Manipal Journal of Nursing and Health Sciences

Volume 7 Issue 2 MJNHS

Article 9

7-1-2021

A review of ongoing trials in exercise and physical activity for postmenopausal osteoporosis

Anupama D S Manipal College of Nursing, anupamademlapura84@gmail.com

Judith Noronha Manipal College of Nursing, judith.n@manipal.edu

Kiran K V Acharya KMC Manipal, manipalortho@gmail.com

Mukhyaprana Prabhu KMC Manipal, mm.prabhu@manipal.edu

Baby S. Nayak MCON, Manipal, baby.s@manipal.edu

Follow this and additional works at: https://impressions.manipal.edu/mjnhs



Part of the Nursing Commons

Recommended Citation

D S, Anupama; Noronha, Judith; Acharya, Kiran K V; Prabhu, Mukhyaprana; and Nayak, Baby S. (2021) "A review of ongoing trials in exercise and physical activity for postmenopausal osteoporosis," Manipal Journal of Nursing and Health Sciences: Vol. 7: Iss. 2, .

Available at: https://impressions.manipal.edu/mjnhs/vol7/iss2/9

This Original Research is brought to you for free and open access by the MAHE Journals at Impressions@MAHE. It has been accepted for inclusion in Manipal Journal of Nursing and Health Sciences by an authorized editor of Impressions@MAHE. For more information, please contact impressions@manipal.edu.

Review of ongoing trials in exercise and physical activity for postmenopausal osteoporosis

Anupama D S*, Judith Angelitta Noronha, Kiran K V Acharya, Mukhyaprana Prabhu, Baby S Nayak

Email: anupamademlapura84@gmail.com

Abstract

Osteoporosis is a major public health problem worldwide. While exercise and physical activity have been shown to improve the bone strength and quality of life of osteoporosis patients, there is still no clarity about the quantum, frequency, and pattern of exercises. This review of ongoing trials on exercise and physical activity among postmenopausal osteoporosis was conducted using the World Health Organization International Clinical Trial Registry Platform (WHO-ICTRP). "Postmenopausal osteoporosis" and "Exercise" were the keywords used for the review. The objective of this review was to identify the ongoing trials in exercise and physical activity for postmenopausal osteoporosis. The results revealed that there were 102 trials registered wherein 17 of them met the inclusion criteria. Four trials registered at the Australian New Zealand Clinical Trial Registry were from Australia. Three trials were from India registered at the Clinical Trial Registry of India. China and Germany each had two trials registered. One trail each has been registered in Istanbul, Serbia, Israel, Brazil, and Japan respectively. In the context of the comprehensive management of osteoporosis, there have been quite a few studies that have been registered across the globe for evidence on the impact of exercises. More studies need to focus on the type, duration, and frequency of exercises and physical activity for postmenopausal osteoporosis.

Keywords: clinical trials, evidence, exercise, physical activity, postmenopausal osteoporosis, trial registry, WHO-ICTRP

Introduction

Human bone undergoes two continuous processes - formation and decalcification of bone (Yao et al., 2020).

Anupama D S¹, Judith Angelitta Noronha², Kiran K V Acharya³, Mukhyaprana Prabhu⁴, Baby S Nayak⁵

- Ph D scholar, Manipal College of Nursing, Manipal, Manipal Academy of Higher Education, Manipal, Karnataka, India-576 104
- ² Professor and Dean, Manipal College of Nursing Manipal, Manipal Academy of Higher Education, Manipal, Karnataka, India-576 104
- ³ Professor and Head of Unit IV, Department of Orthopaedics, KMC Manipal, Manipal Academy of Higher Education, Manipal, Karnataka, India-576 104
- ⁴ Professor, Department of Medicine, KMC Manipal, Manipal Academy of Higher Education, Manipal, Karnataka, India-576 104
- ⁵ Professor and Head, Department of Child Health Nursing, Manipal College of Nursing Manipal, Manipal Academy of Higher Education, Manipal, Karnataka, India-576 104

Manuscript received: 22 April 2021 Revision accepted: 25 June 2021

*Corresponding Author

The condition of deficient bone density is termed as osteoporosis. Deficient bone density is caused by either excessive resorption due to disease conditions such as hyperparathyroidism with osteitis fibrosa cystica or with too little bone formation (Rockville, 2004).

The available data published from nine industrialized countries include North America, Europe, Japan, and Australia show that osteoporosis affects up to 49 million people, and the prevalence ranges from nine to 38 percent among women and one to eight percent of men (Wade et al., 2014).

