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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.

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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.

Strenghts 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 adhesion 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.

The main outcome of this research is to examine the nutritional habits and the levels of PA in women during pregnancy and the postpartum period by means of validated questionnaires and accelerometers.
The secondary outcomes are:
i) To calculate the relationship between the level of PA and nutritional habits during pregnancy and the postpartum period in terms of the results for mothers in: weight gain, the incidence of pregnancy-related diabetes mellitus, pre-eclampsia and pregnancy-induced hypertension and type of birth. This relationship is also examined in terms of the results for newborn babies: duration of pregnancy, weight at birth, Apgar score 1 min / 5 min, type of reanimation and umbilical cord blood pH.
ii) To identify the factors that influence the performance of PA during each stage of pregnancy and the postpartum period (using the Spanish version of the Pregnancy Symptoms Inventory "PSI" and the Edinburgh scale).

Methods/Design

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

A multicentre study will be undertaken in 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.

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

Inclusion criteria:

i) Women aged from 18 to 40 years old.

ii) Pregnancy having lasted 14 weeks or less.

iii) A single foetus.

iv) Quarterly pregnancy check-ups in Primary Care facilities.

v) The intention of giving birth in the Virgen de la Salud Hospital.

vi) Comprehension of spoken and written Spanish.

Exclusion criteria:

i) Women with conditions prior to pregnancy that hinder or limit the practice of PA at the time of recruitment (one or more contraindications for PA according to the ACOG, diabetes or arterial hypertension prior to pregnancy, or more than one previous abortion).

ii) Not signing the informed consent document.

Iii) Not understanding written and spoken Spanish.

Variables

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

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

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

Physical activity: PA will be measured using:

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

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

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

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

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

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

Birth data: type of analgesia during birth (none, epidural, spinal), onset of birth (spontaneous / induced, reason for induction), duration of pregnancy (weeks and days), type of birth (natural, instrumental, caesarean), reasons for an instrumental or caesarean birth, episiotomy (yes/no), perineal tear (yes/no, grade I/II/III/IV), type of birth (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), foetal calotte pH (if performed), cord pinching (early/late), commencement of breast feeding in the first two hours of life (yes/no).

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 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

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.

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

Discussion

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

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

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

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

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

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

Abbreviations:

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

Declarations:

a. Ethics and Dissemination

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

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

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

b. Consent for publication

Not applicable

c. Availability of data and material

The data supporting our findings are contained within the manuscript.

