

Original Research

Feasibility, Clinical Efficacy, and Maternal Outcomes of a Remote Exercise Program in Pregnant Women with Obesity: The GROB Randomized Control Pilot Study

Diana Bernardo^{1,2,3,4,5,†} , Carolina Bobadilla-Agouborde^{5,6,7} , Clarinda Festas^{4,8,9} ,
Carlos Carvalho¹⁰ , Pedro Pugliesi Abdalla¹¹ , Carmen Amezcua-Prieto^{6,12,13} ,
Zeltia Naia-Entonado¹⁴ , Cristina Carvalho Mesquita^{15,16} , Jorge Mota^{5,17} ,
Paula Clara Santos^{5,15,16,17,*} 

¹Department of Physical Medicine and Rehabilitation, University Hospital Center of São João, 4200-319 Porto, Portugal

²Now with KinesioLab Research Unit in Human Movement, Piaget Institute, 4405-678 Vila Nova de Gaia, Portugal

³Now with Department of Physiotherapy, Health School, Institute Piaget, 4405-678 Vila Nova de Gaia, Portugal

⁴Now with Department of Physiotherapy, Health School Fernando Pessoa, 4249-004 Porto, Portugal

⁵Research Center in Physical Activity, Health and Leisure (CIAFEL), Faculty of Sport University of Porto (FADEUP), 4200-450 Porto, Portugal

⁶Department of Preventive Medicine and Public Health, Faculty of Medicine, University of Granada, 18010 Granada, Spain

⁷Departamento de Procesos Terapéuticos, Facultad de Ciencias de la Salud, Universidad Católica de Temuco, Temuco 4813302, Chile

⁸I3ID-FP, Instituto de Investigação, Inovação e Desenvolvimento Fernando Pessoa, FP-BHS, Biomedical and Health Sciences, 4249-004 Porto, Portugal

⁹RISE, I3ID Centro de Investigação em Saúde, Universidade Fernando Pessoa, Rua Dr. Plácido da Costa, 4200-450 Porto, Portugal

¹⁰Department of Physiotherapy, Clinical Physiotherapy Practice, 4100-465 Porto, Portugal

¹¹Study and Research Group in Anthropometry, Training, and Sport (GEPETE), University of São Paulo, School of Physical Education and Sport of Ribeirão Preto (EEFERP-USP), 14040-907 Ribeirão Preto (São Paulo), Brazil

¹²CIBER de Epidemiología y Salud Pública, Instituto de Salud Carlos III, 28029 Madrid, Spain

¹³Department of Preventive Medicine and Public Health, Instituto de Investigación Biosanitaria IBS, 18010 Granada, Spain

¹⁴Department of Physiotherapy, Medicine and Biomedical Sciences, Faculty of Physiotherapy, University of A Coruña, 15071 Coruña, Spain

¹⁵Centro de Investigação em Reabilitação, Escola Superior de Saúde, Instituto Politécnico do Porto, 4249-015 Porto, Portugal

¹⁶Departamento de Fisioterapia, Escola Superior de Saúde, Instituto Politécnico do Porto, 4249-015 Porto, Portugal

¹⁷Laboratory for Integrative and Translational Research in Population Health (ITR), Instituto de Saúde Pública, Universidade do Porto, 4200-450 Porto, Portugal

*Correspondence: paulaclara@ess.ipp.pt (Paula Clara Santos)

†These authors contributed equally.

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Abstract

Background: Obesity is common in women of reproductive age and increases the risk during pregnancy. Exercising during this period reduces health complications. Home e-health programs are effective in overcoming exercise barriers as pregnant women use technology and the internet for health information. **Methods:** A single-blind randomized controlled feasibility study with pregnant women with obesity (body mass index [BMI] ≥ 30 kg/m²) was conducted in the University Hospital Center of São João between January and April 2023. Pregnant women were randomized to a control group with standard care and to an experimental group with 8-week remote exercise program using a Phoenix® biofeedback device. Feasibility outcome measures were recruitment rate ($\geq 35\%$), loss to follow-up ($\leq 15\%$), and program fidelity (≥ 1 session/week). Secondary outcomes were evaluated through Pregnancy Physical Activity Questionnaire, Oswestry Index on Disability, and weight assessments at baseline and at the end of the program. **Results:** Of the 63 eligible participants, 24 (38.1%) were successfully randomized and completed the baseline assessment. Of these, 3 (4.8%) from experimental group did not perform the initial onboarding. The control group had 8.3% of follow-up losses and for the experimental group there were no follow-up losses. Program fidelity (mean ≥ 1 session/week) was fulfilled by 66.7% of successfully randomized participants. Regarding secondary outcomes assessed between baseline and the 8th week, experimental group compared to control group had higher levels of physical activity for sports activities, a lower level of inactivity, and lower disability rates caused by low back pain. **Conclusions:** Based on the recruitment rate, losses to follow-up, and fidelity rate, the GROB (obesity in pregnancy) study was deemed feasible and worthy of consideration for a larger study. Moreover, the GROB study has the potential to improve maternal outcomes by reducing sedentarism and disability caused by low back pain. **Clinical Trial Registration:** The study has been registered on <https://classic.clinicaltrials.gov/> (registration number: NCT05331586).

Keywords: pregnancy; exercise; physical activity; obesity; e-health; remote



1. Introduction

E-health is a network of technological applications that, with the assistance of the Internet, provides healthcare services, aiming to enhance the quality of life and expedite healthcare delivery [1]. This type of intervention holds the advantage of resembling in-person care, fostering active patient engagement, and yielding more positive clinical outcomes [2]. It has been demonstrated that e-health not only eliminates geographical barriers but also offers a pathway to surmount emotional and social challenges [2,3]. The utilization of e-health through lifestyle interventions proves effective in ameliorating clinical and health outcomes among individuals with cardiometabolic diseases [4], including obesity [5].

