Health-Related Quality of Life in Postpartum Recovery of Women who Practice Hypopressive Physical Activity. Randomized Clinical Trial

Juan Carlos Sánchez-García
  Universidad de Granada

María José Aguilar-Cordero
  Universidad de Granada

Maria Montiel-Troya (✉ mariamontiel@go.ugr.es)
  Editorial Universidad de Granada   https://orcid.org/0000-0002-3105-535X

Ana Eugenia Marín-Jiménez
  Universidad de Granada

Elena Mellado-García
  La lobilla Health Service Malaga, Spain

Raquel Rodríguez-Blanque
  Universidad de Granada

Abstract

Background

Practicing physical exercise is a way of maintaining a healthy lifestyle and it has been demonstrated that it benefits and improves quality of life after labour.

Aim

To determine whether a workout programme using the Low-Pressure Fitness methodology has an impact on the Health-Related Quality of Life after labour.

Material and Method

We carried out a 12-weeks randomized clinical trial. It started at week 16 after labour and ended at postpartum week 28. Women followed a moderate intensity workout programme, using the Low-Pressure Fitness methodology in the treatment group, and we had a control group of sedentary women to perform a comparison. We used the SF-36v2 questionnaire at the postpartum weeks 16 and 28 to assess the Health-Related Quality of Life in women.

Results

We found statistically significant differences ($p < 0.05$) in general health components, vitality, emotional role, and mental health in the sample group of women under the Low-Pressure Fitness, who obtained a higher score.

We found statistically significant differences in all aspects between the postpartum weeks 16 and 28.

The interaction between time and group affect in general health components, vitality, emotional role and the score of mental component. In all of them the score is higher at week 28 and in the Low-Pressure Fitness group.

Conclusions

Physical exercise, following the Low-Pressure Fitness method, improves Health-Related Quality of Life after labour. We found that, when both the treatment and control groups are categorized by body-mass index, the Low-Pressure Fitness method was not determinant to improve the postpartum Health-Related Quality of Life.

1. Background

Health-Related Quality of Life (HRQoL) is defined by Urzúa [1] as "the well-being level obtained from the self-assessment that is made from diverse domains of someone's life, considering the impact that these domains have in his/her own health state". The use of this concept is especially important when describing the impact of a disease in the life of patients and in the assessment of the efficacy of treatments.

The American College of Sports Medicine (ACSM) [2], in its last edition about physical exercise prescription, recommends practicing 150 minutes of weekly exercise in adults, spreading the physical activity among most days of the week, in order to improve the cardiovascular and central nervous systems. Currently, the American College of Obstetricians and Gynecologists (ACOG) [3] recommends regular exercise during pregnancy and after labour, in the absence of medical and obstetric complications, at least three times a week for 30–40 minutes, being a continuous

activity preferred over an intermittent one [2]. After labour, physical exercise not only help women recuperate their pregestational weight, but also improves mental health, generates positive feelings, and reduces depression [4–7].

For all these reasons, we suggest the hypothesis that moderated physical exercise, following the guidelines of the Low-Pressure Fitness (LPF) method, developed from week 16 until week 28 after labour, will be associated to a better score in the SF-36v2 Health Questionnaire.

The LPF methodology consists of a series of hypopressive exercises aimed at improving the muscle tone of the pelvic area and abdomen. The basis of these exercises is the reduction of intrabdominal pressure in a combination of physical and respiratory exercise with specific techniques[8]. The SF-36v2 is a questionnaire of 36 questions where positive and negative aspects of health are valued, this is used globally to assess the relationship between quality of life and health[9].

2. Aim

To determine the impact of a physical exercise programme, under the LPF methodology, on the HRQoL of women after labour.

3. Methodology

Design

We designed an open-label randomized clinical trial in which both subjects and researchers knew about the treatments. We followed the CONSORT rules published in 2010 [8]. The trial is registered in the USA National Institutes of Health (ClinicalTrials.gov) and titled "Physical Activity in Pregnancy and Postpartum Period, Effects on Women". Number NCT02761967. This project was approved by the Ethical Committee for Research in Granada, with the license number 2601.20.15.

