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Effectiveness of an mHealth-based impact exercise program for bone health in postmenopausal women: a randomised controlled trial protocol

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Abstract

Background Osteoporosis, a major global health concern, increases fracture risk due to reduced bone mineral density (BMD), particularly in postmenopausal women. Weight-bearing and high-impact exercises are recommended for bone health, yet accurately quantifying mechanical loading outside the laboratory remains a challenge. Without precise tools, it is difficult to assess whether individuals engage in sufficient osteogenic activity. Moreover, poor adherence to structured exercise programs limits their effectiveness. Mobile health (mHealth) technologies offer a promising solution by enabling real-time mechanical loading monitoring in free-living conditions and providing personalized feedback to improve adherence. This study evaluates the effectiveness of an individualized mHealth-based intervention in optimizing exercise adherence and promoting bone health in postmenopausal women through real-time quantification of mechanical loading.

Methods A single-blind randomized controlled trial (RCT) will include 120 postmenopausal women (≤ 10 years since menopause, < 150 min/week of moderate-to-vigorous physical activity). Participants will be randomly assigned (1:1) to an intervention group (mHealth-based impact exercise program) or a control group (usual care). The 9-month intervention will use wearable activity monitors (Fitbit Versa 3) to track step cadence, impact frequency, and intensity. Exercise targets include fast walking (≥ 100 steps/min), progressive jump training (≥ 3.9 G impact forces), and wrist wall strikes for radius bone adaptation. Primary outcomes include changes in BMD (DXA) at the lumbar spine, proximal femur, and distal radius. Secondary outcomes include bone geometry, and bone turnover markers (β-CTX, P1 NP). Functional mobility, muscle strength, physical activity levels, quality of life and adherence will also be assessed.

Discussion This study will provide insights into optimal mechanical loading for osteoporosis prevention and assess the feasibility of mHealth solutions for improving adherence to osteogenic exercise programs. Findings may inform future guidelines on digital health applications for musculoskeletal health. Trial registration: NCT06741956.

Keywords Osteoporosis, Bone mineral density, High-impact exercise, MHealth, Wearable activity monitors

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Background

Osteoporosis is a major public health concern, characterized by the deterioration of bone tissue microarchitecture and low bone mineral density (BMD), leading to reduced bone strength and increased fracture risk [1]. It is estimated that over 200 million people worldwide suffer from osteoporosis, with prevalence expected to rise due to population aging and lifestyle changes [2]. One in three women is expected to experience an osteoporotic fracture during their lifetime [3]. Between 1990 and 2019, the global burden of osteoporosis-related fractures has escalated significantly, with disability-adjusted life years (DALYs) increasing by 121% and mortality rising by 149% [2]. Osteoporosis imposes a significant economic burden on healthcare systems. Direct medical expenses, including medications, occupational therapy, and inpatient and outpatient care, are expected to reach $25 billion in the United States by 2025, while indirect costs, such as loss of productivity, could exceed $95 billion by 2040 [4]. In Europe, osteoporosis-related fragility fractures cost healthcare systems over €56 billion annually [5].

Given the substantial burden of osteoporosis, prevention should be prioritized, with non-pharmacological strategies—such as dietary modifications and regular physical exercise—playing a pivotal role in its management [3]. Physical activity is a cornerstone of osteoporosis prevention, as extensive research has demonstrated its significant impact on bone health and fracture risk reduction [6]. A large-scale longitudinal cohort study reported a 17% lower incidence of osteoporosis among postmenopausal women who engaged in regular exercise [7], while a UK Biobank study found that higher total physical activity levels were associated with a 22% reduced risk of osteoporosis, with leisure-time physical activity exerting the strongest protective effect [8]. Similarly, an 8-year prospective study in Sweden found that women in the highest quartile of physical activity had a 30% lower risk of any fracture and a 54% lower risk of hip fractures, alongside improvements in bone structure, including a 4% larger cortical bone area in the tibia, an increase in tibial cortical BMD and lower cortical porosity in the radius, suggesting enhanced bone microarchitecture [9]. Recent guidelines underscore that while physical activity contributes to increased bone size and strength, its effects on BMD remain modest. Notably, mechanical loading—encompassing both weight-bearing activities and muscle-induced forces—plays a crucial role in bone adaptation by enhancing bone geometry, improving structural integrity, and stimulating osteogenic responses through mechanotransduction. Within this framework, weight-bearing, impact-based exercises generate the necessary ground reaction forces to induce mechanical loading, which is particularly important for maintaining bone strength post-menopause. High-impact activities, such as jumping and resistance training, elicit greater osteogenic stimuli compared to low-impact, weight-bearing activities like walking (Flores et al., 2022). To translate these findings into effective public health strategies, osteoporosis prevention programs should align with the World Health Organization (WHO) recommendations, which advocate for at least 150 min of moderate-to-vigorous physical activity (MVPA) per week—an essential threshold for musculoskeletal health and bone strength optimization [10]. Notably, each additional 60 min of MVPA per day has been linked to a 0.028 g/cm^2 higher BMD in women [11], reinforcing the crucial role of sustained physical activity in osteoporosis prevention.

For exercise to stimulate bone adaptation, mechanical loading must exceed habitual deformation thresholds in the primary load direction, requiring sufficient intensity, frequency, and variability [12]. Effective bone-loading exercise should be dynamic, introduce novel movement patterns, and include intermittent high-intensity impacts, all while being supported by adequate calcium and vitamin D intake. Low-magnitude, repetitive loads are insufficient to drive meaningful skeletal adaptations, highlighting the importance of high-intensity activities for osteoporosis prevention [11]. However, clinical guidelines recommending physical activity remain broad [13, 14], and the optimal dose of exercise—encompassing frequency, intensity, duration, and type—remains unclear [11, 13, 15]. Given that joint loading and bone adaptation are influenced by both exercise selection and intensity, high-impact, weight-bearing activities such as running and jumping provide superior osteogenic benefits compared to low-intensity alternatives [16]. Among the most effective exercise modalities, fast-paced walking has demonstrated significant osteogenic effects. While an increase of 1,000 daily steps correlates with a 0.005 g/cm^2 increase in hip BMD [11], walking speed is equally critical. Speeds exceeding 5–6.3 km/h are associated with greater bone mineral gains, underscoring the importance of both movement quantity and intensity [17–19]. Beyond walking, jumping exercises offer even greater osteogenic benefits. Progressive exposure to impact loading—starting with 10 jumps per day and increasing to 60—at intensities exceeding four times body weight, performed at least four times per week, has been shown to preserve BMD in postmenopausal women [6, 20–24]. Lastly, sustained interventions extending beyond eight months, with session durations of 40–45 min, appear necessary to achieve significant osteogenic effects [19]. While some studies advocate daily impact exercises to maximize adaptation [6], others emphasize the efficacy of short, high-intensity impacts interspersed with rest periods to optimize skeletal recovery [22, 23]. These findings

highlight the need for long-term adherence to structured, high-impact exercise programs to maintain bone strength and prevent osteoporosis.

