

Protocol



# Women's Involvement in Steady Exercise (WISE): Study Protocol for a Randomized Controlled Trial

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Abstract: Background: Physical inactivity is a serious public health problem for people of all ages and is currently the fourth highest global risk factor for mortality. The transition period from adolescence to adulthood coincides with a marked reduction in participation in physical activity, with more than 50% (and up to 80%) of young adults stopping physical activity. This decrease in physical activity is more evident in women than in men. Despite efforts, existing programs face challenges in effectively initiating and maintaining physical activity among individuals, particularly women, for extended durations. To address these limitations, the Women's Involvement in Steady Exercise (WISE) randomized controlled trial (RCT) seeks to assess the efficacy of a digital high-intensity training intervention complemented by nutritional plans and other health-related advice. Methods: The study will be a three-center, randomized (1:1), controlled, parallel-group trial with a six-month intervention period. A total of 300 participants will be recruited at three study sites in Spain, Serbia and Italy. The participants will be randomized to one of the two groups and will follow a six-month program. The primary outcome of the study is the daily step count. Self-reported physical activity, the adherence to the exercise program, body composition, physical activity enjoyment, quality of sleep and physical capacities will also be evaluated.

Keywords: health promotion; exercise; patient adherence; sedentary behavior; mobile applications

# 1. Introduction

Physical inactivity is a serious public health problem for people of all ages and is currently the fourth highest global risk factor for mortality [1]. A lack of physical activity is related to pathologies such as type 2 diabetes, coronary heart disease and certain types of cancer, among others [2]. In addition, in the case of children and adolescents, several studies have shown that those who perform greater physical activity have better physical

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**Copyright:** © 2023 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https://creativecommons.org/license s/by/4.0/). and mental health and better psychosocial well-being than those who lead a sedentary lifestyle [3].

It is estimated that 23% of the adult population and 81% of adolescents (between 11– 17 years) do not meet the physical activity recommendations of the World Health Organization (WHO) [4]. These indications suggest that children and adolescents between 5 and 17 should perform at least 60 min a day of moderate-to-vigorous-intensity exercise, mostly aerobic, as well as incorporating strength/impact activities at least three days a week. On the other hand, the recommendations for adults between the ages of 18 and 64 are that they should perform at least 150–300 min of moderate-intensity aerobic physical activity, or at least 75–150 min of vigorous-intensity aerobic physical activity, combined with muscle-strengthening activities at moderate intensity or greater on two or more days a week [5].

Statistics from the European Union (EU) member states reveal that 60% of individuals aged 15 and above rarely or never participate in exercise or sports, and over 50% seldom or never engage in other forms of physical activity such as cycling, walking, gardening or household chores [6]. The transition period from adolescence to adulthood coincides with a marked reduction in participation in physical activity, with more than 50% (and up to 80%) of young adults stopping physical activity [7]. This decrease in physical activity is more evident in women than in men. According to the data provided in 2020 by the Survey of Sports Habits in Spain, in annual terms, only 53.9% of women practiced sport in 2020 compared to 65.5% of men. The difference between men and women is most evident in younger age groups: 15% of men aged 15–24 never exercise or play sports compared to 33% of women in the same age range [8].

Evidence reports that the best way to combat the consequences of a sedentary lifestyle is to exercise. However, one of the great problems of sports practice is the lack of adherence [9], that is, the lack of continuity to perform some type of physical activity. Barriers to physical activity and sports participation for women include a lack of time, lack of interest or low motivational level, societal norms and expectations related to gender roles and appearance, lack of social support, fear of injury, limited access to exercise facilities or prohibitive costs of training programs, cultural norms and stereotypes and personal beliefs and attitudes, among other factors. These barriers may vary by age, ethnicity and socio-economic status [10–14].