All participant women signed an informed consent form before the study, following the rules stablished at the Helsinki Declaration and reviewed by the World Medical Association regarding Informed Consent, on May 5th, 2015 [9].

Subjects

The subjects were women whose babies were 14 weeks old, meaning their labour took place on the first fortnight of September 2016. The recruitment took place on the first fortnight of October 2016 at the Healthcare Centers of the Granada-Metropolitan Healthcare District (SAS). We selected women that fulfilled the inclusion criterion of labour date, and they were later contacted by phone. The recruitment responsible researcher phoned the eligible subjects and provided them with verbal information. Those subjects that showed interest in participating in the project were sent an email that included an attached file with further information about the study.

Inclusion criteria

The inclusion criteria were to have a healthy pregnancy and an eutocic delivery.

Exclusion criterion

All women that did not sign the informed consent form.

Once the study ended, we excluded all subjects that attended less than 80% of the planned sessions.

Study

Between the postpartum weeks 14 to 16 during the second fortnight of December 2016, we met the subjects to obtain a written informed consent. In the next individual meeting, during the same two weeks, we collected their anthropometric data and HRQoL questionnaire.

The study covered a 12-week period, from January to the end of March of 2017. We carried out three weekly sessions of 60 minutes each on Mondays, Wednesdays, and Fridays. Each session consisted on three phases. The first one was a warming up session for the muscles involved in the workout. In the second or main phase, the subjects followed each of the postures of the hypopressive method described by Rial & Pinsach [10]. The final phase consisted on stretching exercises and relaxation.

After 12 weeks, we collected the post-study data which consisted again on anthropometric data and a HRQoL questionnaire.

The subjects in the Sedentary group, attended the regular appointments of postpartum control, just as the subjects in the LPF group.

Variables and Assessment Tools

Social-demographic and Anthropometric Variables

The following variables were collected in the personalized meeting with the researcher in charge: subject age, marital status, height, weight at 16 weeks after labour (Weight1), weight at 28 weeks after labour (Weight2), parity, gestation time, education level, social class, and previous physical activity.

The weight (Kg) was assessed with a calibrated scale. The height (m) was measured with a calibrated metal stadiometer. To calculate the body-mass index (BMI) we used the formula BMI = weight (in Kg)/height^2(in m^2) [11–14]. We classified the subjects following the World Health Organization (WHO) classification regarding nutritional states, in accordance with the BMI, in the following categories: Low weight < 18.50 Kg/m^2, Normoweight 18.50−24.99 Kg/m^2, Overweight 25−29.99 Kg/m^2, and Obesity ≥ 30.00 Kg/m^2.

The subjects' Social Class was ranked using a questionnaire of social class assessment in health sciences by Álvarez-Dardet et al., 1995 [20], which ranks subjects in five social groups according to their working abilities.

The previous physical activity was assessed in postpartum week 16 according to the subjects' personal report to the question "a typical day of a typical week" using the tool Global Physical Activity Questionnaire (GPAQ, from WHO "Global recommendations on physical activity for health") [21].

Level of Effort and Workout Intensity

We used the classical Borg Scale of Perceived Exertion, or Rating of Perceived Exertion (RPE) [22], in which scores between 12 and 14 "somewhat hard" mean moderate level.

Heart rate was measured at the end of each workout using the pulse oxymeter Quirumed OXYM2000 in all women that had an RPE higher than 14.

Health Related Quality of Life (HRQoL)

We used the self-administered SF-36v2 questionnaire on weeks 16 and 28 after labour to evaluate HRQoL. It is a 4-week reminder, with 8 health state domains or aspects. These domains are Physical Function (PF), Physical Role (PR), Body Pain (BP), General Health (GH), Vitality (VT), Social Function (SF), Emotional Role (ER), and Mental Health (MH). We included Physical Components Summary (PCS) and Mental Components Summary (MCS) [23] measurements.