Despite level 1a evidence supporting these exercise strategies, adherence remains a major challenge. Many patients specifically cite lack of time and transportation difficulties as primary reasons for non-adherence to supervised training programs [25]. To improve long-term engagement, interventions should be easily accessible, incorporate flexible scheduling, and minimize logistical barriers to participation. To increase adherence, strategies such as regular contact with study personnel and adequate exercise monitoring are necessary to ensure safety and confidence [26]. Mobile health (mHealth) technologies offer promising solutions by providing real-time skeletal mechanics data during locomotion. Despite the potential benefits of wearable activity trackers in promoting physical activity in premenopausal women [27, 28], their effectiveness in postmenopausal women remains unexplored. Given the necessity of reaching a minimum threshold of mechanical stimulation for bone adaptation, precise quantification of musculoskeletal loading using wearable activity monitors could be an effective strategy. However, osteoporosis prevention interventions leveraging such technologies are scarce, highlighting the need for further investigation to enhance intervention efficacy and adherence. Therefore, considering the uncertainty surrounding optimal loading patterns for clinically meaningful bone adaptations—primarily due to challenges in quantifying bone-loading forces in clinical settings [29]— this study aims to evaluate the effectiveness of a progressive, structured mHealth-based impact exercise intervention in improving BMD in postmenopausal women over nine months. In addition to assessing BMD as the primary outcome, the study will examine secondary outcomes, including changes in bone structure, body composition, functional mobility, physical activity levels, and quality of life. The study will also assess the feasibility and acceptability of the intervention by measuring participant adherence to prescribed exercise targets, such as step count, jump count, and wrist impacts. Finally, an exploratory analysis will investigate the relationship between adherence to impact-loading exercises (frequency, intensity, duration) and changes in BMD and secondary outcomes, providing insights into the dose–response relationship for osteogenic exercise.

Methods

Study design

This study is a single-blind (assessor), randomized controlled trial (RCT) designed to evaluate the effectiveness of an mHealth-based intervention for osteoporosis prevention in postmenopausal women. Participants will be randomly assigned in a 1:1 ratio, using a computer-generated randomization sequence, to either the Intervention Group (EG): A 9-month lifestyle modification program focused on increasing impact activity and physical activity levels and b) Control Group (CON): Participants will continue with their usual treatment without a structured intervention (Fig. 1). The randomization process will be overseen by an independent researcher who is not involved in participant recruitment, assessment, or intervention delivery to maintain allocation concealment. Random allocation will be implemented using concealed, permuted block randomization (block size of 4 or 6, randomly varied) to prevent prediction of assignment and maintain balance across study arms. A centralized web-based randomization system will generate the assignments, which will be stored securely and accessed only by an independent investigator responsible for participant enrollment. Group assignments will be communicated to participants only after baseline assessments have been completed to minimize selection bias. The study has been approved by the Andalusian Biomedical Research Ethics Committee (approval code: 0486-N- 22) and was registered at ClinicalTrials.gov under the identifier NCT06741956 on December 15, 2024. The intervention is described using the TIDIER checklist and the RCT protocol using the SPIRIT statement (Supplementary file 1). This study will undergo periodic internal audits to ensure compliance with the study protocol, ethical guidelines, and regulatory requirements.

Participants

For this study, the participants will be recruited by medical personnel through the gynecology units of the Virgen del Rocío hospital in Seville. Press releases will be published in local newspapers and on social media (radio, internet, etc.). In addition, information brochures will be distributed in primary care centers and informational meetings will be held with potential participants. Fragility fracture risk factors, independent of BMD, include advanced age, long-term glucocorticoid treatment, low body weight, previous fractures, smoking, and excessive alcohol consumption. Various disorders can lead to accelerated bone loss regardless of age and estrogen status. These secondary causes of osteoporosis include alterations in calcium metabolism or vitamin D deficiency, inflammatory diseases (e.g., rheumatoid arthritis), or chronic kidney disease [30].

Participants will be recruited from postmenopausal women who are over 40 years old and within 10 years of menopause onset. Eligible participants must be physically inactive, defined as engaging in less than 150 min of MVPA per week over the past 6 months, and must provide written informed consent. Informed consent will be