In order to overcome these barriers, different strategies have been described, such as group training, supervised training and different, more "dynamic" exercise modalities such as those that combine moderate aerobic exercise with strength exercise or highintensity functional training [15]. One of these interventions is High Intensity Interval Training (hereinafter HIIT). This training modality is acquiring great acceptance as one of its main advantages is that it is a form of exercise of short duration (the sessions usually last between 20 and 30 min). However, despite its short execution time, its effects are maintained in the long term (up to 48 h after having completed the training [16]). Furthermore, it has been seen in some studies that participants prefer this type of exercise to a traditional exercise program because they enjoy it more and find it more motivating [17]. A review of HIIT programs has shown that a range of HIIT protocols, including those that use cycling, running and bodyweight exercises, can enhance cardiorespiratory fitness and other health markers in both healthy individuals and those with chronic diseases such as diabetes and hypertension [18]. Other studies have suggested that HIIT programs involving Tabata-style intervals (i.e., exercise periods that involve performing an exercise at maximum intensity for 20 s, followed by 10 s of rest, and repeating this cycle for a total of four minutes) can be effective for improving fitness in inexperienced populations [19,20]. However, it is worth noting that a gradual progression and individualized programming are crucial to prevent injury and ensure long-term success with a HIIT program.

The evidence also reports that new technologies could be a great tool to combat the aforementioned adhesion problems. Some studies have shown that new technologies, such

as phone apps or smartwatches, can be a useful support to improve exercise adherence [21,22]. The Xiaomi Mi Band smartwatches have shown good accuracy in the measurement of steps [23,24], although more studies are needed in this regard as there is a lack of literature on the subject. Leveraging behavior change theories and techniques (BCTs) is a critical factor in enhancing the effectiveness of e-health interventions as they enable the targeting of key components for behavior change [25]. The Consolidated Standards of Reporting Trials (CONSORT) statement [26] and the World Health Organization (WHO) [27] have stressed the importance of incorporating a theory-based approach in the creation of digital interventions, according to their recommendations.

On the other hand, nutrition is well-recognized as a central component of a healthy lifestyle. Maintaining a healthy diet is a challenge for adolescents and young adults [28]. Dietary behaviors also tend to worsen during early adulthood, when young individuals transition into independent living [29]. Dietary behavior change programs are needed that appeal to large numbers and diverse types of people who could benefit from the educational/behavior change procedures. Innovative approaches to dietary change are needed to engage participants in enjoyable experiences to reach the largest number of participants.

For these reasons, in order to engage young women in physical activity habits, it is necessary to create a new perspective of promoting exercise. New ways of encouraging physical activity should be included. These should include a combination of new technologies with shorter and more varied exercise sessions that facilitate women's enjoyment of physical activity and appear as a new way of improving their adherence to exercise within a healthier lifestyle.

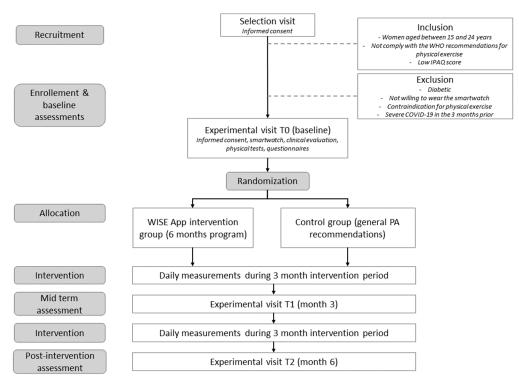
# Study Aims

The primary goal of the Women's Involvement in Steady Exercise (WISE) randomized controlled trial (RCT) is to evaluate the adherence to a six-month HIIT program, accompanied by nutritional plans and other health-related advice, delivered via a mobile application, among sedentary young women aged 15 to 24 years. This trial aims to determine the effectiveness of the exercise intervention by assessing the changes in the participants' daily step count over the six-month period. The secondary objectives include analyzing the medium- and long-term effects of the program on various variables, including physical activity, anthropometric measurements, body composition, physical capacities, well-being and psychological mediators.

# 2. Materials and Methods

# 2.1. Study Design

The WISE experimental RCT consists of three components embedded into a smartphone app: (1) a remote HIIT program with video sessions; (2) an interface that includes health information; (3) an activity monitoring tool. The study will be a three-center, randomized (1:1), controlled, parallel-group trial with a six-month intervention period. Young women will be recruited from the communities at three study sites in Spain (University of Valencia, Valencia), Serbia (University Nikola Tesla, Belgrade) and Italy (SPORTLAB, Parma). This study protocol will be reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [30], and will follow the CONSORT (Consolidated Standards for Reporting Trials) guidelines for the transparent reporting of parallel group randomized trials [31]. To gain a comprehensive understanding of the study design, refer to Figure 1.



**Figure 1.** Study flow chart. WHO, World Health Organization; IPAQ, international physical activity questionnaire; PA, physical activity.

