

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Analysis of nutritional habits and levels of physical activity together with the consequences of the same during pregnancy, birth and the postpartum period of women in health area no. 1, Toledo (Spain). PrePaN Study.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-029487
Article Type:	Protocol
Date Submitted by the Author:	31-Jan-2019
Complete List of Authors:	<p>Muñoz Muñoz, Aránzazu; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department; Buenavista Primary Care Centre, SESCOAM.</p> <p>Cantarino, Sagrario; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department, De Dios Aguado, María de las Mercedes; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department;; Yepes Primary Care Centre</p> <p>Velasco Abellán, Minerva; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department;; Department of Emergency. Castilla-La Mancha Health System</p> <p>González López, Beatriz; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department;; Polan Primary Care Centre</p> <p>Molina Gallego, Brigida; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department;; FENNSI Group, Hospital Nacional de Paraplégicos</p> <p>González Pascual, Juan Luis; Universidad Europea de Madrid, School of Biomedical and Health Sciences; Nursing Department.</p> <p>Arias Palencia, Natalia María; Universidad de Castilla- La Mancha, School of Education; Universidad de castilla- La Mancha, Health and Social Research Center</p>
Keywords:	accelerometer, pregnancy outcomes, physical activity, neonatal outcomes

SCHOLARONE™
Manuscripts

1
2
3 **Analysis of nutritional habits and levels of physical activity together with the**
4 **consequences of the same during pregnancy, birth and the postpartum period of**
5 **women in health area no. 1, Toledo (Spain). PrePaN Study.**
6
7

8 Muñoz Muñoz, Aránzazu ^{1,2}; Gómez Cantarino, Sagrario¹; De Dios Aguado, María De
9 Las Mercedes ^{1,3}; Velasco Abellán, Minerva ^{1,4}; González López, Beatriz ^{1,5}; Molina
10 Gallego, Brígida ^{1,6}; González Pascual, Juan Luis ⁷; Arias Palencia, Natalia María ^{8,9}.
11
12

13
14 1- ENDOCU Group, University School of Nursing and Physiotherapy Toledo (Nursing,
15 pain and Care), Toledo, Spain.

16 2- Buenavista Primary Care Centre, SESCAM, Toledo, Spain.

17 3- Yepes Primary Centre, SESCAM, Toledo, Spain.

18 4- Department of Emergency. Castilla-La Mancha Health System, Toledo, Spain.

19 5- Polan Primary Care Centre, SESCAM, Toledo, Spain

20 6- FENNSI Group, Hospital Nacional de Parapléjicos, SESCAM, Toledo, Spain.

21 7- School of Biomedical and Health Sciences; Nursing Department. Universidad Europea
22 de Madrid, Madrid, Spain.

23 8- School of Education, Universidad de Castilla-La Mancha, Cuenca, Spain.

24 9- Health and Social Research Center, Universidad de Castilla-La Mancha, Cuenca,
25 Spain.
26

27 E-mails authors:
28

29 ara_mnz@hotmail.com

30 Sagrario.gomez@uclm.es

31 mded@sescam.jccm.es

32 minerva.velasco@uclm.es

33 begolo@sescam.jccm.es

34 Brigida.molina@uclm.es

35 juanluis.gonzalez2@universidadeuropea.es

36 Natalia.arias@uclm.es
37
38

39 Corresponding author:
40

41 Sagrario Gómez Cantarino. Department of Nursing, Physiotherapy and occupational
42 therapy. School of Nursing and Physiotherapy Toledo, University of Castilla- La Mancha,
43 Toledo, Spain.

44 Avd/ Carlos III s/n, 45071, Toledo, Spain.

45 Sagrario.gomez@uclm.es

46 +34670225048
47
48

49 **Key words:** accelerometer, neonatal outcomes, physical activity, pregnancy outcomes.
50

51 **Word count:** 2787
52
53
54
55

Abstract

Introduction: Pregnant women who eat a balanced diet usually practice physical activity (PA) regularly; there are many studies on PA during pregnancy and the results for the mother and baby. However, the guideline for PA during pregnancy is very general and is not quantified.

Objectives: To examine the nutritional habits and levels of PA of women during pregnancy and the postpartum period using validated questionnaires and accelerometers. Secondly, it will determine the effects of these aspects on the mother and newborn baby. Its third objective is to identify the factors which influence the practice of PA during this phase.

Methods and analysis: This is a prospective cohort study lasting two years. The sample will be recruited in three Primary Care centers in the Toledo (Spain) health area. The participants will be pregnant women aged from 18 to 40 years old who attended all the check-ups during their pregnancy and postpartum period. PA will be quantified using a GT3X (ActiGraph) accelerometer, while nutritional habits and physical exercise will be evaluated using validated questionnaires. The symptoms of pregnancy and the postpartum period will be recorded, together with biochemical parameters and anthropometric data. The primary outcomes will be determined in the pregnant women: weight gain, the incidence of gestational diabetes mellitus, pre-eclampsia and pregnancy-induced hypertension. Secondary outcomes include duration of pregnancy and weight at birth, Apgar score (1 min/ 5 min), type of reanimation (I/II/III/IV), and umbilical cord blood pH in the newborn babies.

Discussion: although the beneficial effects of PA during pregnancy are known, there is a need to perform studies that quantify the amount of PA undertaken by women during pregnancy, postpartum and the postpartum period. The objective of such studies is to establish science-based individualized guidelines for PA for women during this stage of their lives.

Strengths and limitations

- Pregnancy is a period in a woman's life, characterized by a greater awareness of their health and care.

-An early investment in health protection generally produces long-term benefits in all population groups, including that of pregnant women.

- This project offers benefits that extend beyond those that can occur in life, which also have an impact on clinical practice and the condition of the type of delivery, neonatal outcomes and a better recovery of the pregnant.

-This research will offer new information about how pregnant and postpartum women, like their neonates, respond to moderate physical activity without showing adverse effects.

-The study will offers results on the nutritional behavior of pregnant women, the impact of diet on their newborn and the influence on the mother's puerperium.

Introduction

When women are pregnant, they take better care of their health and are more receptive and likely to make changes that lead to a healthier lifestyle. Recommendations to increase physical activity (PA) and to eat a healthy diet therefore have a positive effect throughout pregnancy and the postpartum period on the mother as well as their newborn baby (Muktabhant et al., 2015).

The scientific literature contains relevant information on the effects of moderate and regular PA during pregnancy: mothers gain less weight and reduce the risk of pregnancy-related diabetes and hypertension (Muktabhant et al., 2015; Poudevigne et al., 2005); higher stress tolerance and earlier neonatal neuro-behavioural maturity (Clapp et al., 1999). Among other recommendations, the American College of Obstetricians and Gynaecologists (ACOG) suggests that pregnant women with no medical or obstetric complications should perform at least 30 minutes of moderate PA every day of the week (Artal et al., 2003). Nevertheless, the World Health Organization (WHO) admits that further research is needed into guidelines for pregnant women on the amount of PA they should undertake. The WHO currently states that the general considerations for PA in adults also apply to pregnant women, i.e., at least 75 minutes of vigorous PA or 150 minutes of moderate PA per week, including the strengthening of the major muscle groups (WHO, 2010).

On the other hand, several studies on the effects of physical exercise during pregnancy found no relevant benefits for the mother and even detected unsatisfactory results in comparison with other more sedentary mothers (Vallim et al., 2011; Kramer et al., 2006). All these considerations show the need for research to confirm the correct guideline for PA that leads to the greatest health benefits for mothers as well as their newborn babies. As well as being physically active, it is also recommended that women eat a healthy diet during pregnancy and the postpartum period. During this life stage, those women who eat a healthy diet were also found to do more exercise (Olmedo-Requena et al., 2014). Data show that low adherence to the Mediterranean diet may be associated with a reduction in the weight of the placenta and low neonatal weight (Timmermans et al., 2014), as well as the risk of pregnancy-associated diabetes in terms of the classification and diagnosis of diabetes (2015), which indicates how important diet is during this phase of women's lives (Karamanos et al., 2014). Epidemiological studies of pregnant women indicate that their weight prior to pregnancy, height, blood levels of glucose and weight gain during pregnancy are factors that influence foetal development (Restrepo et al., 2009).

While it is important that mothers should not gain excessive weight during pregnancy, they should also return to their pre-pregnancy weight after giving birth. This is because there is an association between the risk of obesity after birth and excessive weight gain during pregnancy (Amorim et al., 2007). On the other hand, controlling weight solely by diet after giving birth is less effective than a combination of diet and physical exercise (Gómez et al., 2016). The promotion of healthy habits in terms of a combination of diet and PA during pregnancy and the postpartum period may therefore be highly beneficial for women.

1
2
3 The main outcome of this research is to examine the nutritional habits and the
4 levels of PA in women during pregnancy and the postpartum period by means of validated
5 questionnaires and accelerometers.

6
7 The secondary outcomes are:

8 i) To calculate the relationship between the level of PA and nutritional habits during
9 pregnancy and the postpartum period in terms of the results for mothers in: weight gain,
10 the incidence of pregnancy-related diabetes mellitus, pre-eclampsia and pregnancy-
11 induced hypertension and type of birth. This relationship is also examined in terms of the
12 results for newborn babies: duration of pregnancy, weight at birth, Apgar score 1 min / 5
13 min, type of reanimation and umbilical cord blood pH.

14 ii) To identify the factors that influence the performance of PA during each stage of
15 pregnancy and the postpartum period (using the Spanish version of the Pregnancy
16 Symptoms Inventory “PSI” and the Edinburgh scale).

21 **Methods/Design**

22
23 A two-year study of cohorts during pregnancy and the postpartum period in Health
24 Area No. 1, Toledo (Spain).

25
26 A multicentre study will be undertaken in the healthcare facilities of Castilla -La
27 Mancha Health Service (SESCAM), in the areas of Primary and Specialised healthcare:
28 i) Buenavista Health Centre; ii) Santa Bárbara Health Centre; iii) Yepes Health Centre;
29 iv) Polán Health Centre and v) the Virgen de la Salud Hospital.

30
31 The sample will be recruited by means of non-probabilistic consecutive sampling
32 in Primary Care facilities.

33 Inclusion criteria:

- 34
35 i) Women aged from 18 to 40 years old.
36
37 ii) Pregnancy having lasted 14 weeks or less.
38
39 iii) A single foetus.
40
41 iv) Quarterly pregnancy check-ups in Primary Care facilities.
42
43 v) The intention of giving birth in the Virgen de la Salud Hospital.
44
45 vi) Comprehension of spoken and written Spanish.

46 Exclusion criteria:

- 47
48 i) Women with conditions prior to pregnancy that hinder or limit the practice of PA at the
49 time of recruitment (one or more contraindications for PA according to the ACOG,
50 diabetes or arterial hypertension prior to pregnancy, or more than one previous abortion).
51
52 ii) Not signing the informed consent document.
53
54
55
56
57
58
59
60

1
2
3 Iii) Not understanding written and spoken Spanish.
4

5 Variables
6

7 *Sociodemographic variables:* the following data will be recorded in the first interview
8 (*Figure 1*): age (years), marital status (married, single, living with partner, others),
9 country of origin, educational level (none, primary, secondary, technical college,
10 university), economic resources (low, medium or high), working status (housewife,
11 unemployed, in work).
12
13

14
15 *Anthropometrics:* all measurements will be taken by trained investigators to minimize
16 inter-observer variability, using the same apparatus: scales (mechanical, with a range up
17 to: max. 220 kg d=50g) and a wall-mounted height gauge (range: 0 to 200 cm). The
18 subjects will be measured in the 1st, 2nd, 3rd and 4th (postpartum) visit in the morning for
19 weight (without shoes and in light clothing) and height (standing upright without shoes
20 and with the median sagittal line touching the board) will be measured in the first visit.
21 The average of two measurements will be taken. Body mass index (BMI) will be
22 calculated as body mass (in kilograms) divided by height² (in metres).
23
24

25
26 *Arterial blood pressure:* will be measured twice, with a 5-min interval between
27 measurements. The first measurement will be made after at least 5 min rest. Women will
28 be seated, in relaxing conditions, with the right arm semi-flexed at heart level. Blood
29 pressure will be measured with an Omron M5-I monitor (Omron Healthcare UK Ltd.).
30
31

32 *Physical activity:* PA will be measured using:
33

34
35 The Spanish version of the Pregnancy Physical Activity Questionnaire (PPAQ) (Chasan-
36 Taber et al., 2004). This self-administered questionnaire contains 32 items which measure
37 the frequency and duration of PA during pregnancy (1st, 2nd and 3rd visit), in terms of:
38 being sedentary, doing household chores/care, work-related activity and sports activities.
39