Obesity is a medical condition that has experienced a significant global increase over the past decades, reaching pandemic proportions [6]. In the year 2016, 15% of adult women worldwide exhibited obesity [7], and it is projected that this figure will rise to 24% by the year 2030 [8].

Obesity is regarded as the most common medical condition among women of reproductive age [9] and is preventable [7]. Furthermore, it is considered a significant risk factor during pregnancy, as pregnant women with obesity often encounter various health complications. These include gestational diabetes, preeclampsia, and gestational hypertension. Additionally, an increase in pregnancy-related complications and adverse effects on maternal health has been observed [10–12].

Engaging in physical activity (PA) during pregnancy can mitigate the impact of these health complications on women's well-being, while also fostering lifestyle modifications that yield long-term benefits [13]. Although all pregnant women without contraindications are recommended to engage in regular PA, the majority of them prefer not to exercise and reduce their level of PA, including domestic and occupational activities [14]. There are various reasons explaining the decline in PA among women during this period. These range from a sense of discomfort during exercise, fear of potential risks to the fetus, to experiences of miscarriages or fertility treatments. Additionally, sociodemographic factors such as lower educational levels, reduced income, and a higher number of children contribute to this trend [14]. A comprehensive intervention aimed at promoting PA in pregnant women with obesity proves effective in enhancing their levels of PA, mitigating gestational weight gain (GWG), and reducing indirect measures of maternal body fat [15].

Given that pregnant women frequently turn to technological applications and the internet as sources of information for health-related matters [16], home-based e-health programs are an excellent strategy to overcome certain barriers associated with the lack of regular exercise [3]. It has been reported that receiving PA recommendations has led to 40.5% (95% confidence interval (95% CI): 38.4–42.4) of women choosing to stay active during pregnancy [17].

Consequently, this type of patient population appears to be one of the primary candidates for this form of medical care [18]. It is important to note that the Coronavirus disease 2019 (COVID-19) pandemic has suspended and minimized hospital visits [19], and remote biofeedback systems can be fundamental for carrying out exercises in the safety of the home and outside of contagion centers.

However, studies are needed to analyze the potential effects of the exercise program during pregnancy in pregnant women with obesity through remotely monitored home-based e-health using a biofeedback. This is the main objective of this study.

2. Materials and Methods

2.1 Objectives

To assess the feasibility of the remote exercise program, data was collected according to the following objectives.

2.1.1 Primary Feasibility Objective

The primary objective of this study was to assess the feasibility of a remote exercise program for pregnant women with obesity to inform upon scalability to power subsequent randomized control trial (RCT) studies. Feasibility studies are pieces of research done before a main study. They are used to estimate important parameters that are needed to design the main study as recruitment rate, losses to follow-up, program fidelity and missing data [20].

2.1.2 Secondary Objectives

The clinical efficacy of this intervention was assessed through the following secondary objectives:

- To assess the effectiveness of remote exercise program to improve PA levels in pregnant women with obesity.
- To assess whether remote exercise program improves maternal outcomes, such as adequate GWG.
- To ascertain whether remote exercise program influences the disability levels caused by low back pain in pregnant women with obesity.

2.2 Study Design and Participants

This study was reported based on the Consolidated Standards of Reporting Trials (CONSORT) reporting checklist (Fig. 1) for pilot and feasibility trials [21]. The “obesity in pregnancy” (GROB) study, is a single-blind randomized controlled prospective feasibility study that was conducted to evaluate the feasibility and potential clinical efficacy on maternal outcomes of a remote exercise program compared to the standard in pregnant women with obesity. The trial was registered at ClinicalTrials.gov (NCT05331586), and ethical approval was received (N/REF.^a 35/22 (14/10/22)- Ethical committee Centro Hospitalar Universitário de São João (CHUSJ)). The study was conducted in accordance with the Declaration of Helsinki.

All women gave their informed, written consent to participate, and the confidentiality of the data provided was assured.

Participants were recruited in CHUSJ, Porto (Portugal), between January and April 2023. Eligible women were pregnant women with obesity (body mass index [BMI] ≥ 30 kg/m²); between the 6th and 20th gestational week and aged 18 or older. Exclusion criteria were: previous bariatric surgery; hemodynamically significant heart disease; restrictive lung disease; incompetent cervix or cerclage; multiple gestation; persistent bleeding; ruptured membranes; pregnancy-induced hypertension; severe anemia [22]; and inability to read and understand Portuguese.

2.3 Recruitment and Randomization

Pregnant women with obesity, followed at CHUSJ, have specific medical appointments for the obesity condition. After the medical consultation, pregnant women with obesity were referred by the research team to an office. The principal investigator checked the eligibility and exclusion criteria and gave general information about the study. Pregnant women who agreed to participate, completed informed consent and a baseline assessment and were randomized (1:1), using a web-based randomization system (<https://www.random.org/>), into an experimental group (remote exercise program) or control group (standard care), this procedure was made by principal investigator.

2.4 Intervention Group

Pregnant women in the experimental group (EG) were provided with a pamphlet detailing the benefits of exercise during pregnancy, international recommendations for GWG and signs and symptoms to stop exercising. They were also introduced to the Phoenix® system and given a thorough explanation of its functioning, specifically, how to connect to the internet, charge the device, perform the initial onboarding, and position the sensors. These tasks are necessary given that the exercise with the device was conducted at home.

Phoenix®, is a biofeedback system that uses inertial motion trackers, placed on the body segments (Fig. 2). This device digitizes movement and provides real-time feedback on performance via a mobile app. It also includes a web-based platform that allows the clinical team to prescribe, monitor, and adapt the exercise program remotely. Prior to this study, a pre-experimental study, was conducted to verify the safety and usability of the Phoenix system in pregnant women with obesity.