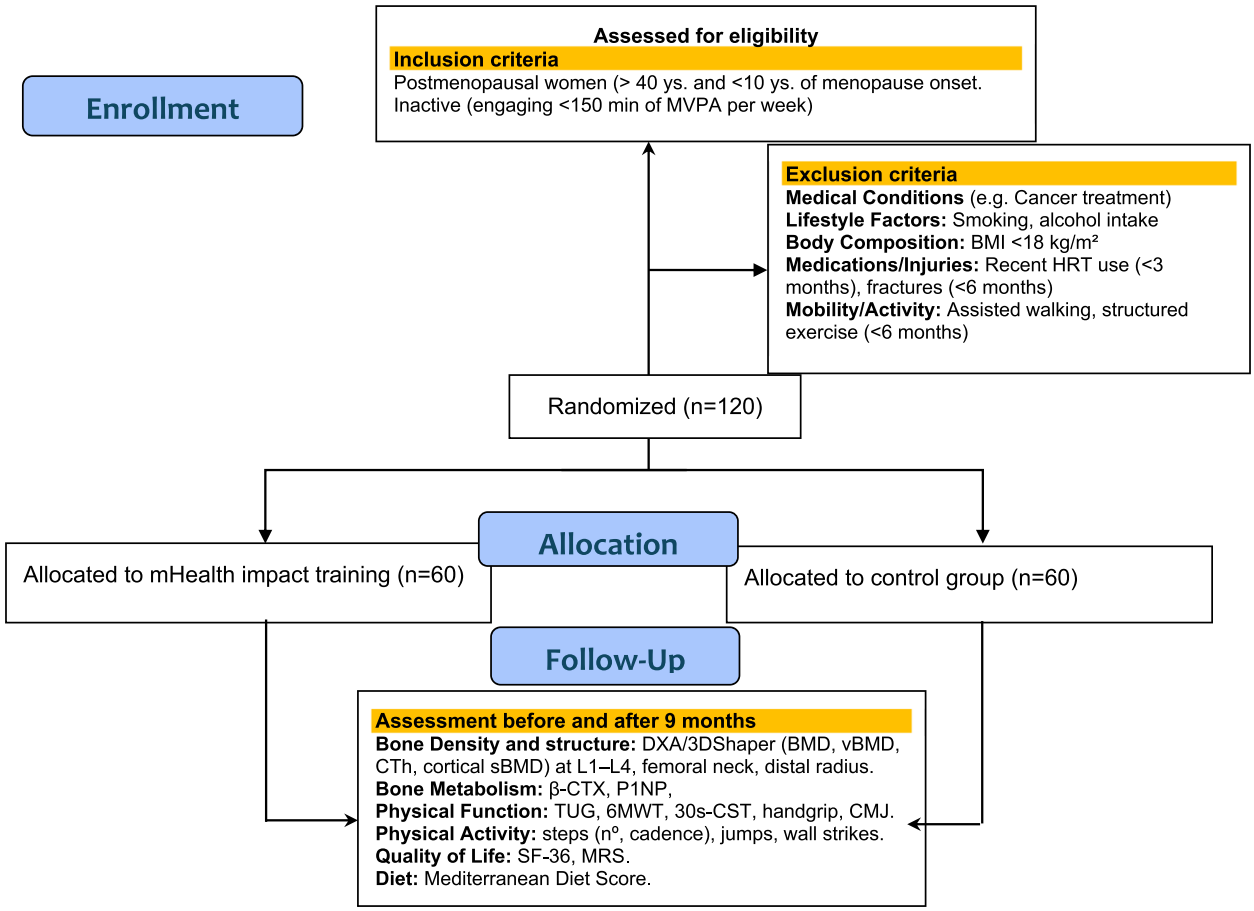

Fig. 1 Flowchart of the study design, including enrollment, allocation, and follow-up assessments. Postmenopausal women meeting the inclusion criteria were randomized into either an mHealth impact training group ($n = 60$) or a control group ($n = 60$). Dual-energy X-ray absorptiometry (DXA) measuring bone mineral density (BMD), volumetric BMD (vBMD), cortical thickness (CTh), Serum levels of procollagen type 1 N-terminal propeptide (P1 NP) and C-terminal telopeptide of type I collagen (β-CTX). Physical function: Timed-up-and-go test (TUG), six-minute walk test (6MWT), 30-s chair stand test (30 s-CST), handgrip strength, and countermovement jump (CMJ). Quality of life: 36-Item Short Form Survey (SF- 36) and Menopause Rating Scale (MRS)

obtained by trained research staff before any trial-related procedures are conducted. Participants must also be willing and able to adhere to the intervention protocol, including regular engagement in high-impact exercises such as jumping. Individuals with contraindications to impact-based activities, including those with pelvic floor dysfunction or related concerns, will be screened to ensure their ability to safely participate in the intervention. Exclusion criteria include surgically induced menopause or current cancer treatment, a BMI below 18 kg/m^2, excessive alcohol consumption (> 14 standard drinks per week), and active smoking. Additionally, women using hormone replacement therapy in the last 3 months, or experienced any fractures in the upper or lower limbs within the previous 6 months will be excluded. Finally, individuals with mobility impairments requiring assistance for walking or those who have participated in structured exercise programs in the past 6 months will not be eligible for inclusion.

This study employs a single-blind design, in which outcome assessors will be blinded to participant allocation. Researchers conducting DXA scans and other outcome assessments will not be informed of group assignments, and participants will be instructed not to disclose their allocation during follow-up visits. Due to the nature of the intervention, it is not possible to blind participants or exercise supervisors to group allocation. However, statistical analyses will be conducted by a blinded researcher, with intervention and control groups coded to ensure unbiased data interpretation. Participants who request it will receive a plain-language summary of the findings. There are no publication restrictions, and findings will be disseminated following open-access principles whenever possible.

Lifestyle intervention

Program to increase physical activity and impact loading

For the intervention, a Fitbit Versa 3 wearable device will be used to monitor step count, step cadence (steps per minute), impact frequency, and impact intensity. The device is linked to the Weapom app, which will provide real-time feedback on the achievement of daily impact-related goals within the intervention program. The research team will remotely supervise participants to ensure compliance with the programmed objectives and will be available to guide them throughout the entire process. This supervision will include regular progress reviews, feedback on performance, and addressing any questions or concerns that may arise during the intervention. Participants will be guided to reach the following milestones, as detailed in Table 1, which provides a comprehensive description of the program. Additionally, Fig. 2 presents a screenshot of the WEAPOM App, where the different objectives for a given day can be observed.

Fig. 2 Screenshot of the WEAPOM App

a) Step Goals

1. Participants will be encouraged to achieve 10,000 steps per day as a primary objective. While this is the primary objective, our program includes progressive targets ranging from 8,000 to 12,000 steps. This approach aligns with evidence suggesting that health benefits, including reductions in morbidity and mortality, can be achieved with lower step counts. For instance, Lee et al. and other studies have demonstrated that as few as 8,000 steps per day are associated with significant health improvements, including reduced risk of all-cause mortality and cardiovascular disease [31].
2. Cadence: Fast walking (e.g., >5–6.3 km/h) is recognized as a key factor in improving BMD. Given the challenges of accurately assessing walking speed in free-living conditions, *step cadence (steps per minute)* may serve as a reliable proxy for intensity. To estimate cadence, a recommended walking speed of approximately 5 km/h and an average stride length of 0.66–0.71 m for adult women was considered [32]. Thus, a walking speed of 5 km/h corresponds to an estimated cadence of 115–125 steps per minute. According to Tudor-Locke et al., ≥100 steps/min is a reliable threshold for moderate-intensity walking, while ≥130 steps/min is indicative of vigorous intensity [33]. Consequently, a cadence from 100 to 125 steps/min was considered in the current study. The WEAPOM app will track the number of daily minutes spent above the cadence threshold set for each day (e.g., 30 min above 115 steps/min). This data will then be used to determine whether participants meet the WHO's recommendation of at least 150 min of MVPA per week [10].

b) Jump training: research indicates that progressively increasing from 10 to 60 jumps per day that generate impact forces exceeding 4 times body weight (BW), performed at least four times per week, is effective for bone adaptation. However, accurately monitoring these impact forces outside the laboratory—where force platforms are unavailable—remains challenging. Notably, physical activities that produce acceleration levels greater than 3.9 G have been positively correlated with improvements in hip BMD [34].

Since an acceleration of 1G produces a force equal to 1 BW, an acceleration of 3.9 G naturally yields an impact force of 3.9 BW regardless of the individual's mass. Based on this principle, the current study will implement a jump training program in which participants progressively increase from 40 to 70 vertical and multidirectional jumps per day. Only jumps generating accelerations exceeding 3.9 G (38.3 m/s^2) will be recorded. The jumps will be organized into 3–5 sets of 10–20 repetitions, with a minimum rest period of 1–2 min between sets, and participants will perform the regimen 4 to 7 days per week to optimize osteogenic stimulation.

c) Wrist impact exercises: To specifically target radius bone strength, participants will perform 32 to 60 wall strikes per day (as illustrated in Fig. 3) from an approximate distance of 10–30 cm, ensuring their arms remain fully extended throughout execution. These distances were determined based on average acceleration values recorded in a pilot study involving 40 postmenopausal women. Three acceleration thresholds were established—10 m/s^2, >20 m/s^2, and >30 m/s^2—to ensure a range of intensities capable of effectively stimulating musculoskeletal adaptation while accounting for individual variability. Greenway et al. [35] reported that the fall against wall exercise generates forces of approximately 0.85 BW. However, due to the dissipation of impact forces against the wall, the actual acceleration experienced in this type of exercise is significantly lower, estimated at 10–15% of BW, corresponding to approximately 0.83–1.25 m/s^2. Given the recognized importance of high-impact mechanical loading for bone adaptation, our study establishes higher acceleration thresholds (10, >20, and >30 m/s^2) to ensure sufficient osteogenic stimulation. These values correspond to ~1.0, 2.0, and 3.0 BW, respectively, substantially exceeding the intensities observed in Greenway et al. Our approach aims to optimize cortical bone loading at the distal radius while considering individual variability in impact execution.