Sample size

This study is a component of a main project registered at Clinical Trials, hence the sample size was calculated for the main project according to previous studies by Barakat et al. (2011) [24]. In their study, Barakat et al. followed a programme of physical exercises with pregnant women form gestation weeks (GW) 6–9 until GW 38–39. They found that the percentage of women with a perception of good/very good health reached 96.9% in the treatment group, compared to 81.8% in the Sedentary group. In order to achieve an 80% power when detecting differences in a null hypothesis test H0:p1 = p2 using a bilateral chi-square test for two independent samples and considering a significance level of 5%, our sample should be of 56 subjects per group, or 112 in total. In this study, the sample size for the Sedentary group was 65 women, and the sample size for the LPF workout was 64 women, a total of 129 subjects.

The programme started 16 weeks after labour, in January 2017, and ended 12 weeks later, at the end of March 2017.

Randomization

The sample allocation was randomized, following an open-label technique of simple and without replacement randomized sampling, where both subjects and researchers knew about the treatments. Once the participants were met at the Healthcare Center and after verifying that they met the inclusion criterion, we introduced copies of the numbers assigned to the subjects in a vase and the main researcher of the randomized clinical trial (RCT) extracted the numbers and assigned firstly the Sedentary group members (n = 65) and then the LPF workout group member (n = 64). The women randomly assigned to the LPF workout group had an interview with the main researcher, who informed them of the benefits of attending the sessions and provided them with the documents explaining the treatment.

Statistical Analysis

We ran a descriptive analysis of the main studied variables per group.

We have made the comparison between groups using *Student's t*-distribution proof for continuous variables and the Chi-Squared Test for qualitative variables.

A factorial desing with two factor with fixed effect has been used to test the effect of group and time factor (data collect postpartum weeks 16–28). We have used partial Eta-Squared to calculate the effect of factors. We have considered Eta-Squared small effect 0.01, medium effect 0.06 and big effect 0.14.

We obtained the commercial license #QM035814 from the company Quality Metric Incorporated to analyze the SF-36v2 Health Questionnaire, and we studied the questionnaire variables in independent groups.

We used SPSS statistical package for Social Sciences Software (version 19 for Windows, SPSS Inc., Chicago, IL, USA) to run the statistical analysis with a statistically significant level defined at < 0.05.

4. Results

During the study we lost subjects in each group, mostly due to subjects returning to their working schedules, being the final sample size 119 subjects. The final sample size for the LPF group was 56 women, and for the Sedentary group was 63 women. Table 1 shows the basal characteristics of the sample.

Table 1
Basal characteristics of the sample

Characteristics	LPF Group (n = 65)	Sedentary Group (n = 64)	p-value
Age in years (Mean ± SD)	n = 65	n = 64	0.331
min-max	32,12 ± 4.43	30,58 ± 4.75	
Marital Status (FrEq. (%))	21−43	22−43	0.396
Height (Mean ± SD)	57 (87.7)	59 (92.2)	0.396
Weight1 (Mean ± SD)	1.646 ± 0,04	1.651 ± 0.06	0.601
BMI1 (Median [Q1 - Q3])	68.15 ± 11.66	70.19 ± 12.41	0.358
Normoweight	24.46 [21.88−27.67]	24.58 [22.66−27.82]	0.443
Overweight	32 (57.1)	34 (54.0)	0.865
Obesity	17 (30.4)	22 (34.9)	
Parity (FrEq. (%))	7 (11.1)	7 (11.1)	0.739
Gestation Time in days (Mean ± SD)	20 (30.77)	17 (26.56)	0.996
Physical Activity Domains (according to intensity) GPAQ			
Daily Activity			0.880
Moderate	57 (93.4)	56 (94.9)	
Vigorous	4 (6.6)	3 (5.1)	
Moderate Movement	0.497	44 (68.8)	0.497
Recreational Activity			
Moderate	52 (80.0)	53 (82.8)	0.681
Vigorous	13 (20.0)	11 (17.2)	
Weight1: weight at postpartum week 16; BMI1: BMI at postpartum week 16.			

We did not find statistically significant differences in the basal characteristics of the sample.