The exercise protocol was carried out for eight weeks, with the physiotherapy team monitoring and modifying exercises as needed through regular contact with the pregnant women.

2.5 Control Group

The control group (CG) received standard antenatal care at CHUSJ. Standard antenatal care consists of regular consultations with doctors, obstetric nurses, and midwives, fetal assessment using ultrasound, and nutrition consultations. Pregnant women in the CG also received a pamphlet with information on the benefits of physical exercise during pregnancy and the Institute of Medicine (IOM) recommendations on GWG. Pregnant women in the CG were not discouraged from exercising on their own.

2.6 Exercise Program Specifications

The proposed exercise program was based on the Frequency, Intensity, Type, and Time (FITT) Model Principle. The Phoenix® Device was available 24 hours/7 days per week, and pregnant women were encouraged to exercise at least three times a week. The exercise type was aerobic, and intensity was kept moderate, evaluated through the borg scale (12–15) [23,24]. The exercises comprised functional movements to build strength and improve metabolic expenditure and followed a sequence of 5-min warm-up exercises, 20-min aerobic and strength exercises, and 5–10 min cool down and stretching exercises [23,24].

2.7 Outcomes Measures

2.7.1 Primary Outcome Measure: Feasibility

Primary outcomes are associated with the feasibility of the study and provide information on the possibility of conducting a larger study and on the changes that need to be made for the implementation of that study. The primary outcomes included recruitment rate, loss to follow-up, and program fidelity [20]. For our study to be considered feasible, the following criteria should be met: recruitment rate of $\geq 35\%$ [25,26]; loss to follow-up $\leq 15\%$ [27,28]; and program mean ≥ 1 session per week. The recruitment rate was defined as the number of patients successfully recruited and randomized from those eligible. Program fidelity is determined by the number of sessions per week and loss to follow-up was defined as participants who missed follow-up assessment.

2.7.2 Secondary Outcomes Measures

At baseline, pregnant women in both the CG and EG completed three questionnaires: characterization questionnaire, Pregnancy Physical Activity Questionnaire (PPAQ), and Oswestry Index on Disability, version 2.0 (ODI V2.0), to assess back pain. Weight measurements were taken using a portable digital scale (Tanita InnerScan BC-545, Arlington Heights, IL, USA) and done by a nurse, blinded for group allocation. Additionally, a pamphlet containing information on PA and recommended GWG was provided to both groups.

The sample characterization questionnaire collected personal and sociodemographic data (including the pregnant woman's age, professional status, gross monthly in-

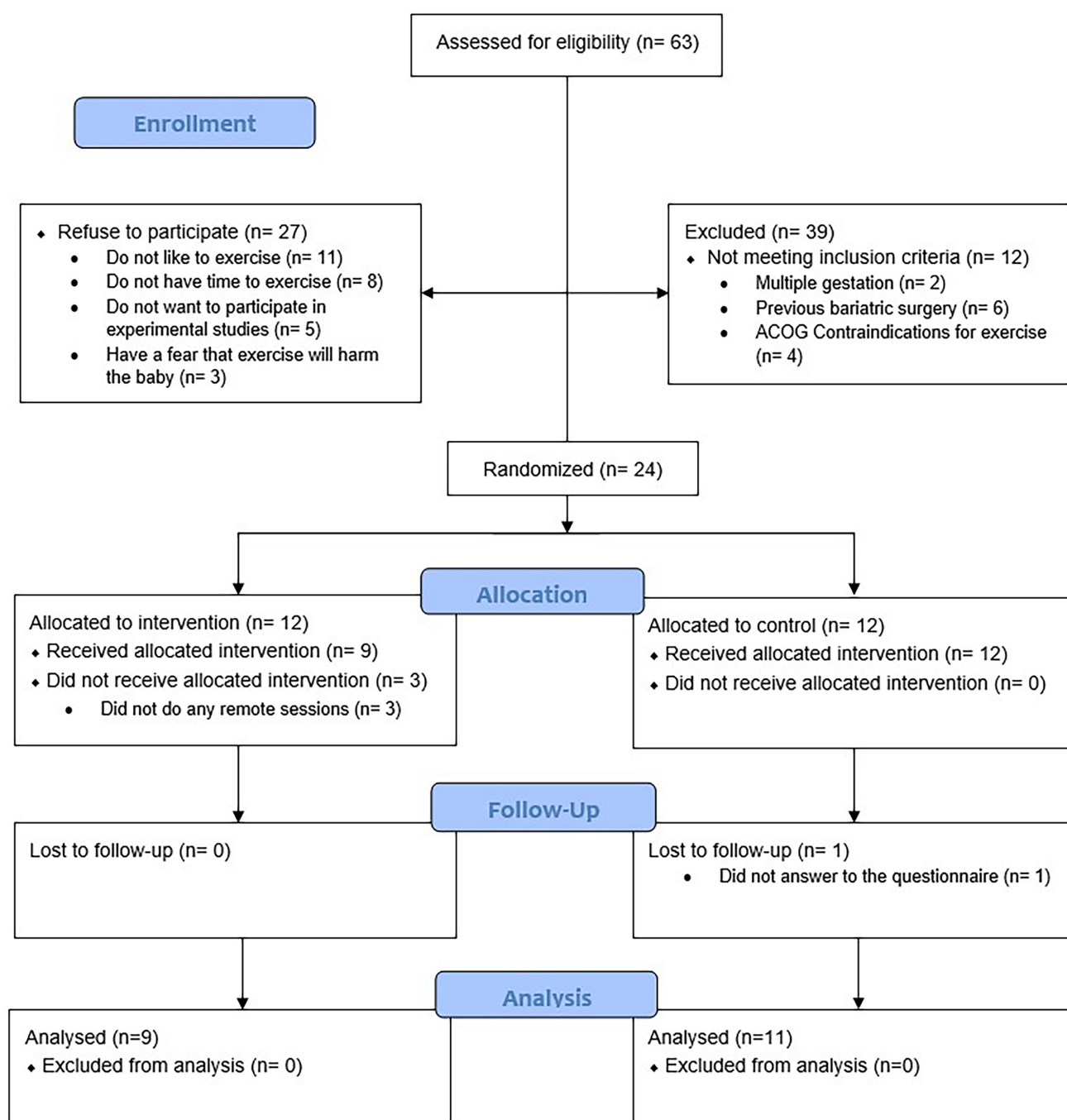


Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) flowchart. ACOG, American college of obstetricians and gynecologists.