This is an mHealth intervention, meaning it is not confined to a specific location. Participants will integrate the program into their daily activities, performing the prescribed exercises in their usual living environments. The use of wearable technology and the WEAPOM app allows for real-time monitoring and guidance, ensuring flexibility and adherence regardless of location. Participants will receive automated feedback from the app on their progress toward the prescribed impact training goals, including the number of jumps exceeding 3.9 G, step targets, and duration of high-intensity walking, ensuring alignment with WHO recommendations for MVPA.

The acceleration achieved during jumps and wrist impact exercises will vary depending on each individual. Participants will have the flexibility to reach the required acceleration thresholds in different ways, according to their preferences and physical capabilities. For example, they may increase execution speed, adjust jump height, or modify the drop distance for wrist impacts. This personalized approach ensures that participants can effectively engage with the intervention while accommodating their own movement patterns and comfort levels. This feedback system will provide personalized performance tracking and adherence monitoring, ensuring

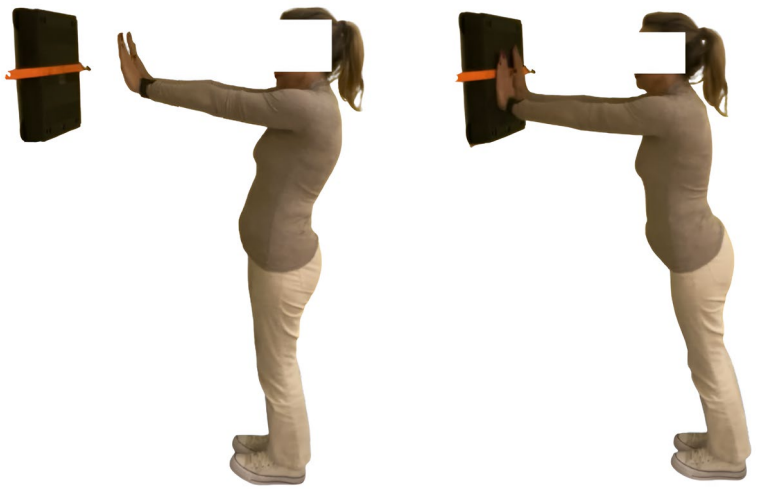

Fig. 3 Illustration of performing a wall strike

Table 1 Comprehensive overview of the intervention program

Month 1					
All-day training routine duration: 45 min | F: 5 d/week					
Session structure	**Type**	**1 st Week**	**2nd week**	**3rd week**	**4 th week**
Impacts	Lower-body	V:40 jumps I: 3.4 G	V:40 jumps I: 3.4 G	V:40 jumps I: 3.4 G	V:40 jumps I: 3.4 G
		V: 8000 steps/day I: 100 steps/min (30 min)	V: 8000 steps/day I: 100 steps/min (30 min)	V: 8000 steps/day I: 100 steps/min (30 min)	V: 8500 steps/day I: 100 steps/min (30 min)
	Upper-body	V = 32 impacts I: ~ 10 cm (> 10 ms^{-2})	V = 32 impacts I: ~ 10 cm (> 10 ms^{-2})	V = 32 impacts I: ~ 10 cm (> 10 ms^{-2})	V = 35 impacts I: ~ 10 cm (> 10 ms^{-2})
Month 2					
All-day training routine duration: 46 min | F: 5 d/week					
Session structure	**Type**	**5 th Week**	**6 th week**	**7 th week**	**8 th week**
Impacts	Upper-body	V:40 jumps I: 3.6 G	V:45 jumps I: 3.6 G	V:45 jumps I: 3.6 G	V:45 jumps I: 3.9 G
		V: 8000 steps/day I: 105 steps/min (30 min)	V: 8000 steps/day I: 105 steps/min (30 min)	V: 8000 steps/day I: 105 steps/min (30 min)	V: 8500 steps/day I: 105 steps/min (30 min)
	Lower-body	V = 35 impacts I: ~ 10 cm (> 10 ms^{-2})	V = 35 impacts I: ~ 10 cm (> 10 ms^{-2})	V = 35 impacts I: ~ 10 cm (> 10 ms^{-2})	V = 40 impacts I: ~ 10 cm (> 10 ms^{-2})
Month 3					
All-day training routine duration: 55 min | F: 5 d/week					
Session structure	**Type**	**9 th Week**	**10 th week**	**11 th week**	**12 th week**
Impacts	Upper-body	V:45 jumps I: 3.9 G	V:50 jumps I: 3.9 G	V:50 jumps I: 3.9 G	V:50 jumps I: 3.9 G
		V: 8500 steps/day I: 105 steps/min (35 min)	V: 9000 steps/day I: 105 steps/min (35 min)	V: 9000 steps/day I: 105 steps/min (35 min)	V: 9500 steps/day I: 105 steps/min (35 min)
	Lower-body	V = 40 impacts I: ~ 20 cm (> 20 ms^{-2})	V = 40 impacts I: ~ 20 cm (> 20 ms^{-2})	V = 40 impacts I: ~ 20 cm (> 20 ms^{-2})	V = 45 impacts I: ~ 20 cm (> 20 ms^{-2})
Month 4					
All-day training routine duration: 57 min | F: 5 d/week					
Session structure	**Type**	**13 th Week**	**14 th week**	**15 th week**	**16 th week**
Impacts	Upper-body	V:50 jumps I: 3.9 G	V:55 jumps I: 3.9 G	V:55 jumps I: 4.3 G	V:55 jumps I: 4.3 G
		V: 9500 steps/day I: 110 steps/min (35 min)	V: 10.000 steps/day I: 110 steps/min (35 min)	V: 10.000 steps/day I: 110 steps/min (35 min)	V: 10.000 steps/day I: 110 steps/min (40 min)
	Lower-body	V = 45 impacts I: ~ 20 cm (> 20 ms^{-2})	V = 45 impacts I: ~ 20 cm (> 20 ms^{-2})	V = 45 impacts I: ~ 20 cm (> 20 ms^{-2})	V = 45 impacts I: ~ 20 cm (> 20 ms^{-2})
Month 5					
All-day training routine duration: 105 min | F: 5 d/week					
Session structure	**Type**	**17 th Week**	**18 th week**	**19 th week**	**20 th week**
Impacts	Upper-body	V:55 jumps I: 4.3 G	V:60 jumps I: 4.3 G	V:60 jumps I: 4.3 G	V:60 jumps I: 4.3 G
		V: 10.000 steps/day I: 110 steps/min (40 min)	V: 10.500 steps/day I: 110 steps/min (40 min)	V: 10.500 steps/day I: 115 steps/min (40 min)	V: 10.500 steps/day I: 115 steps/min (40 min)
	Lower-body	V = 50 impacts I: ~ 20 cm (> 20 ms^{-2})	V = 50 impacts I: ~ 20 cm (> 20 ms^{-2})	V = 50 impacts I: ~ 20 cm (> 20 ms^{-2})	V = 50 impacts I: ~ 20 cm (> 20 ms^{-2})
Month 6					
All-day training routine duration: 110 min | F: 5 d/week					
Session structure	**Type**	**21 st Week**	**22nd week**	**33rd week**	**24 th week**
Impacts	Upper-body	V:60 jumps I: 4.7 G	V:60 jumps I: 4.7 G	V:60 jumps I: 4.7 G	V:60 jumps I: 4.7 G
		V: 10.500 steps/day I: 115 steps/min (40 min)	V: 11.000 steps/day I: 115 steps/min (40 min)	V: 11.000 steps/day I: 115 steps/min (40 min)	V: 11.000 steps/day I: 115 steps/min (40 min)
	Lower-body	V = 50 impacts I: ~ 30 cm (> 30 ms^{-2})	V = 50 impacts I: 30 cm (> 30 ms^{-2})	V = 50 impacts I: ~ 30 cm (> 30 ms^{-2})	V = 50 impacts I: ~ 30 cm (> 30 ms^{-2})