With the purpose of knowing if group, data recopilation week and the interaction between week and group affect each of the measured parameters of the survey, a factorial design with two factors with fixed effect has been used.

Table 2 shows the average and typical deviation for each aspect per group, week and interaction between week and group, p-value for each comparison and factor effect in the value of each aspect.

	Table 2: Average score (SD) per group, postpartum week and interaction week*group. (LPF, n=56; Sedentary, n=63)													
Aspect	Group				Postpartum week				Interaction Week*Group					
									LPF		Seden			
	LPF	Seden	p	efecto	16 post	28 post	p	efecto	16 post	28 post	16 post	28 post	p	efect
PF	75.54 (14.40)	74.56 (14.27)	0.597	0.001	72.52 (15.46)	77.52 (12.64)	0.007	0.031	72.86 (14.95)	78.21 (13.43)	72.22 (16.01)	76.90 (11.96)	0.855	0.000
RP	44.87 (16.40)	43.95 (13.44)	0.611	0.001	38.97 (14.84)	49.79 (12.86)	<0.001	0.137	38.06 (15.55)	51.67 (14.38)	39.78 (14.26)	48.12 (11.20)	0.144	0.009
BP	60.27 (17.53)	60.46 (12.71)	0.922	0.000	58.55 (14.89)	62.19 (15.22)	0.054	0.016	57.21 (16.75)	63.32 (17.90)	59.73 (13.04)	61.19 (12.44)	0.237	0.006
GH	77.88 (9.60)	76.86 (7.63)	0.298	0.005	73.34 (8.78)	81.34 (6.30)	<0.001	0.225	72.77 (9.67)	83.00 (6.26)	73.86 (7.95)	79.86 (6.01)	0.033	0.019
VT	55.25 (17.25)	51.14 (14.56)	0.020	0.023	45.54 (14.94)	60.61 (13.23)	<0.001	0.252	43.64 (14.08)	66.85 (11.30)	47.22 (15.59)	55.06 (12.39)	<0.001	0.076
SF	83.37 (11.79)	81.15 (12.92)	0.158	0.008	79.31 (13.26)	85.08 (10.83)	<0.001	0.057	79.46 (12.25)	87.28 (9.97)	79.17 (14.20)	83.14 (11.26)	0.221	0.006
ER	36.83 (12.64)	33.53 (9.69)	0.006	0.032	28.71 (9.19)	41.46 (9.42)	<0.001	0.340	28.87 (9.40)	44.79 (10.24)	28.57 (9.07)	38.49 (7.55)	0.012	0.027
MH	78.30 (10.45)	75.32 (9.89)	0.018	0.024	73.53 (10.94)	79.92 (8.41)	<0.001	0.101	74.73 (11.46)	81.88 (7.95)	72.46 (10.43)	78.17 (8.49)	0.570	0.001
PCS	48.28 (5.15)	48.47 (4.16)	0.749	0.000	47.37 (4.71)	49.39 (4.36)	0.001	0.050	46.89 (4.96)	49.67 (5.00)	47.80 (4.48)	49.15 (3.73)	0.228	0.006
MCS	44.74 (5.16)	42.81 (3.97)	<0.001	0.064	41.16 (4.25)	46.28 (3.51)	<0.001	0.333	41.36 (4.66)	48.11 (2.99)	40.97 (3.89)	44.65 (3.13)	0.002	0.042

PF: Physical function; PR: Physical Role; BP: Body Pain; GH: General Health; VT: Vitality; SF: Social Function; ER: Emotional Role; MH: Mental Health; PCS: Physical Component Summary; MCS: Mental Component Summary.