40
41 Accelerometry will use Actigraph brand GT3X accelerometers to objectively measure
42 PA levels during the three trimester of pregnancy and during the postpartum period.
43 Accelerometry has been used in several population groups, including pregnant women,
44 to quantify PA and relate the data obtained with other factors (Aguilar et al., 2014). The
45 criteria for the inclusion of data in the analysis of results will be a minimum recording of
46 4 days, including at least three weekdays and one weekend day, with imperceptible
47 recording of 600 minutes per day (Trost et al., 2005). The device will be worn on an
48 elastic strap on the wrist of the non-dominant hand during seven consecutive days and
49 nights, except for bathing and performing activities in the water, in each one of the
50 measurements (*Figure 1*). The data gathering interval in this study will last for 60 seconds
51 (epochs), as this has been shown to be valid for measuring PA in adults. The
52 accelerometer will also supply information on posture, sleep latency, total sleep time,
53 sleep efficiency, the intensity of PA, periods of activity, periods of sedentary behaviour,
54 rhythm intervals, gross acceleration, energy consumption, MET ratios and the number of
55
56
57
58
59
60

1
2
3 steps (Chen et al., 2005). All subjects will be verbally and in writing instructed on how
4 to use the accelerometer. Data will be downloaded using Actilife v6. 13. 3 software.
5

6
7 To identify the factors which influence carrying out PA the Spanish version of the
8 Pregnancy Symptoms Inventory (PSI) will be used (Foxcroft et al., 2013) during
9 pregnancy, while the Edinburg depression scale will be used in the postpartum period
10 (Vega-Dienstmaier et al., 2002). The PSI is a self-administered questionnaire that
11 evaluates the frequency and degree of limitation of everyday activities arising due to
12 different causes (not at all, a little, a lot) involving 41 intrinsic symptoms of pregnancy.
13 The Edinburgh scale consists of 10 questions with four possible replies, of which the
14 subjects must choose one based on how they felt over the past seven days. Although the
15 final score will indicate the probability of post-natal depression, it will not vary according
16 to its severity.
17
18
19

20
21 *Variables associated with nutritional habits:* the “Young Adolescents’ Nutrition
22 Assessment on Computer” (YANA-C) (Vereecken et al., 2005) will be used, together
23 with the Mediterranean diet adherence questionnaire (PREDIMED) (Martínez-González
24 et al., 2012) to gather data on the diet of pregnant and postpartum women. YANA-C
25 consists of listing the foods consumed in the previous 24 hours, and it is divided into
26 breakfast, mid-morning, lunch, tea, dinner and after dinner. PREDIMED is a self-
27 administered questionnaire containing 14 questions that are answered by a score showing
28 low (< 9 points) or good adherence to the Mediterranean diet (> 9 points).
29
30
31

32 *Pregnancy data:* duration of pregnancy (weeks and days of amenorrhea, according to the
33 date of the last period and confirmation by ultrasound scan), medical problems during
34 pregnancy (Yes/No). The possibility of a premature birth, arterial hypertension,
35 gestational diabetes (defined according to the criteria of the American Diabetes
36 Association (ADA) (2015)), retarded intrauterine growth and a reduction in amniotic
37 fluid, among others).
38
39

40
41 *Birth data:* type of analgesia during birth (none, epidural, spinal), onset of birth
42 (spontaneous / induced, reason for induction), duration of pregnancy (weeks and days),
43 type of birth (natural, instrumental, caesarean), reasons for an instrumental or caesarean
44 birth, episiotomy (yes/no), perineal tear (yes/no, grade I/II/III/IV), type of birth
45 (spontaneous, manual, directed), duration of dilation (minutes), duration of expulsion
46 (minutes).
47
48

49
50 *Neonatal data:* weight (grams), sex (male/female), 1/5 minutes APGAR scale score, type
51 of reanimation (I/II/III/IV), umbilical cord blood pH (arterial and venous), foetal calotte
52 pH (if performed), cord pinching (early/late), commencement of breast feeding in the first
53 two hours of life (yes/no).
54

55
56 *Postpartum data:* bleeding (physiological/moderate/severe), condition of perineum
57 (haematoma/oedema/pain/haemorrhoids/suture dehiscence) and postpartum
58 complications.
59
60

1
2
3 Data corresponding to pregnancy, birth, the newborn baby and postpartum period will be
4 obtained from the clinical history of the mother.
5

6 Patient and public involvement 7

8 There was no patient or public involvement in the design of this protocol.
9

10 Statistical analysis 11

12
13 Regression models will be used to examine the relationship between dependent
14 variables and patient health, measured using one or more explanatory variables that
15 express exposure to a risk factor.
16

17 Sample size has been calculated using *Epidat 4.1*, with an exposed/non-exposed
18 ratio of 1. A prevalence of 14% is assumed in the group of exposed (sedentary) women
19 and a prevalence of 3% is assumed in the group of non-exposed women (who are active
20 according to the current criteria of the American College of Sports Medicine- 30
21 minutes/day of moderately intense (80%) PA every day or almost every day,
22 accumulating at least 150 min/week). Approximately 5% should be added to these
23 premises to account for possible non-responders (women who do not wish to take part in
24 the study).
25
26
27
28

29 **Discussion** 30

31 The study results will make it possible to better advise pregnant women about
32 recommendable PA and nutrition. They will also make it possible to update health
33 education programs for this population group, leading to many benefits for mothers as
34 well as their children.
35
36

37 Adherence to an exercise routine is influenced by factors such as: the habit of
38 exercising prior to pregnancy, sociocultural level, equality and the insistence by
39 healthcare workers that pregnant women undertake PA. The study by Nascimento et al.
40 (2015) showed that half of the women taking part ceased doing physical activity during
41 pregnancy
42
43
44

45 It is therefore important that healthcare personnel offer information on the risks
46 and benefits of PA, while also setting personalised guidelines adapted to the specific
47 needs of each woman. All of the information supplied to future mothers must therefore
48 be supported by scientific evidence. The aim is to guide future mothers towards a healthy
49 lifestyle and to change their habits. This is not only to prevent pathologies during
50 pregnancy and the postpartum period, but rather to ensure that their new habits last
51 throughout their life.
52
53
54

55 The study will also record biochemical parameters which, in association with the
56 data gathered using the scales and accelerometer, will make it possible to prevent the risk
57 of non-transmissible diseases during pregnancy and the postpartum period. Biochemical
58 changes are closely linked to the amount of mothers' PA and the quality and type of their
59
60

1
2
3 diet during pregnancy and the postpartum period. An example of this relationship is the
4 use of the biochemical parameter of glucose as a gestational diabetes marker. Pérez-Ferre
5 et al. (2015) intervened in a group of women with gestational diabetes, changing their
6 dietary habits and encouraging physical exercise. They found that the risk of developing
7 type 2 diabetes in the future fell in the intervention group in comparison with the control
8 group (Perez-Ferre et al., 2015).
9

10
11
12 Larger studies are therefore necessary which quantify the PA of women during
13 pregnancy and the postpartum period, to set guidelines based on scientific evidence.
14 Accelerometers supply reliable and exact data, and they may be considered to be a
15 motivating factor in maternal education programs, as they make pregnant women aware
16 of the amount of PA they perform, thereby stimulating the regular practice of PA.
17
18

19 20 **Abbreviations:**

21
22 PA, Physical Activity; ACOG, American College of Obstetricians and Gynaecologists;
23 WHO, World Health Organization; PSI, Pregnancy Symptoms Inventory; SESCAM,
24 Castilla -La Mancha Health Service; THC, Toledo Hospital Complex; BMI, Body mass
25 index; PPAQ, Pregnancy Physical Activity Questionnaire; PSI, Pregnancy Symptoms
26 Inventory; YANA-C, Young Adolescents' Nutrition Assessment on Computer;
27 PREDIMED, Mediterranean diet adherence questionnaire; ADA, American Diabetes
28 Association.
29
30
31

32 **Declarations:**

33 34 a. Ethics and Dissemination

35
36
37 This research project has been approved by the Toledo Hospital Complex (THC)
38 Clinical Research Ethics Committee, approval number 125. It has also been approved by
39 the Primary and Specialised Care Nursing Boards for implementation and development.
40

41
42 Before they sign the consent document to take part in the study, all the participants
43 will be informed verbally and in writing about the study procedure as well as its
44 objectives. Data confidentiality will be guaranteed, and it will also be possible for
45 participants to revoke their consent for the study at any stage of the same.
46

47
48 Study outcomes will be disseminated at international conferences and published
49 in peer-reviewed scientific journals.
50

51 52 b. Consent for publication

53
54 Not applicable

55 56 c. Availability of data and material

57
58 The data supporting our findings are contained within the manuscript.
59
60

1
2
3 d. Conflicts of interests
4

5 The authors declare that they have no competing interests and they have no commercial
6 or public commitments that would prevent them from undertaking this research.
7

8
9 e. Funding

10 This research did not receive any specific grant from funding agencies in the public,
11 commercial, or not-for-profit sectors.
12
13

14 f. Author Statement

15
16 Conceived and designed the experiments: AMM, MMDA, MVA, SGC and NAP., JLGP,
17 BGL, BMG, SGC and NAP gave statistical and epidemiological support. Contributed
18 reagents/ materials/analysis tools: AMM, MMDA, MVA, BGL, BMG. Wrote the paper:
19 AMM, SGC and NAP. All authors established the methods and questionnaires, provided
20 comments on the drafts, and read and approved the final version.
21
22

23
24 g. Acknowledgements

25
26 We thank the healthcare facilities of Castilla -La Mancha Health Service (SESCAM), in
27 the areas of Primary and Specialised healthcare: i) Buenavista Health Centre; ii) Santa
28 Bárbara Health Centre; iii) Yepes Health Centre; iv) Polán Health Centre and v) the
29 Virgen de la Salud Hospital, that have shown their interest in participating in our study.
30
31

32
33
34 **References**
35

36
37 Aguilar, M.J., Sanchez, A.M., Guisado, R., Rodriguez, R., Noack, J., Pozo, M.D., 2014.
38 [Accelerometer description as a method to assess physical activity in different periods of
39 life; systematic review]. *NutrHosp.* 29(6):1250-61.
40
41

42 American Diabetes Association, 2015. Classification and diagnosis of diabetes. *Diabetes*
43 *Care.* 38(Suppl 1): S8–S16.
44

45
46 Amorim, A.R., Linne, Y.M., Lourenco, P.M., 2007. Diet or exercise, or both, for weight
47 reduction in women after childbirth. *Cochrane DatabaseSyst Rev.* (3): Cd005627.
48

49 Amorim, A.R., Rossner, S., Neovius, M., Lourenco, P.M., Linne, Y., 2007. Does excess
50 pregnancy weight gain constitute a major risk for increasing long-term BMI? *Obesity*
51 *(Silver Spring).* 15(5):1278-86.
52
53

54 Artal, R., O'Toole, M., 2003. Exercise during pregnancy and the postpartum period.
55 *Clinical Obstet Gynecol.*; 46(2):496
56
57
58
59
60

1
2
3 Chasan-Taber, L., Schmidt, M.D., Roberts, D.E., Hosmer, D., Markenson, G., Freedson,
4 P.S., 2004. Development and validation of a pregnancy physical activity questionnaire.
5 *Med Sci Sports Exerc.* 36(10):1750–60.
6

7
8 Chen, K.Y., Bassett, D.R., 2005. The technology of accelerometry-based activity
9 monitors: current and future. *Med Sci Sports Exerc.* 37(11):S490.
10

11 Clapp, J.F., Lopez, B., Harcar-Sevcik, R., 1999. Neonatal behavioral profile of the
12 offspring of women who continued to exercise regularly throughout pregnancy. *Am J*
13 *ObstetGynecol*; 180(1):91-4.
14

15
16 Foxcroft, K.F., Callaway, L.K., Byrne, N.M., Webster, J. 2013. Development and
17 validation of a pregnancy symptoms inventory. *BMC Pregnancy Childbirth.* 13:3.
18

19
20 Freedson, P.S., Melanson, E., Sirard, J., 1998. Calibration of the Computer Science and
21 applications. Inc. accelerometer. *Med Sci Sports Exerc.* 30(5):777–81.
22

23 Gómez, S., et al., 2016. Vivencias, experiencias y diferencias sexuales: mujer puérpera
24 española e inmigrante. Área sanitaria Palma de Mallorca (España). *Rev. Enf. Ref.*
25 [online]. Vol.serIV, n.9, pp.115-123. ISSN 0874-0283.
26

27
28 Karamanos, B., Thanopoulou, A., Anastasiou, E., et al., 2014. Relation of the
29 Mediterranean diet with the incidence of gestational diabetes. *Eur J Clin Nutr.* 68(1):8-13.
30

31
32 Kramer MS McDonald SW. Aerobic exercise for women during pregnancy. *Cochrane*
33 *Database Syst Rev* 2006; 2:CD000180.
34

35 Magann, E.F., Evans, S.F., Weitz, B., Newnham, J., 2002. Antepartum, intrapartum, and
36 neonatal significance of exercise on healthy low-risk pregnant working women.
37 *ObstetGynecol.* 99(3):466-72.
38

39
40 Martínez-González, M.A., Corella, D., Salas-Salvadó, J., Ros, E., Covas, M.I., Fiol, M.,
41 Wärnberg, J., Arós, F., Ruíz-Gutiérrez, V., Lamuela-Raventós, R.M., Lapetra, J., Muñoz,
42 M.A., Martínez, J.A., Sáez, G., Serra-Majem, L., Pintó, X., Mitjavila, M.T., Tur, J.A.,
43 Portillo, M.P., Estruch, R., 2012. Cohort profile: design and methods of the predimed
44 study. *Int J Epidemiol.* 41:377-85.
45

46
47 Muktabhant, B., Lawrie, T.A., Lumbiganon, P., Laopaiboon, M., 2015. Diet or exercise,
48 or both, for preventing excessive weight gain in pregnancy. *Cochrane Database Syst Rev.*
49 (6): Cd007145.
50

51
52 Nascimento, S.L., Surita, F.G., Godoy, A.C., Kasawara, K.T., Morais, S.S., 2015.
53 Physical activity patterns and factors related to exercise during pregnancy: a cross
54 sectional study. *PLoSOne.* 10(6): e0128953.
55

56
57 Olmedo-Requena, R., Fernandez, J.G., Prieto, C.A., Moreno, J.M., Bueno-Cavanillas, A.,
58 Jimenez-Moleon, J.J., 2014. Factors associated with a low adherence to a Mediterranean
59
60

1
2
3 diet pattern in healthy Spanish women before pregnancy. *PublicHealthNutr.* 17(3):648-
4 56.