Table 1 (continued)

Month 7					
All-day training routine duration: 112 min | F: 5 d/week					
Session structure	**Type**	**25 th Week**	**26 th week**	**27 th week**	**28 th week**
Impacts	Upper-body	V:65 jumps I: 4.7 G	V:65 jumps I: 4.7 G	V:65 jumps I: 4.9 G	V:65 jumps I: 4.9 G
		V: 11.000 steps/day I: 120 steps/min (40 min)	V: 11.500 steps/day I: 120 steps/min (40 min)	V: 11.500 steps/day I: 120 steps/min (40 min)	V: 11.500 steps/day I: 120 steps/min (40 min)
	Lower-body	V = 55 impacts I: ~ 30 cm (> 30 ms^{-2})	V = 55 impacts I: ~ 30 cm (> 30 ms^{-2})	V = 55 impacts I: ~ 30 cm (> 30 ms^{-2})	V = 55 impacts I: ~ 30 cm (> 30 ms^{-2})
Month 8					
All-day training routine duration: 115 min | F: 5 d/week					
Session structure	**Type**	**29 th Week**	**30 th week**	**31 st Week**	**32nd week**
Impacts	Upper-body	V:65 jumps I: 4.9 G	V:65 jumps I: 4.9 G	V:65 jumps I: 4.9 G	V:67 jumps I: 4.9 G
		V: 12.000 steps/day I: 120 steps/min (40 min)	V: 12.000 steps/day I: 120 steps/min (40 min)	V: 12.000 steps/day I: 120 steps/min (45 min)	V: 12.000 steps/day I: 120 steps/min (45 min)
	Lower-body	V = 60 impacts I: ~ 30 cm (> 30 ms^{-2})	V = 60 impacts I: ~ 30 cm (> 30 ms^{-2})	V = 60 impacts I: ~ 30 cm (> 30 ms^{-2})	V = 60 impacts I: ~ 30 cm (> 30 ms^{-2})
Month 9					
All-day training routine duration: 120 min | F: 5 d/week					
Session structure	**Type**	**23rd Week**	**24 th week**	**35 th week**	**36 th week**
Impacts	Upper-body	V:67 jumps I: 5.1 G	V:67 jumps I: 5.1 G	V:70 jumps I: 5.1 G	V:70 jumps I: 5.1 G
		V: 12.000 steps/day I: 120 steps/min (45 min)	V: 12.000 steps/day I: 125 steps/min (45 min)	V: 12.000 steps/day I: 125 steps/min (45 min)	V: 12.000 steps/day I: 125 steps/min (45 min)
	Lower-body	V = 65 impacts I: ~ 30 cm (> 30 ms^{-2})	V = 65 impacts I: ~ 30 cm (> 30 ms^{-2})	V = 65 impacts I: ~ 30 cm (> 30 ms^{-2})	V = 65 impacts I: ~ 30 cm (> 30 ms^{-2})

V volume, *I* intensity, *F* frequency

participants stay engaged and meet their osteogenic stimulus thresholds throughout the intervention.

Evaluators will monitor participants' compliance with each objective through the platform, ensuring adherence to the intervention. Progress will be regularly assessed, and participants will receive feedback via push notifications or WhatsApp messages to encourage engagement and adherence to the program. This real-time monitoring and communication strategy will help reinforce motivation and ensure that participants meet the prescribed impact and activity targets.

Control group

Participants randomly assigned to CON will receive general advice from medical staff on the positive effects of physical activity and nutritional aspects for the prevention of osteoporosis. Participants in this group will carry the device, but will not have access to the WEAPOM *App*.

Variables

Primary outcome

Bone composition assessment The primary outcome of the study will be BMD, assessed using dual-energy X-ray absorptiometry (DXA) (Lunar Prodigy Advance, GE Healthcare, USA). BMD (g/cm^2) will be measured at multiple skeletal sites, including the lumbar vertebrae (L1-L4), femur of the right leg (femoral neck, Ward's triangle, and greater trochanter), and forearm (distal and midshaft radius). A specialist technician, independent of the study, will conduct the analysis. The obtained BMD values will be expressed in g/cm^2 and converted into T-scores and Z-scores based on reference values for Caucasian females and the Spanish population. The DXA device will be calibrated daily using a phantom to ensure measurement accuracy.

DXA is considered the gold standard for BMD assessment due to its high precision and reproducibility. The device will be calibrated daily using a phantom to ensure measurement accuracy. The reliability of DXA measurements in previous studies has shown intraclass correlation coefficients (ICCs) exceeding 0.99 ((ICC = 0.996; CV < 0.1%), supporting its excellent test–retest reliability [36].

Secondary outcomes

Body composition and anthropometric assessment Total and regional body composition will also be assessed using DXA, providing measurements of lean mass, fat mass, and fat percentage at both whole-body and segmental levels. Additionally, waist circumference (cm) will be measured at the midpoint between the lowest ribs and the iliac crest while the participant is standing (Harpenden tape, Holtain Ltd). Height will be recorded using a stadiometer (SECA, Hamburg, Germany) with participants standing barefoot.

DXA provides a valid and reliable method for assessing body composition, with high ICCs for whole body mass (ICC = 0.999; CV = 2.3%), fat mass (ICC = 0.998; CV = 1.6%), and lean mass (ICC = 0.995; CV = 0.3%) measurements [36]. Anthropometric measures such as waist circumference have been shown to have high reliability (ICC > 0.96) and strong correlations (r > 0.78) with DXA-derived abdominal fat [37].