d. Conflicts of interests

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

e. Funding

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

f. Author Statement

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

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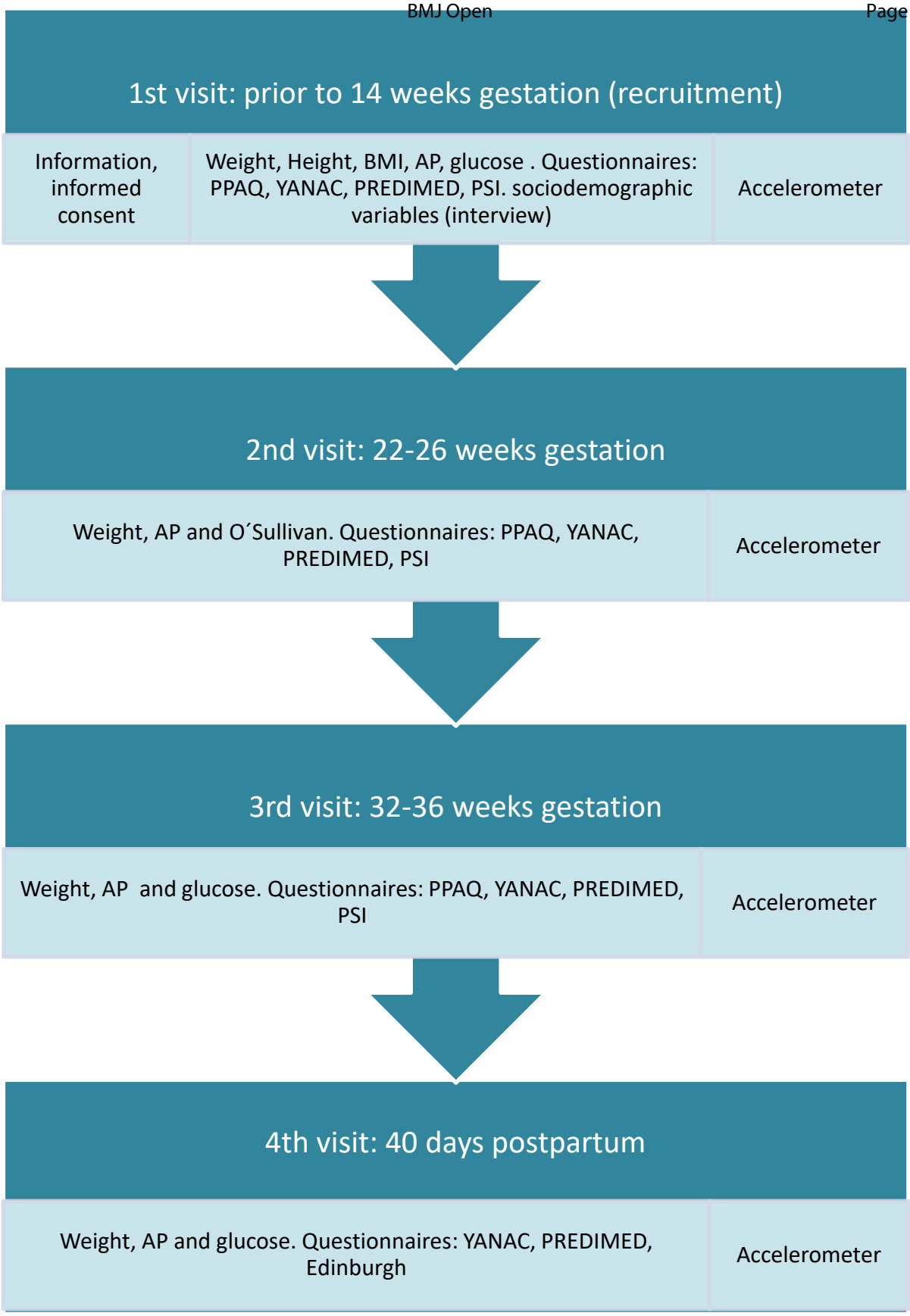
Figure Legends

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



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Key words: accelerometer, neonatal outcomes, physical activity, pregnancy outcomes.
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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 a 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

Strenghts 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). 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

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

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, pre-eclampsia and hypertension [1,2]; higher stress tolerance and earlier neonatal neuro-behavioural maturity [3]. 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 [4]. 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 [5].

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 [6,7]. 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 [8]. Data show that low adhesion to the Mediterranean diet may be associated with a reduction in the weight of the placenta and low neonatal weight[9,10], as well as the risk of pregnancy-associated diabetes in terms of the classification and diagnosis of diabetes [11], which indicates how important diet is during this phase of women's lives[12]. 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 fetal development [10].

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[13]. On the other hand, controlling weight solely by diet after giving birth is less effective than a combination of diet and physical exercise[14]. 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[15].

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

The secondary objectives are:

i) To calculate the relationship between the level of PA and nutritional habits during pregnancy and the postpartum period in terms of the results for mothers in: weight gain, the incidence of pregnancy-related diabetes mellitus, pre-eclampsia and pregnancy-induced hypertension and type of birth. This relationship is also examined in terms of the

results for newborn babies: duration of pregnancy, weight at birth, Apgar score 1 min / 5 min, type of reanimation and umbilical cord blood pH.
ii) To identify the factors that influence the performance of PA during each stage of pregnancy and the postpartum period (using the Spanish version of the Pregnancy Symptoms Inventory "PSI" and the Edinburgh scale).

Methods/Design

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

A multicentre study will be undertaken in 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.

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

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

Inclusion criteria:

i) Women aged from 18 to 40 years old.

ii) Pregnancy having lasted 14 weeks or less.

iii) A single foetus.

iv) Quarterly pregnancy check-ups in Primary Care facilities.

v) The intention of giving birth in the Virgen de la Salud Hospital.

vi) Comprehension of spoken and written Spanish.