6 Perez-Ferre, N., Del Valle, L., Torrejon, M.J., Barca, I., Calvo, M.I., Matia, P., et al.,
7 2015. Diabetes mellitus and abnormal glucose tolerance development after gestational
8 diabetes: A three-year, prospective, randomized, clinical-based, Mediterranean lifestyle
9 interventional study with parallel groups. *ClinNutr.* 34(4):579-85.

12 Poudevigne, M.S., O'Connor, P.J.,2005. Physical activity and mood during pregnancy.
13 *MedSci Sports Exerc* (8); 37:1374-80.

16 Restrepo, S., Parra, B., 2009. Implicaciones del estado nutricional materno en el peso al
17 nacer del neonato. *Perspectivas en nutrición humana.* 11(2):179-186

19 Sanabria-Martinez, G., Garcia-Hermoso, A., Poyatos-Leon, R., Alvarez-Bueno. C.,
20 Sanchez-Lopez, M., Martinez-Vizcaino, V.,2015. Effectiveness of physical activity
21 interventions on preventing gestational diabetes mellitus and excessive maternal weight
22 gain: a meta-analysis. *Bjog.*122(9):1167-1174.

25 Timmermans, S., Steegers-Theunissen, R.P., Vujkovic, M., et al, 2012. The
26 Mediterranean diet and fetal size parameters: the Generation R Study. *Br J Nutr.*
27 108(8):1399-1409.

30 Trost, S.G., K.L. McIver, and R.R. Pate, Conducting accelerometer-based activity
31 assessments in field-based research. *Med Sci Sports Exerc*, 2005. 37(11 Suppl): p. S531-
32 43.

35 Vallim, A.L., Osis, M.J., Cecatti, J.G., Baciuk, E.P., Silveira, C., Cavalcante, S.R, 2011.
36 Water exercises and quality of life during pregnancy. *ReprodHealth.* 8:14

39 Vega-Dienstmaier, J.M., Mazzotti, G., Campos, M., 2002. Validación de una versión en
40 español de la escala de depresión postnatal de Edimburgo. *ActasEspPsiquitr.* 30 (2): 106-
41 111.

44 Vereecken, C.A., Covents, M., Matthys, C., Maes, L.,2005. Young adolescents' nutrition
45 assessment on computer (YANA-C). *Eur J ClinNutr.* 59(5):658-67.

48 WHO, 2010. WHO Guidelines Approved by the Guidelines Review Committee. Global
49 Recommendations on Physical Activity for Health. Geneva: World Health Organization.

51 **Figure Legends**

52 Fig. 1. Data gathering phases. AP, arterial blood pressure; BMI, body mass index.
53
54
55
56
57
58
59
60

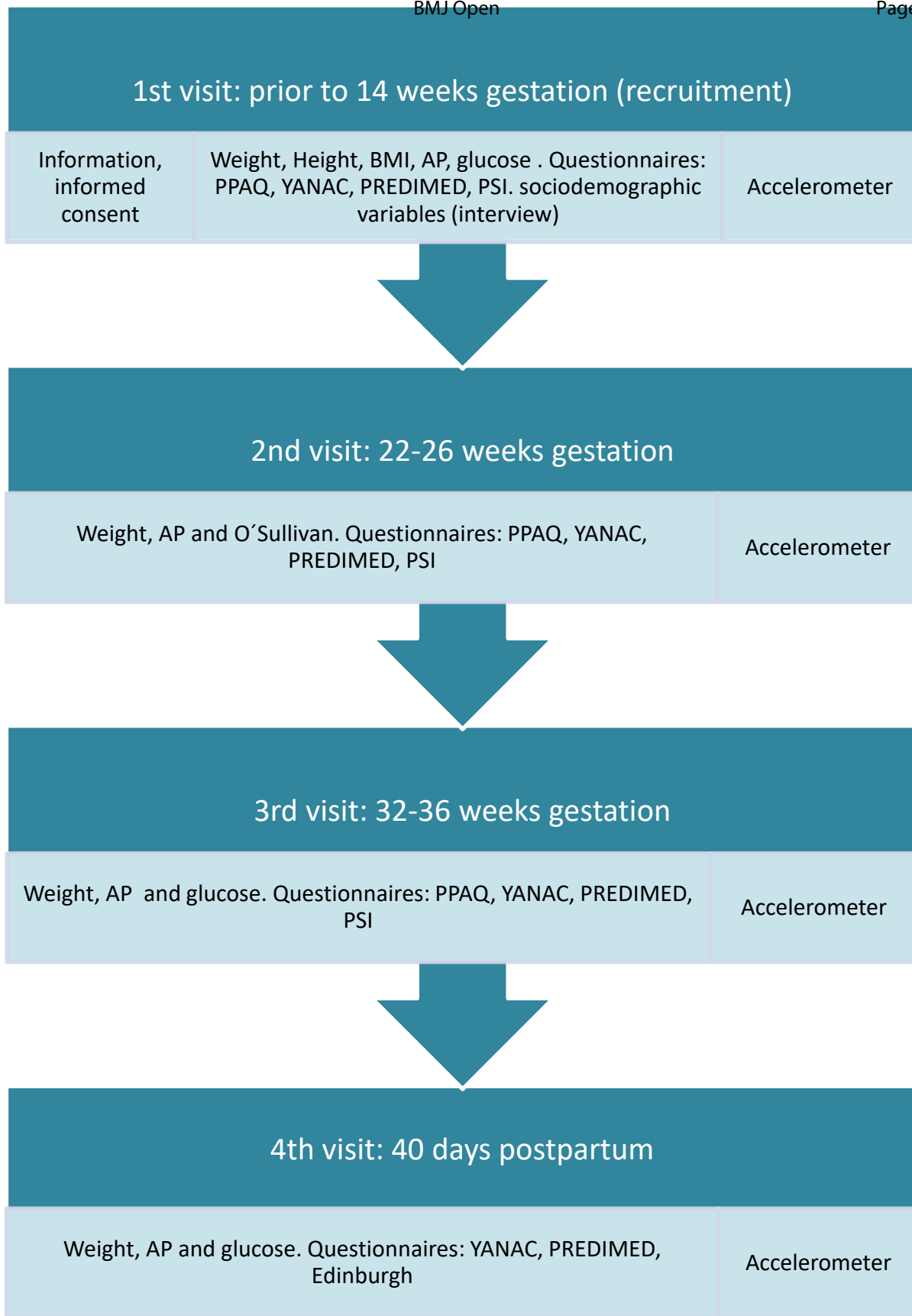


Fig. 1. Data gathering phases. AP, arterial blood pressure; BMI, body mass index.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56

BMJ Open

Analysis of nutritional habits and levels of physical activity during pregnancy, birth and the postpartum period of women in health area no. 1, Toledo (Spain). The PrePaN study protocol.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-029487.R1
Article Type:	Protocol
Date Submitted by the Author:	09-May-2019
Complete List of Authors:	Muñoz Muñoz, Aránzazu; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department; Buenavista Primary Care Centre, SESCAM. Cantarino, Sagrario; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department, De Dios Aguado, María de las Mercedes; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department;; Yepes Primary Care Centre Velasco Abellán, Minerva; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department;; Department of Emergency. Castilla-La Mancha Health System González López, Beatriz; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department;; Polan Primary Care Centre Molina Gallego, Brigida; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department;; FENNSI Group, Hospital Nacional de Paraplégicos González Pascual, Juan Luis; Universidad Europea de Madrid, School of Biomedical and Health Sciences; Nursing Department. Arias Palencia, Natalia María; Universidad de Castilla- La Mancha, School of Education; Universidad de castilla- La Mancha, Health and Social Research Center
Primary Subject Heading:	Obstetrics and gynaecology
Secondary Subject Heading:	Obstetrics and gynaecology
Keywords:	accelerometer, pregnancy outcomes, physical activity, neonatal outcomes

SCHOLARONE™
Manuscripts

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 **Analysis of nutritional habits and levels of physical activity during pregnancy, birth**
4 **and the postpartum period of women in health area no. 1, Toledo (Spain). The**
5 **PrePaN study protocol.**
6
7

8 Muñoz Muñoz, Aránzazu ^{1,2}; Gómez Cantarino, Sagrario¹; De Dios Aguado, María De
9 Las Mercedes ^{1,3}; Velasco Abellán, Minerva ^{1,4}; González López, Beatriz ^{1,5}; Molina
10 Gallego, Brígida ^{1,6}; González Pascual, Juan Luis ⁷; Arias Palencia, Natalia María ^{8,9}.
11
12

13
14 1- ENDOCU Group, University School of Nursing and Physiotherapy Toledo (Nursing,
15 pain and Care), Toledo, Spain.

16 2- Buenavista Primary Care Centre, SESCAM, Toledo, Spain.

17 3- Yepes Primary Centre, SESCAM, Toledo, Spain.

18 4- Department of Emergency. Castilla-La Mancha Health System, Toledo, Spain.

19 5- Polan Primary Care Centre, SESCAM, Toledo, Spain

20 6- FENNSI Group, Hospital Nacional de Paraplégicos, SESCAM, Toledo, Spain.

21 7- School of Biomedical and Health Sciences; Nursing Department. Universidad Europea
22 de Madrid, Madrid, Spain.

23 8- School of Education, Universidad de Castilla-La Mancha, Cuenca, Spain.

24 9- Health and Social Research Center, Universidad de Castilla-La Mancha, Cuenca,
25 Spain.
26
27

28
29
30
31 E-mails authors:

32 ara_mnz@hotmail.com

33 Sagrario.gomez@uclm.es

34 mded@sescam.jccm.es

35 minerva.velasco@uclm.es

36 begolo@sescam.jccm.es

37 Brigida.molina@uclm.es

38 juanluis.gonzalez2@universidadeuropea.es

39 Natalia.arias@uclm.es
40
41
42
43

44 Corresponding author:

45 Sagrario Gómez Cantarino. Department of Nursing, Physiotherapy and occupational
46 therapy. School of Nursing and Physiotherapy Toledo, University of Castilla- La Mancha,
47 Toledo, Spain.

48 Avd/ Carlos III s/n, 45071, Toledo, Spain.

49 Sagrario.gomez@uclm.es

50 +34670225048
51
52
53
54
55

56 **Key words:** accelerometer, neonatal outcomes, physical activity, pregnancy outcomes.

57 **Word count:** 2787
58
59
60

Abstract

Introduction: Pregnant women who eat a balanced diet usually practice physical activity (PA) regularly; there are many studies on PA during pregnancy and the results for the mother and baby. However, the guideline for PA during pregnancy is very general and is not quantified. The primary objective is to examine the nutritional habits and levels of PA of women during pregnancy and the postpartum period using validated questionnaires and accelerometers. Secondly, it will determine the effects of these aspects on the mother and newborn baby. Its third objective is to identify the factors which influence the practice of PA during this phase.

Methods and analysis: This is a prospective cohort study lasting two years. From September 2018 to September 2020. The sample will be recruited in three Primary Care centers in the Toledo (Spain) health area. The participants will be pregnant women aged from 18 to 40 years old who should attend all the check-ups during their pregnancy and the postpartum period. PA will be quantified using an accelerometer, while nutritional habits and physical exercise will be evaluated using validated questionnaires. The symptoms of pregnancy and the postpartum period will be recorded, together with biochemical parameters and anthropometric data. The primary outcomes will be determined in the pregnant women: weight gain, the incidence of gestational diabetes mellitus, pre-eclampsia and pregnancy-induced hypertension. Secondary outcomes include duration of pregnancy and weight at birth, Apgar score (1 min/ 5 min), type of reanimation (I/II/III/IV), and umbilical cord blood pH in the newborn babies.