The study published from the Asian countries reveals the spiking trend. The prevalence of osteoporosis has increased in China over the last 12 years, affecting more than one-third of people aged 50 years and older. The incidence of osteoporosis increased with age and was higher amongst women than men (Chen et al., 2016). Osteoporosis risk in women is associated

How to cite this article: Anupama, D. S., Noronha, J. A., Acharya, K. K., Prabhu, M., & Nayak, B. S. (2021). Review of ongoing trials in exercise and physical activity for postmenopausal osteoporosis. *Manipal Journal of Nursing and Health Sciences*, 7 (2). 50-61.

with age, age of the menopause, and post-menopausal duration (Tian et al., 2017). It is more common among postmenopausal women, accounting for around 25 to 30 percent of its occurrence in the United States and similarly in Europe (Keen & Reddivari, 2020). According to WHO standards, a high proportion of elderly Australian women have osteoporosis (Henry et al., 2000). In India, osteoporosis among women is a major public health challenge, as the survey reveals, by 2015, about 230 million people over the age of 50 were confirmed to have been suffering from it (Khadilkar & Mandlik, 2015). Women in South India of the Asian sub-continent often suffers from low bone mineral density (Bala et al., 2016).

Management of postmenopausal osteoporosis encompasses non-pharmacological treatment, e.g., weight bearing, fall-prevention strategies, and therapeutic management (Michaelsson & Aspenberg, 2016). Consistent practice of lifestyle intervention reduces bone deterioration, which comprises adequate calcium and vitamin D supplements, regular exercises, smoking cessation, fall prevention advice, and the regulation of heavy alcohol usage (Rosen & Drezner, 2021). It is definitive that exercises are effective in treating osteoporosis, improving bone strength, and avoiding serious complications such as hip and spine fracture (Andreoli et al., 2012).

A recently published systematic review presented the trend of exercise in maintaining and improving bone mineral density (Benedetti et al., 2018). Earlier, a study conducted to evaluate the efficacy of postmenopausal osteoporosis exercises found that bone mass improvement was modest but significant (Aloia et al., 1978). In addition, a systematic review found that exercises are beneficial in improving and reversing osteoporosis. However, the quantum and types of exercises need to be further studied for postmenopausal osteoporosis (Hamilton et al., 2010). Along with the exercises, yoga is also found to be effective in the rehabilitation of osteoporotic patients (Tuzun et al., 2010).

There is always poor compliance to osteoporosis medications. The fear of drug-related side effects is the most quoted cause for the non-compliance (Papaioannou et al., 2007). Comprehensive management of osteoporosis is focusing on lifestyle modification including exercises with or without medications. Exercise is now gaining acceptance and is still in the initial phase of research (Babu et al., 2013).

Past research publications illustrate the need for further research in this field. Currently, several studies have been registered in the various clinical trial registries around the world. However, the quantum of the studies is unknown. Therefore, this review will enable us to comprehend the number of studies registered, and it would enlighten and proliferate the interest in exercise and physical activity for the management of postmenopausal osteoporosis. It helps to highlight the research trends in this area and facilitates more collaborative research. Thus, the objective of this review was to identify the ongoing trials in exercise and physical activity for postmenopausal osteoporosis.

Materials and Methods

The World Health Organization-International Clinical Trial Registry Platform (WHO-ICTRP) which is a database to access the complete view of research with all completed and ongoing trials in the world was searched. This trial registry can be accessible to those who are into policy formulation and to the public. It maintains transparency and acts as a quality control agency for trials worldwide. However, the collated information in the database is unavailable. database cumulates the data from Australian New Zealand Clinical Trials Registry, Chinese Clinical Trial Registry, Clinical Trials.gov, EU Clinical Trials Register (EU-CTR), Iranian registry of clinical trials (IRCT), ISRCTN, The Netherlands National Trial Register, Brazilian Clinical Trials Registry (ReBec), Clinical Trials Registry – India, Clinical Research Information Service - Republic of Korea, Cuban Public Registry of Clinical Trials, German Clinical Trials Register, Iranian Registry of Clinical Trials, Japan Primary Registries Network, Pan African Clinical Trial Registry, Sri Lanka Clinical Trials Registry, Thai Clinical Trials Registry (TCTR) and Peruvian Clinical Trials Registry (REPEC).

The database was searched using the keywords "postmenopausal osteoporosis" AND exercise OR "physical activity" OR yoga. The ongoing

trials on exercise training (any type of exercise) on postmenopausal osteoporotic patients were included. Completed and published trials were excluded. The trials were searched from their inception to Dec 2020.

Inclusion criteria of the studies for this review

Population. The trials, which included postmenopausal women with osteoporosis above 40 years were included.

Intervention. The study participants had undergone some kind of exercise, physical activity, and yoga. This could be combined with any other treatment modalities.