## 2.2. Participants

2.2.1. Eligibility Criteria

Participants eligible for the trial must comply with all of the following:

- 1. Young women aged between 15 and 24 years.
- 2. Sedentary young women who do not comply with the WHO recommendations for physical exercise and with a low international physical activity questionnaire (IPAQ) score, which means that they do not perform at least one of these:
  - Three or more days of vigorous activity for at least 20 minutes a day.
  - Five or more days of moderate-intensity activity.
  - walk at least 30 minutes a day every day.
  - Five or more days of combining activities of moderate or vigorous intensity or walking reached a minimum of 600 MET (min/week).

The presence of one of the following criteria will lead to the exclusion of the participant:

- 1. Young women with diabetes.
- 2. Young women with possible heart problems or another type of contraindication that does not allow physical exercise (for this item the physical activity readiness questionnaire (PAR-Q) survey is used).
- 3. Young women who are not willing to wear the smartwatch during the six-month intervention.
- 4. Young women who have contracted severe COVID-19 prior to the intervention. Severe COVID-19 is defined as dyspnea, a respiratory rate of 30 or more breaths per minute, a blood oxygen saturation of 93% or less, a ratio of the partial pressure of arterial oxygen to the fraction of inspired oxygen (Pao2:Fio2) of less than 300 mm Hg, or infiltrates in more than 50% of the lung field [32].

#### 2.2.2. Recruitment

A total of 300 participants (150 per group) will be recruited between the three countries. Each country will recruit 100 young women for the study. Dissemination of the project will be conducted via email and posters in close contact with universities, schools and local authorities. Through the information of the posters and emails, interested participants will contact the investigators and will be informed about the study in order to decide if they finally want to participate. Those willing to participate will be summoned for a personal interview to check if they meet the inclusion criteria. Participants who meet the inclusion criteria will be invited to participate in the study and will sign a written consent form before being included in the study. At the start of the study, a wearable device (Xiaomi Mi Band 5) will be distributed to all participants.

#### 2.2.3. Sample Size and Power Analysis

Sample size estimations were derived from the primary outcome measure of daily step count, measured using the Xiaomi Mi Band 5. A priori sample size calculation was conducted based on a previous meta-analysis [33], which reported an effect size of d = 0.51 (95% CI 0.12 to 0.91, I<sup>2</sup> = 90%), compared with control groups, for physical activity interventions that included wearables and smartphone apps. Our sample size estimation was based on an intermediate effect size of d = 0.50.

To detect a difference equivalent to an effect size of 0.5 on the primary outcome with 90% power and a two-sided type I error of 0.05, a sample size of 240 is required. Specifically, assuming that the statistical unit is an individual day and considering an intraclass correlation coefficient of 0.5 to account for interindividual and intraindividual variability, a total of 2002 individual days per group (equivalent to 22 participants per group) are necessary. We suggest including a total of 300 participants (150 per group) in order to protect against a potential dropout of 20%, inherent to such a trial.

#### 2.2.4. Randomization, Allocation and Blinding

After the first experimental visit (T0), the participants will be randomized using a computer-generated randomization list into one of the two conditions with a 1:1 allocation. The allocation will be transmitted using numbered (0 = control/1 = Intervention), opaque and sealed envelopes, which will be given to the young women and then registered by the data collectors. The assessors will be blinded to the treatment allocation, although double blinding is not applicable in interventions of this nature as it is impossible to conceal the allocation from the participants. The participants will be instructed not to reveal their allocation to the assessors to ensure unbiased assessment.

## 2.3. Intervention

# 2.3.1. Procedure

All participants will undergo a total of four visits, including the initial inclusion visit and three experimental visits (T0, T1 and T2), as detailed in Table 1. During the selection visit, qualified personnel will make sure that the young women fulfil the inclusion criteria and that they (or their parent/legal representative in case the girl was a minor) sign the informed consent form after explaining the project itself and after responding to all of their questions. One week after the initial visit, the T0 experimental visit will be conducted to measure all of the baseline assessments before the start of the intervention. At the halfway mark of the program (i.e., three months in), a mid-term measurement will be carried out, denoted as T1. The T2 experimental visit will be scheduled at the end of the program (i.e., after six months of intervention). The three experimental sessions will be identical.