Discussion: although the beneficial effects of PA during pregnancy are known, there is a need to perform studies that quantify the amount of PA undertaken by women during pregnancy and the postpartum period. The objective of such studies is to establish science-based individualized guidelines for PA for women during this time

Strengths and limitations

-This research will offer new information about how pregnant and postpartum women, like their neonates, respond to moderate physical activity without showing adverse effects.

-The study will offer new information about nutritional behavior of pregnant women, the impact of diet on their newborn and the influence on the mother's puerperium.

The Yana- C questionnaire has not been validated in pregnant women.

To control for the limitation mentioned above we will use a self-administered questionnaire about good adhesion to the Mediterranean diet (PREDIMED). Also, we will validate the Yana-C questionnaire in pregnant women.

Introduction

When women are pregnant, they take better care of their health and are more receptive and likely to make changes that lead to a healthier lifestyle. Recommendations to increase physical activity (PA) and to eat a healthy diet therefore have a positive effect

1
2
3 throughout pregnancy and the postpartum period on the mother as well as their newborn
4 baby [1].

5
6 The scientific literature contains relevant information on the effects of moderate
7 and regular PA during pregnancy: mothers gain less weight and reduce the risk of
8 pregnancy-related diabetes, pre-eclampsia and hypertension [1,2]; higher stress tolerance
9 and earlier neonatal neuro-behavioural maturity [3]. Among other recommendations, the
10 American College of Obstetricians and Gynaecologists (ACOG) suggests that pregnant
11 women with no medical or obstetric complications should perform at least 30 minutes of
12 moderate PA every day of the week [4]. Nevertheless, the World Health Organization
13 (WHO) admits that further research is needed into guidelines for pregnant women on the
14 amount of PA they should undertake. The WHO currently states that the general
15 considerations for PA in adults also apply to pregnant women, i.e., at least 75 minutes of
16 vigorous PA or 150 minutes of moderate PA per week, including the strengthening of the
17 major muscle groups [5].

18
19 On the other hand, several studies on the effects of physical exercise during pregnancy
20 found no relevant benefits for the mother and even detected unsatisfactory results in
21 comparison with other more sedentary mothers [6,7]. All these considerations show the
22 need for research to confirm the correct guideline for PA that leads to the greatest health
23 benefits for mothers as well as their newborn babies.

24
25 As well as being physically active, it is also recommended that women eat a healthy diet
26 during pregnancy and the postpartum period. During this life stage, those women who eat
27 a healthy diet were also found to do more exercise [8]. Data show that low adherence to
28 the Mediterranean diet may be associated with a reduction in the weight of the placenta
29 and low neonatal weight[9,10], as well as the risk of pregnancy-associated diabetes in
30 terms of the classification and diagnosis of diabetes [11], which indicates how important
31 diet is during this phase of women's lives[12]. Epidemiological studies of pregnant
32 women indicate that their weight prior to pregnancy, height, blood levels of glucose and
33 weight gain during pregnancy are factors that influence fetal development [10].

34
35 While it is important that mothers should not gain excessive weight during
36 pregnancy, they should also return to their pre-pregnancy weight after giving birth. This
37 is because there is an association between the risk of obesity after birth and excessive
38 weight gain during pregnancy[13]. On the other hand, controlling weight solely by diet
39 after giving birth is less effective than a combination of diet and physical exercise[14].
40 The promotion of healthy habits in terms of a combination of diet and PA during
41 pregnancy and the postpartum period may therefore be highly beneficial for women[15].

42
43 The main objective of this research are to examine independently the nutritional
44 habits and the levels of PA in women during pregnancy and the postpartum period by
45 means of validated questionnaires and accelerometers.

46
47 The secondary objectives are:

48
49 i) To calculate the relationship between the level of PA and nutritional habits during
50 pregnancy and the postpartum period in terms of the results for mothers in: weight gain,
51 the incidence of pregnancy-related diabetes mellitus, pre-eclampsia and pregnancy-
52 induced hypertension and type of birth. This relationship is also examined in terms of the
53
54
55
56
57
58
59
60

1
2
3 results for newborn babies: duration of pregnancy, weight at birth, Apgar score 1 min / 5
4 min, type of reanimation and umbilical cord blood pH.

5
6 ii) To identify the factors that influence the performance of PA during each stage of
7 pregnancy and the postpartum period (using the Spanish version of the Pregnancy
8 Symptoms Inventory “PSI” and the Edinburgh scale).
9

10 11 **Methods/Design**

12
13 A two-year study of cohorts during pregnancy and the postpartum period in Health
14 Area No. 1, Toledo (Spain).
15

16
17 A multicentre study will be undertaken in the healthcare facilities of Castilla -La
18 Mancha Health Service (SESCAM), in the areas of Primary and Specialised healthcare:
19 i) Buenavista Health Centre; ii) Santa Bárbara Health Centre; iii) Yepes Health Centre;
20 iv) Polán Health Centre and v) the Virgen de la Salud Hospital.
21

22
23 The sample will be recruited by matrons by means of non-probabilistic
24 consecutive sampling in Primary Care facilities.
25

26
27 Study recruitment started on 01 September 2018 and the study is expected to last
28 until September 2020.
29

30 Inclusion criteria:

- 31
32 i) Women aged from 18 to 40 years old.
33
34 ii) Pregnancy having lasted 14 weeks or less.
35
36 iii) A single foetus.
37
38 iv) Quarterly pregnancy check-ups in Primary Care facilities.
39
40 v) The intention of giving birth in the Virgen de la Salud Hospital.
41
42 vi) Comprehension of spoken and written Spanish.
43
44

45 Exclusion criteria:

- 46
47 i) Women with conditions prior to pregnancy that hinder or limit the practice of PA at the
48 time of recruitment (one or more contraindications for PA according to the ACOG,
49 diabetes or arterial hypertension prior to pregnancy, or more than one previous abortion).
50
51 ii) Not signing the informed consent document.
52
53 iii) Not understanding written and spoken Spanish.
54
55 iv) Women who do not complete the follow-up.
56
57

58 Variables (Figure 1):

59
60

1
2
3 *Sociodemographic variables:* the following data will be recorded in the first interview
4 age (years), marital status (married, single, living with partner, others), country of origin,
5 educational level (none, primary, secondary, technical college, university), economic
6 resources (low, medium or high), working status (housewife, unemployed, in work).
7
8

9 *Anthropometrics:* all measurements will be taken by trained investigators to minimize
10 inter-observer variability, using the same apparatus: scales (mechanical, with a range up
11 to: max. 220 kg d=50g) and a wall-mounted height gauge (range: 0 to 200 cm). The
12 subjects will be measured in the 1st, 2nd, 3rd and 4th (postpartum) visit in the morning for
13 weight (without shoes and in light clothing) and height (standing upright without shoes
14 and with the median sagittal line touching the board) will be measured in the first visit.
15 The average of two measurements will be taken. Body mass index (BMI) will be
16 calculated as body mass (in kilograms) divided by height² (in metres).
17
18
19

20 *Arterial blood pressure:* will be measured twice, with a 5-min interval between
21 measurements. The first measurement will be made after at least 5 min rest. Women will
22 be seated, in relaxing conditions, with the right arm semi-flexed at heart level. Blood
23 pressure will be measured with an Omron M5-I monitor (Omron Healthcare UK Ltd.).
24
25

26 *Biochemical parameters:*

27
28
29 Study data will be collected by trained research staff. All blood samples will be taken
30 from the right or left cubital fossa, after an 8–12 h fast, between 08:00–10:00 am. We will
31 determine glucose, insulin and O'Sullivan. In the study population women will be
32 routinely screened for gestational diabetes at 22–26 weeks of gestation with a nonfasting
33 oral glucose challenge test in which venous blood will be sampled 1 hour after a 50-g oral
34 glucose load. If the 1-hour glucose result are at least 140 mg / dL, the participant will be
35 referred to a 100-g fasting glucose 3-hour tolerance test. Normal results will be a blood
36 glucose below 1055 mg / dL at baseline, below 190 mg / dL at 1 hour, below 165 mg /
37 dL at 2 hours, and below 145 mg / dL at 3 hours.
38
39
40

41 *Physical activity:* PA will be measured using:

42
43
44 The Spanish version of the Pregnancy Physical Activity Questionnaire (PPAQ)[16]. This
45 self-administered questionnaire contains 32 items which measure the frequency and
46 duration of PA during pregnancy (1st, 2nd and 3rd visit), in terms of: being sedentary, doing
47 household chores/care, work-related activity and sports activities.
48
49

50 Accelerometry will use Actigraph brand GT3X accelerometers to objectively measure
51 PA levels during the three trimesters of pregnancy and during the postpartum period.
52 Accelerometry has been used in several population groups, including pregnant women,
53 to quantify PA and relate the data obtained with other factors [17]. The criteria for the
54 inclusion of data in the analysis of results will be a minimum recording of 4 days,
55 including at least three weekdays and one weekend day, with imperceptible recording of
56 600 minutes per day[18,19]. The device will be worn on an elastic strap on the wrist of
57 the non-dominant hand during seven consecutive days and nights, except for bathing and
58
59
60

1
2
3 performing activities in the water, in each one of the measurements (*Figure 1*). The data
4 gathering interval in this study will last for 60 seconds (epochs), as this has been shown
5 to be valid for measuring PA in adults. The accelerometer will also supply information
6 on posture, sleep latency, total sleep time, sleep efficiency, the intensity of PA, periods
7 of activity, periods of sedentary behaviour, rhythm intervals, gross acceleration, energy
8 consumption, MET ratios and the number of steps [20]. All subjects will be verbally and
9 in writing instructed on how to use the accelerometer. Data will be downloaded using
10 Actilife v6. 13. 3 software.
11
12
13

14 To identify the factors which influence carrying out PA the Spanish version of the
15 Pregnancy Symptoms Inventory (PSI) will be used [21] during pregnancy, while the
16 Edinburg depression scale will be used in the postpartum period[22]. The PSI is a self-
17 administered questionnaire that evaluates the frequency and degree of limitation of
18 everyday activities arising due to different causes (not at all, a little, a lot) involving 41
19 intrinsic symptoms of pregnancy. The Edinburgh scale consists of 10 questions with four
20 possible replies, of which the subjects must choose one based on how they felt over the
21 past seven days. Although the final score will indicate the probability of post-natal
22 depression, it will not vary according to its severity.
23
24
25
26

27 *Variables associated with nutritional habits:* the “Young Adolescents’ Nutrition
28 Assessment on Computer” (YANA-C) [23] will be used, together with the Mediterranean
29 diet adherence questionnaire (PREDIMED) [24] to gather data on the diet of pregnant and
30 postpartum women.
31
32

33 YANA-C consists of listing the foods consumed in the previous 24 hours, and it is divided
34 into breakfast, mid-morning, lunch, tea, dinner and after dinner. Energy (kcal) and
35 macronutrient intake (percentages) will be measured by two non-consecutive 24-h recalls
36 (weekday and weekend day), using YANA-C software program. Percentages of Energy
37 intake from carbohydrate, protein, fat and macronutrients (g) relative to weight (kg) will
38 be calculated.
39
40
41
42

43 PREDIMED is a self-administered questionnaire containing 14 questions that are
44 answered by a score showing low (< 9 points) or good adhesion to the Mediterranean diet
45 (> 9 points).
46
47

48 *Pregnancy data:* duration of pregnancy (weeks and days of amenorrhea, according to the
49 date of the last period and confirmation by ultrasound scan), medical problems during
50 pregnancy (Yes/No) premature birth (fewer than 37 weeks' gestational age), arterial
51 hypertension, gestational diabetes (defined according to the criteria of the American
52 Diabetes Association (ADA) [25], fetal growth restriction and a reduction in amniotic
53 fluid).
54
55

56 *Birth data:* type of analgesia during birth (none, epidural, spinal), onset of birth
57 (spontaneous / induced, reason for induction), duration of pregnancy (weeks and days),
58 type of birth (natural, instrumental, caesarean), reasons for an instrumental or caesarean
59
60

1
2
3 birth, episiotomy (yes/no), perineal tear (yes/no, grade I/II/III/IV), type of birth
4 (spontaneous, manual, directed), duration of dilation (minutes), duration of expulsion
5 (minutes).
6

7
8 *Neonatal data:* weight (grams), sex (male/female), 1/5 minutes APGAR scale score, type
9 of reanimation (I/II/III/IV), umbilical cord blood pH (arterial and venous), fetal calotte
10 pH (if performed).
11

