COMPARISON OF FEMALE SEXUAL SATISFACTION OF PRIMIPAROUS WOMEN BEFORE AND AFTER PREGNANCY AND ITS IMPACT IN LIFE QUALITY: A PROSPECTIVE COHORT STUDY

Final Degree Project

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ABREVIATIONS

WHO: World Health Organization.

WAS: World Association of Sexology.

FSFI: Female sexual Function Index.

WHOQOL-BREF: World Health Organization Quality of Life (short version).

ASSIR: Atención a la Salud Sexual y Reproductiva.

IC: Informed Consent.

SPSS: Statistical for Social Sciences Software.

CEIC: Comité Ètic d'Investigació Clínica/Clinical Research Ethical Committee.

HUDJT: Hospital Universitari Josep Trueta.

GC: General Coordinator.

NHS: National Healthcare System.

ABSTRACT.

Background: Approximately a 90% of of women suffer sexual problems after the delivery. Changes such as dyspareunia, lack of libido, vaginal dryness and lack of orgasm can have significant effects on female sexual response and sexual interest for what sexual activity tends to be reduced after pregnancy. These problems are related with several factors such as parity, breast feeding, mode of delivery, episiotomy, stress, fatigue and physical and psychological problems which can cause a decrease in sexual satisfaction during this period and many of them may leave long-term sequels.

Despite having this knowledge about the changes that can occur in sexuality during pregnancy and postpartum, it still a taboo subject on which in general, gynecoobstetricians remain silent and the patient feels intimidated to aboard. Women tend to assume that changes in sexual satisfaction after pregnancy are part of normality and the silence of medical staff only favors this belief.

Objective: The aim of this study is to make a prospective cohort study to compare female sexual satisfaction before and after pregnancy and delivery and it's impact in life quality. We also want to determine the influence of some co-variables that we considered important in sexual satisfaction (age, lactation sex orientation, mode of delivery, premature delivery, episiotomy, multiple pregnancy, post-partum depression, occupation, age of partner, years of relationship). A long term objective, taking into account the results of our study, is to implement strategies to prevent or to treat the sexual disfunction that occurs after delivery.

Design: The study will be a multicenter observational prospective cohort. We will use a consecutive method of sampling of patients attending Gynecology and Obstetrics Department of five sanitary centers. The University Hospital Josep Trueta will be the coordinator center.

Participants: Primiparous women over 18 years that accomplish the inclusion criteria and none of the exclusion criteria.

Methods: We will record sexual satisfaction and life quality of our patients using the FSFI and the WHOQOL-BREF questionnaires, respectively. Those questionnaires will be answered in three times (first pregnancy control, 6 weeks after delivery and a year after delivery). Once we collected all the data a statistical analysis will be performed by a specialist.

Keywords: sexual satisfaction, life quality, pregnancy, primiparous women.

INTRODUCTION.

1. Health and sexuality:

In the 1948 the World Health Organization (WHO) defined health as a state of physical, mental and social complete well-being (1). At that time, this statement was innovative for its breadth and ambition. It exceeded the negative definition of health as absence of disease and included the physical, mental and social spheres. At this time sexuality and sexual health wasn't even contemplated as an important part of well-being.

In 1975, the WHO took a step away and considered that sexuality was also an important part of people health and well-being (2). The term sexuality was defined as a fundamental dimension of the fact of being a human being, based on sex, including gender, sex and gender identities, sexual orientation, eroticism, emotional bonding and love, and reproduction. Sexuality is experienced or expressed in the form of thoughts, fantasies, desires, beliefs, attitudes, values, activities, practices, roles and relationships. It can be said that it is the result of the interaction of biological, psychological, socio-economic, cultural, ethical and religious or spiritual factors (3). In summary, sexuality is experienced and expressed in everything we are, feel, think and do.