Recruitment status. Pre-initiation (those studies registered but not recruited) and actively recruiting

The data abstracted from the studies included the database in which the trial is registered, scientific title, year of registration, country, design, inclusion criteria, sample size, type of intervention, duration, and the status of the study.

Results

The initial search revealed 102 studies. Based on the recruitment status, inclusion criteria, type of intervention, only 17 studies were included in the review. There were three studies registered at CTRI of India, four trials from Australia registered at ACTRN, two each from Germany and China, one each from Istanbul, Serbia, Pakistan, and Israel were registered at clinicaltrials.gov. One from Brazil registered at NCN and one from Japan registered at JPRN-UMIN. Among the 85 studies which were excluded, 44 completed their trials, 21 trials included other than postmenopausal women like adolescents, children, men, and premenopausal women, ten trials included other diseases like breast cancer survivors, sarcopenia, etc., two trials were withdrawn or terminated, six trials included other interventions like drugs, fish liver oil, etc. and three studies had no updates on recruitment status. The details of excluded studies are summarized in Figure 1.

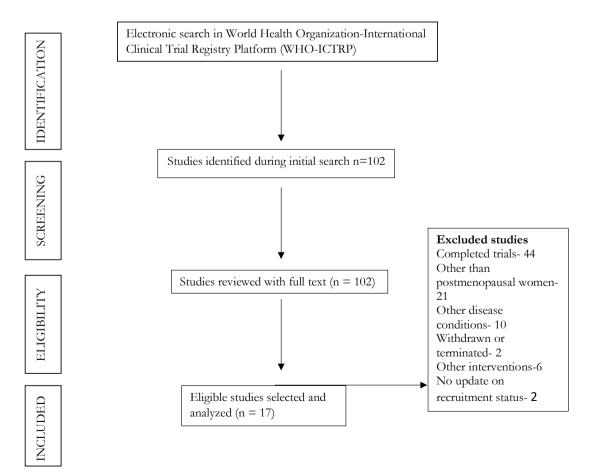


Figure 1. Details of the studies included in the review

The analysis of the studies exhibited that majority of the studies were randomized control trials (n=12), and five studies were of non-randomized trials. The sample size varied from 27 to 428. The interventions included were yoga, high-intensity resistance exercises, aerobic exercise, weight-bearing exercises, progressive resistance training exercises, and "Wu Xing Jian Gu" exercises. Among 16 studies selected, 11 were active and recruiting participants for the studies, the remaining studies were in the preinitiation period or not recruiting. A detailed description is given in Table 1.

The majority (13) of the trials with different interventions have a bone mineral density as the primary or secondary outcome measurement. Two studies have included voga as the intervention with the different outcome measures such as bone health, quality of life, and compliance. Another study has the outcome of static balance score and dynamic balance score. Highintensity resistance exercises intervention is specified to evaluate its effect on BMD in two trials. Aerobic exercise was an intervention in two trials, one of which had enzyme activity of the matrix as an outcome measure, and bone mineral density in another trial. Weightbearing exercises and progressive resistance training are the key interventions with changes in the physical disability, isometric leg strength, bone mineral density, postural balance change as the outcome measures. Two trials included pain as the outcome measure.

Discussion

This review provides the current details of the registered studies on the effect of exercise, physical activity, and yoga on postmenopausal osteoporosis, which are underway. There were a minimal number of trials registered across the globe. Maximum trials (4) were registered at ACTRN from Australia, next to it three trials from India at CTRI. China and Germany each registered two trials. One trail each has been registered in Istanbul, Serbia, Israel, Brazil, and Japan. An estimated 75 million people in Europe, the United States, and Japan are affected. In Europe alone, it is estimated that 22 million women between the age group of 50 and 84 years suffer from osteoporosis (International Osteoporosis Foundation, 2020).

Consequently, in comparison to the severity of the osteoporosis problem, the number of trials registered is much smaller.

There are many limitations amongst the trials identified. Firstly, not all the studies were randomized trials. Also, the interventions included in the trials are heterogeneous, such as yoga, high-intensity resistance exercises, progressive resistance training, and whole-body vibration with high-intensity resistance training and Wu Xing Jain gu exercises. Some trials along with exercises found to be paired with other lifestyle changes. The duration of follow-up varied from three months to 16 years. Every type of exercise and physical activity has an impact and effect on the body. Thus, the complexity in combining the exercises makes it very difficult to generalize.