12
13 *Postpartum data:* bleeding (physiological/moderate/severe), condition of perineum
14 (haematoma/oedema/pain/haemorrhoids/suture dehiscence) and postpartum
15 complications.
16

17
18 Data corresponding to pregnancy, birth, the newborn baby and in the postpartum period
19 will be obtained from the clinical history of the mother.
20

21 Patient and public involvement

22
23 There was no patient or public involvement in the design of this protocol.
24

25 Statistical analysis

26
27 Sample size has been calculated using *Epidat 4.1*, with an exposed/non-exposed
28 ratio of 1. The outcome variable will be gestational diabetes mellitus. A prevalence of
29 14% is assumed in the group of exposed (sedentary) women and a prevalence of 3% is
30 assumed in the group of non-exposed women (who are active according to the current
31 criteria of the American College of Sports Medicine- 30 minutes/day of moderately
32 intense PA every day or almost every day, accumulating at least 150 min/week). A 5%
33 alpha error and 80% statistical power will be assumed. Following these premises, it will
34 be estimated that 194 pregnant women should be included in the study. Approximately
35 5% should be added to these premises to account for possible non-responders (women
36 who do not wish to take part in the study) and drop-outs.
37

38
39 Descriptive statistics with precision estimates will be used to report the prevalence
40 of each parameter using a cross-sectional data. Mixed regression models will be used to
41 examine the relationship between dependent variables and patient health, measured using
42 one or more explanatory variables that express exposure to a risk factor and controlling
43 for baseline values. The results will be expressed as absolute differences in changes in
44 variables between the baseline and final measurements (95% confidence interval)
45

46 All statistical analyses will be performed with the statistical software IBM® SPSS®
47 Statistics 24, and the level of significance will be set at $p < 0.05$.
48
49

50 **Discussion**

51
52 Adherence to an exercise routine is influenced by factors such as: the habit of
53 exercising prior to pregnancy, sociocultural level, equality and the insistence by
54 healthcare workers that pregnant women undertake PA. The study by Nascimento et al.
55 [26] showed that half of the women taking part ceased doing physical activity during
56 pregnancy.
57
58
59
60

1
2
3 It is therefore important that healthcare personnel offer information on the risks
4 and benefits of PA, while also setting personalised guidelines adapted to the specific
5 needs of each woman. All of the information supplied to future mothers must be supported
6 by scientific evidence. The aim is to guide future mothers towards a healthy lifestyle and
7 to change their habits. This is not only to prevent pathologies during pregnancy and in the
8 postpartum period, but rather to ensure that their new habits last throughout their life.
9
10
11

12 The study results will make it possible to better advise pregnant women about
13 recommendable PA and nutrition. They will also make it possible to update health
14 education programs for this population group, leading to many benefits for mothers as
15 well as their children.
16
17

18 The study will also record biochemical parameters which, in association with the
19 data gathered using the scales and accelerometer, will make it possible to prevent the risk
20 of non-transmissible diseases during pregnancy and in the postpartum period.
21 Biochemical changes are closely linked to the amount of mothers' PA and the quality and
22 type of their diet during pregnancy and in the postpartum period. An example of this
23 relationship is the use of the biochemical parameter of glucose as a gestational diabetes
24 marker. Pérez-Ferre et al. [11,27] intervened in a group of women with gestational
25 diabetes, changing their dietary habits and encouraging physical exercise. They found
26 that the risk of developing type 2 diabetes in the future fell in the intervention group in
27 comparison with the control group [11]
28
29
30
31

32 Several limitations to our study should be considered. First of all, as with any
33 observational study, we cannot eliminate residual confounding by unmeasured factors.
34 However, we will be able include information on previously identified factors such as
35 age, BMI before pregnancy and race / ethnicity, and consider other sociodemographic
36 characteristics. Secondly, it is possible that accelerometers may produce some reactivity
37 by the participants (Hawthorne effect) in wearing the device; however, unlike self-
38 reports, accelerometer estimates do not suffer from bias due to social desirability and
39 recall problems. Finally, the Yana- C questionnaire has not been validated in pregnant
40 women. To control this limitation, we will use a self-administered questionnaire about
41 good adherence to the Mediterranean diet (PREDIMED).
42
43
44
45

46 Larger studies like ours are therefore necessary which quantify the PA of women
47 during pregnancy and in the postpartum period, to set guidelines based on scientific
48 evidence. The present study will help identify the frequency, duration, intensity and type
49 of PA in pregnant women and their impact on delivery, mother and new-born outcomes.
50 This information will promote education for health by health professionals and involve
51 practice in these women.
52
53
54

55 **Abbreviations:**

56 PA, Physical Activity; ACOG, American College of Obstetricians and Gynaecologists;
57 WHO, World Health Organization; PSI, Pregnancy Symptoms Inventory; SESCAM,
58
59
60

1
2
3 Castilla -La Mancha Health Service; THC, Toledo Hospital Complex; BMI, Body mass
4 index; PPAQ, Pregnancy Physical Activity Questionnaire; PSI, Pregnancy Symptoms
5 Inventory; YANA-C, Young Adolescents' Nutrition Assessment on Computer;
6 PREDIMED, Mediterranean diet adherence questionnaire; ADA, American Diabetes
7 Association.
8
9

10 **Declarations:**

11 a. Ethics and Dissemination

12
13
14
15 This research project has been approved by the Toledo Hospital Complex (THC)
16 Clinical Research Ethics Committee, approval number 125. It has also been approved by
17 the Primary and Specialised Care Nursing Boards for implementation and development.
18

19
20 Before they sign the consent document to take part in the study, all the participants
21 will be informed verbally and in writing about the study procedure as well as its
22 objectives. Data confidentiality will be guaranteed, and it will also be possible for
23 participants to revoke their consent for the study at any stage of the same.
24

25
26 Study outcomes will be disseminated at international conferences and published
27 in peer-reviewed scientific journals.
28

29 b. Consent for publication

30
31 Not applicable
32

33 c. Availability of data and material

34
35 The data supporting our findings are contained within the manuscript.
36

37 d. Conflicts of interests

38
39 The authors declare that they have no competing interests and they have no commercial
40 or public commitments that would prevent them from undertaking this research.
41

42 e. Funding

43
44 This research did not receive any specific grant from funding agencies in the public,
45 commercial, or not-for-profit sectors.
46

47 f. Author Statement

48
49 Conceived and designed the experiments: AMM, MMDA, MVA, SGC and NAP., JLGP,
50 BGL, BMG, SGC and NAP gave statistical and epidemiological support. Contributed
51 reagents/ materials/analysis tools: AMM, MMDA, MVA, BGL, BMG. Wrote the paper:
52 AMM, SGC and NAP. All authors established the methods and questionnaires, provided
53 comments on the drafts, and read and approved the final version.
54

55 g. Acknowledgements

We thank the healthcare facilities of Castilla -La Mancha Health Service (SESCAM), in the areas of Primary and Specialised healthcare: i) Buenavista Health Centre; ii) Santa Bárbara Health Centre; iii) Yepes Health Centre; iv) Polán Health Centre and v) the Virgen de la Salud Hospital, that have shown their interest in participating in our study.

References

1. Muktabhant B, Lawrie TA, Lumbiganon P, Laopaiboon M. Diet or exercise, or both, for preventing excessive weight gain in pregnancy. *Cochrane Database Syst Rev.* 2015;(6).
2. Aune D, Saugstad OD, Henriksen T, Tonstad S. Physical activity and the risk of preeclampsia: a systematic review and meta-analysis. *Epidemiology.* 2014;25(3):331–343.
3. Clapp III JF, Lopez B, Harcar-Sevcik R. Neonatal behavioral profile of the offspring of women who continued to exercise regularly throughout pregnancy. *Am J Obstet Gynecol.* 1999;180(1):91–94.
4. Artal R, O'Toole M. Exercise during pregnancy and the postpartum period. *Clin Obstet Gynecol.* 2003;46(2):496–499.
5. Organization WH. WHO guidelines approved by the guidelines review committee. Use Tuberc Interferon-Gamma Release Assays IGRAs Low-Middle-Income Ctries Policy Statement Geneva World Health Organ. 2011;
6. Vallim AL, Osis MJ, Cecatti JG, Baciuk ÉP, Silveira C, Cavalcante SR. Water exercises and quality of life during pregnancy. *Reprod Health.* 2011;8(1):14.
7. Kramer MS, McDonald SW. Aerobic exercise for women during pregnancy. *Cochrane Database Syst Rev.* 2006;(3).
8. Olmedo-Requena R, Fernández JG, Prieto CA, Moreno JM, Bueno-Cavanillas A, Jiménez-Moleón JJ. Factors associated with a low adherence to a Mediterranean diet pattern in healthy Spanish women before pregnancy. *Public Health Nutr.* 2014;17(3):648–656.
9. Timmermans S, Steegers-Theunissen R, Vujkovic M, den Breeijen H, Russcher H, Lindemans J, et al. The Mediterranean diet and fetal size parameters: the Generation R Study. 2014;
10. Mesa SLR, Sosa BEP. Implicaciones del estado nutricional materno en el peso al nacer del neonato. *Perspect En Nutr Humana.* 2011;11(2):179–186.
11. Pérez-Ferre N, Del Valle L, Torrejón MJ, Barca I, Calvo MI, Matía P, et al. Diabetes mellitus and abnormal glucose tolerance development after gestational diabetes: A three-year, prospective, randomized, clinical-based, Mediterranean lifestyle interventional study with parallel groups. *Clin Nutr.* 2015;34(4):579–585.

12. Karamanos B, Thanopoulou A, Anastasiou E, Assaad-Khalil S, Albache N, Bachaoui M, et al. Relation of the Mediterranean diet with the incidence of gestational diabetes. *Eur J Clin Nutr.* 2014;68(1):8.
13. Amorim AR, Rössner S, Neovius M, Lourenço PM, Linné Y. Does excess pregnancy weight gain constitute a major risk for increasing long-term BMI? *Obesity.* 2007;15(5):1278–1286.
14. Gomez Cantarino S, Comas Matas M, Velasco A, Campos S, Santos AP dos, Puerto Fernandez I del. Vivencias, experiências e diferenças sexuais: mulher puérpera espanhola e imigrante. *Área Palma sanitária de Maiorca (Espanha). Rev Enferm Referência.* 2016;(9):115–123.
15. Magann EF, Evans SF, Weitz B, Newnham J. Antepartum, intrapartum, and neonatal significance of exercise on healthy low-risk pregnant working women. *Obstet Gynecol.* 2002;99(3):466–472.
16. Chasan-Taber L, Schmidt MD, Roberts DE, Hosmer D, Markenson G, Freedson PS. Development and validation of a pregnancy physical activity questionnaire: Corrigendum. *Med Sci Sports Exerc.* 2011;43(1).
17. Aguilar MC, Sánchez AL, Guisado RB, Rodríguez RB, Noack JS, Pozo MC. Accelerometer description as a method to assess physical activity in different periods of life; systematic review. 2014.
18. Trost SG, Mciver KL, Pate RR. Conducting accelerometer-based activity assessments in field-based research. *Med Sci Sports Exerc.* 2005;37(11 Suppl):S531–43.
19. Freedson PS, Melanson E, Sirard J. Calibration of the Computer Science and Applications, Inc. accelerometer. *Med Sci Sports Exerc.* 1998;30(5):777–781.
20. Chen KY, Bassett DR Jr. The technology of accelerometry-based activity monitors: current and future. *Med Sci Sports Exerc.* 2005;37(11):S490–S500.
21. Foxcroft KF, Callaway LK, Byrne NM, Webster J. Development and validation of a pregnancy symptoms inventory. *BMC Pregnancy Childbirth.* 2013;13(1):3.
22. Vega-Dienstmaier JM, Mazzotti Suarez G, Campos Sanchez M. Validación de una versión en español de la Escala de Depresión Postnatal de Edimburgo. *Actas Esp Psiquiatr.* 2002;30(2):106–111.
23. Vereecken CA, Covents M, Matthys C, Maes L. Young adolescents' nutrition assessment on computer (YANA-C). *Eur J Clin Nutr.* 2005;59(5):658.
24. Martínez-González MÁ, Corella D, Salas-Salvadó J, Ros E, Covas MI, Fiol M, et al. Cohort profile: design and methods of the PREDIMED study. *Int J Epidemiol.* 2010;41(2):377–385.
25. Association AD. 2. Classification and diagnosis of diabetes. *Diabetes Care.* 2017;40(Supplement 1):S11–S24.

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
26. Nascimento SL, Surita FG, Godoy AC, Kasawara KT, Morais SS. Physical activity patterns and factors related to exercise during pregnancy: a cross sectional study. *PloS One*. 2015;10(6):e0128953.
27. Sanabria-Martínez G, García-Hermoso A, Poyatos-León R, Álvarez-Bueno C, Sánchez-López M, Martínez-Vizcaíno V. Effectiveness of physical activity interventions on preventing gestational diabetes mellitus and excessive maternal weight gain: a meta-analysis. *BJOG Int J Obstet Gynaecol*. 2015;122(9):1167–1174.