Exclusion criteria:

i) Women with conditions prior to pregnancy that hinder or limit the practice of PA at the time of recruitment (one or more contraindications for PA according to the ACOG, diabetes or arterial hypertension prior to pregnancy, or more than one previous abortion).

ii) Not signing the informed consent document.

iii) Not understanding written and spoken Spanish.

iv) Women who do not complete the follow-up.

Variables *(Figure 1)*:

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

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

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

Biochemical parameters:

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

Physical activity: PA will be measured using:

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

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

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

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

Variables associated with nutritional habits: the "Young Adolescents' Nutrition Assessment on Computer" (YANA-C) [23] will be used, together with the Mediterranean diet adherence questionnaire (PREDIMED) [24]to gather data on the diet of pregnant and postpartum women.

YANA-C consists of listing the foods consumed in the previous 24 hours, and it is divided into breakfast, mid-morning, lunch, tea, dinner and after dinner. Energy (kcal) and macronutrient intake (percentages) will be measured by two non-consecutive 24-h recalls

(weekday and weekend day), using YANA-C software program. Percentages of Energy intake from carbohydrate, protein, fat and macronutrients (g) relative to weight (kg) will be calculated.

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

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

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

birth, episiotomy (yes/no), perineal tear (yes/no, grade I/II/III/IV), type of birth (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 has been calculated using *Epidat 4.1*, with an exposed/non-exposed ratio of 1. The outcome variable will be gestational diabetes mellitus. A prevalence of 14% is assumed in the group of exposed (sedentary) women and a prevalence of 3% is assumed in the group of non-exposed women (who are 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 will be assumed. Following these premises, it will be 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 do 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

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

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

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

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

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

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

Abbreviations:

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

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

Declarations:

a. Ethics and Dissemination

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

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

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

b. Consent for publication

Not applicable

c. Availability of data and material

The data supporting our findings are contained within the manuscript.

d. Conflicts of interests

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

e. Funding

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

f. Author Statement

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

g. Acknowledgements

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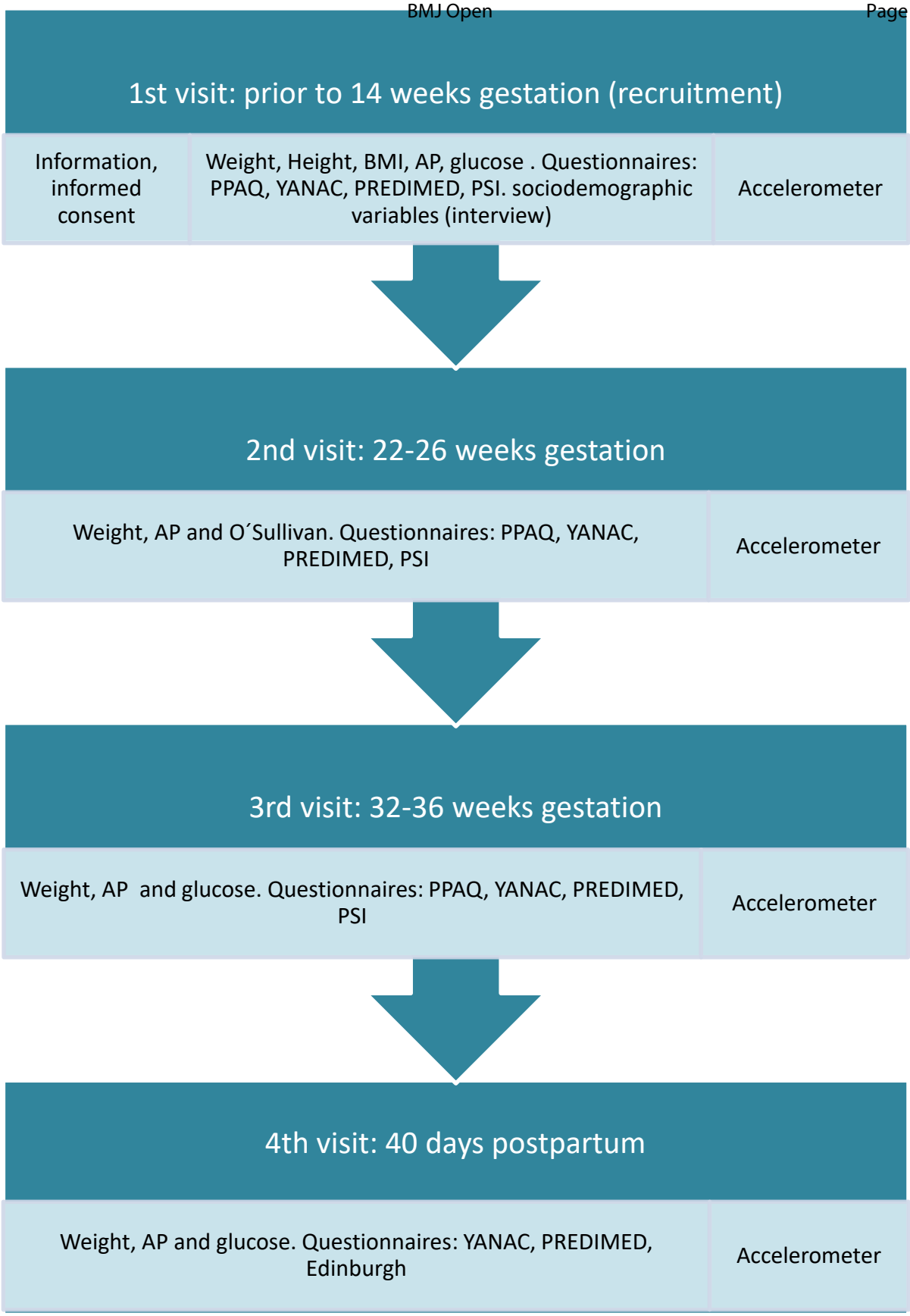
Figure Legends