				Study	Period			
	Selection Visit	Т0			Interv	rention	L	
TIMEPOINT	<b>M-</b> 1	0	$M_1$	M2	M3/T1	$M_4$	$M_5$	M6/T2
ENROLMENT:								
Eligibility screen	Х							
Informed consent	Х							
Randomization		Х						
INTERVENTIONS:								
Intervention group		←						<b></b>
Control group		←						<b></b>
ASSESSMENTS:								
Step count		←						<b></b>
Adherence		←						<b></b>
IPAQ		Х			Х			Х
Height		Х						
Weight		Х			Х			Х
Body composition		Х			Х			Х
Plank test		Х			Х			Х
HLPCQ		Х			Х			Х
PSQI		Х			Х			Х
PACES		Х			Х			Х
Period pain		Х			Х			Х
CPM		Х			Х			Х
6MWT		Х			Х			Х

Table 1. Timeline for enrolment, interventions and assessments.

IPAQ, International Physical Activity Questionnaire; HLPCQ, Healthy Lifestyle and Personal Control Questionnaire; PSQI, Pittsburgh Sleep Quality Index; PACES, Physical Activity Enjoyment Scale; CPM, Conditioned Pain Modulation; 6MWT, 6 Minutes Walking Test. Continue line: duration over time.

# 2.3.2. Intervention Group

In order to promote behavior change, we implemented 12 BCTs within the intervention program. Table 2 displays how the BCTs have been implemented within the WISE intervention group.

Table 2. BCT implementation in	the intervention gro	oup following Michie et al	's taxonomy [34].

ВСТ	Implementation in the WISE RCT		
Goal setting behavior (1.1)	Set monthly step goal		
Easthack on hohevior (2.2)	Feedback on daily steps via the activity monitoring tool included in		
Feedback on behavior (2.2)	the application with weekly graphs		
	Weekly diary used to document whether participants performed the		
Self-monitoring of behavior (2.3)	exercise video and if they were engaged in any additional exercise		
	during the study period		
Each act on $autama(a)$ of holes $(2.7)$	Bioimpedance sheet with all the information of the changes in their		
Feedback on outcome(s) of behavior (2.7)	body composition after 3 and 6 months of exercise		
Social support (practical) (3.2)	Social days created so the participants can exercise together in real life		
Social support (emotional) (3.3)	Promote social interaction through social media groups		
Instruction on how to perform a behavior (4.1	)		
Behavioral practice/rehearsal (8.1)	Exercise videos		
Demonstration of the behavior (6.1)			

1

2

1

2

20"

Information about healt	h consequences (5	<b>1</b> ) <b>*</b>	ation about the benefits of exercise and a healthy style given through the application
Prompts/cu	ies (7.1)	Push	n notification through the application
Graded tas	ks (8.7)	Exerc	rise program with increased difficulty
	BCTs, behavior randomized co	<u> </u>	ISE, Women's Involvement in Steady Exercise; RCT
	The WIS	E intervention is compos	sed of four main features:
	sessions their own develope consist o the partic will be di than the will last warm-up progressi	a week via the WISE app n home without the need d by two experts in phy f four exercises, and, fro cipants can choose one a different every week. The first, and the intensity week between 20 and 30 min app to 10–15 min of HIIT tr toon for the WISE exercise	he intervention group will receive two HIIT video p (Figure 2A). These sessions will be carried out at d of sport equipment. The exercise program will be rsical activity and sports sciences. Each session will om session 10, with two different intensities so that according to their physical condition. The exercises second session will always have a greater intensity will be increased from week to week. Each session and will follow the following structure: 5–7 min of raining; 5–7 min of stretching. Table 3 shows the se protocol. The complete WISE exercise protocol ssions can be seen in Table S1.
Table 3. WISE exercise protocol progression.			
Month Session	Work Time	Recovery Time	Level
1 $1$ $2$	20"	20"	Initiation and no impact Medium-advanced with impact

3	1	20″	10″	Initiation and no impact	
3 2		20	10	Medium-advanced with impact	
From week 12th, we introduce 2 different intensity levels in each session (one without impact or less demanding) so					
the participants can choice between the 2 levels in order to better adapt their effort					
1	1	30″	20″	Medium	
4 2	2	30	20	Advanced	
5 and 6	1	40″	15″	Medium	
	2	40		Advanced	
	-				

15"

2. Education in healthy habits: once a week, the participants will receive reading material, with an approximate duration of 2 to 5 min, on general advice on nutrition, sleep (Figure 2B) and well-being (Figure 2C), written by experts in the field. Dietary guidelines will also be created by a team of professionals specialized in nutrition to stimulate the participants and give them basic indications on proper eating behavior. These reading materials will be delivered to the participants through the WISE application and will appear by means of a push notification. The complete list of messages for the WISE participants can be seen in Table S2.