come, educational qualifications, and household), anthropometric data (height and pregestational weight), clinical history (previous diseases and contraindications to American college of obstetricians and gynecologists (ACOG)), and obstetric history (type of pregnancy and pregnancy planning; history of abortion or risk).

The PPAQ [29] aims to measure the duration, frequency, and intensity of activities performed at home, in child and elderly care, with occupations, sports, and exercises during the trimester of pregnancy, providing a quan-

titative measure of types of PA intensity, including sedentary lifestyle [30]. The energy expenditure on the activity in metabolic equivalents (METs) (intensity) is multiplied by the activity duration per day and thus obtains the average measurement of energy spent weekly (METs.h.week^{-1}) [29]. It is a valid tool for assessing PA in pregnant women with obesity [31] and is important because PA levels during pregnancy, especially in pregnant women with obesity, tend to be low [30].

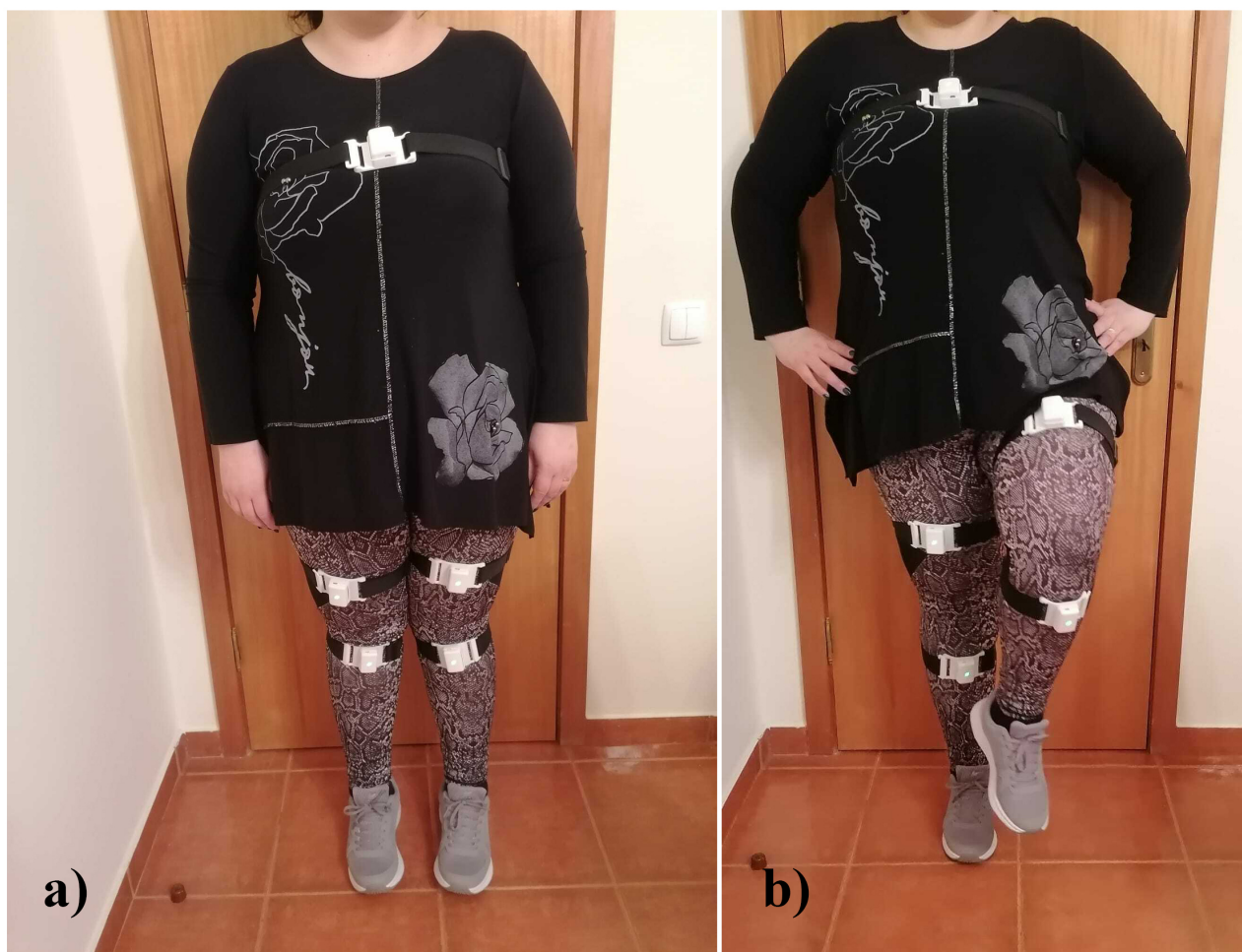


Fig. 2. Exercise with Biofeedback sensors. (a) Motion trackers placed on body-segments. (b) Pregnant women performing exercise in interaction with Phoenix®.