From that moment, sexuality became part of the concept of health and nowadays it is included in what is called sexual health. How is sexual health defined? Sexual health is the experience of the permanent process of achieving physical, psychological, and socio-cultural well-being related to sexuality (3, 4). Sexual health is observed in free and responsible expressions of sexual abilities that promote a harmonious personal and social well-being, thus entrusting individual and social life (5). It requires a positive and respectful approach to sexuality and sexual relations, as well as the possibility of having pleasant and safe sexual experiences, free from coercion, discrimination and violence (3). It is not simply the absence of dysfunction or disease or both. So, sexual health requires tree basic elements (2):

1. The chance to enjoy a sexual activity in concordance with a social and personal ethics.
2. The exercise of sexuality without fear, shame, guiltiness, fallacies and psychological or social factors that can interfere with sexual relations.
3. The realization of a sexual activity free of organic disorders, illness or others factors that can difficult them.

Sexual health is not only a part of WHO health concept, is also fundamental for life quality and human rights (6). According to the statement of the 13th. World Congress of Sexology, 1997, Valencia, Spain reviewed and expanded in 2014, sexual rights are fundamental and universal human rights, based on the freedom, dignity and equality inherent in all human beings.

Since health is a fundamental human right, sexual health must be a basic human right too. To ensure the development of healthy sexuality in human beings and societies, the following sexual rights must be recognized, promoted, respected and defended by all societies with all their means. In conclusion, we can say that sexual health is the result of an environment that recognizes, respects and exercises these sexual rights (7). Sexual rights that are included in the WAS statement (7):

1. The right to equality and non-discrimination.
2. The right to life, liberty, and security of the person.
3. The right to autonomy and bodily integrity.
4. The right to be free from torture and cruel, inhuman, or degrading treatment or punishment.
5. The right to be free from all forms of violence and coercion.
6. The right to privacy.
7. The right to the highest attainable standard of health, including sexual health; with the possibility of pleasurable, satisfying, and safe sexual experiences.
8. The right to enjoy the benefits of scientific progress and its application.
9. The right to information.
10. The right to education and the right to comprehensive sexuality education.

11. The right to enter, form, and dissolve marriage and similar types of relationships based on equality and full and free consent.
12. The right to decide whether to have children, the number and spacing of children, and to have the information and the means to do so.
13. The right to the freedom of thought, opinion, and expression.
14. The right to freedom of association and peaceful assembly.
15. The right to participation in public and political life.
16. The right to access to justice, remedies, and redress.

In conclusion, for sexual health is a fundamental part of human health and to be attained and maintained, the sexual rights of all persons must be respected, protected and fulfilled (3).

2. Sexuality approach at sanitary level:

It has been more than 40 years that sexuality was integrated into the concept of health but, it still not being properly addressed for health care providers (2). Despite the international emphasis on sexual health, it's being insufficient in developing countries. There are several reasons for that, including lack of access to information, education, promotion and health care services, poverty, and one of the most important factors, taboos surrounding discussion of sexuality (8).

Currently in Spain, there is no training in the curriculum of the Bachelor of Medicine and Surgery regarding sexuality disorders, a situation that should not exempt doctors from the responsibility of training in this field (9). In addition, no favor will be done to the health of our patients if we do not keep in mind that sexuality is a basic element of physical, psychic and social well-being, which we must study and treat in order to provide the patient with a better quality of life (9).

Another problem added to the approach to sexuality is the lack of promotion and education in sexual health (10). Is true that it is a difficult topic to address in primary care since the lack of time does not allow creating a suitable therapeutic climate for it, but it is important to promote a healthy sexuality not only in the sanitary services but also at the educational level which could help to avoid many of the sexual dysfunctions that affect patients (9).

Apart of the lack of education and promotion, there is the fact that sex remains a taboo subject in our society. This affects mainly the familiar environment and the educational and sanitary services and has serious consequences, mainly hindering the knowledge in sexual health. The principal reason for the existence of this taboo is that in Western civilization we have inherited beliefs based on Judeo-Christian tradition and cultural assumptions derived from myths that have severely curtailed access to our sexuality (11). We know, that throughout our lives, sexuality has a very important role in biological and social development. If it is treated as uncomfortable subject or it is ignored because of the taboo, deficits in sexual education can appear that are associated with significant sexual dysfunctions that could be avoided (9).