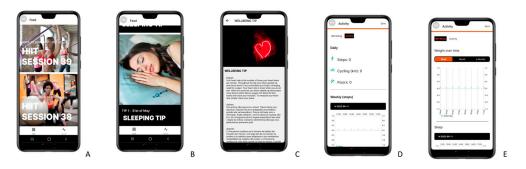
Initiation and no impact

Medium-advanced with impact

Initiation and no impact

- 3. Activity tracker: participants will be able to check their activity at any time of the day through the Xiao Mi Band 5 smartwatch (Figure 2D). The data will also be displayed in the app with weekly charts so participants can see their progression. The participants will also be able to track their weight and their sleep over time (Figure 2E) through the application. Moreover, their heart rate will be recorded. This tool aims to give feedback on behavior and promote self-monitoring of physical activity.
- 4. Motivational activities: in order to motivate the participants to perform the videos, social media, email, WhatsApp groups and/or other channels, such as Viber

(depending on the availability/popularity in each country), will be created for the participants to communicate with each other. In addition, social meetings will be organized through "Open Days" held in each country and transmitted through streaming so all the participants can attend the event. During the "Open Days", talks on nutrition and physical activity will be held, as well as in-person meetings to perform the exercises. Moreover, the participants can expose their doubts and concerns, which can be solved in a personal manner during these events.



**Figure 2.** Screenshots examples of the WISE application. (**A**) HIIT video sessions. (**B**) Sleeping tips. (**C**) Well-being tips. (**D**) The activity monitoring tool. (**E**) The weight and sleep monitoring tool.

## 2.3.3. Control Condition

The participants in the control group will benefit from general physical activity recommendations (at the start of the intervention: general physical activity guidelines) and will also have access to the activity monitoring tool supplied by the smartwatch. The content of both groups is summarized in Table 4.

Table 4. Summary of the groups' content.

Intervention Group (Videos)	Control Group		
50 HIIT video exercise sessions	Physical activity recommendations (at the start of the intervention: general physical activity guidelines) *		
Communication group			
Activity monitoring tool (mobile app + Xiaomi Mi Band 5)	Activity monitoring tool (Xiaomi Mi Band 5)		
Education in healthy habits			
HIIT, High Intensity Interval Training. * At the end of the program, the participants will have acces			

to the HIIT video sessions.

# 2.3.4. Adverse Events

Throughout the experiment, adverse events will be monitored for each procedure. Any adverse events or reactions that are thought to be causally associated with the intervention will be recorded and managed.

#### 2.4. Outcome Measures

## 2.4.1. Primary Outcomes

The primary outcome of this study will be the change in daily steps from baseline to three months and six months. Daily steps will be assessed using the Xiaomi Mi Band 5 smartwatch, a reliable wearable activity tracker that has been validated in previous research [35–37]. Days with missing data, defined as days with fewer than 1000 steps, based on previous literature [38,39], will be excluded from the analysis [40,41] to ensure accurate and comprehensive data representation.

2.4.2. Secondary Outcomes

The secondary outcomes include changes in: (1) physical activity; (2) anthropometric measurements and body composition; (3) physical capacities; (4) well-being. In addition, psychological mediators will also be examined.

The following criteria will be used in order to measure the WISE program adherence [42]:

- Retention (completion): the participants following the WISE exercise videos and showing up to the follow-up measurements.
- Attendance: percentage of videos completed of the total of 50 videos
- Duration: adherence to a minimum of 20 min of exercise two times a week.
- Intensity: intensity levels of the sessions will be assessed at the end of each session using the modified Borg Scale, which measures perceived exertion [43].

These items will be measured through a weekly online exercise diary, where the participants will be asked if they completed both video sessions. They will also be asked about their perceived exertion after each session. This will allow us to assess whether they are following the 20 min of exercise two times a week rule, completing the video sessions, so we can see the number of videos completed at the end of the program.