The presence of low back pain was measured with ODI V2.0. It was translated, adapted, and validated for the Portuguese population [32]. The ODI V2.0 is an instrument used to assess disability in activities of daily living caused by low back pain. Each section is scored on a 0–5 scale, 5 representing the greatest disability. The index is calculated by dividing the summed score by the total possible score, which is then multiplied by 100 and expressed as a percentage [32]. It is one of the most commonly used instruments to assess low back pain and has been shown to be valid and reliable [33], being frequently used in the evaluation of pregnant women [34].

Weight gain during pregnancy was measured by the difference between weight at 8 weeks of intervention and weight at baseline. According to the IOM, the recommended weight gain for pregnant women with obesity, during the second and third trimesters of pregnancy, should not exceed 0.22 kg per week [35].

During the intervention period (EG), exercise results were automatically downloaded to the Phoenix® platform. The research team had access to exercise execution time, execution difficulties, fatigue, and pain feedback. Finally,

a final assessment was conducted after the 8-week intervention. Participants from both groups completed the questionnaires (PPAQ and ODI) again and weight was measured.

2.8 Data Analysis

The principles of intention-to-treat analysis were used in this study. The data analysis was performed for the entire sample, using the SPSS® v.20.0 software package (IBM, Armonk, NY, USA). The significance level was 0.05 and the confidence interval adopted was 95%. Demographic characteristics were described using frequencies, percentages, means, and standard deviations or median and interquartile ranges. The groups were compared in terms of homogeneity using the Student's *t*-test or the U Mann–Whitney test for continuous variables and the Fisher exact test for categorical variables.

This study was expected to have 24 participants, as the pilot study did not require a large sample size [36]. In feasibility studies [37] and pilot studies [38], a minimum of 12 and a maximum of 30 participants for each group were considered appropriate.

Table 1. Baseline characteristics of all women included in the GROB study.

Maternal characteristics	Control Group (n = 12)	Experimental Group (n = 12)	p value
Maternal age in years, mean (SD)	31.8 ± 4.9	29.8 ± 3.4	0.304 ^a
Gestational week, mean (SD)	15.9 ± 2.2	15.7 ± 3.2	0.151 ^a
Pregestational body mass index, median (IQR) ¹	35.7 (3.9)	36.8 (8.3)	0.684 ^b
Obesity grade ²			0.089 ^c
Grade I, n (%)	5 (41.7)	3 (25.0)	
Grade II, n (%)	7 (58.3)	5 (41.7)	
Grade III, n (%)	0 (0.0)	4 (33.0)	
Maternal marital status			0.202 ^c
Married/cohabiting, n (%)	10 (83.3)	9 (75.0)	
Single with/without a partner, n (%)	2 (16.7)	3 (25.0)	
Maternal qualifications			0.085 ^c
Higher education or above, n (%)	4 (33.3)	5 (58.4)	
Mandatory level or below, n (%)	8 (66.7)	3 (41.7)	
Maternal employment status			0.028 ^c
Employed/student, n (%)	12 (100.0)	8 (66.6)	
Unemployed/full-time mother, n (%)	0 (0.0)	4 (33.3)	
Pre-gestational low back pain, n (%)	7 (58.3)	8 (66.7)	0.178 ^c

^aStudent's *t* test; ^bMann-Whitney U test; ^cFisher exact test. ¹IQR, Interquartile Range; ²Grade I ≥30.0 and <34.9 kg/m²; Grade II ≥35 and <49.9 kg/m²; Grade III ≥40.0 kg/m² (based on World Health Organization (WHO)). GROB, obesity in pregnancy; SD, standard deviation.

Feasibility outcomes and baseline characteristics of the sample were measured using descriptive statistics. For secondary outcomes, we used the Wilcoxon test for intra-group analysis and the U Mann-Whitney test for intergroup analysis. To calculate the intervention effect size, we used the $r = z/\sqrt{N}$ formula [39].

2.9 Data Availability

The data associated with the paper are not publicly available but are available from the corresponding author on reasonable request.

3. Results

Of the 63 eligible pregnant women invited to participate in the study, 39 (61.9%) were excluded at recruitment (Fig. 1). Of these, 12 (19.0%) did not meet the inclusion criteria and 27 (42.9%) refused to participate. The reasons for refusal were varied, with 17.5% citing disliking exercise, 12.7% lacking time to exercise, 7.9% not wanting to be part of an experimental study, and 4.8% fearing harm to the baby's growth from exercise.

Ultimately, 24 pregnant women (38.1%) were included in the study. All 24 randomized pregnant women completed the initial assessment (Table 1). There were no statistical differences between the groups on sociodemographic variables (age, gestational week, pre-gestational body mass index, obesity grade, marital status, maternal qualifications), except for maternal employment status, being all participants from CG classified as "Employed" or "Student". Regarding clinical variables (pre-gestational low back pain) no statistically significant differences were found either.

3.1 Primary Outcome

3.1.1 Recruitment Rate

Of the 63 eligible pregnant women invited to participate in the study, 24 pregnant women were included in the study, being the recruitment rate (38.1%) higher than the established (≥35%) to classify the study as feasible.

3.1.2 Loss to Follow-up

Of the 12 pregnant women allocated to the EG, 3 (4.8%) did not perform the initial onboarding despite having taken the Phoenix® device home. The pregnant women who didn't do the onboarding reported a lack of desire to start the exercise program. Statistically, the three pregnant women were between 29–33 years of age and had obesity indices classified as grade II. No statistically significant differences ($p = 0.675$) from the experimental group were found. All pregnant women allocated to the EG performed the second moment of evaluation, with no follow-up losses, whereas in the GC, one participant did not attend the final assessment resulting in a follow-up loss of 8.3%, but lower to the cut-off (≤15%) to classify the program as non-feasible.