A study conducted in Turkey compared the effects of yoga with classical osteoporotic exercise and found that yoga was effective in improving pain, social functions, and balancing (Tüzün et al., 2010). As per our review, only two trials were registered to evaluate yoga's effectiveness. In comparing standard osteoporotic exercises with yoga, more trials must be necessary. There was a trial registered to evaluate the impact of whole-body vibration in conjunction with exercises. Reported types of exercises in the trials vary from trial to trial. Thus, to establish strong evidence on exercise variety, more detailed work is needed.

The common primary outcome measure in all the studies was bone mineral density. In only one study, it was changed to the enzyme activity of matrix metalloproteinase with functional status improvement.

Further, strength hip fracture and vertebral fracture are the most common complications of osteoporosis (Varacallo & Pizzutillo, 2018). Lifestyle modifications make it more likely to prevent complications and improve the quality of life. In many studies, exercises are found to be effective in improving bone strength and preventing complications in women with postmenopausal osteoporosis. Even then, the pattern and frequency of exercises are still unclear. A current guideline recommends exercises for the prevention and management of osteoporosis. Further, many

 Table 1

 Summary of Ongoing Trials Registered in Various Databases

	1			
	Status	Recruiting	Mot yet recruiting	Mot yet recruiting
	Outcome	Femoral neck BMD Lumbar spine BMD 1 RM for leg extensors. 1 RM for leg extensors 30-second sit to stand test. Time up and go test.	Primary outcome measures: Impact on bone health Secondary outcomes: Quality of life Changes Compliance with dietary modifications Compliance with physical activity and yoga	Primary: BMD lumbar spine secondary: BMD total hip, fat-free mass, maximum leg strength, menopausal complaints, mid-thigh muscle density, para-vertebral muscle density.
	Duration	8 months	2.6 yrs	18 months
	Intervention	In this group, Supervised High-intensity Progressive Resistance Training, High intensity weight bearing/ Impact exercises, and High challenging Balance Training will be given 2 times/week for 40-50 minutes sessions progressively over eight months.	Experiment: Yoga with dietary modifications include a calcium-rich diet, calcium, and vitamin D supplementation along with brisk walking for 30 min. Control: Non-yoga participants will be given a basic bone health care program.	High-Intensity Resistance (HIT-RT) and Endurance exercise (HIIT) Ambulatory, consistently supervised group exercise training (Three training sessions of 40-45 min/week each).
	əzis əldm62	108	140	27
	Inclusion criteria	 Postmenopausal women aged 45-70 years. Body mass index (BMI) <30kg/m2 Community ambulant without walking aid Good general health Willing for exercise therapy 	Women aged 50 - 65 years, Menopausal at least since five years diagnosed as osteoporosis at femur or lumbar spine using DXA Normal ECG findings Cognitive, able to do their day-to-day activities.	48 -58 years postmenopausal women with osteopenia and osteoporosis at the lumbar spine or femoral neck Bone mineral density (BMD) <-1.0 standard deviation (SD) T-Score, WHO)
4353	Design	Randomized controlled trial	Non- randomized, Active Controlled Trial	(Clinical Trial)
ייייי אייייייייייייייייייייייייייייייי	Year of Registn Country	2020 Pakistan	2019 India	2019 Germany
Sufficiently of String 11 tais inclusion in various Fatacus	Scientific title	Effects of High-Intensity Multi-Modal Exercise Training on bone density and functional performance in Postmenopausal women	Bone exercise for life: An intervention model on bone health and quality of life among menopausal women	Effects of an optimized 18-months physical exercise on (Early)-Postmenopausal risk factors in women with Osteopenia and Osteoporosis (Actlife)
باب و دیسانا	Database	gov/US-NLM	CTRI/India	gov/US-NLM
Š	IS &	1	7	m

 Table 1 Cont...