Table 1 presents the assessment schedule, following the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) schedule template. Table 5 provides an overview of all the outcome measures.

Table 5. Outcomes measures of the WISE RCT.

Outcome	Assessment Method			
Primary outcome				
	The Xiaomi Mi Band 5 smartwatch will be used to assess the daily step			
Daily step count over 6 months	count. Days with missing data and/or days with fewer than 1000 steps will			
	be excluded from the analysis.			
	Secondary outcomes			
	Physical activity			
	Self-reported behaviors will be gathered using the International Physical			
	Activity Questionnaire (IPAQ). The IPAQ assesses walking and activities of			
Self-reported physical activity and	a moderate and vigorous intensity that are performed continuously for at			
sedentary behaviors	least 10 min in all domains of everyday life (i.e., leisure, occupational,			
sedentary benaviors	household and transport) in the last 7 days. The IPAQ demonstrates			
	acceptable levels of test-retest reliability and fair to moderate associations			
	with accelerometer measures [40,41].			
Ar	thropometric data and body composition			
	Using a calibrated digital scale, body mass is measured to the nearest 0.1kg;			
BMI, Body mass and height	height is measured to the nearest 0.1 cm using a wall-mounted stadiometer.			
Divil, Dody mass and height	The BMI is automatically calculated by the body composition analyzer as			
	the ratio of body mass (kg) to height squared (m <sup>2</sup> ).			
	Assessment of body composition is conducted using bioelectrical			
Body composition	impedance analysis with the multi frequency segmented body composition			
	analyzer InBody 230 (InBodyUSA, Cerritos, CA) [44].			
	Physical capacities			
	The plank test protocol requires participants to maintain a static prone			
	position with only forearms and toes touching the ground. Proper form			
	requires feet together with toes curled under the feet, elbows forearm			
Muscle strength	distance apart, and hands clasped together against the floor mat.			
	Participants maintain eye contact with their hands, a neutral spine, and a			
	straight line from head to ankles. The test begins when the participant			
	demonstrates the correct position. Participants are allowed to deviate from			

	the correct position once and can continue the test if they immediately
	resume the correct starting position. The test is terminated on the second
	deviation from the correct position or if the participant does not return to
	the correct position after the first warning [45]. The plank test protocol is a
	reliable test [46] and has been used with children [45] and young adults [46].
	The 6 Minute Walk Test measures aerobic capacity and endurance through
	sub-maximal exercise. The outcome by which to compare changes in perfor-
Endurance	mance capacity is the distance traveled during a period of 6 min. Reference
	equations have been developed for healthy young adults [47], and have
	proved Excellent test-retest reliability, interrater reliability and intrarater re-
	liability for different populations [48–52].
	Well-being
	The Healthy Lifestyle and Personal Control Questionnaire (HLPCQ) will be
	used to examine several dimensions of daily living. The HLPCQ has been
	described as a good tool for assessing the efficacy of future health-promot-
Quality of life	ing interventions to improve individuals' lifestyle and well-being. This
	questionnaire is a 26-item tool in which the respondent is asked to indicate
	the frequency of adopting 26 positively stated lifestyle habits using a Likert-
	type scale (1 = Never or rarely, 2 = Sometimes, 3 = Often and 4 = Always) [53].
	Quality of sleep will be assessed with The Pittsburgh Sleep Quality Index
	(PSQI), a self-administered questionnaire used to evaluate sleep quality dur-
	ing the past month. The validity of the PSQI has been confirmed by several
	studies in different patient populations and languages [54–57]. The PSQI
Quality of sleep	consists of seven clinically derived components that assess sleep difficulty,
Quality of sleep	and the sum of these seven component scores yields a global score of subjec-
	tive sleep quality [57]. The PSQI demonstrates moderate convergent validity
	compared to measures of insomnia and fatigue and good divergent validity
	with measures of daytime sleepiness and circadian phase preference in
	young adults [58].
	Pain intensity will be measured using the visual analogue scale (VAS).
	A 100-mm line bounded by "no pain" on the left (0) and "worst pain possi-
Period pain	ble" (100) on the right will be used to indicate the average pain during the
	period. The minimum clinically detectable difference (MCID) of this scale
	has been set at 30 mm [59]. It is also a scale that has been validated [60].
	Psychological mediators
	The Physical Activity Enjoyment Scale (PACES) is used to evaluate per-
	ceived enjoyment of physical activity during the intervention. The question-
Perceived enjoyment	naire comprises 16 items, where participants rate their feelings about the
	physical activity they have been engaging in using a 7-point Likert scale,
	ranging between 1 (not at all) and 7 (very much) [61]. PACES shows a very
	high internal consistency (Cronbach's alpha = 0.908) and the test-retest relia-
	bility indicates a good temporary agreement (Spearman rho = 0.815, <i>p</i> <
	0.001) in adolescents with overweight and obesity [62].
	Program adherence
Retention, Attendance, Duration and In-	
tensity	scribed before.
	en's Involvement in Steady Exercise; RCT, randomized controlled trial; BMI, body mass