Figure Legends

Fig. 1. Data gathering phases. AP, arterial blood pressure; BMI, body mass index.

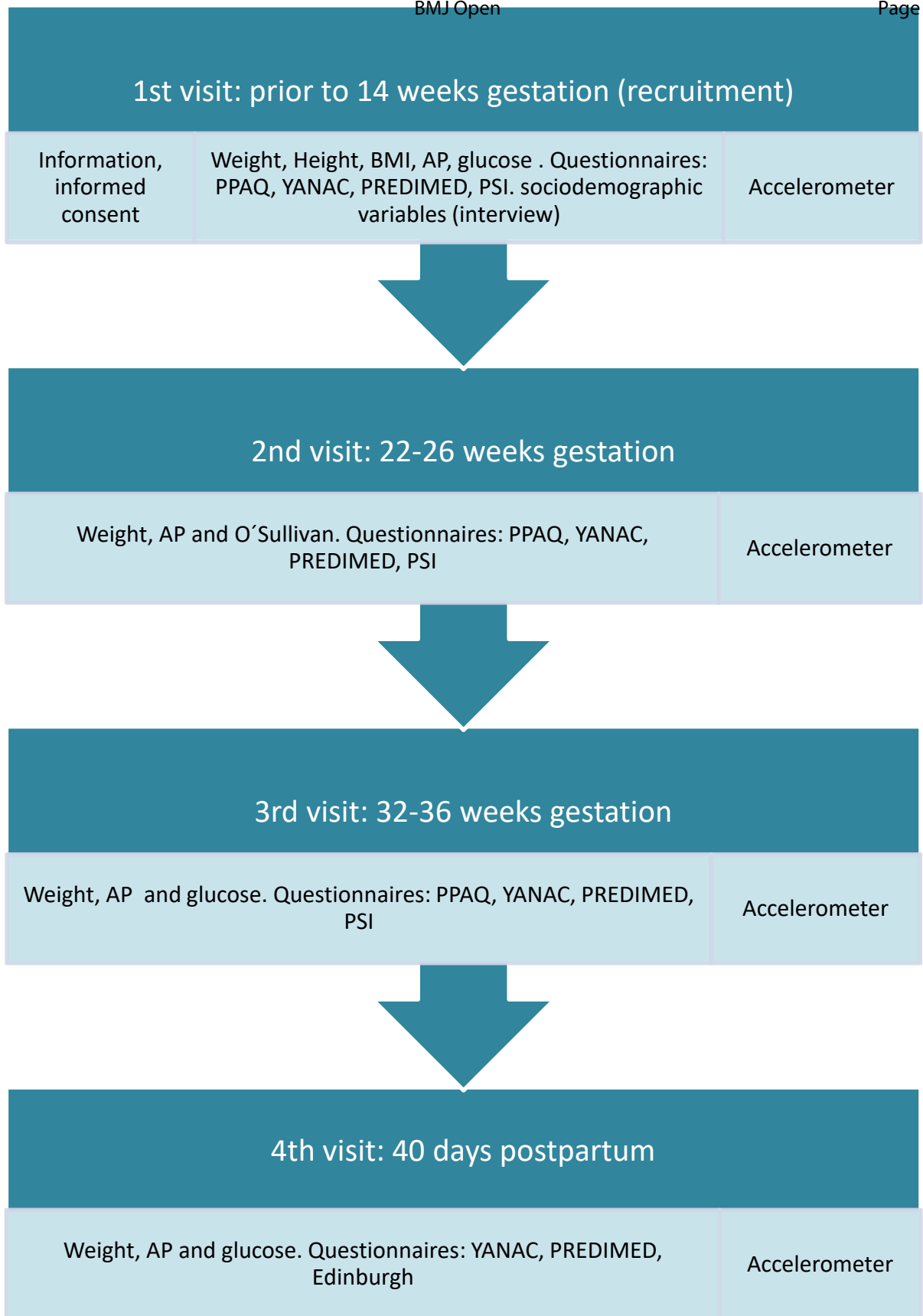


Fig. 1. Data gathering phases. AP, arterial blood pressure; BMI, body mass index.

BMJ Open

Analysis of nutritional habits and levels of physical activity during pregnancy, birth and the postpartum period of women in health area no. 1, Toledo (Spain). The PrePaN study protocol.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-029487.R2
Article Type:	Protocol
Date Submitted by the Author:	09-Jun-2019
Complete List of Authors:	Muñoz Muñoz, Aránzazu; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department; Buenavista Primary Care Centre, SESCAM. Cantarino, Sagrario; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department, De Dios Aguado, María de las Mercedes; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department;; Yepes Primary Care Centre Velasco Abellán, Minerva; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department;; Department of Emergency. Castilla-La Mancha Health System González López, Beatriz; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department;; Polan Primary Care Centre Molina Gallego, Brigida; Universidad de Castilla-La Mancha - Campus de Toledo, Nursing, Physiotherapy and Occupational Therapy Department;; FENNSI Group, Hospital Nacional de Paraplégicos González Pascual, Juan Luis; Universidad Europea de Madrid, School of Biomedical and Health Sciences; Nursing Department. Arias Palencia, Natalia María; Universidad de Castilla- La Mancha, School of Education; Universidad de castilla- La Mancha, Health and Social Research Center
Primary Subject Heading:	Obstetrics and gynaecology
Secondary Subject Heading:	Obstetrics and gynaecology
Keywords:	accelerometer, pregnancy outcomes, physical activity, neonatal outcomes

SCHOLARONE™
Manuscripts

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 **Analysis of nutritional habits and levels of physical activity during pregnancy, birth**
4 **and the postpartum period of women in health area no. 1, Toledo (Spain). The**
5 **PrePaN study protocol.**
6
7

8 Muñoz Muñoz, Aránzazu ^{1,2}; Gómez Cantarino, Sagrario¹; De Dios Aguado, María De
9 Las Mercedes ^{1,3}; Velasco Abellán, Minerva ^{1,4}; González López, Beatriz ^{1,5}; Molina
10 Gallego, Brígida ^{1,6}; González Pascual, Juan Luis ⁷; Arias Palencia, Natalia María ^{8,9}.
11
12

13
14 1- ENDOCU Group, University School of Nursing and Physiotherapy Toledo (Nursing,
15 pain and Care), Toledo, Spain.

16 2- Buenavista Primary Care Centre, SESCAM, Toledo, Spain.

17 3- Yepes Primary Centre, SESCAM, Toledo, Spain.

18 4- Department of Emergency. Castilla-La Mancha Health System, Toledo, Spain.

19 5- Polan Primary Care Centre, SESCAM, Toledo, Spain

20 6- FENNSI Group, Hospital Nacional de Paraplégicos, SESCAM, Toledo, Spain.

21 7- School of Biomedical and Health Sciences; Nursing Department. Universidad Europea
22 de Madrid, Madrid, Spain.

23 8- School of Education, Universidad de Castilla-La Mancha, Cuenca, Spain.

24 9- Health and Social Research Center, Universidad de Castilla-La Mancha, Cuenca,
25 Spain.
26
27

28
29
30
31 E-mails authors:

32 ara_mnz@hotmail.com

33 Sagrario.gomez@uclm.es

34 mded@sescam.jccm.es

35 minerva.velasco@uclm.es

36 begolo@sescam.jccm.es

37 Brigida.molina@uclm.es

38 juanluis.gonzalez2@universidadeuropea.es

39 Natalia.arias@uclm.es
40
41
42
43

44 Corresponding author:

45 Sagrario Gómez Cantarino. Department of Nursing, Physiotherapy and occupational
46 therapy. School of Nursing and Physiotherapy Toledo, University of Castilla- La Mancha,
47 Toledo, Spain.

48 Avd/ Carlos III s/n, 45071, Toledo, Spain.

49 Sagrario.gomez@uclm.es

50 +34670225048
51
52
53
54
55

56 **Key words:** accelerometer, neonatal outcomes, physical activity, pregnancy outcomes.

57 **Word count:** 2787
58
59
60

Abstract

Introduction: Pregnant women who eat a balanced diet usually practice physical activity (PA) regularly; there are many studies on PA during pregnancy and the results for the mother and baby. However, the guideline for PA during pregnancy is very general and is not quantified. The primary objective of this study is to examine the nutritional habits and levels of PA of women during pregnancy and the postpartum period. Secondly, it will determine the effects of these aspects on the mother and newborn baby. Its third objective is to identify the factors which influence the practice of PA during this phase.

Methods and analysis: This is a prospective cohort study lasting two years. From September 2018 to September 2020. The sample will be recruited in three Primary Care centers in the Toledo (Spain) health area. The participants will be pregnant women aged from 18 to 40 years old who should attend all the check-ups during their pregnancy and the postpartum period. PA will be quantified using accelerometry, while nutritional habits and physical exercise will be evaluated using validated questionnaires. The symptoms of pregnancy and the postpartum period will be recorded, together with biochemical parameters and anthropometric data. The primary outcomes will be determined in the pregnant women: weight gain, the incidence of gestational diabetes mellitus, pre-eclampsia and pregnancy-induced hypertension. Secondary outcomes include duration of pregnancy and weight at birth, Apgar score (1 min/ 5 min), type of reanimation (I/II/III/IV), and umbilical cord blood pH in the newborn babies.

Discussion: although the beneficial effects of PA during pregnancy are known, there is a need to perform studies that quantify the amount of PA undertaken by women during pregnancy and the postpartum period. The objective of such studies is to establish science-based individualized guidelines for PA for women during this stage of their lives.

Strengths and limitations

-This research will offer new information about how pregnant and postpartum women, like their neonates, respond to moderate physical activity without showing adverse effects.

-The study will offers new information about nutritional behavior of pregnant women, the impact of diet on their newborn and the influence on the mother's puerperium.

The Yana- C questionnaire has not been validated in pregnant women.

To control for the limitation mentioned above we will use a self-administered questionnaire about good adhesion to the Mediterranean diet (PREDIMED).

Introduction

When women are pregnant, they take better care of their health and are more receptive and likely to make changes that lead to a healthier lifestyle. Recommendations to increase physical activity (PA) and to eat a healthy diet therefore have a positive effect throughout pregnancy and the postpartum period on the mother as well as their newborn baby [1].

1
2
3 The scientific literature contains relevant information on the effects of moderate
4 and regular PA during pregnancy: mothers gain less weight and reduce the risk of
5 pregnancy-related diabetes, pre-eclampsia and hypertension [1, 2]; higher stress tolerance
6 and earlier neonatal neuro-behavioural maturity [3]. Among other recommendations, the
7 American College of Obstetricians and Gynaecologists (ACOG) suggests that pregnant
8 women with no medical or obstetric complications should perform at least 30 minutes of
9 moderate PA every day of the week [4]. Nevertheless, the World Health Organization
10 (WHO) admits that further research is needed into guidelines for pregnant women on the
11 amount of PA they should undertake. The WHO currently states that the general
12 considerations for PA in adults also apply to pregnant women, i.e., at least 75 minutes of
13 vigorous PA or 150 minutes of moderate PA per week, including the strengthening of the
14 major muscle groups [5].

15
16 On the other hand, several studies on the effects of physical exercise during pregnancy
17 found no relevant benefits for the mother and even detected unsatisfactory results in
18 comparison with other more sedentary mothers [6, 7]. All these considerations show the
19 need for research to confirm the correct guideline for PA that leads to the greatest health
20 benefits for mothers as well as their newborn babies.

21
22 As well as being physically active, it is also recommended that women eat a healthy diet
23 during pregnancy and the postpartum period. During this life stage, those women who eat
24 a healthy diet were also found to do more exercise [8]. Data show that low adherence to
25 the Mediterranean diet may be associated with a reduction in the weight of the placenta
26 and low neonatal weight [9, 10], as well as the risk of pregnancy-associated diabetes in
27 terms of the classification and diagnosis of diabetes [11], which indicates how important
28 diet is during this phase of women's lives [12]. Epidemiological studies of pregnant
29 women indicate that their weight prior to pregnancy, height, blood levels of glucose and
30 weight gain during pregnancy are factors that influence fetal development [10].

31
32 While it is important that mothers should not gain excessive weight during
33 pregnancy, they should also return to their pre-pregnancy weight after giving birth. This
34 is because there is an association between the risk of obesity after birth and excessive
35 weight gain during pregnancy [13, 14]. On the other hand, controlling weight solely by
36 diet after giving birth is less effective than a combination of diet and physical exercise
37 [14]. The promotion of healthy habits in terms of a combination of diet and PA during
38 pregnancy and the postpartum period may therefore be highly beneficial for women
39 [15,16].

40
41 The main objective of this research are to examine independently the nutritional
42 habits and the levels of PA in women during pregnancy and the postpartum period by
43 means of validated questionnaires and accelerometers.