Due to these multiple reasons, patients tend not to consult about possible problems or doubts related to sex or their sexuality since it is an intimate issue that make them feel ashamed. In our society we learn that sexuality is not spoken and if it is spoken it is from the point of view of sexual risks and dangers. We are not taught that sexuality is about who we are, of knowing and accepting ourselves, of self-esteem, of emotions, of learning to relate in a healthy way (9). This only favors that sexuality-related problems are perpetuated or more serious than they should be, since they are not treated at the appropriate time.

As we see, despite all the social advances that have taken place in other areas in our society, sexuality is still a pending issue. New policies for education and promotion of sexual health should be available to the entire population. In addition, we believe that the role of health personnel is also important, which should be able to address the sexual health of patients through an honest and open dialogue that facilitates patient consultation.

In conclusion, sexual health is currently part of general health and as such should be addressed naturally in the health care system, which is something that we did not achieve yet and we pretend to improve in this work.

3. Female sexuality:

At sanitary context, sexual health is an issue that currently remains on the sidelines as we have already seen. This applies for both sexes, but is also known

that for females it can be even more complicated, the reason for that is given by cultural and historical facts.

Female sexuality has been through different phases along history were female role has not always been the same.

More than 500 years ago, women were considered as personal property, destined to propitiate sexual pleasure and reproductive functions for men, while men had the right to practice sexual relations with several women and sex for them was considered as another reality of daily life (12). In ancient Greece, women were considered second-class citizens, they lacked legal and political rights that were the same as slaves. Women were considered mere bearers of children (12).

With the rise of Christianity, Church also manifested its negative position around sex. Female figure started to be considered the representation of sin following the myth of Adam and Eve. In this myth, as in others throughout history, women appear as the origin of evil, as a cause of sin or temptation to sin, which leaded to Christianity having an image of women as something dangerous, source of sin and destruction.

The XVIII and XIX centuries were the most dark period for female sexuality, where they were held at home or in a convent. The Judeo-Christian tradition considered women as simple sexual objects, whose end role were procreation and to serve their children (13).

Is at the beginning of the XX century were female role start to become relevant with the birth of the feminist movement. At the second half of the XX century there were scientific and social advances in defense of information and access to contraceptive methods, this is how women started to be separated of their only function until then: reproduction (13).

As we see, female sexuality has not been important along history which explains that even today the approach to female sexuality is still complicated or less taken into account.

Nevertheless, things are changing in our current society and in the social time we are living. Nowadays we know several things about female sexuality. We know that women go under different sexual phases along their development, we also know that structural problems in female genitalia can cause sexual insatisfaction, women’s libido changes with hormonal factors and depending the menstruation

cycle, is also known how female sexuality changes during pregnancy and in the postpartum period (14). But despite having all this knowledge, its approach is still being less than it should be because patients are reluctant to consult and doctors have little habit of addressing sexual issues as we explained above.

4. Female sexuality during pregnancy and postpartum:

Sexual activity during pregnancy, immediate postpartum and its consequences has been subject to doubt for a long time (15). Pregnancy is a crucial period in which changes occur in pregnant women that affect and modify their entire bio-psycho-social being, which also brings changes in female sexuality.

Anthropological studies demonstrate very different practices, from tribes that restrict sexual activity for fear that the sperm will blind or injure the embryo (the Chukchees), to tribes that encourage sexual intercourses because they imagine that the embryo is something liquid that must be nourished by the sperm (15).

It is currently known that the effects of pregnancy are not uniform, for some women pregnancy can be a period of enjoyment and increased sexual awareness, while others experience a decrease in their sexual desires.

Nowadays, it is known that during normal pregnancy sexual activity can be maintained (provided there is no evidence of infection or other complications) without fear of any fetal damage, while activity should be avoided when there is a threat of abortion or preterm birth (16).

Is also known that during pregnancy there are different phases regarding sexuality, which do not occur in the same way in all women but are quite widespread. In the first trimester there is usually a decrease in libido, a decrease in sexual relations and sexual response. This is related to the fact that many women experience nausea and vomiting and during this period there are changes in the body that can make the stimulation painful, as is the case with the mammary vessel congestion. In the second trimester, body modifications appear due to the development of pregnancy, which usually results in a decrease in self-esteem, however, it is a phase where there is a higher frequency of sexual relations because the anatomical and functional changes that occur favor sexual intercourse. The last trimester is similar to the first one, where women have a decreased libido that is related to physical discomfort and fear of childbirth (17).