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



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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.

Strenghts 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].

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, pre-eclampsia and hypertension [1, 2]; higher stress tolerance and earlier neonatal neuro-behavioural maturity [3]. 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 [4]. 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 [5].

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 [6, 7]. 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 [8]. Data show that low adhesion to the Mediterranean diet may be associated with a reduction in the weight of the placenta and low neonatal weight [9, 10], as well as the risk of pregnancy-associated diabetes in terms of the classification and diagnosis of diabetes [11], which indicates how important diet is during this phase of women's lives [12]. 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 fetal development [10].

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 [13, 14]. On the other hand, controlling weight solely by diet after giving birth is less effective than a combination of diet and physical exercise [14]. 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 [15,16].

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

The secondary objectives are:

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

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

Methods/Design

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

A multicentre study will be undertaken in 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.

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

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

Inclusion criteria:

i) Women aged from 18 to 40 years old.

ii) Pregnancy having lasted 14 weeks or less.

iii) A single foetus.

iv) Quarterly pregnancy check-ups in Primary Care facilities.

v) The intention of giving birth in the Virgen de la Salud Hospital.

vi) Comprehension of spoken and written Spanish.

Exclusion criteria:

i) Women with conditions prior to pregnancy that hinder or limit the practice of PA at the time of recruitment (one or more contraindications for PA according to the ACOG, diabetes or arterial hypertension prior to pregnancy, or more than one previous abortion).

ii) Not signing the informed consent document.

iii) Not understanding written and spoken Spanish.

iv) Women who do not complete the follow-up.

Variables *(Figure 1)*:

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

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

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

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

Biochemical parameters:

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

Physical activity: PA will be measured using:

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

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

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

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

Variables associated with nutritional habits: the "Young Adolescents' Nutrition Assessment on Computer" (YANA-C) [24] will be used, together with the Mediterranean diet adherence questionnaire (PREDIMED) [25] to gather data on the diet of pregnant and postpartum women.

YANA-C consists of listing the foods consumed in the previous 24 hours, and it is divided into breakfast, mid-morning, lunch, tea, dinner and after dinner. Energy (kcal) and macronutrient intake (percentages) will be measured by two non-consecutive 24-h recalls

(weekday and weekend day), using YANA-C software program. Percentages of Energy intake from carbohydrate, protein, fat and macronutrients (g) relative to weight (kg) will be calculated.