44
45 The secondary objectives are:

46
47 i) To calculate the relationship between the level of PA and nutritional habits during
48 pregnancy and the postpartum period in terms of the results for mothers in: weight gain,
49 the incidence of pregnancy-related diabetes mellitus, pre-eclampsia and pregnancy-
50 induced hypertension and type of birth. This relationship is also examined in terms of the
51 results for newborn babies: duration of pregnancy, weight at birth, Apgar score 1 min / 5
52 min, type of reanimation and umbilical cord blood pH.

1
2
3 ii) To identify the factors that influence the performance of PA during each stage of
4 pregnancy and the postpartum period (using the Spanish version of the Pregnancy
5 Symptoms Inventory “PSI” and the Edinburgh scale).
6
7

8 **Methods/Design**

9

10 A two-year study of cohorts during pregnancy and the postpartum period in Health
11 Area No. 1, Toledo (Spain).
12
13

14 A multicentre study will be undertaken in the healthcare facilities of Castilla -La
15 Mancha Health Service (SESCAM), in the areas of Primary and Specialised healthcare:
16 i) Buenavista Health Centre; ii) Santa Bárbara Health Centre; iii) Yepes Health Centre;
17 iv) Polán Health Centre and v) the Virgen de la Salud Hospital.
18
19

20 The sample will be recruited by matrons by means of non-probabilistic
21 consecutive sampling in Primary Care facilities.
22
23

24 Study recruitment started on 01 September 2018 and the study is expected to last
25 until September 2020.
26

27 Inclusion criteria:

28

- 29 i) Women aged from 18 to 40 years old.
30
31 ii) Pregnancy having lasted 14 weeks or less.
32
33 iii) A single foetus.
34
35 iv) Quarterly pregnancy check-ups in Primary Care facilities.
36
37 v) The intention of giving birth in the Virgen de la Salud Hospital.
38
39 vi) Comprehension of spoken and written Spanish.
40
41

42 Exclusion criteria:

43

- 44 i) Women with conditions prior to pregnancy that hinder or limit the practice of PA at the
45 time of recruitment (one or more contraindications for PA according to the ACOG,
46 diabetes or arterial hypertension prior to pregnancy, or more than one previous abortion).
47
48 ii) Not signing the informed consent document.
49
50 iii) Not understanding written and spoken Spanish.
51
52 iv) Women who do not complete the follow-up.
53
54

55 Variables (Figure 1):

56

57 *Sociodemographic variables:* the following data will be recorded in the first interview
58 age (years), marital status (married, single, living with partner, others), country of origin,
59
60

1
2
3 educational level (none, primary, secondary, technical college, university), economic
4 resources (low, medium or high), working status (housewife, unemployed, in work).
5

6
7 *Anthropometrics:* all measurements will be taken by trained investigators to minimize
8 inter-observer variability, using the same apparatus: scales (mechanical, with a range up
9 to: max. 220 kg d=50g) and a wall-mounted height gauge (range: 0 to 200 cm). The
10 subjects will be measured in the 1st, 2nd, 3rd and 4th (postpartum) visit in the morning for
11 weight (without shoes and in light clothing) and height (standing upright without shoes
12 and with the median sagittal line touching the board) will be measured in the first visit.
13 The average of two measurements will be taken. Body mass index (BMI) will be
14 calculated as body mass (in kilograms) divided by height² (in metres).
15
16

17
18 *Arterial blood pressure:* will be measured twice, with a 5-min interval between
19 measurements. The first measurement will be made after at least 5 min rest. Women will
20 be seated, in relaxing conditions, with the right arm semi-flexed at heart level. Blood
21 pressure will be measured with an Omron M5-I monitor (Omron Healthcare UK Ltd.).
22
23

24 *Biochemical parameters:*

25
26 Study data will be collected by trained research staff. All blood samples will be taken
27 from the right or left cubital fossa, after an 8–12 h fast, between 08:00–10:00 am. We will
28 determine glucose, insulin and O'Sullivan. In the study population women will be
29 routinely screened for gestational diabetes at 22–26 weeks of gestation with a nonfasting
30 oral glucose challenge test in which venous blood will be sampled 1 hour after a 50-g oral
31 glucose load. If the 1-hour glucose result are at least 140 mg / dL, the participant will be
32 referred to a 100-g fasting glucose 3-hour tolerance test. Normal results will be a blood
33 glucose below 1055 mg / dL at baseline, below 190 mg / dL at 1 hour, below 165 mg /
34 dL at 2 hours, and below 145 mg / dL at 3 hours.
35
36
37
38

39 *Physical activity:* PA will be measured using:

40
41 The Spanish version of the Pregnancy Physical Activity Questionnaire (PPAQ) [17]. This
42 self-administered questionnaire contains 32 items which measure the frequency and
43 duration of PA during pregnancy (1st, 2nd and 3rd visit), in terms of: being sedentary, doing
44 household chores/care, work-related activity and sports activities.
45
46

47 Accelerometry will use Actigraph brand GT3X accelerometers to objectively measure
48 PA levels during the three trimesters of pregnancy and during the postpartum period.
49 Accelerometry has been used in several population groups, including pregnant women,
50 to quantify PA and relate the data obtained with other factors [18]. The criteria for the
51 inclusion of data in the analysis of results will be a minimum recording of 4 days,
52 including at least three weekdays and one weekend day, with imperceptible recording of
53 600 minutes per day [19, 20]. The device will be worn on an elastic strap on the wrist of
54 the non-dominant hand during seven consecutive days and nights, except for bathing and
55 performing activities in the water, in each one of the measurements (*Figure 1*). The data
56 gathering interval in this study will last for 60 seconds (epochs), as this has been shown
57
58
59
60

1
2
3 to be valid for measuring PA in adults. The accelerometer will also supply information
4 on posture, sleep latency, total sleep time, sleep efficiency, the intensity of PA, periods
5 of activity, periods of sedentary behaviour, rhythm intervals, gross acceleration, energy
6 consumption, MET ratios and the number of steps [21]. All subjects will be verbally and
7 in writing instructed on how to use the accelerometer. Data will be downloaded using
8 Actilife v6. 13. 3 software.
9
10

11
12 To identify the factors which influence carrying out PA the Spanish version of the
13 Pregnancy Symptoms Inventory (PSI) will be used [22] during pregnancy, while the
14 Edinburg depression scale will be used in the postpartum period [23]. The PSI is a self-
15 administered questionnaire that evaluates the frequency and degree of limitation of
16 everyday activities arising due to different causes (not at all, a little, a lot) involving 41
17 intrinsic symptoms of pregnancy. The Edinburgh scale consists of 10 questions with four
18 possible replies, of which the subjects must choose one based on how they felt over the
19 past seven days. Although the final score will indicate the probability of post-natal
20 depression, it will not vary according to its severity.
21
22

23
24 *Variables associated with nutritional habits:* the “Young Adolescents’ Nutrition
25 Assessment on Computer” (YANA-C) [24] will be used, together with the Mediterranean
26 diet adherence questionnaire (PREDIMED) [25] to gather data on the diet of pregnant
27 and postpartum women.
28
29

30
31 YANA-C consists of listing the foods consumed in the previous 24 hours, and it is divided
32 into breakfast, mid-morning, lunch, tea, dinner and after dinner. Energy (kcal) and
33 macronutrient intake (percentages) will be measured by two non-consecutive 24-h recalls
34
35 (weekday and weekend day), using YANA-C software program. Percentages of Energy
36 intake from carbohydrate, protein, fat and macronutrients (g) relative to weight (kg) will
37 be calculated.
38
39

40
41 PREDIMED is a self-administered questionnaire containing 14 questions that are
42 answered by a score showing low (< 9 points) or good adhesion to the Mediterranean diet
43 (> 9 points).
44

45
46 *Pregnancy data:* duration of pregnancy (weeks and days of amenorrhea, according to the
47 date of the last period and confirmation by ultrasound scan), medical problems during
48 pregnancy (Yes/No) premature birth (fewer than 37 weeks' gestational age), arterial
49 hypertension, gestational diabetes (defined according to the criteria of the American
50 Diabetes Association (ADA) [26], fetal growth restriction and a reduction in amniotic
51 fluid).
52
53

54
55 *Birth data:* type of analgesia during birth (none, epidural, spinal), onset of birth
56 (spontaneous / induced, reason for induction), duration of pregnancy (weeks and days),
57 type of birth (natural, instrumental, caesarean), reasons for an instrumental or caesarean
58 birth, episiotomy (yes/no), perineal tear (yes/no, grade I/II/III/IV), type of birth
59
60

(spontaneous, manual, directed), duration of dilation (minutes), duration of expulsion (minutes).

Neonatal data: weight (grams), sex (male/female), 1/5 minutes APGAR scale score, type of reanimation (I/II/III/IV), umbilical cord blood pH (arterial and venous), fetal calotte pH (if performed).

Postpartum data: bleeding (physiological/moderate/severe), condition of perineum (haematoma/oedema/pain/haemorrhoids/suture dehiscence) and postpartum complications.

Data corresponding to pregnancy, birth, the newborn baby and in the postpartum period will be obtained from the clinical history of the mother.

Patient and public involvement

There was no patient or public involvement in the design of this protocol.

Statistical analysis

Sample size was calculated using *Epidat 4.1*, with an exposed/non-exposed ratio of 1. The outcome variable was gestational diabetes mellitus. A prevalence of 14% was assumed in the group of exposed (sedentary) women and a prevalence of 3% [27] was assumed in the group of non-exposed women (who were active according to the current criteria of the American College of Sports Medicine- 30 minutes/day of moderately intense PA every day or almost every day, accumulating at least 150 min/week). A 5% alpha error and 80% statistical power were assumed. Following these premises, it was estimated that 194 pregnant women should be included in the study. Approximately 5% should be added to these premises to account for possible non-responders (women who did not wish to take part in the study) and drop-outs.

Descriptive statistics with precision estimates will be used to report the prevalence of each parameter using a cross-sectional data. Mixed regression models will be used to examine the relationship between dependent variables and patient health, measured using one or more explanatory variables that express exposure to a risk factor and controlling for baseline values. The results will be expressed as absolute differences in changes in variables between the baseline and final measurements (95% confidence interval). All statistical analyses will be performed with the statistical software IBM® SPSS® Statistics 24, and the level of significance will be set at $p < 0.05$.

Discussion

The results of the study will allow better advise to pregnant women about PA and nutrition. They will also make it possible to update health education programs for this population group, leading to more benefits for mothers as well as their children.

The adherence to an exercise routine is influenced by factors such as: the habit of exercising before pregnancy, the sociocultural level, equality and the insistence by

1
2
3 healthcare workers that pregnant women perform PA. The study by Nascimento et al.
4 (2015) showed that half of the participating women stopped doing physical activity during
5 pregnancy [28].
6
7

8 Therefore, it is important that healthcare professional provide information about
9 the risks and benefits of PA, while establishing personalized guidelines adapted to the
10 specific needs of each woman. All information supplied to future mothers must therefore
11 be supported by scientific evidence [29]. The goal is to guide future mothers towards a
12 healthy lifestyle and to change their habits. This is not only to prevent pathologies during
13 pregnancy and in the postpartum period, but rather to ensure that their new habits last a
14 lifetime.
15
16
17

18 The study will also record biochemical parameters which, in association with the
19 data collected through the scales and the accelerometer, will allow to prevent the risk of
20 non-transmissible diseases during pregnancy and in the postpartum period. Biochemical
21 changes are closely linked to the amount of mothers' PA, and both the quality and type
22 of their diet during pregnancy and in the postpartum period. An example of this
23 relationship is the use of the biochemical parameter of glucose as a gestational diabetes
24 marker [30]. Pérez-Ferre et al. (2015) intervened in a group of women with gestational
25 diabetes, by changing their dietary habits and encouraging physical exercise. They found
26 that the risk of developing type 2 diabetes in the future decreased in the intervention group
27 compared to the control group [11].
28
29
30
31
32

33 Therefore, it is necessary to perform more extensive studies on the quantity of PA
34 of women during pregnancy and in the postpartum period, to set guidelines based on
35 scientific evidence. Accelerometers provide reliable and accurate data, and they may be
36 considered a motivating factor in maternal education programs, as they make pregnant
37 women aware of the amount of PA they perform, thereby stimulating the regular practice
38 of PA.
39
40
41

42 **Abbreviations:**

43
44 PA, Physical Activity; ACOG, American College of Obstetricians and Gynaecologists;
45 WHO, World Health Organization; PSI, Pregnancy Symptoms Inventory; SESCO,
46 Castilla-La Mancha Health Service; THC, Toledo Hospital Complex; BMI, Body mass
47 index; PPAQ, Pregnancy Physical Activity Questionnaire; PSI, Pregnancy Symptoms
48 Inventory; YANA-C, Young Adolescents' Nutrition Assessment on Computer;
49 PREDIMED, Mediterranean diet adherence questionnaire; ADA, American Diabetes
50 Association.
51
52
53
54
55