Regarding postpartum, studies have shown that 91.3% of women suffer sexual problems during this period (8). During postpartum, the changes such as dyspareunia, lack of libido, vaginal dryness and lack of orgasm can have significant effects on female sexual response and interest for what sexual activity tends to be reduced. These problems are related with several factors such as parity, breast feeding, mode of delivery, episiotomy, stress, fatigue and physical and psychological problems such as postpartum depression, which cause a decrease in sexual satisfaction during this period, many of them may leave long-term sequels (8).

Despite having this knowledge about the changes that can occur in sexuality during pregnancy and postpartum, it still a subject poorly approached and on which, in general, gynecoobstetricians remain silent and the couple is feel intimidated to board. This only increases subsequent sexual dysfunctions, many of which could be prevented or treated. On the other hand, what usually happens is that women assume that changes in sexual satisfaction are a normal fact after pregnancy and silence on the part of medical staff only favors this belief.

Therefore, it is important to overcome the taboos surrounding sexuality and to achieve this, the role of medical staff is very important as they should facilitate its approach, providing information during consultations and encouraging patients to ask about possible doubts they may have, and with that to identify possible problems and provide solutions to them.

JUSTIFICATION.

We believe that sexual health is a topic that is rarely addressed in the field of public health. As we have seen before, there are many taboos that surround sexuality and despite the recommendations of international organizations, little has been done in this regard to solve this situation.

Sexual health is part of the well-being of patients and therefore, a deficit in this subject can have an important impact on their quality of life. There is a huge diversity of problems related to sexual activity that affect both sexes and those also have a high prevalence.

We know that many of these problems could be avoided with an adequate approach at the health level. Medical personnel should make it easier for patients to deal with these issues and thus, little by little, try to make the taboo that surrounds sexuality disappear.

Among the problems related to sexual health, the changes that occur in female sexuality during pregnancy and postpartum are well known as well as it is known that they can end up producing a long-term decrease in female sexual satisfaction. These changes in many cases are considered as part of normality and are not taken into account by both patients and doctors.

For this reason, we believe that there is a need for a change in the way of addressing sexual health at the National Healthcare System (NHS) mainly by doctors who should provide resources to patients so the problems related to their sexuality can be easily exposed and solved.

Therefore, this study intends to implement a model to assess female sexual satisfaction before and after pregnancy based on surveys with the objective of identifying the changes that occur in it and the main causes of these changes. It is also intended to assess the impact that these changes may have on the life quality of patients in order to determine the importance of sexual health in personal well-being.

With this, we intent to provide medical staff with a tool to facilitate the approach of possible problems that patients may have in relation to sex and thus improve

their identification and reduce their impact, reducing the taboo and discomfort that may involve treating these issues.

In this study, the dependent variable (study outcome) is sexual satisfaction. This variable has been selected because what is intended is to assess the sexuality of women, and compare the changes and possible sexual dysfunctions that occur after delivery. We believe that it is an appropriate parameter since through this survey information is obtained from various aspects that are fundamental for sexual satisfaction.

As an independent variable, we use pregnancy since, as explained in the introduction, it is related to various factors that can modify the woman's sexual satisfaction, not only during postpartum but also in a long term. We think that this factors could be prevented, minimized or properly treated after delivery with the right strategies.

In order to compare sexual satisfaction, we will apply female sexual function index (FSFI) questionnaire (see ANNEX 5-7). The life quality will be assessed with the WHOQOL-BREF questionnaire (see ANNEX 8-9), to be able to determine the impact of the changes in sexual satisfaction in life quality of our patients. Both will be performed in primiparous women of legal age in three times (first pregnancy control, six weeks after delivery, one year after delivery). The population under 18 is excluded due to legal issues, since the opinion of legal tutors must be taken into account. We also consider that most of them are cases of unwanted pregnancies happens, women without a stable partner, or without economic independence in which there are many more factors that can affect their sexual satisfaction apart from the pregnancy itself.

HIPOTESIS.