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

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

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

(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

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

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

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

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

Abbreviations:

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

Declarations:

a. Ethics and Dissemination

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

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

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

b. Consent for publication

Not applicable

c. Availability of data and material

The data supporting our findings are contained within the manuscript.

d. Conflicts of interests

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

e. Funding

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

f. Author Statement

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

g. Acknowledgements

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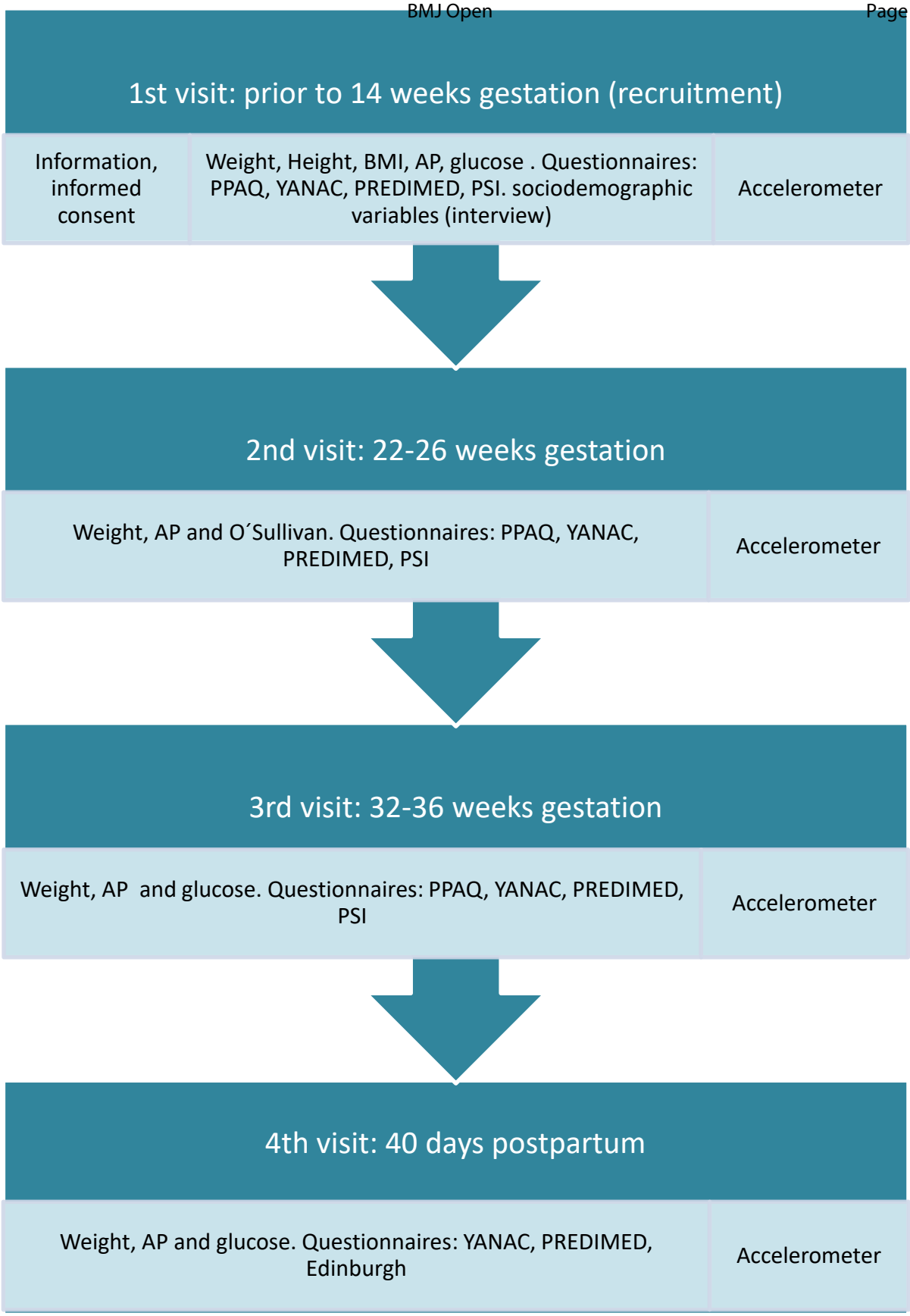
Figure Legends

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



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