56 **Declarations:**

57
58 a. Ethics and Dissemination
59
60

1
2
3 This research project has been approved by the Toledo Hospital Complex (THC)
4 Clinical Research Ethics Committee, approval number 125. It has also been approved by
5 the Primary and Specialised Care Nursing Boards for implementation and development.
6
7

8 Before they sign the consent document to take part in the study, all the participants
9 will be informed verbally and in writing about the study procedure as well as its
10 objectives. Data confidentiality will be guaranteed, and it will also be possible for
11 participants to revoke their consent for the study at any stage of the same.
12
13

14 Study outcomes will be disseminated at international conferences and published
15 in peer-reviewed scientific journals.
16
17

18 b. Consent for publication

19 Not applicable
20
21

22 c. Availability of data and material

23 The data supporting our findings are contained within the manuscript.
24
25

26 d. Conflicts of interests

27 The authors declare that they have no competing interests and they have no commercial
28 or public commitments that would prevent them from undertaking this research.
29
30

31 e. Funding

32 This research did not receive any specific grant from funding agencies in the public,
33 commercial, or not-for-profit sectors.
34
35

36 f. Author Statement

37 Conceived and designed the experiments: AMM, MMDA, MVA, SGC and NAP., JLGP,
38 BGL, BMG, SGC and NAP gave statistical and epidemiological support. Contributed
39 reagents/ materials/analysis tools: AMM, MMDA, MVA, BGL, BMG. Wrote the paper:
40 AMM, SGC and NAP. All authors established the methods and questionnaires, provided
41 comments on the drafts, and read and approved the final version.
42
43

44 g. Acknowledgements

45 We thank the healthcare facilities of Castilla -La Mancha Health Service (SESCAM), in
46 the areas of Primary and Specialised healthcare: i) Buenavista Health Centre; ii) Santa
47 Bárbara Health Centre; iii) Yepes Health Centre; iv) Polán Health Centre and v) the
48 Virgen de la Salud Hospital, that have shown their interest in participating in our study.
49
50

51 References

52
53
54
55
56
57
58
59
60 1 Muktabhant B, Lawrie TA, Lumbiganon P, *et al.* Diet or exercise, or both, for

1
2
3 preventing excessive weight gain in pregnancy. *Cochrane Database Syst Rev* 2015.

4
5 2 Aune D, Saugstad OD, Henriksen T, *et al*. Physical activity and the risk of
6 preeclampsia: a systematic review and meta-analysis. *Epidemiology* 2014;**25**:331–343.

7
8 3 Clapp III JF, Lopez B, Harcar-Sevcik R. Neonatal behavioral profile of the
9 offspring of women who continued to exercise regularly throughout pregnancy. *Am J*
10 *Obstet Gynecol* 1999;**180**:91–94.

11
12 4 Artal R, O'Toole M. Exercise during pregnancy and the postpartum period. *Clin*
13 *Obstet Gynecol* 2003;**46**:496–499.

14
15 5 Organization WH. WHO guidelines approved by the guidelines review
16 committee. *Use Tuberc Interferon-Gamma Release Assays IGRAs Low- Middle-Income*
17 *Ctries Policy Statement Geneva World Health Organ* 2011.

18
19 6 Vallim AL, Osis MJ, Cecatti JG, *et al*. Water exercises and quality of life during
20 pregnancy. *Reprod Health* 2011;**8**:14.

21
22 7 Kramer MS, McDonald SW. Aerobic exercise for women during pregnancy.
23 *Cochrane Database Syst Rev* 2006.

24
25 8 Olmedo-Requena R, Fernández JG, Prieto CA, *et al*. Factors associated with a
26 low adherence to a Mediterranean diet pattern in healthy Spanish women before
27 pregnancy. *Public Health Nutr* 2014;**17**:648–656.

28
29 9 Timmermans S, Steegers-Theunissen R, Vujkovic M, *et al*. The Mediterranean
30 diet and fetal size parameters: the Generation R Study. 2014.

31
32 10 Mesa SLR, Sosa BEP. Implicaciones del estado nutricional materno en el peso al
33 nacer del neonato. *Perspect En Nutr Humana* 2011;**11**:179–186.

34
35 11 Pérez-Ferre N, Del Valle L, Torrejón MJ, *et al*. Diabetes mellitus and abnormal
36 glucose tolerance development after gestational diabetes: A three-year, prospective,
37 randomized, clinical-based, Mediterranean lifestyle interventional study with parallel
38 groups. *Clin Nutr* 2015;**34**:579–585.

39
40 12 Karamanos B, Thanopoulou A, Anastasiou E, *et al*. Relation of the
41 Mediterranean diet with the incidence of gestational diabetes. *Eur J Clin Nutr*
42 2014;**68**:8.

43
44 13 Amorim AR, Rössner S, Neovius M, *et al*. Does excess pregnancy weight gain
45 constitute a major risk for increasing long-term BMI? *Obesity* 2007;**15**:1278–1286.

46
47 14 Adegboye ARA, Linne YM. Diet or exercise, or both, for weight reduction in
48 women after childbirth. *Cochrane Database Syst Rev* 2013.

49
50 15 Gomez Cantarino S, Comas Matas M, Velasco A, *et al*. Vivencias, experiências
51 e diferenças sexuais: mulher puérpera espanhola e imigrante. Área Palma sanitária de
52
53
54
55
56
57
58
59
60

- 1
2
3 Maiorca (Espanha). *Rev Enferm Referência* 2016;:115–123.
4
5 16 Magann EF, Evans SF, Weitz B, *et al.* Antepartum, intrapartum, and neonatal
6 significance of exercise on healthy low-risk pregnant working women. *Obstet Gynecol*
7 2002;**99**:466–472.
8
9
10 17 Chasan-Taber L, Schmidt MD, Roberts DE, *et al.* Development and validation
11 of a pregnancy physical activity questionnaire: Corrigendum. *Med Sci Sports Exerc*
12 2011;**43**.
13
14 18 Aguilar MC, Sánchez AL, Guisado RB, *et al.* *Accelerometer description as a*
15 *method to assess physical activity in different periods of life; systematic review.* 2014.
16
17 19 Trost SG, Mciver KL, Pate RR. Conducting accelerometer-based activity
18 assessments in field-based research. *Med Sci Sports Exerc* 2005;**37**:S531–43.
19
20 20 Freedson PS, Melanson E, Sirard J. Calibration of the Computer Science and
21 Applications, Inc. accelerometer. *Med Sci Sports Exerc* 1998;**30**:777–781.
22
23 21 Chen KY, DAVID R BASSETT J. The technology of accelerometry-based
24 activity monitors: current and future. *Med Sci Sports Exerc* 2005;**37**:S490–S500.
25
26 22 Foxcroft KF, Callaway LK, Byrne NM, *et al.* Development and validation of a
27 pregnancy symptoms inventory. *BMC Pregnancy Childbirth* 2013;**13**:3.
28
29 23 Vega-Dienstmaier JM, Mazzotti Suarez G, Campos Sanchez M. Validación de
30 una versión en español de la Escala de Depresión Postnatal de Edimburgo. *Actas Esp*
31 *Psiquiatr* 2002;**30**:106–111.
32
33 24 Vereecken CA, Covents M, Matthys C, *et al.* Young adolescents' nutrition
34 assessment on computer (YANA-C). *Eur J Clin Nutr* 2005;**59**:658.
35
36 25 Martínez-González MÁ, Corella D, Salas-Salvado J, *et al.* Cohort profile: design
37 and methods of the PREDIMED study. *Int J Epidemiol* 2010;**41**:377–385.
38
39 26 Association AD. 2. Classification and diagnosis of diabetes. *Diabetes Care*
40 2017;**40**:S11–S24.
41
42 27 Han S, Middleton P, Crowther CA. Exercise for pregnant women for preventing
43 gestational diabetes mellitus. *Cochrane Database Syst Rev* 2012.
44
45 28 Nascimento SL, Surita FG, Godoy AC, *et al.* Physical activity patterns and
46 factors related to exercise during pregnancy: a cross sectional study. *PloS One*
47 2015;**10**:e0128953.
48
49 29 Poyatos-León R, Sanabria-Martínez G, García-Prieto JC, *et al.* A follow-up
50 study to assess the determinants and consequences of physical activity in pregnant
51 women of Cuenca, Spain. *BMC Public Health* 2016;**16**:437.
52
53
54
55
56
57
58
59
60

1
2
3 30 Sanabria-Martínez G, García-Hermoso A, Poyatos-León R, *et al.* Effectiveness
4 of physical activity interventions on preventing gestational diabetes mellitus and
5 excessive maternal weight gain: a meta-analysis. *BJOG Int J Obstet Gynaecol*
6 2015;**122**:1167–1174.
7
8
9
10
11
12

13 **Figure Legends**

14
15 Fig. 1. Data gathering phases. AP, arterial blood pressure; BMI, body mass index.
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

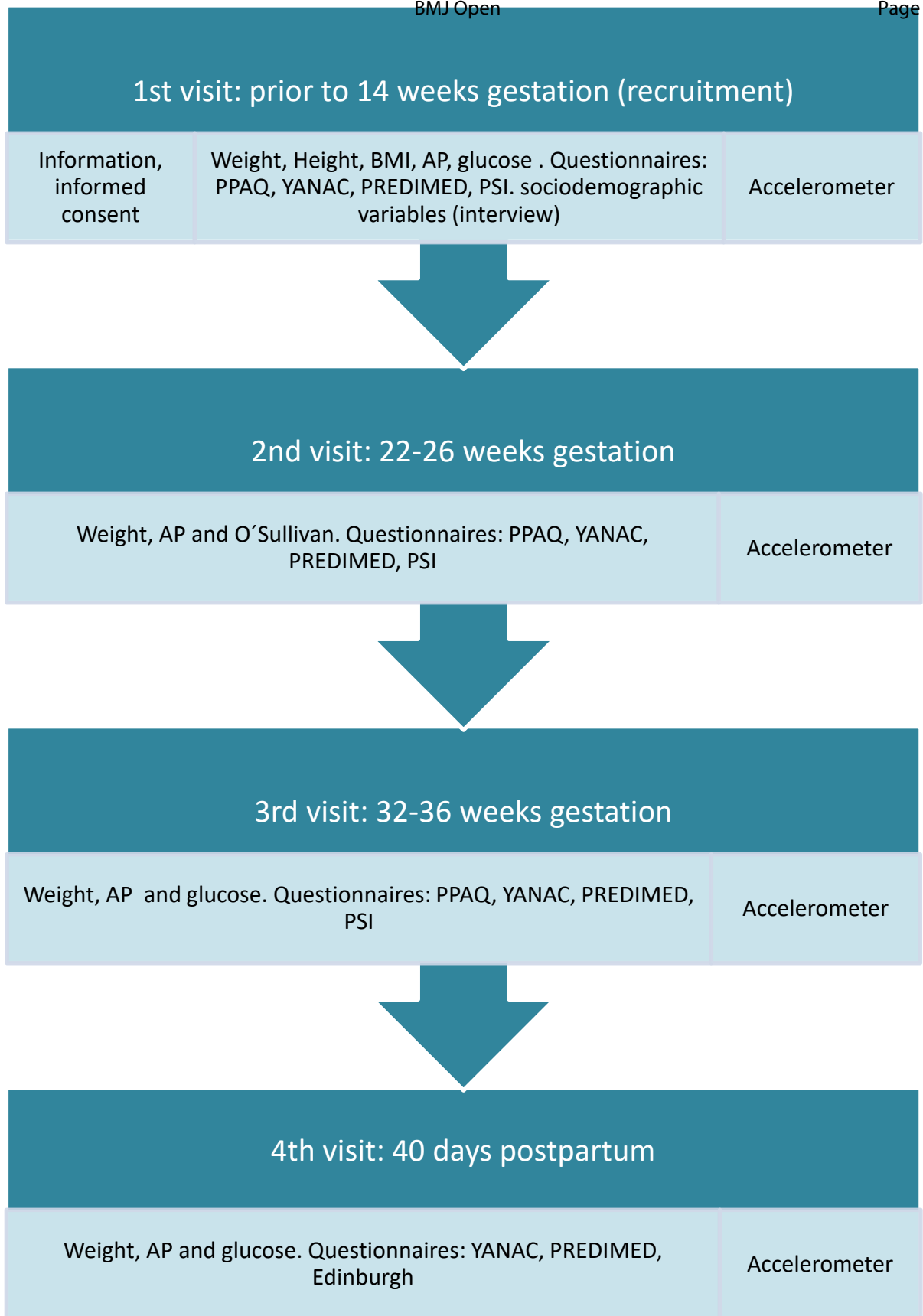


Fig. 1. Data gathering phases. AP, arterial blood pressure; BMI, body mass index.