Based on the available literature and previous studies on postpartum sexual dysfunction and its associated factors, as well as on the experience of clinical practice, our main hypothesis is that:

- The changes that occur during pregnancy and delivery can produce sexual dysfunction in women that can affect their sexual satisfaction producing a decrease in it that can be maintained in a long term.

Our secondary hypotheses are that:

- The decrease in sexual satisfaction has a significant impact on the life quality of patients.
- Many of the causes to which sexual dissatisfaction is associated could be prevented, minimized or treated with appropriate strategies and thus improving the quality of life of patients.

OBJECTIVE:

In order to confirm our hypothesis, our main objective is:

1. To compare female sexual satisfaction before and after pregnancy in adult primiparous women (first pregnancy control, six weeks after delivery, one year after delivery).

Our secondary objective is:

2. To measure the impact of the changes in sexual satisfaction in the life quality of our patients.
3. To determine the influence of the co-variables analyzed in sexual satisfaction after delivery. The co-variables we think should be taken into account are:
    - Age.
    - Lactation.
    - Sex orientation.
    - Mode of delivery.
    - Premature delivery.
    - Episiotomy.
    - Multiple pregnancy.
    - Post-partum depression.
    - Occupation.
    - Age of partner
    - Years of relationship.

METHODOLOGY

1. Study design:

This is a prospective observational study of a cohort. It is a multicentric study that will be carried out in the health centers of the community of Girona. Centers participating are:

Doctor Josep Trueta University Hospital.

- ASSIR Gironès - Pla de l'Estany:
    - o Banyoles Primary Care Center.
    - o Celrà Primary Care Center.
    - o Sarrià de Ter Primary Care Center.
    - o Güell Primary Care Center.

Study population:

Primiparous women older than 18 years that live in Girona.

→ Inclusion criteria:

- Age > 18 years.
- Primiparous.
- Good knowledge of Spanish o Catalan language.

→ Exclusion criteria:

- Serious mental illness (major depression, psychotic disorder, bipolar disorder, personality disorder, drug abuse disorder other than tobacco related ones).
- Single.
- Previously urogenital surgery.
- Adoptive, foster or stepchildren at home.
- Urogenital or anorectal abnormalities.
- Neurological disorders.

2. Sample:

Sample size:

We used de program GRANMO to calculate the size of the sample we need for this study. We cannot calculate the sample size exactly because we do not have a background.

To do so, we will assume that patients will initially have a high sexual satisfaction (approximately a punctuation of 25) and after pregnancy there will be a clinically significant decrease with a minimum of 15 points. With these data, and considering that we will be able to recruit 150 patients, we will have a power of 100% to detect as statistically significant the difference between the score between the pre- and posttest as detailed above.

Sampling method:

A non-probabilistic consecutive sampling method will be performed for a year. The patients will be recruited at the Gynaecology and Obstetrics Department of:

- Doctor Josep Trueta University Hospital.
- ASSIR Gironès - Pla de l'Estany:
    - Banyoles Primary Care Center.
    - Celrà Primary Care Center.
    - Sarrià de Ter Primary Care Center.
    - Güell Primary Care Center.

3. Variables:

Independent variable: pregnancy.

It's a dichotomous nominal qualitative variable. It is express by yes or not. We will considered that the pregnancy is confirmed at the first appointment with the gynecologist. The first pregnancy control should be done between the 6th and 9th weeks of pregnancy. During this visit a vaginal echography is done to confirm the presence of de amniotic sac.

Primary outcome variable: sexual satisfaction.

It's a discrete quantitative variable. It is measured with the Female Sexual Function Index (FSFI). FSFI questions are coded from 0.0 to 5.0. Based on

clinical considerations, the scale is considered to have six sexual domains (desire, arousal, lubrication, orgasm, satisfaction, pain), each contributing to the overarching construct of female sexual function (23). The maximum score for each domain is 6.0, obtained by summing item responses and multiplying by a correction factor. The total composite sexual function score is a sum of domain scores and ranges from 2.0 (not sexually active and no desire) to 36.0 (See ANNEX 6-7).

Secondary variable: life quality.