Bone structure and microarchitecture Bone structure and microarchitecture will be evaluated using 3D-SHAPER (Galgo Medical, Barcelona, Spain), an advanced software algorithm that reconstructs three-dimensional (3D) models from standard hip DXA scans. The 3D-SHAPER software computes several key volumetric and structural bone parameters, including: Trabecular and cortical volumetric BMD (vBMD); Cortical thickness (CTh, mm) and cortical surface BMD (cortical sBMD, mg/cm^2): Reflects the density of cortical bone at the outer surface, which plays a key role in load distribution and mechanical stability.These parameters will be assessed at multiple skeletal sites, including the tibia, femur, and distal radius, to capture site-specific variations in bone structure. By differentiating trabecular and cortical compartments, this approach provides a more comprehensive evaluation of bone fragility and fracture risk, which may not be fully captured by conventional DXA measurements.

3D-SHAPER technology has been validated against high-resolution peripheral quantitative computed tomography (HR-pQCT), demonstrating excellent agreement (r2 > 0.84) with direct volumetric bone density measurements [38]. It has also been shown to improve fracture risk prediction beyond DXA-based areal BMD [39].

Bone biomarkers To minimize the impact of diurnal variation, fasting blood samples will be collected between 08:00 and 10:00 AM using Vacutainer® tubes. Immediately after collection, samples will be processed, and aliquots will be stored at − 80ºC until analysis to preserve biomarker stability. The following bone turnover markers will be measured at baseline and at 36 weeks using electrochemiluminescence immunoassay (ECLIA) on a Modular Analytics E170 analyzer (Roche Diagnostics, Switzerland): a) serum β-CrossLaps (β-CTX): a specific marker of bone resorption, reflecting the degradation of type I collagen by osteoclasts and b) procollagen Type 1 N-Terminal Propeptide (P1 NP): a key marker of bone formation, indicating osteoblast activity and collagen synthesis. These biomarkers will provide valuable insights into bone remodeling dynamics, enabling a more detailed evaluation of the osteogenic effects of the intervention beyond BMD measurements.

Due to the high reproducibility exhibited by these bone turnover markers in clinical studies, the National Bone Health Alliance and the American Association for Clinical Chemistry have recommended them as the most widely accepted biomarkers for evaluating interventions in osteoporosis [40].

Quality of life Quality of Life will be assessed using the Short-Form Health Survey (SF- 36) [41], a validated 36-item questionnaire that evaluates eight health domains, including physical functioning, role limitations due to physical or emotional health, bodily pain, general health perceptions, vitality, social functioning, and mental health. Each domain is scored from 0 to 100, with higher scores indicating better health status. The SF- 36 is widely used in osteoporosis research to assess the impact of musculoskeletal health on overall well-being. The SF-36 has demonstrated excellent psychometric properties in this population, with Cronbach's alpha > 0.80 for all subscales and ICC > 0.85 [42]. It has been widely used in osteoporosis research due to its high construct validity in musculoskeletal health assessments [43].

Symptoms of menopause Participants will complete the Menopause Rating Scale (MRS) questionnaire, which is a menopause-specific quality of life scale developed and validated to assess the severity of symptoms related to menopause [44]. It consists of 11 items, which cover three dimensions: (1) somatic symptoms, which include vasomotor symptoms, cardiac discomfort, sleep problems, and joint or muscle discomfort (items 1–3 and 11, respectively); (2) psychological symptoms, including depressed mood, irritability, anxiety, and physical or mental exhaustion (items 4 to 7, respectively); and (3) urogenital symptoms, including sexual problems, bladder problems, and vaginal dryness (points 8 to 10, respectively). A five-point rating scale for each item allows

participants to describe the perceived severity of symptoms (no complaints, 0; mild, 1; moderate, 2; severe, 3; and extremely severe, 4). The subscales are analyzed by summing the individual scores for each subscale. A value of 17 is used as a cut-off point to determine a high MRS score, indicating an impaired quality of life and severe menopausal symptoms [44]. The MRS has been validated in multiple languages, showing high internal consistency (Cronbach's alpha >0.86) in our country and good consistency and test–retest stability in postmenopausal populations [45]. It is widely used in clinical and epidemiological studies to assess menopausal symptom burden.

Physical function, strength, and muscular power of the lower body A series of common physical function tests related to the risk of falls will be performed to examine mobility and dynamic balance, including: Timed up and go (TUG) [46], to assess dynamic balance and functional mobility. Participants will be instructed to rise from a chair without using their arms, walk 3 m, turn around a cone, return to the chair, and sit down as quickly and safely as possible. Two trials will be carried out with 3 min rest between them, registering the best time (in seconds). The 30 s chair stand test (30 s-CST), in which the number of times in 30 s that the participant can get up from a chair to stand fully from a sitting position with a straight back and feet supported is counted on the ground, with arms crossed over the chest [47]. Participants will perform a 6-m walk test at their fastest but safe walking speed. Gait speed (m/s) will be measured using photocell timing gates (Microgate, Bolzano, Italy). Lower limb explosive power will be assessed using a force platform (Kistler, Switzerland). Participants will perform three maximal CMJ trials with hands placed on their hips to minimize arm contribution. The best jump will be recorded, and key parameters such as jump height (cm), peak power (W), and impulse (N·s) will be analyzed. Furthermore, handgrip strength will be assessed using a digital hand dynamometer (TKK 5401, Takei Scientific Instruments, Japan) to evaluate upper limb muscle strength. Participants will perform three maximal grip strength trials per hand, with the highest value recorded in kilograms (kg).

Physical activity and sedentary behavior Physical activity and sedentary behavior will be objectively measured using a Fitbit Versa 3 triaxial accelerometer (Fitbit Inc, San Francisco, CA, USA), worn on the wrist. Baseline data on physical activity (PA) and sedentary behavior (SB) will be collected for 7 consecutive days before the intervention begins to ensure an accurate pre-intervention assessment. Participants will be instructed to wear the device continuously, except during water-based activities, and will receive guidance on proper usage during an initial appointment prior to any exposure to the intervention protocol. The Fitbit Versa 3 will serve two distinct purposes within the study: as an objective outcome measure, providing data on PA levels, SB patterns, and mechanical loading stimuli throughout the study period. Data will be processed using Fitbit's proprietary algorithms and exported for further analysis. As a component of the intervention, where real-time feedback will be provided to participants through the Fitbit app, particularly regarding daily step count, jump count (> 3.9 G), and wrist drop impacts—key indicators of mechanical loading relevant to bone adaptation.

To address potential concerns regarding the dual role of the Fitbit device, baseline PA and SB data will be collected prior to participants receiving any instruction related to the intervention. During the initial evaluation, researchers will explain the correct use of the device and instruct participants that they will be contacted once the intervention is ready to begin. This ensures that initial measurements reflect habitual activity levels without influence from the study protocol. After baseline data collection is complete, participants will receive training on the intervention, including specific movement patterns and loading strategies designed to optimize bone health.

The primary outcomes related to physical activity will include (1) the total number of daily steps, (2) the number of steps taken above the cadence threshold set for each day, and (3) the total number of weekly minutes spent in MVPA. The WEAPOM app will track and record these variables in real time, ensuring accurate monitoring of participants' adherence to the intervention.