 Summary of Ongoing Trials Registered in Various Databases

Status	Mot yet recruiting	Recruiting	Вестиiting
Outcome	Primary outcome: Quality of life Secondary outcome: Bone health status, physical functional ability and medication adherence.	Static balance score Berg balance test score Dynamic balance score Single leg stance test score Tandem stance test score Tandem walk test score. Timed sit and walk test score.	Primary outcome changes in enzyme activity of matrix metalloproteinase-2, and tissue inhibitor of matrix metalloproteinase 9, and tissue inhibitor of matrix metalloproteinase 1 (TIMP-1) in serum functional assessment of the musculoskeletal system using "Chair Rising Test". Functional assessment of the musculoskeletal system using "Chair Rising Test". Eunctional assessment of the musculoskeletal system using "One-Leg Stance Test". Secondary outcome: Detection of genotypes for the polymorphisms
Duration	6 months	6 months	weeks
Intervention	Lifestyle modification intervention program: Exercises will be taught to a patient once, on their visit to the outpatient department and asked them to practice at least thrice in a week by looking into the video. Brochure on osteoporosis	To learn the exercises, the patients will be referred to a yoga-training program certified by yoga alliance. Both groups will be taught exercise series. The yoga group will be taught "tree pose".	Aerobic exercise will be conducted as a dose walk, 3-5 km/h, lasting 50 minutes per day, at least five days per week, for 12 weeks. Resistance training and balance exercises will be conducted as a group program and will involve exercises to strengthen the muscles of the upper and lower extremities and balance exercises.
əzis əldme2	120	20	100
Inclusion criteria	Postmenopausal women whose bone density score is between 1 and 2.5 ±SD	35–85-year females - Patients with a T score of bone mineral densitometry lower than -2.5.	Females 50-70 years Osteoporosis, diagnosed by central osteo- densitometry.
Design	Randomized, parallel-group trial method	Randomized. Intervention model	(Clinical Trial).
Year of Registn Oount	2019 India	2019 Istanbul	2018 Serbia
Scientific title	Effectiveness of lifestyle modification intervention program on quality of life, bone health status, physical function capacity and medication adherence among postmenopausal women with osteoporosis: A mixedmethod study.	The effect of Yoga Asana 'Vrksasana (Tree Pose)' on balance in the patients with osteoporosis	Influence of specifically designed exercise program on serum matrix metalloproteinase and functional status in women with Postmenopausal Osteoporosis.
Database	CTRI/India	ClinicalTrials. gov/US-NLM	Clinical trials.
ıs 8	4	r _V	9

 Table 1 Cont...

 Summary of Ongoing Trials Registered in Various Databases

Status	Recruiting	Recruiting	Recruiting
Outcome	Primary: Change of physical disability Secondary: Change in lumbar range of motion - flexion and extension, change in pain intensity, change in health-related quality of life.	Primary outcomes: Isometric leg strength is measured by the strain gauge, Grip strength is measured by a grip strength dynamometer, Lower body strength, endurance, and muscular power. Secondary outcomes: Body composition, Quality of life, Functional ability and risk of fall.	Primary outcome: Bone mineral density, bone microarchitecture, lean skeletal muscle mass, Bone turnover markers, c-terminal telopeptide (B-CTX), and procollagen type 1 propeptide (P1NP).
Duration	months	10 weeks	16 weeks
Intervention	Weight-bearing group: Performing exercises in a weight-bearing posture Control group: Non-weight- bearing group performing exercises in a non-weight-bearing posture.	Treatments comprise two one-hour group-based sessions for ten weeks. The first session each week is 100% exercise (progressive resistance training), the second session is 50% education and 50% exercise.	Exercise intervention will involve a progressive increase in the volume and intensity of high-impact exercise, in the form of hopping and skipping.
əzis əldme2	04	45	20
Inclusion criteria	50 years and more women with osteoporosis (T score lower than -2.5) women who had suffered from nonspecific low back pain for the last three months or more.	Both male and female individuals aged 50 years or older who are independently mobile (including with a walking aid). Individuals with a history of, or at risk of sarcopenia, osteoporosis, or poor balance.	45 years and above and experienced menopause- Low BMD (<-1.0 T-score at the hip or lumbar spine). Confirmed by DXA scan
Design	Non- randomized Interventional (Clinical Trial)	Non- randomized trial	Non- randomized trial
Year of Registn Countty	2018 Israel	2018 Australia	2018 Australia
Scientific title	Comparison of the effect 2018 Israel of a weight-bearing protocol and a non-weight bearing protocol on osteoporotic women with chronic low back pain	The effectiveness of group-based exercise physiology services at alleviating multiple morbidities associated with ageing.	Wearable devices for assessing exercise targeting bone health in post-menopausal women with low bone mineral density
Database	Ginicaltrials.	Australia Australia	ACTRN/ Australia
IS ON	_	∞	6

 Table 1 Cont...