3.1.3 Program Fidelity

Program fidelity was less than ideal, with only 6 pregnant women (66.7%) complying with the assumption of 1 session per week in EG. On average, participants completed 1.4 ± 0.9 sessions per week. The participants who performed the fewest sessions (<1 session per week) completed an average of 0.63 ± 0.9 sessions per week, resulting in only 6 sessions over the 8 weeks of the proposed intervention.

3.2 Secondary Outcomes

In the intra-group analysis (baseline vs. 8 weeks of the study) of PA levels, weight, and low back pain (Table 2), it was found that both groups significantly reduced the time spent on occupational activities (CG: $p = 0.014$; median of 70.1 (132.7) vs. 50.8 (148.3) METs.h.week⁻¹; EG: $p = 0.034$; median of 5.3 (98.3) vs. 3.0 (38.2) METs.h.week⁻¹) and increase the weight (CG: $p = 0.003$; median 99.8 (19.2) vs. 103.8 (21.0) kg; EG: $p = 0.007$; median 100.5 (43.5) vs. 108.1 (35.5) kg). Regarding CG, data show that levels of inactivity was increased ($p = 0.012$; median of 27.8 (33.4) vs. 35.0 (31.2) METs.h.week⁻¹) and low back pain ($p = 0.008$; median of 6.0 (7.0) vs. 10.0 (10.5) on ODI score).

The EG significant increase their total PA levels ($p = 0.050$; median 192.7 (177.0) vs. 200.1 (202.6) METs.h.week⁻¹) and in light and moderate intensities (Light $p = 0.035$; median 61.6 (124.6) vs. 68.7 (168.7) METs.h.week⁻¹; Moderate $p = 0.028$; median 39.5 (119.7) vs. 41.9 (115.8) METs.h.week⁻¹).

The percentage data shows that EG reduced their time spent on sedentary activities from 32.1% to 29.9% and increased their time spent on sports activities from 8.5% to 10.6%. On the other hand, CG increased the time spent on sedentary activities (28.9 vs. 31.9%) and inactivity (12.1 vs. 20.8%).

In the intergroup evaluation, pregnant women from the EG showed significantly higher levels of energy expenditure in vigorous and sports activities at baseline and after 8 weeks, compared to pregnant women from the GC group.

3.3 Change between Baseline and the 8th Week Assessments

Table 3 shows a greater change in outcome measures for the EG after eight weeks, which occurred for energy expenditure in light-intensity activities ($p = 0.025$), moderate-intensity activities ($p = 0.005$) and sports activities ($p = 0.049$). The difference in measures after the 8-week intervention and baseline was significantly greater in the CG for inactivity ($p = 0.024$), and the CG also had significantly higher disability values (ODI) than the EG ($p = 0.001$). According to Cohen [40], the intervention had a large effect for light-intensity (0.50) and moderate-intensity activities (0.63), and for reducing disability related to low back pain (0.82), and the effect was intermediate for sports and transportation activities. The intervention had a small effect on gestational weight gain (0.20) and total activity (0.10).

4. Discussion

In the past, pregnant women were discouraged from exercising. However, this was mainly due to social and cultural prejudices and unfounded concerns about safety for the fetus, and was not based on scientific research [24]. Today, the benefits of regular exercise for pregnant women without contraindications are well-established [41]. However, despite the significant benefits, many women remain

inactive or significantly reduce their exercise during pregnancy [42], especially pregnant women with overweight and obesity [43].

The COVID-19 pandemic has rapidly transformed the healthcare systems and the way health is delivered to users, with e-health being one of the main drivers of change [44]. The use of virtual systems is an increasingly common reality, being used for a wide variety of conditions/pathologies [45,46], limiting unnecessary in-person visits, especially for at-risk patients [44], and has the potential to reach more people, at lower costs [47], overcoming some barriers related to the non-practice of exercise on a regular basis [3].

GROB is the first study, according to our knowledge, designed to investigate the feasibility and clinical efficacy of remote monitored exercise program using a biofeedback system for expecting mothers with obesity.

The data demonstrate that the GROB study is feasible in recruitment rate and losses of follow-up and can be reproduced on a large scale. The recruitment rate was higher than expected (38.1%), however, it is important to reflect on the refusal rate to participate. Of the eligible pregnant women to enter the study, 42.9% refused due to not liking exercise and fear that it may harm the baby's health. Similar data were found by other authors [27,48]. Regarding fidelity to the remote exercise program, only 66.9% of pregnant women complied with the treatment fidelity assumption of one session per week, despite pregnant women having access to the remote exercise program 24 hours a day, seven days a week. Behavioral changes, according to Prochaska & Diclemente (1992), go through five stage [49]. Pre-contemplation is the initial stage of change when the individual begins to consider the consequences, purpose, and possibility of change. The contemplation stage is an important point in the change process. In this phase, the individual is directly and actively considering change and has reached a point of readiness to engage in the process [49]. We consider that the pregnant women in the EG are in the contemplation stage. PA participation rates are low despite positive attitudes toward PA, this suggests a disconnect between the women's intention about PA and their actions—a knowledge-action gap [50]. That means pregnant women recognize behavioral change as important to promote benefits in their health and the baby's health, but they are not yet sufficiently determined to advance to the preparation, action, and maintenance of new behaviors.

The preparation phase presupposes literacy, study, and mental preparation for change [49]. At this stage, the motivation given by the professional who accompanies the pregnant woman is important, making it clear that the multidisciplinary team has a primary role in behavioral change. In a large-scale study, person-centered strategies using behavior change techniques should be used to address intrapersonal and social factors to translate pregnant women's positive attitudes into increased PA participation [50].

Table 2. Results of physical activity intensity and activity (PPAQ), Low Back Pain (ODI) and Gestational Weight Gain (Weight) between groups.