Eating patterns To assess the dietary intake, the Mediterranean Diet Score [48], will be used to evaluate adherence to the traditional Mediterranean dietary pattern. It consists of 11 items (unrefined cereals, potatoes, fruits, vegetables, legumes, fish, olive oil, red meat and derivatives, poultry, dairy products and alcohol), whose scores range from 0 to 5 depending on the frequency of consumption. To ensure the accuracy and reliability of dietary intake data, several process measures will be implemented. Participants will receive detailed instructions on how to complete the Mediterranean Diet Score during an initial briefing session. Additionally, trained researchers will be available to clarify doubts and assist participants if needed. To enhance compliance, reminders will be sent throughout the assessment period. Any missing or inconsistent data will be reviewed and addressed through follow-up contacts with participants. The Mediterranean

Diet Score has demonstrated good construct validity and test–retest reliability [49].

Sociodemographic information and medical history

The history will include questions about coexisting medical conditions that may contribute to bone loss. We include a detailed history to evaluate clinical risk factors for fracture and secondary causes of bone loss. Age, medications associated with bone loss, smoking, alcohol intake, family history of osteoporosis, and/or hip fracture together with information on lifestyles, use of vitamins and medications will be collected. The initial laboratory evaluation will include serum creatinine, calcium, phosphorus, magnesium, parathyroid hormone (PTH), 25-hydroxyvitamin D, and liver function tests.

Sample size calculation The initial sample size was estimated using the G*Power software based on an expected change in femoral neck BMD of 0.011 g/cm^2, which has been considered a clinically significant threshold in previous research [20]. This change corresponds to reported BMD variations in response to mechanical loading interventions and has been used as a reference value in longitudinal bone adaptation studies. To detect this effect with a power of 90% (1-β = 0.90) and a two-tailed α of 0.05, a total of 96 participants (48 per group) is required, assuming a repeated-measures ANOVA with within-subject correlations. Based on prior studies and expected dropout rates in longitudinal interventions, a 25% loss to follow-up was anticipated. To account for this, a minimum of 60 participants per group (N = 120 total) will be recruited. If the actual attrition rate exceeds 25%, additional recruitment strategies will be considered to ensure adequate statistical power. Additionally, intention-to-treat (ITT) analyses will be implemented to mitigate the impact of missing data.

Data management Personal information from potential and enrolled participants will be collected only after obtaining informed consent and handled in compliance with data protection regulations. Each participant will be assigned a unique identification code, and all data will be anonymized to prevent direct identification. Identifiable information (e.g., names, contact details) will be stored separately in the hospital's official registration system, which is a password-protected, encrypted database with access restricted to authorized personnel. Data sharing will occur only in aggregated or anonymized form, ensuring confidentiality. All data will be securely stored for 4 years after study completion and then permanently anonymized or deleted. Compliance with confidentiality protocols will be monitored regularly, and any breach will be reported and managed according to institutional guidelines. Further details are available in the Data Management Plan upon request.

Automated range checks will be implemented to detect out-of-range or implausible values, ensuring data accuracy. Data will be coded and anonymized before analysis, with restricted access granted only to authorized personnel. Regular quality control checks will be performed to verify consistency and completeness. Full details of the data management procedures are documented in the Data Management Plan, which is available upon request. This study does not include an independent data monitoring committee, as it is not a high-risk interventional trial. However, data oversight will be conducted by the principal investigators and a designated research team to ensure data integrity, adherence to the study protocol, and compliance with ethical guidelines. The research team will perform regular data quality checks and monitor for any adverse events or deviations from the protocol. Any major findings or necessary amendments will be reported to the institutional ethics committee and relevant regulatory bodies.

Adverse event reporting and management All adverse events will be systematically collected, assessed, reported, and managed following standardized procedures to ensure participant safety. Participants will be monitored throughout the study, and any solicited or spontaneously reported adverse events related to the intervention or trial conduct will be documented. Adverse events will be recorded at each assessment point through structured interviews, participant self-reports, and clinical observations. Each adverse events will be assessed in terms of severity (mild, moderate, severe), causality (related, possibly related, unrelated), and expectedness based on prior evidence. All serious adverse events will be immediately reported to the ethics committee and relevant regulatory authorities. Non-serious adverse events will be recorded in the study database and reviewed periodically by the research team. Participants experiencing adverse events will receive appropriate medical attention, and necessary modifications to the intervention will be considered if safety concerns arise.

Procedures

Interested participants will first undergo an eligibility screening, including a review of their medical history and lifestyle habits. Those meeting the inclusion criteria will be invited to an in-person appointment, where the study details will be explained, and written informed consent will be obtained. Following enrollment, baseline

assessments will be conducted on a single day to optimize efficiency and minimize participant burden. Upon arrival at the hospital center, participants will complete sociodemographic and clinical questionnaires and undergo biochemical analysis and DXA scanning. Additionally, they will complete physical fitness assessments, including mobility, strength, and impact force evaluations. Participants will also receive additional questionnaires to complete at home (dietary intake, quality of life, and menopausal symptoms). After completing the baseline evaluations, each participant will be provided with a Fitbit Versa 3 accelerometer, which they will be instructed to wear continuously, except during water-based activities. Baseline physical activity data will be collected over nine consecutive days before the intervention begins to ensure an accurate pre-intervention assessment.

To ensure proper usage of the wearable device and app-based exercise monitoring system, participants will undergo a familiarization session. This familiarization process includes standardized testing procedures to assess impact forces and validate the smartwatch's ability to monitor mechanical loading. As part of this process, participants will perform a wall strikes while standing upright, impacting the wall from distances ranging from 10 to 30 cm. They will be instructed to fully extend their elbows (i.e., outstretched hands) and maintain a 90° arm angle relative to the vertical. Each participant will complete ten trials, striking at varying distances on a force platform (Kistler, Switzerland) while simultaneously recording acceleration data using the Fitbit Versa 3 smartwatch. Proper posture and controlled impact force will be emphasized to ensure consistency across trials. Participants will also perform five CMJs under the same experimental conditions to analyze impact forces and their correlation across different measurement tools. CMJ assessments will be conducted using both the force platform and the Fitbit Versa 3 accelerometer worn on the wrist. While the force platform will capture ground reaction forces (N), the smartwatch will record impact acceleration (G-forces). These measurements will be synchronized to establish the relationship between the forces recorded by the platform and those detected by the wearable device, enabling validation of the smartwatch for monitoring mechanical loading in osteoporosis prevention programs.