 Summary of Ongoing Trials Registered in Various Databases

Status	Recruiting	Recruiting	Recruiting
Outcome	Primary outcome: Postural balance - semi-static – change Secondary outcome: Postural balance - dynamic – change, Muscular strength - Hand grip – change. Muscular strength - Isokinetic dynamometry – change. Muscular strength – one maximal repetition (RM)- change. Body composition and bone mineral density – change.	Primary outcome: Change in areal bone mineral density (BMD) of the total hip (DXA) and lumbar spine. Secondary: BMC at the total hip, BMC Areal Bone Mineral Density (aBMD) at the femoral neck, BMC at the lumbar spine,	Primary outcome: Bone mineral density Level of physical activity Shoulder range of motion. Grip strength Pinch strength Michigan Hand outcome Questionnaire (MHQ) upper extremity function. Quality of life Secondary outcome: Michigan hand outcome Questionnaire (MHQ) upper extremity function
Duration	weeks	8 months	months
Intervention	The experimental group, which will supplement vitamin D3 50,000 IU/ week, is in two capsules (25,000 IU/week each) and perform with a progressive resistance-training program. The placebo group will inject two capsules of equal size, volume, and colouration, composed of lactose, without the vitamin D3 supplement.	High-intensity progressive resistance and impact loading exercise program	Structured exercises involving aerobic, weight bearing, and hand exercises will be given for three months five times a week. Control group: Routine medical care is given by the Physician.
əzis əldme2	40	160	366
Inclusion criteria	- Age > 60 years Osteoporosis or osteopenia (bone mineral density lower than -1.5 standard deviations of the T-score);	45 years postmenopausal women (>=5 years) - Low bone mass (BMD > 1 SD below the age- matched mean) - Community ambulant without walking aid - Good general health - Taking antiresorptive agents	40-65 years Type 2 diabetes mellitus with postmenopausal osteoporosis.
Design	Interventional Randomized prospective clinical trial, double-blind, placebo- controlled intervention	Randomized controlled trial	Randomized, parallel-group, placebo- Controlled trial
Year of Registn Oountt	2019 Brazil	2017 Australia	2017 India
Scientific title	Effects of Vitamin D supplementation in muscle strength and postural balance training in vulnerable elderly women	Effect of high-intensity resistance and impact training on fracture risk in postmenopausal women with low bone mass who may or may not be on antiresorptive bone medication: The MEDEX-OP trial	Effectiveness of structured exercise-based rehabilitation program on quality of life and hand function in type 2 diabetes mellitus with postmenopausal osteoporosis.
Database	gov/ US-NLM	. ACTRN/ Australia	12 CTRI/ India
l2 S	10	11	12

 Table 1 Cont...

 Summary of Ongoing Trials Registered in Various Databases

Status	Not yet recruiting No updates	Recruiting	gnibn99\notheitiniə19
Outcome	BMD BMD	Primary: Bone mineral density PINP S-CTX Athletic ability	Primary: The transition of low back pain by numerical rating scale Secondary: - Bone density, muscle mass, muscle strength, changes in the body's ability Changes in intramuscular fat degeneration Changes in bone metabolism markers Trends of low back pain (JOABPEQ).
Duration	2 yrs	1 × .	Not clear
Intervention	"Wu Xing Jian Gu Exercise" (It is the Chinese form of exercise which includes five elements)	Double leg jump training, stride jump of the way. Each jumping form repeated jumps 8-15 times in a row, enough rest between the groups, five groups. Use of perceived exertion level table (RPE) monitor exercise intensity and be controlled at RPE 13-15 points.	Intervention: Drug therapy (bisphosphonate, vitamin D3) with exercise. Control: Drug therapy (bisphosphonate, vitamin D3) without exercise
əzis əldme2	194	100	72
Inclusion criteria	To meet the WHO diagnostic criteria for osteoporosis, aged 60 to 75 years. - Did not find the tumour or accept the relevant treatment within five years. - Did not use drugs that affect bone metabolism.	Females within 10 years after menopause aged 50-70 years old; total bone mass decreased by more than 37% or T value of small -2.5.	Men and women 50-90 years old osteoporosis patients. In DXA, bone density YAM is less than 80% in either the lumbar spine or femur. Patients that meet the definition of sarcopenia, who have muscle mass reduction.
Design	study study	Interventional study	Randomized control trial
Year of Registn Oountry	2016 China	2016 China	2015 Japan
Scientific title	The study of the clinical effect of appropriate technology 'Wu xing Jian Gu Exercise' on osteoporosis.	Effect of different exercise modes on bone mineral density in postmenopausal women with severe osteoporosis.	Effect of exercise on low back pain from osteoporosis and sarcopenia.
SI Database	3 China	14 ChicTR/ China	15 JPRN-UMIN/ Japan
" Z	13	\vdash	Η

 Table 1 Cont...