Secondary outcomes		Control Group (n = 11)		Experimental Group (n = 9)		p value ^c
		Median (IQR) ^a	Time spent ^d %	Median (IQR) ^a	Time spent ^d %	
Intensity Type (METs.h.wk ⁻¹) ²	Total Intensity					
	At baseline	218.8 (230.8)	100	192.7 (177.0)	100	0.618
	After 8 weeks	160.1 (155.9)	100	200.1 (202.6)	100	0.581
	p value ^b	0.534		0.050		
	Sedentary					
	At baseline	48.1 (74.7)	28.9	60.9 (121.7)	32.1	0.305
	After 8 weeks	50.4 (69.8)	31.9	45.2 (53.9)	29.9	0.424
	p value ^b	0.674		0.293		
	Light					
	At baseline	82.6 (53.4)	42.9	61.6 (124.6)	38.5	0.032
	After 8 weeks	79.8 (67.0)	41.5	68.7 (168.7)	40.2	0.043
	p value ^b	0.999		0.035		
	Moderate					
	At baseline	66.9 (106.2)	27.6	39.5 (119.7)	27.4	0.405
	After 8 weeks	42.2 (103.2)	26.0	41.9 (115.8)	28.5	0.516
	p value ^b	0.106		0.028		
	Vigorous					
	At baseline	0.0 (1.6)	0.6	0.0 (7.9)	1.9	0.048
	After 8 weeks	0.0 (1.6)	0.7	4.5 (5.5)	1.4	0.050
	p value ^b	0.999		0.180		
Activity Type (METs.h.wk ⁻¹)	Domestic					
	At baseline	58.4 (53.7)	39.2	63.2 (187.8)	47.7	0.029
	After 8 weeks	58.4 (53.7)	41.6	44.0 (268.8)	48.3	0.034
	p value ^b	0.074		0.063		
	Occupational					
	At baseline	70.1 (132.7)	36.6	3.0 (38.2)	13.7	0.066
	After 8 weeks	50.8 (148.3)	26.9	5.3 (98.3)	10.5	0.149
	p value ^b	0.014		0.034		
	Sport/Exercise					
	At baseline	3.6 (5.2)	2.7	12.9 (25.4)	8.5	0.020
	After 8 weeks	1.9 (11.7)	2.5	17.2 (20.7)	10.6	0.018
	p value ^b	0.399		0.214		
	Transport					
	At baseline	15.8 (23.6)	9.4	19.3 (24.1)	21.6	0.759
	After 8 weeks	14.9 (18.4)	8.2	21.0 (34.6)	10.2	0.047
	p value ^b	0.066		0.109		
	Inactivity					
	At baseline	27.8 (33.4)	12.1	37.3 (28.7)	9.5	0.947
	After 8 weeks	35.0 (31.2)	20.8	41.9 (29.3)	20.4	0.677
	p value ^b	0.012		0.588		
Maternal Outcomes	Weight (kg)		NA		NA	
	At baseline	99.8 (19.2)		100.5 (43.5)		0.196
	After 8 weeks	103.8 (21.0)		108.1 (35.5)		0.362
	p value ^b	0.003		0.007		
	Low Back Pain (ODI¹)		NA		NA	
	At baseline, n = 7	6.0 (7.0)		15.0 (27.0)		0.045
	After 8 weeks, n = 7	10.0 (10.5)		15.0 (21.0)		0.290
	p value ^b	0.008		0.705		

^aIQR, interquartile range; ^bp value intragroup analysis with Wilcoxon test; ^cp value intergroup analysis with Mann-Whitney U test; ^dCalculated through the mean; ¹Oswestry index on disability; ²Sedentary <1.5 METs, light ≥1.5 and <3.0 METs, moderate ≥3.0 and <6.0 METs, vigorous ≥6.0 METs. NA, not applicable; METs, metabolic equivalents; ODI, Oswestry Index on Disability.

Table 3. Changes on secondary outcomes after 8 weeks of intervention in GROB study.

Change from baseline to 8th week		Control Group (n = 11)	Experimental Group (n = 9)	<i>p</i> value ^b	Effect size (<i>r</i>) ^c
		Median (IQR) ^a	Median (IQR) ^a		
Intensity (METs.h·wk ⁻¹)	Total Intensity	14.7 (35.9)	13.7 (23.5)	0.676	0.10
	Sedentary	12.3 (21.2)	0.0 (13.8)	0.298	0.23
	Light	0.0 (14.0)	4.4 (15.5)	0.079	0.39
	Moderate	0.0 (5.7)	3.4 (3.8)	0.003	0.66
	Vigorous	0.0 (0.0)	0.0 (2.4)	0.109	0.36
	Domestic	0.0 (5.3)	4.4 (14.0)	0.586	0.12
	Occupational	-3.0 (0.5)	-3.0 (2.2)	0.669	0.10
	Sport/Exercise	0.0 (2.5)	3.4 (6.3)	0.005	0.44
	Transport	0.0 (8.8)	0.0 (8.3)	0.011	0.50
	Inactivity	12.3 (21.7)	0.0 (9.9)	0.024	0.50
Weight (kg) ¹		5.0 (3.5)	4.1 (1.9)	0.401	0.20
Low Back Pain (ODI)		6.0 (1.5)	0.0 (3.0)	0.001	0.82

^aIQR, Interquartile Range; ^b*p* value Intergroup analysis with Mann-Whitney U test. ^ccalculates through $r = z/\sqrt{N}$; ¹Weight Gain during the remote exercise program.

We recognize that the low recruitment rate of 1.5 patients per week with a period of inclusion of 16 weeks for 24 women, may have been due to poor engagement between obstetricians, who are responsible for obesity pregnancy consultations, and the GROB study. Studies show that users who are educated and advised to take part in PA and exercise by health professionals actually increase their levels of PA [51,52], it will therefore be important for health professionals to be more involved in promoting PA programs, especially in pregnant women with specific conditions such as obesity.