All participants, regardless of group allocation, will receive a daily vitamin D supplement of 600 IU/day, in accordance with current clinical guidelines for bone health. In participants with vitamin D deficiency, defined as serum 25-hydroxyvitamin D (25(OH)D) levels < 20 ng/mL, additional supplementation will be provided for four months based on baseline serum levels: a) < 20 ng/mL: 25,000 IU per month; b) < 15 ng/mL: 25,000 IU every 15 days and c) < 10 ng/mL: 25,000 IU per week. To ensure appropriate monitoring, serum 25(OH)D levels will be reassessed at four months following supplementation to evaluate treatment efficacy and adjust doses if necessary. A final assessment will be conducted at nine months to track long-term status. This monitoring approach aligns with international recommendations, which suggest reassessment three to six months after initiating supplementation to confirm adequate levels and prevent excessive vitamin D accumulation [50]. Calcium intake will be estimated using a validated 3-day dietary recall. If intake is insufficient, participants will receive supplementation to reach a total daily intake of 1200 mg, in line with osteoporosis prevention guidelines [51].

This approach ensures that both intervention and control groups receive standardized supplementation, while vitamin D-deficient participants are managed according to best-practice clinical guidelines with periodic reassessments to optimize treatment.

Statistical analysis

Data will be tested for normality using the Shapiro–Wilk test. Descriptive statistics will be presented as means and standard deviations (SD) for normally distributed variables and medians with interquartile ranges (IQR) for non-normally distributed variables. Baseline differences between groups will be assessed using independent t-tests for continuous variables and Chi-square tests for categorical variables. If assumptions of normality are violated, the Mann–Whitney U test will be applied instead of the t-test.

To evaluate longitudinal changes and between-group differences, random-effects mixed models will be used, incorporating both fixed effects (group, time, and group × time interaction) and random effects (individual variability). This approach accounts for within-subject correlations and missing data while providing robust estimates of intervention effects over time. In the presence of a significant group × time interaction, Tukey's post hoc test will be conducted to determine specific differences. Cohen's d will be calculated to determine effect sizes, interpreted as small (~ 0.2), medium (~ 0.5), or large (~ 0.8 or greater).

To explore the relationship between intervention adherence and BMD changes, generalized additive models (GAMs) and multivariable regression analyses will be employed. These methods allow for the identification of nonlinear associations and potential dose–response relationships. Additionally, mediation and moderation analyses will be conducted to assess whether baseline characteristics (e.g., physical activity, initial BMD) influence the observed effects.

For physical activity data, the individual daily average number of acceleration peaks will be classified into five predefined mechanical loading categories: 0.3–1.0 g (walking), 1.1–2.4 g (stepping), 2.5–3.8 g (jogging), 3.9–5.3 g (running/jumping), and 5.4–9.2 g (high-impact jumping or drop landing). These data will be normalized to the control group's mean values and compared using appropriate statistical tests. This study is not designed to experimentally determine the optimal dose of mechanical loading for bone adaptation. Instead, secondary analyses will be conducted to explore associations between compliance levels and BMD changes. These analyses aim to provide insights into potential dose–response relationships rather than establish causality.

To enhance data quality and manage large datasets, data preprocessing techniques (e.g., imputation, standardization, discretization) will be applied before implementing machine learning algorithms for feature selection and dimensionality reduction. Hyperparameter tuning will be performed to optimize model performance, and predictive models will be validated against test datasets to identify key factors influencing BMD changes.

For analysis, adherence rates and acceptability ratings will be summarised using descriptive statistics. Regression models will be used to examine whether higher adherence predicts greater improvements in BMD and secondary outcomes. Sensitivity analyses will compare baseline characteristics of high-adherence versus low-adherence participants to identify potential predictors of engagement. All statistical analyses will be performed using SPSS v.25 (IBM Corp., Armonk, NY, USA) and R (R Core Team, Vienna, Austria). The significance level will be set at $p < 0.05$.

Discussion

This study aims to evaluate the effectiveness of an mHealth-based intervention designed to enhance bone health in postmenopausal women through structured impact exercises. Using a combination of wearable technology and digital monitoring, the intervention provides real-time feedback to encourage adherence to osteogenic physical activity. A single-blind, randomised controlled trial will assess changes BMD as the primary outcome, alongside secondary measures of bone structure, body composition, functional mobility, physical activity, and quality of life. By leveraging objective monitoring via wearable sensors, this study seeks to address challenges in both exercise adherence and quantifying mechanical loading in free-living conditions.

This trial makes an important contribution to the field by integrating real-time impact monitoring into an osteogenic exercise program, bridging a gap in current osteoporosis prevention strategies. While high-impact exercise is well-documented to improve bone health, translating these benefits into sustainable, scalable interventions remains a challenge. The use of wearable activity monitors enables precise measurement of movement intensity, providing a novel approach to assessing compliance and dose–response relationships. Findings from this study will inform future guidelines on digital health applications for bone health and contribute to understanding the optimal loading parameters necessary to maintain BMD post-menopause. Furthermore, the study's emphasis on real-world adherence may provide insights into how behavioural engagement with digital health tools influences long-term outcomes. If effective, this intervention has the potential to provide a low-cost, accessible strategy for osteoporosis prevention, reducing reliance on supervised exercise programs and improving long-term engagement in bone-strengthening activities. By harnessing widely available consumer technology, this approach could be scaled beyond clinical settings to support broader public health efforts.

In conclusion, this study seeks to advance the evidence base for mHealth interventions in osteoporosis prevention by combining wearable tracking, real-time feedback, and structured impact exercise. Findings will provide valuable insights into both the physiological effects of impact exercise and the role of digital tools in supporting long-term adherence, with potential applications for future large-scale prevention efforts.

Abbreviations

BMD	Bone Mineral Density
CMJ	Countermovement Jump
CON	Control Group
CTH	Cortical Thickness
DXA	Dual-Energy X-Ray Absorptiometry
HR-pQCT	High-Resolution Peripheral Quantitative Computed Tomography
ICC	Intraclass Correlation Coefficient
MRS	Menopause Rating Scale
MVPA	Moderate-to-Vigorous Physical Activity
PA	Physical Activity
P1 NP	Procollagen Type 1 N-Terminal Propeptide
RCT	Randomized Controlled Trial
SB	Sedentary Behavior
SF- 36	Short-Form Health Survey
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
TIDIER	Template for Intervention Description and Replication
TUG	Timed-Up and Go Test
vBMD	Volumetric Bone Mineral Density
WHO	World Health Organization

Authors' contributions

B.S.; S.T.: Study design and manuscript writing. C.M; J.G; L.C; M.A.O; A.F.; H.G.; G.R.; J.P.; V.F.: Critical manuscript review. A.S.A, M.A.G, M.M.M, E.C, R.D.M: Contributed to the design of clinical variables as part of the medical team. C.R.; H.S.T.: Design and validation of the platform. All authors have read and approved the final manuscript.

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Data availability
The datasets generated and during the current study will be available from the completion of the trial in the repository of the University of Seville, accessible at https://idus.us.es/home.

Declarations

Ethics approval and consent to participate
This study has been approved by the Andalusian Biomedical Research Ethics Committee (Approval Code: 0486-N- 22). All participants will provide written informed consent before participating in the study.

Consent for publication
Not applicable. This manuscript does not contain data from any individual person in any form.

Competing interests
The authors declare no competing interests.

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