 Summary of Ongoing Trials Registered in Various Databases

Status	Recruiting	Active, not recruiting
Outcome	Bone mineral density (BMD) of the left femoral neck	overall-fractures Bone mineral density at lumbar spine and proximal femur. Secondary: Ten-year coronary heart disease. Metabolic syndrome Z-score.
Duration	21 months	16 yrs
Intervention	Intervention arm 1: Participants will stand on the 30 Hz WBV device installed in their home for 10 minutes five days per week for nine months. Compliance is recorded by the device. Arm 2 HiRIT + WBV: Participants will stand on the WBV device installed in their home for ten minutes five days per week for nine months and attend Griffith University for a 30-minute high-intensity resistance and impact training (HiRIT) session, supervised by a trained exercise physiologist or exercise scientist, twice per week for nine months.	Physical exercise Two sessions/week, 50 weeks/year over 12 years of high-intensity exercise training.
ezis eldme	428	20
Inclusion criteria	Women 60 years - at least five-year post- menopause - with low bone mineral density (hip BMD t score less than or equal to -1.0) - with or without anti-absorptive osteoporosis drug with no plans to change therapy for the next 21 months.	48 years and older
Design	controlled trial.	Non- randomized Intervention model.
Registn Country	Australia	2010 Germany
Year of ntsig9A	2015	2010
Scientific title	A semi-blind, block- randomized clinical trial investigating the effects of low-intensity whole-body vibration (WBV) with or without exercise on risk factors for hip fracture in postmenopausal women.	Effects of exercise on fracture risk, bone mineral density and falls in postmenopausal women. A 16-year follow-up of the Erlangen fitness and prevention study.
SI Database No	16 ACTRN/ Australia	17 ClinicalTrials. gov

more study findings are required to ensure the ideal amount of exercise to improve skeletally or to prevent complications such as a fracture (Bittar et al., 2021).

Although exercises are shown to be effective in reversing bone loss, it depends on the individual characteristics of patients with osteoporosis. The quantum of loads of exercise on the skeleton should be chosen with caution. The age-related bone fragility may be avoided with the proper load. There is a need for good evidence to recommend exercise for the therapist (Russo, 2009). However, as per our review, there were only a minimum of 17 trials identified from different countries

Future recommendations for research

In the context of the comprehensive management of osteoporosis, there have been quite a few studies that have been registered across the globe for evidence on the impact of exercises. Such registered trials are also encouraging and triggering in escalating the research in the area covering the quantum, duration, pattern, and exercise frequency. It had extended the avenues for extensive research to benefit therapists and patients. This review report of ongoing trials envisages a forum for multi-centric collaborative research as well as for conjugating the various exercise systems.

Strengths and limitations

This review gives an overall idea about the quantity of the ongoing randomized control trials in the area of exercise, yoga, and physical activity on osteoporosis. Vigorous search methods were included to search the registry. Also, it provides the base for furthermore systematic reviews in this area.

The trials included were registered in the trial registry from the very recent year of 2008. Many trials were registered prospectively, and some have registered retrospectively which may provide varied information after the completion of the study. The review might have missed some of the studies, which were conducted before the mandate for registration. Some authors may not update the status of the study in the trial registry, which would have an impact on accurate data.

Conclusion

The present review of ongoing clinical trials provided information to support existing evidence on several current forward-looking initiatives. The number of trials in this area is only satisfactory. Many non-randomized trials have, however, also been registered. Further, many studies have been combined with other treatment modalities, so it may be difficult to establish the relationship of exercise with osteoporosis. More studies need to focus on the type, duration, and frequency of exercises for postmenopausal osteoporotic patients.

Source of support: None

Conflict of interest: None

Source of support in the form of grants: None

References

Aloia, J. F., Cohn, S. H., Ostuni, J. A., Cane, R., & Ellis, K. (1978). Prevention of involutional bone loss by exercise. *Annals of Internal Medicine*, 89(3), 356-358. https://doi.org/10.7326/0003-4819-89-3-356

Andreoli, A., Celi, M., Volpe, S. L., Sorge, R., & Tarantino, U. (2012). Long-term effect of exercise on bone mineral density and body composition in post-menopausal ex-elite athletes: a retrospective study. *European Journal of Clinical Nutrition*, 66(1), 69–74. https://doi.org/10.1038/ejcn.2011.104

Babu, A. S., Padmakumar, R., & Maiya, A. G. (2013). A review of ongoing trials in exercise based rehabilitation for pulmonary arterial hypertension. *The Indian Journal of Medical Research*, 137(5), 900-906.