WISE, Women's Involvement in Steady Exercise; RCT, randomized controlled trial; BMI, body mass index; PPT, pressure pain threshold.

3. Statistical Analyses Plan

All the statistical analysis will be performed using the SPSS version 24 Software (SPSS Inc., USA). If adherence issues occur, all analyses will be evaluated by intention-to-treat principles, with a level of significance of 0.05. Continuous outcomes will be presented using mean and standard deviation if they follow a normal distribution. On the other hand, count outcomes, such as WISE sessions completed, will be reported through the median and percentage of achievement. At the basal assessment, an independent-samples Student's t-test will be performed to rule out differences between groups of age and height of participants.

In order to answer the first aim of this study, the changes in the adherence variables, such as daily steps, the Borg scale and the IPA questionnaire, will be analyzed by 1-withinsubject factor multivariate analysis of variance (MANOVA). The Bonferroni adjustment will be used for post-hoc comparisons between the T0, T1 and T2 times assessments. On the other hand, the secondary outcomes of the study will be tested by 2-factor mixed MANOVA to analyze the effects of a within-subject factor (time assessment from T0 to T4), the between-subject factor (group) and their interaction. As mentioned above, Bonferroni adjustment will be used for times and groups comparisons. In addition, the same statistical test will be carried out considering the country of origin of the data as a covariate, and the findings will be reported according to their statistical significance. For all the statistical analyses, differences will be declared statistically significant if the *p*-value is less than 0.05. The exact p-value and 95% confidence interval will be reported.

# 4. Ethics and Dissemination

The WISE RCT adheres to the Helsinki declaration principles. The research protocol has been reviewed and approved by the Human Research Ethics Committee of the University of Valencia (protocol number 1944476). The study is registered in the ClinicalTrials.gov (NCT05467280). Written informed consent will be obtained from each participant. All of the investigators, the ethics committees and the trial registry will be informed of any modifications that must be made to the study protocol. The results will be disseminated through international conference presentations and in relevant scientific journals.

#### 5. Conclusions

This study aims to investigate the effectiveness of an online HIIT program with nutritional plans and other health-related advice in improving exercise adherence and various health outcomes among sedentary young women. A significant contribution of this study is the development of guidelines to promote exercise engagement in this population.

We expect that the WISE program will improve the participants' knowledge of physical activity, proper nutrition and healthy habits. The program's physical activity component will involve monitoring the participants' heart rate, number of steps and body composition, including fat percentage, visceral fat, water and muscle mass. The diet and healthy habits component will offer basic guidelines and advice on healthy eating, quality sleep and adequate water intake, all delivered via a mobile application.

However, the study design has some limitations, including the program's duration of six consecutive months, which includes vacations and local holidays, as well as the challenge of ensuring that the participants adhere to the program, such as wearing the smartwatches. Depending on the results obtained, the WISE program may consider adjusting the sessions to be more individualized. Additionally, as noted by DiPietro et al. [63], it is important to acknowledge that the WHO recommendations used as a filter in this study are general guidelines for the population as a whole and may not be specifically tailored to certain subpopulations, such as sedentary young women. Finally, increasing the sample size will enable the development of a specification equation (via regression analysis) to determine the general health status of the women in each age group. **Supplementary Materials:** The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/healthcare11091279/s1, Table S1: WISE exercise protocol with links to the videos of the sessions; Table S2: Messages sent to the participants as readings about education in healthy habits.

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**Institutional Review Board Statement:** The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of University of Valencia (1944476, 5 May 2022). The trial protocol has been registered on the Clinical Trials Registry (NCT05467280).

**Informed Consent Statement:** Informed consent was obtained from all subjects involved in the study.

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