Just as can be seen on Table 2 aspects of vitality (VT), emotional role (RE), mental health (MH) and mental component punctuation (MCS) are affected by the origin group, in all cases the LPF group having a higher punctuation. In vitality (VT), emotional role (RE) and mental health (MH) the effect of group over punctuation is small, for the sum of mental component punctuation (MCS) the variable group has a medium effect. Time affects all variables, except body pain (BP). In all cases punctuation is higher on week 28. On week 16 postpartum, there are several aspects with average score under 50, being emotional role (RE) the lowest, with a mean of 28.71 points. Also in the lower punctuation range are emotional role (RE) and vitality (VT) possibly implying that women experience certain physical limitations 4 months after delivery. After 12 weeks, on week 28 postpartum, basically all aspects, score mean punctuations above 50, except emotional role (RE), which increases to a mean punctuation of 41.46. The effect of time on physical component (PF) is small. For the social function (SF) and physical component punctuation, it could be considered medium. For physical role (RP), general health (GH) vitality (VT), emotional role (RE), mental health (MH) and sum of mental components punctuation (MCS), the effect is higher, with emotional role (RE) being the highest of all.

The effect of group-week interaction is significative for general health (GH), vitality (VT) emotional role (RE) and mental component punctuations (MCS), Table 2 shows the median for each according to group and week, being in all cases higher on week 28, particularly for LPF group. The effect of interaction is small for general health (GH) and emotional role (RE), while medium for vitality (VT) and sum of mental component punctuation (MCS). Figure 2 shows the estimated population marginal means for each group and week, with a distinct line for each group.

The effect of time and group, and their interaction with each category according to Body Mass Index (BMI) has been studied for physical components punctuation (PCS) and mental component punctuation (MCS). The results of this

analysis, with means and standard deviations for each group can be found on Table 3.

Tabla 3: PCS and MCS average score (SD) per group, postpartum week and Interaction week*group según IMC
(Normoweight: LPF, n=32, Sedentary, n=34; Overweight: LPF, n=17, Sedentary, n=22; Obesity: LPF, n=7, Sedentary, n=7)

Aspect	BMI	Group				Postpartum week				Interaction week*group					
										LPF		Seden			
		LPF	Seden	p	efect	16 post	28 post	p	efect	16 post	28 post	16 post	28 post	p	efect
PCS	Normoweight	48.06 (4.40)	49.31 (4.50)	0.103	0.021	47.83 (4.53)	49.58 (4.28)	0.022	0.041	46.79 (4.02)	49.33 (4.46)	48.81 (4.82)	49.81 (4.16)	0.315	0.008
	Overweight	48.01 (6.41)	48.35 (3.26)	0.757	0.001	46.85 (4.96)	49.55 (4.43)	0.011	0.084	46.11 (6.31)	49.90 (6.12)	47.42 (3.65)	49.27 (2.58)	0.373	0.011
	Obesity	49.96 (4.97)	44.78 (2.91)	0.003	0.310	46.66 (4.98)	48.07 (4.66)	0.382	0.032	49.27 (5.27)	50.64 (4.96)	44.05 (3.17)	45.50 (2.67)	0.979	0.000
MSC	Normoweight	43.82 (4.94)	43.37 (4.33)	0.491	0.004	40.96 (4.30)	46.21 (3.25)	<0.001	0.343	40.29 (4.15)	47.35 (2.56)	41.59 (4.40)	45.15 (3.49)	0.008	0.054
	Overweight	46.95 (4.79)	42.51 (3.12)	<0.001	0.320	42.36 (4.01)	46.55 (3.97)	<0.001	0.311	44.15 (4.54)	49.77 (3.15)	40.97 (2.96)	44.06 (2.48)	0.099	0.036
	Obesity	43.57 (5.75)	50.00 (4.13)	0.062	0.137	38.73 (3.73)	45.83 (3.55)	<0.001	0.548	39.96 (4.75)	47.63 (3.24)	37.96 (2.47)	44.03 (3.04)	0.445	0.025

PCS: Physical Component Summary; MCS: Mental Component Summary.

Group affects physical component punctuation (PCS) in women with obesity, in this case LPF shows a higher punctuation. Punctuation for mental components (MCS) is affected by group in the category for overweight women, having an average punctuation higher tan LPF. In both cases the effect of group can be considered high.

Time factor affects all categories in both of the studied components except Obesity on physical component punctuation (PCS). In all cases punctuation is higher on week 28 postpartum. The effect of time can be considered médium for physical component punctuation (PCS) and big for mental component punctuation (MCS).