Bala, S., Prabha, M., & Krishna, T. P. (2016). Prevalence and risk factors of low bone mineral density with quantitative ultrasonography among south Indian postmenopausal women. *International Journal of Community Medicine and Public Health*, *3*(7), 1735-1740. http://dx.doi.org/10.18203/2394-6040.ijcmph20162034

Benedetti, M. G., Furlini, G., Zati, A., & Letizia Mauro, G. (2018). The effectiveness of physical exercise on bone density in osteoporotic patients. *BioMed Research International*, 2018, 1-10. https://doi.org/10.1155/2018/4840531

Bittar, S. T., Santos, H. H., Leandro, L. S., Oliveira, L. S., & Cirilo-Sousa, M. S. (2021). Chronic Effectiveness of Walking with Blood Flow Restriction on

- the Activation and Strength in Osteoporotic Older Women: A Randomized Clinical Trial. *Preprints*, 2021, 2021030497.
- Black, D. M., & Rosen, C. J. (2016). Postmenopausal osteoporosis. New England Journal of Medicine, 374(3), 254-262.
- Chen, P., Li, Z., & Hu, Y. (2016). Prevalence of osteoporosis in China: a meta-analysis and systematic review. *BMC Public Health*, *16*(1), 1-11. https://doi.org/10.1186/s12889-016-3712-7
- Hamilton, C. J., Swan, V. J. D., & Jamal, S. A. (2010). The effects of exercise and physical activity participation on bone mass and geometry in postmenopausal women: a systematic review of pQCT studies. *Osteoporosis International*, 21(1), 11-23. https://doi.org/10.1007/s00198-009-0967-1
- Henry, M. J., Pasco, J. A., Nicholson, G. C., Seeman, E., & Kotowicz, M. A. (2000). Prevalence of osteoporosis in Australian women: Geelong osteoporosis study. *Journal of Clinical Densitometry*, *3*(3), 261-268. https://doi.org/10.1385/jcd:3:3:261
- International Osteoporosis Foundation. (2020) Bone Health [Internet]. Iofbonehealth.org. [cited 31 July 2020]. Available from: https://www.iofbonehealth.org/
- Keen, M. U., & Reddivari, A. K. R. (2020). Osteoporosis in Females. *StatPearls* [Internet].
- Khadilkar, A. V., & Mandlik, R. M. (2015). Epidemiology and treatment of osteoporosis in women: An Indian perspective. *International Journal of Women's Health*, 7, 841-850. https://doi.org/10.2147/IJWH.S54623
- Michaelsson, K., & Aspenberg, P. (2016). Postmenopausal osteoporosis. *New England Journal of Medicine*, *374*(21), 2095-2097. https://doi.org/10.1056/NEJMc1602599
- Papaioannou, A., Kennedy, C. C., Dolovich, L., Lau, E., & Adachi, J. D. (2007). Patient adherence to osteoporosis medications: problems, consequences, and management strategies. *Drugs & Aging*, 24(1),

- 37-55. https://doi.org/10.2165/00002512-200724010-00003
- Rosen, H. N., & Drezner, M. K. (2021). Overview of the management of osteoporosis in postmenopausal women. *UpToDate*. Retrieved Mar 2021 [Internet]. Available from: https://www.uptodate.com/contents/overview-of-the-management-of-osteoporosis-in-postmenopausal-women
- Rockville. (2004). Bone Health and Osteoporosis: A Report of the Surgeon General. Office of the Surgeon General (US). https://www.ncbi.nlm.nih.gov/books/NBK45513/
- Russo, C. R. (2009). The effects of exercise on bone. Basic concepts and implications for the prevention of fractures. *Clinical Cases in Mineral and Bone Metabolism*, 6(3), 223-228.
- Tian, L., Yang, R., Wei, L., et al. (2017). Prevalence of osteoporosis and related lifestyle and metabolic factors of postmenopausal women and elderly men: A cross-sectional study in Gansu province, Northwestern of China. *Medicine*, *96*(43), e8294. https://doi.org/10.1097/MD.000000000000008294
- Tüzün, S., Aktas, I., Akarirmak, Ü., Sipahi, S., & Tüzün, F. (2010). Yoga might be an alternative training for the quality of life and balance in postmenopausal osteoporosis. *European Journal of Physical and Rehabilitation Medicine*, 46(1), 69-72.
- Varacallo, M., & Pizzutillo, P. (2018). Osteoporosis in spinal cord injuries. In: StatPearls. StatPearls Publishing, Treasure Island (FL)
- Wade, S. W., Strader, C., Fitzpatrick, L. A., Anthony, M. S., & O'Malley, C. D. (2014). Estimating prevalence of osteoporosis: examples from industrialized countries. *Archives of Osteoporosis*, *9*(1), 1-10. https://doi.org/10.1007/s11657-014-0182-3
- Yao, W., Zhang, H., Kulyar, M. F.E. A., et al. (2020). Effect of total flavonoids of Rhizoma Drynariae in thiram induced cytotoxicity of chondrocyte via BMP-2/ Runx2 and IHH/PTHrP expressions. *Ecotoxicology* and Environmental Safety, 206, 111194. doi:10.1016/j. ecoenv.2020.111194



Copyright: ©2021 by the authors. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https://creativecommons.org/licenses/by/4.0/)