It is a continuous quantitative variable. It is measured with the WHOQOL-BREF questioner. The WHOQOL-BREF contains a total of 26 questions, one question from each of the 24 facets contained in the WHOQOL-100 and two global questions: global quality of life and general health. Each item has 5 ordinal response options and they all produce a profile of four areas: physical, psychological, social relations and environment (31) (See ANNEX 8-9).

4. Co-variables:

We will obtain this data directly from clinical history or asking verbally to the patient in the first pregnancy control, once the patient has been properly informed and has signed the IC (informed consent, see ANNEX 3-4).

- Age: it is discrete quantitative variable. It will be measured in years. Throughout our lives we go through different sexual stages. Youth, around 20-30 years is considered the stage of sexual fullness. The desire is high and we try to satisfy it in an impulsive and immediate way. However, the maturation process makes the interest of young people change. Therefore, it is common that at some point we begin to be more interested in the emotional and emotional aspects of a relationship and less about sex.

  In adulthood, sexuality is lived more deeply and intensely. Women experience at this stage the highest peak of sexual desire.

  Between 40-50 years there is usually a decrease in the frequency of sexual intercourse, which is often related to boredom, routine and accommodation after years with the same partner.
- Lactation: It's a dichotomous nominal qualitative variable measured as yes or not. During breastfeeding the prolactin hormone levels increase and

estrogen levels decrease, which can lead to decreased libido, reduced satisfaction and dyspareunia in sexual intercourse.

- Sexual orientation: It's a categorical qualitative variable. Heterosexual/homosexual/bisexual. The sexual orientation of the patient influences the type of sexual practice that the couple can carry out, for that we consider that it's an important factor to consider when assessing sexual satisfaction.
- Mode of delivery: Vaginal delivery or cesarean section. Depending on the type of delivery the recovery time after birth varies. The possible sequelae are also different depending the type of delivery, it could have an important impact on sexual satisfaction and for that we decided that to contemplate it.

  Cesarean section: It's a dichotomous nominal qualitative variable measured as yes or not. A cesarean section, also called a C-section, is a surgical procedure performed if a vaginal delivery is not possible. During this procedure, the baby is delivered through surgical incisions made in the abdomen and the uterus. If the delivery occurs by caesarean section, it is recommended to wait 6-7 weeks to allow a good healing of the uterine wall before reinitiate sexual intercourses.

  Vaginal delivery: In case of vaginal partum we will contemplate the following subtypes of delivery:

  - Spontaneous vaginal delivery: It's a dichotomous nominal qualitative variable measured as yes or not. Occurs when a pregnant female goes into labor without the use of drugs or techniques to induce labor, and delivers her baby in the normal manner, without forceps, vacuum extraction, or a cesarean section. If a natural birth occurs, sexual activity may be able to resume earlier.
  - Episiotomy: It's a dichotomous nominal qualitative variable measured as yes or not. An episiotomy is a surgical incision made in the perineum (the area of skin between the vagina and the anus). The incision enlarges the vaginal opening to allow the baby's head to pass through more easily and to prevent tearing of the mother's skin. It is important to know if a episiotomy was performed during de delivery as it can cause long-term dyspareunia. In cases where an episiotomy is performed, the recovery time may be somewhat longer.

- Forceps delivery: It's a dichotomous nominal qualitative variable measured as yes or not. Forceps look like two large spoons that the doctor inserts into the vagina and around the baby's head during a forceps delivery. The forceps are put into place and, the doctor uses them to gently deliver the baby's head through the vagina. The rest of the baby is delivered normally.
- Vacuum extraction: It's a dichotomous nominal qualitative variable measured as yes or not. A vacuum extractor looks like a small suction cup that is placed on the baby's head to help deliver the baby. A vacuum is created using a pump, and the baby is pulled down the birth canal with the instrument and with the help of the mother's contractions. The pump can often leave a bruise on the baby's head, which typically resolves over the first 48 hours.
- Induced labor: It's a dichotomous nominal qualitative variable measured as yes or not. Induction of labor usually means that labor needs to be started for a number of reasons. It is most often used for pregnancies with medical problems or other complications. Labor is usually induced with a synthetic form of the drug oxytocin given intravenously.
- Thierry spatula delivery: It's a dichotomous nominal qualitative variable measured as yes or not. It's a metallic instrument consisting of two spatulas or spoons that are not articulated between them and whose main objective is to expand the birth canal. They are used when the baby's head is correctly positioned, facing down, but has difficulty descending. Thus, they serve to widen the birth canal and allow us to perform some traction of the fetal head, but they are not suitable when some rotation movement is needed.

