualisation, design, protocol writing, or manuscript writing. They also bear no interest in the results or outcomes of the study. They play no role in the decision of the authors to submit the report for publication. The authors acknowledge their support.

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Appendix 1. SPIRIT 2013 checklist: recommended items to address in a clinical trial protocol and related documents*

Section / Item	Item No.	Description	Checklist
ADMINISTRATIVE INFORMATION			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	√
Trial registration	2a	Trial identifier and registry name. If not yet registered, the name of intended registry	√
	2b	All items from the World Health Organization Trial Registration Data Set	√
Protocol version	3	Date and version identifier	
Funding	4	Sources and types of financial, material, and other support	√
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	√
	5b	Name and contact information for the trial sponsor	√
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	√
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
INTRODUCTION			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including a summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	√
	6b	Explanation for choice of comparators	√
Objectives	7	Specific objectives or hypotheses	√
Trial design	8	Description of trial design including type of trial (e.g., parallel-group, crossover, factorial, single group), allocation ratio, and framework (e.g., superiority, equivalence, noninferiority, exploratory)	√
METHODS: PARTICIPANTS, INTERVENTIONS, AND OUTCOMES			
Study setting	9	Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where the list of study sites can be obtained	√
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	√
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	√
	11b	Criteria for discontinuing or modifying allocated replication, including how and when they will be administered	√
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g., drug tablet return, laboratory tests)	√
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	√
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure),analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	√
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure 2)	√
Sample size	14	Estimated number of participants needed to achieve the study Objectives and how it was determined, including clinical and Statistical assumptions supporting any sample size calculations	√
Recruitment	15	Strategies for achieving adequate participant enrolment to reach the target sample size	√
METHODS: ASSIGNMENT OF INTERVENTIONS (FOR CONTROLLED TRIALS)			
Allocation			
Sequence generation	16a	Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce the predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions	√
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	√
Implementation	16c	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to interventions	√

Blinding (masking)	17a	Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how	√
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	√
METHODS: DATA COLLECTION, MANAGEMENT, AND ANALYSIS			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	√
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	√
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	√
Statistic al method s	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	√
	20b	Methods for any additional analyses (e.g., subgroup and adjusted analyses)	√
	20c	Definition of analysis population relating to protocol non-adherence (e.g., as randomised analysis), and any statistical methods to handle missing data (e.g., multiple imputation)	√
METHODS: MONITORING			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	√
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
ETHICS AND DISSEMINATION			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board(REC/IRB) approval	√
Protocol amendments	25	Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	√
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	√
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	√
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	√
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	√
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data-sharing arrangements), including any publication restrictions	√
	31b	Authorship eligibility guidelines and any intended use of professional writers	√
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	√
APPENDICES			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	√
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

* It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license. [Informed consent Model: will be produced on request]

Appendix 2. The TIDieR (Template for Intervention Description and Replication) checklist*: information to include when describing an intervention and the location of the information

Item number	Item	Where located**	
		Primary paper (page or appendix number)	Other† (details)
BRIEF NAME			
1.	Provide the name or a phrase that describes the intervention.	Title page	
WHY			
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Pg 4	
WHAT			
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in the training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Pg 7–9	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Pg 6–9	
WHO PROVIDED			
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Pg 6, 7, 9	
HOW			
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Pg 5, 6	
WHERE			
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Pg 5, 6	
WHEN and HOW MUCH			
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Pg 6; Table 1, 2	
TAILORING			
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Pg 6; Table 1, 2	
MODIFICATIONS			
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	
HOW WELL			
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Pg 7	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A	

** Authors – use N/A if an item is not applicable for the intervention being described. Reviewers – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see BMJ 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a randomised trial is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of Item 5 of the CONSORT 2010 Statement. When a clinical trial protocol is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of Item 11 of the SPIRIT 2013 Statement (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Appendix 3. CERT: Consensus on Exercise Reporting Template. A checklist for what to include when reporting exercise programs

Section / Topic	Item #	Checklist item	Location**	
			Primary paper (page, table, appendix)	Other† (paper or protocol, website (URL)
WHAT: materials	1	Detailed description of the type of exercise equipment (e.g. weights, exercise equipment such as machines, treadmill, bicycle ergometer etc.)	Pg 7–9	
WHO: provider	2	Detailed description of the qualifications, teaching/supervising expertise, and/or training undertaken by the exercise instructor	Pg 6–9	
HOW: delivery	3	Describe whether exercises are performed individually or in a group	Pg 5, 6	
	4	Describe whether exercises are supervised or unsupervised and how they are delivered	Pg 5, 6	
	5	Detailed description of how adherence to exercise is measured and reported	Pg 7	
	6	Detailed description of motivation strategies	Pg 7	
	7a	Detailed description of the decision rule(s) for determining exercise progression	Pg 7	
	7b	Detailed description of how the exercise program was progressed	Pg 6	
	8	Detailed description of each exercise to enable replication (e.g. photographs, illustrations, video etc.)	N/A	
	9	Detailed description of any home program component (e.g. other exercises, stretching etc.)	Pg 6; Tables 1, 2	
	10	Describe whether there are any non-exercise components (e.g. education, cognitive	Pg 6	
	11	Describe the type and number of adverse events that occurred during exercise	N/A (Pg 7 / protocol paper)	
WHERE: location	12	Describe the setting in which the exercises are performed	Pg 4, 5	
WHEN, HOW MUCH: dosage	13	Detailed description of the exercise intervention including, but not limited to, number of exercise repetitions / sets / sessions, session duration, intervention/program duration etc.	Pg 4, 5; Tables 1, 2	
TAILORING: what, how	14a	Describe whether the exercises are generic (one size fits all) or tailored whether tailored to the individual	Pg 6	
	14b	Detailed description of how exercises are tailored to the individual	Pg 5, 6; Tables 1, 2	
	15	Describe the decision rule for determining the starting level at which people commence an exercise program (such as beginner, intermediate, advanced etc.)	Tables 1, 2	
HOW WELL: planned, actual	16a	Describe how adherence or fidelity to the exercise intervention is assessed/measured	Pg 7	
	16b	Describe the extent to which the intervention was delivered as planned	N/A (protocol paper)	

The CERT Checklist is designed for reporting details of an exercise intervention. The CERT Checklist should be used in conjunction with a reporting checklist appropriate for the study type e.g. the CONSORT Statement (www.consort-statement.org) for randomised controlled trials, the SPIRIT Statement (www.spirit-statement.org) for a clinical trial protocol. For further guidance regarding reporting guidelines please consult the EQUATOR network (www.equator-network.org)

** Authors – please use N/A if an item is not applicable. Reviewers – please use "?" if information is not provided or not/insufficiently reported

† If the information is not provided in the primary paper that is under consideration, please provide details of where this information is available e.g. in a published protocol, published papers (provide citation details) or on a website (provide the URL).