Interaction between time and group affects the mental component punctuation (MCS) in the case of normal weight women, with higher punctuation on week 28. The effect of this interaction being medium for LPF group.

The effect of this interaction on each Body Mass Index (BMI) category is showed in Fig. 3.

5. Discussion

The high number of participants in this study, including the high follow-up rate, gives strength to this study. Our results can be extrapolated to help other women with healthy pregnancies and eutocic deliveries.

Although using a self-administered questionnaire could be considered a limitation, Ware el al. (1993) [25] claimed that there were no differences in the internal consistency between the SF-36v2 questionnaire and interviewer-administered questionnaires. Attracting pregnant women to participate in the study was also a limitation, which we attribute to the lack of existing information in the Healthcare Services about the importance of physical activity for pregnant women. The need to reduce the environmental barriers was an additional limitation we had to resolve, which we did by offering a daycare service to the women participating in the study.

Singh et al., 2015 [26] tried to determine the impact of parity in women's HRQoL. They studied 60 women that met the inclusion criterion and found that women with a higher level of parity tend to have worse HRQoL. In our study we did not find statistically significant differences between groups regarding parity. However, we did find that HRQoL is inversely associated with sedentariness during the studied period, meaning that HRQoL is reduced as sedentariness increases.

Haas et al., 2005 [27], already confirmed that the lack of physical exercise, before, during, and after pregnancy, is associated to a worse state in all health indicators. Doya et al., 2013 [28], examined the effect of specific workouts of

physical training during pregnancy, and particularly the ones centered in core, on QoL at the end of pregnancy and during the 2 months after labour. They studied a sample size of 49 nulliparous women between pregnancy weeks 24 and 36 and the treatment group carried out a structured training programme centered on trunk fitness. They measured HRQoL using questionnaire SF-36v2 on pregnancy week 24 and 2 months after labour. They found that all the SF-36v2 domains were more favourable in the training group two months after labour than in the sedentary group. Their results are similar to the ones we obtained in our study using the SF-36v2 questionnaire at six months after labour.

Haruna et al., 2.013 [29], carried out a clinical trial studying a workout programme at three months after labour, consisting on a 4-weeks programme of 90 minutes of exercise per week. They found that the workout programme for healthy women during the postpartum period improved their HRQoL and self-esteem. However, in that study they only found a statistically significant difference between the domains PF and VT, but not between PCS and MCS. Their results are in contrast with the results of our study, in which from the fourth to the sixth postpartum month we found statistically significant differences in the SF-36v2 domains GH, VT, SF, ER and MH. We reach the same conclusion as Haruna et al., confirming that physical exercise contributes to improving HRQoL.

In a systematic revision of the scientific literature published by our research group *(Sánchez-García, 2016)*, we concluded that supervised workouts of moderate intensity and with a longer duration than six weeks yields statistically significant results in HRQoL, which we also confirm in our clinical study. Additionally, in our study we found the exception that categorizing women on both groups by BMI creates a statistically significant increment of the recorded scores in the SF-36v2 questionnaire of the PCS and MCS in both groups.

Similarly, Yan and Chen [31], carried out a pilot simple randomized blind study with the objective of exploring whether aerobic workouts improve postpartum stress, sleep quality, fatigue, and depression. To measure their data, they used the perceived stress scale, postpartum fatigue scale, postpartum sleep quality scale, and the Edinburgh postnatal depression scale. They found results similar to ours, which can motivate women that gave birth to practice postpartum physical exercise to improve the studied parameters. In this same line of research, an additional study [32] was made where the improvement of the sleep quality associated to postpartum physical exercise was studied.

Conclusions

In this study we found that offering a physical exercise programme following the Low Pressure Fitness method to postpartum women significantly improves the HRQoL of these women. Sedentary women improve their SF-36v2 questionnaire score. However, that improvement is normal just as postpartum period advances, having scores clearly lower than women that get exercise during the postpartum period.