Pregnant women in the GROB study have high levels of sedentary behavior, same results were found in other studies [42,43]. The characteristics of PA at baseline is homogeneous for both groups, with over 70% of time spent in activities with intensity levels lower than 3 METs (sedentary + light), and predominantly in domestic activities. The CG significantly increased the time spent in inactivity (less than 1.5 METs) compared to the EG in the evaluation between 8 weeks and baseline. After 8 weeks of intervention, pregnant women in the EG significantly increased the time spent in moderate activities and decreased the time spent in sedentary activities, which is in line with international recommendations for physical exercise in pregnant women, especially in pregnant women with obesity [24]. The recommendations suggest that pregnant women reduce sedentary behavior and that inactive pregnant women and those who are overweight or obese are gradually encouraged to start an exercise program [24]. These results demonstrate a large positive effect size of remote physical exercise programs, both in reducing sedentary time and increasing sports activities.

Regarding the secondary outcomes of GWG, the data show that pregnant women in both groups significantly increased their weight over the eight weeks. In 2009, the IOM published revised guidelines on GWG, based on pre-pregnancy BMI [35]. The pregnant women in the GROB

study exceeded the recommended weekly weight gain, failing to comply with international guidelines, showing that PA was not associated with control of GWG. Similar data were found by other authors who showed that a 16-week program of moderate-intensity antenatal exercise in overweight/obese women did not alter maternal weight gain, however, the exercise intervention led to an improvement in aerobic fitness in the expectant mothers [53]. On the other hand, a 2023 systematic review with meta-analysis evaluating the effectiveness of structured physical exercise on GWG in overweight and obese pregnant women suggests that interventions carried out exclusively in a supervised hospital setting result in better outcomes in the management of weight gain in pregnancy [53]. This can be attributed to the fact that pregnant women who exercise unsupervised tend to increase their calorie intake [54]. The last secondary outcome was achieved: pregnant women significantly reduced their levels of disability related to low back pain between the baseline and the end (8 weeks) of the remote exercise program intervention. These results indicate that just 8 weeks of intervention is effective in increasing PA practice, time spent on sports activities, and decreasing levels of sedentary behavior. This increase in PA contributed to effective and sustained relief of low back pain symptoms, which is consistent with the results of other studies [55,56].

E-health interventions lead to greater efficacy and patient satisfaction [18], and results of previous systematic reviews and meta-analyses indicate that is an effective intervention vehicle to promote PA among adults [57,58] and have the potential to improve maternal outcomes, such as reducing postpartum depression and the retaining weight gained during pregnancy [59].

This study has provided a comprehensive insight into the complexities of a future large-scale study. The first barrier is the involvement of the entire clinical team. To involve and motivate pregnant women to change their behaviors, it is necessary for all members of the multidisciplinary

team who provide care to pregnant woman to be enlightened, informed, and an auxiliary resource for remote physical exercise.

Health literacy plays a fundamental role in maternal behavior and influences maternal and fetal health. A lack of health literacy is associated with unhealthy behaviors during pregnancy [60]. We believe that the low level of knowledge among pregnant women about the benefits of physical exercise during pregnancy is the second barrier in this study. In a larger-scale study, it would be interesting to use facilitating factors such as group clarification sessions, addressing questions about exercise, social support as well as fun and enjoyment, which are essential for initiating and maintaining behavior change. This can facilitate the shift from intention to action, which is necessary to create behavior change, and may be more effective in improving pregnant women's participation in PA than educational strategies alone [50].

We consider GROB study strengths: a pioneering study using a remote home device to carry out safe and adapted physical exercises for pregnant women with obesity; a randomized controlled trial and followed the initial protocol. Assessments of secondary outcomes were carried out using validated and reliable questionnaires for the GROB study population group.

The current study has limitations that need to be addressed: the small sample size, program fidelity, and the recruitment ratio per week. However, the good recruitment rate and the low number of losses at follow-up suggest the feasibility of conducting a larger study. We can also consider the intervention time of 8 weeks as a limitation. Some studies suggest that exercise should be maintained until the end of pregnancy or for at least 12 weeks for more evident clinical findings [27,28,53], and it would be important to assess the pregnant woman's motivation for PA before offering her an exercise program. Regarding secondary outcomes, we can also mention as a limitation the fact that maternal weight was not adjusted for maternal gestational age. Finally, because of the nature of the intervention, the participants were not blinded to study allocation, which could influence study results, namely the increase in unrelated PA to the remote exercise program.

5. Conclusions

This randomized control pilot study of a remote exercise program for pregnant women with obesity demonstrated to be feasible, however, the recruitment rates and program fidelity were low. This study seems to show clinical efficacy in increasing maternal PA levels and reducing disability caused by low back pain but was not effective in control weight gain.

Abbreviations

PA, Physical Activity; CHUSJ, Centro Hospitalar Universitário de São João; EG, Experimental Group; CG,

Control Group; IOM, Institute of Medicine; GWG, Gestational Weight Gain; GROB, Grávidas com Obesidade.

Availability of Data and Materials

The data associated with the paper are not publicly available but are available from the corresponding author on reasonable request.

Author Contributions

The conception study design and data acquisition were DB, PCS and CC responsibility. DB, CBA, CF, PPA, CAP, JM, ZNE and CCM analyzed and interpreted data and drafted the manuscript. The critical review regarding important intellectual content was carried out by PPA, CAP, CCM, and ZNE. All authors contributed to editorial changes in the manuscript. All authors approve the final version of the manuscript.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of CHUSJ (N/REF.^a 35/22 (14/10/22) and it was conducted in accordance with the Declaration of Helsinki. All women gave their informed, written consent to participate, and the confidentiality of the data provided was assured.

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Conflict of Interest

The authors declare no conflict of interest.

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