Based on the above described study concludes that it is beneficial to recommend physical exercise following the Low Pressure Fitness methodology in postpartum to any woman who has no contraindication to be able to perform physical exercise.

Declarations

-The has the ethics approval and consent to participate.

-All the authors give the consent for publication.

-Availability of data and material is total, because there have been created from ourselves .

-Competing interests does not exit.

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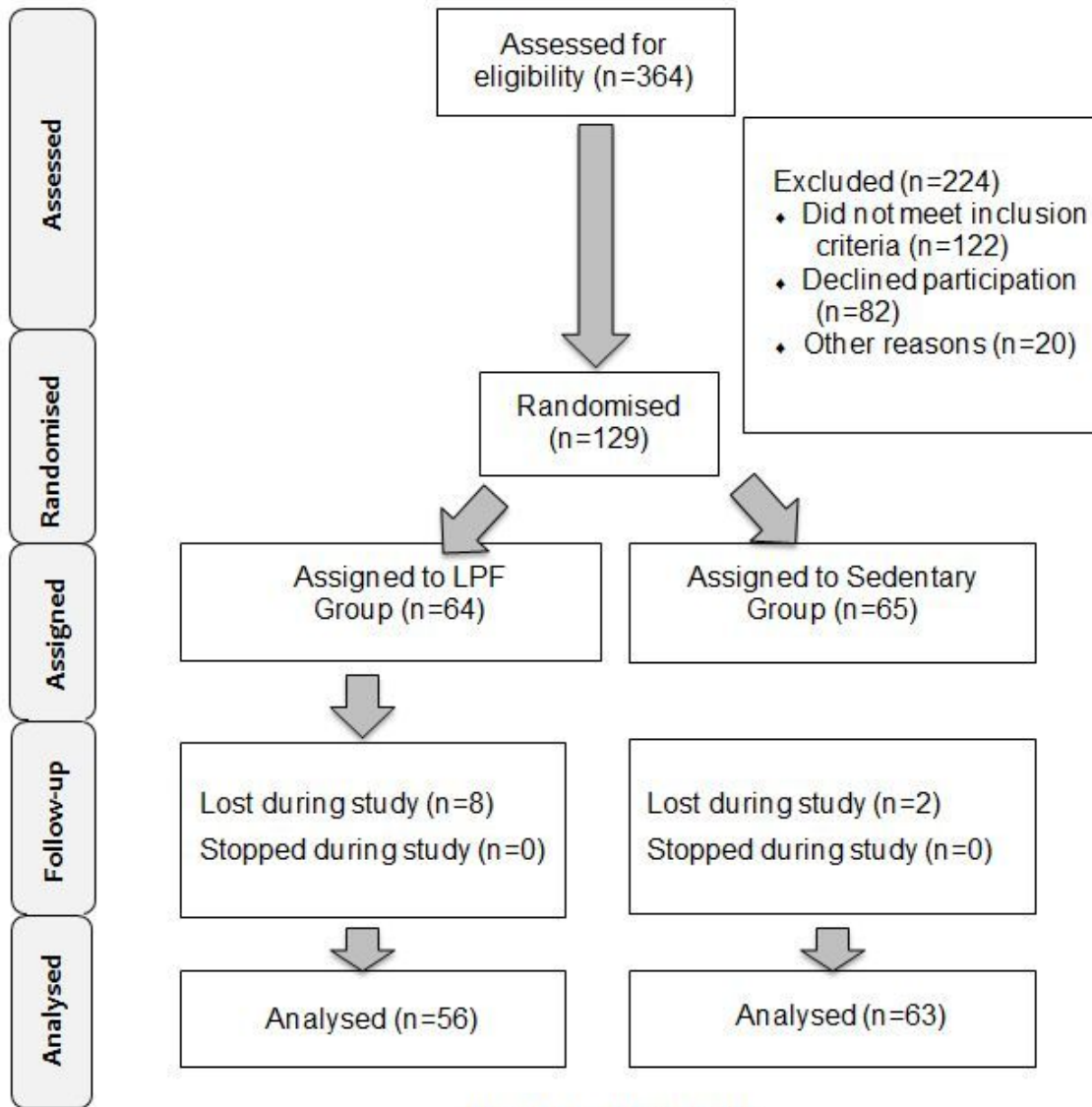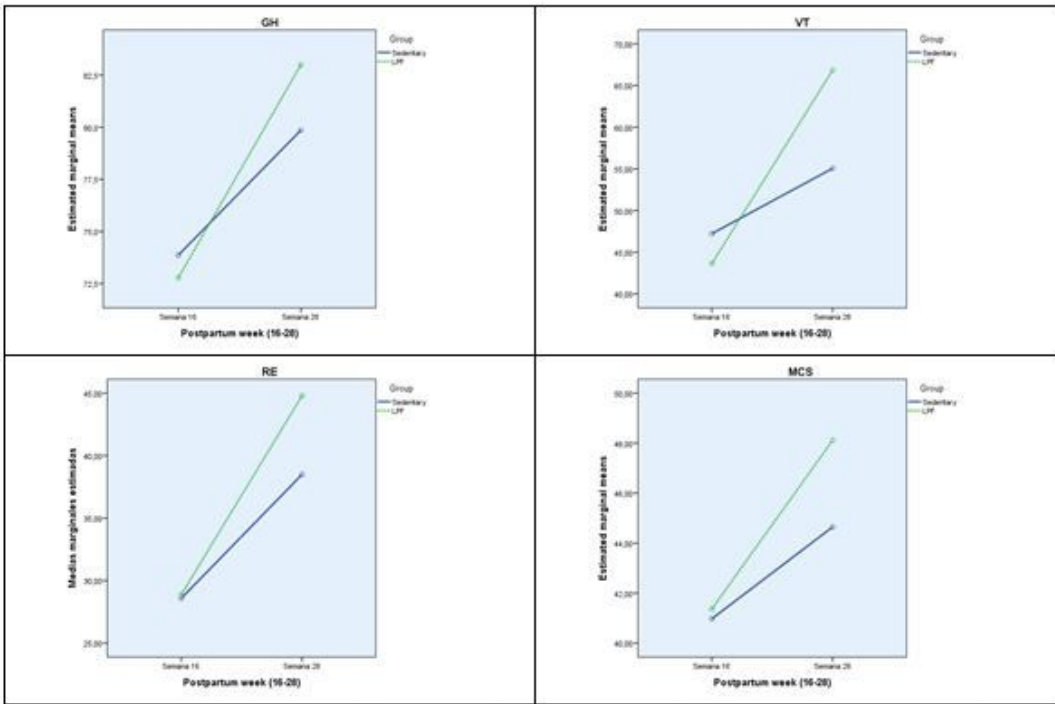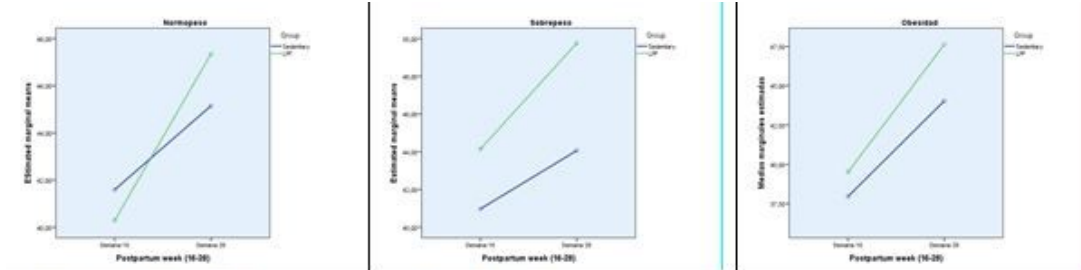
Figures

Figure 1: Flowchart

Figure 1

describes the sample selection.

GH: General Health; VT: Vitality; ER: Emotional Role; MCS: Mental Component Summary.

Figure 2

Population marginal means, estimated on each week for each group.

MCS: sum of mental components punctuation

Figure 3

marginal population means estimated for each week for each MCS group according to BMI.