- Premature delivery: It's a dichotomous nominal qualitative variable measured as yes or not. A premature birth is the one that occurs before the 37th week of pregnancy. Premature babies, especially those who were born much earlier, often have complicated medical problems. This is a factor that also affects the mother as it causes an increase in her worry and stress. In addition, premature birth is usually less planned because complications may occur more commonly.

- Multiple pregnancy: It's a dichotomous nominal qualitative variable measured as yes or not. Multiple pregnancies are considered high risk in themselves. This is because multiple pregnancy involves a higher risk of complications. If these complications occur, they may have long-term sequelae or lengthen the patient's recovery process.
- Post-partum depression: It's a dichotomous nominal qualitative variable measured as yes or not. Postpartum depression is a mood disorder that can affect women after giving birth. Mothers suffering from postpartum depression have feelings of extreme sadness, anxiety and tiredness that make it difficult for them to perform daily activities of caring for themselves and others. Therefore, patients suffering from this disorder do not usually have sexual intercourse or these are markedly diminished.
- Occupation: It's a nominal qualitative variable. The patient occupation is an important co-variable as it could be a factor of stress, tiredness that could be related with a decrease in the frequency of sexual intercourses.
- Years of relationship: It's a quantitative discrete variable measured in years. We consider it an important covariate since generally the longer the relationship, the greater the trust that can facilitate the restart of sexual activity.
- Age of partner: It's a quantitative discrete variable measured in years. Age is important as explained above. Not only can the age of our patient influence sexuality, it is also important to consider the age of your partner.

5. Data collection:

Information will be recorded directly from the patient or from its medical history. At the first pregnancy control, the patient will be given an explanatory sheet (see ANNEX 1-2) and the IC (see ANNEX 3-4) that she must sign if she agrees to participate in the study. Once those documents are signed and pregnancy is confirmed we will record personal patient data to see if she meets de inclusion and exclusion criteria. We will collect the following data:

- Identification of the patient.
- Age.
- Sexual orientation.

- Single or multiple pregnancy.
- Antecedent of abortion.
- Previous pathologies. Especially urogenital or anorectal.
- Previous surgeries. Especially urogenital or anorectal.
- Mental illness.
- Occupation.
- Age of partner.
- Years of relationship.

Once we have collected this information and the patient meets the necessary criteria to participate in our study, both surveys, the FSFI (see ANNEX 5-6) and the WHOQOL-BREF (see ANNEX 8-9) will be delivered. The patient must implement the questionnaires at the time and then deliver them.

Subsequently, a second data collection will be carried out with the same questionnaires in the consultation that takes place 6 weeks postpartum in which the patient is discharged. In this case, the surveys should also be answered and delivered immediately.

Finally, the third survey that will be carried out one year after delivery, will be done online with the aim to avoid the need of the patient to go to the consult and with that, try to reduce the drop-outs of the study.

Procedure	First trimester	Six weeks after birth	One year after birth
Study information and informed consent (CI)	✓		
FSFI	✓	✓	✓
WHOQOL-BREF	✓	✓	✓

STATISTICAL ANALYSIS.

The statistical analysis will be performed by the statistical analyst. It will be done using the Statistical for Social Sciences (SPSS) software.

1. Statistical plan:

We will ask the statistical analyst for the following activities:

- To describe the sample based on sociodemographic data.
- To describe the sample based on the collected variables to be able to evaluate the type of sample we have.
- To describe the results obtained based on the confusing variables.
- To determine if there are significant differences between the dependent variable before pregnancy and at 6 weeks postpartum, and also between before pregnancy and one year after delivery.
- To stablish the relationship between sexual satisfaction (outcome variable) and the life quality of patients.
- To stablish the relationship between the change in sexual satisfaction and change in quality of life.
- To assess whether sexual satisfaction before and after childbirth (6 weeks and one year) is affected or not by the confusing variables (co-variables described in the methodology section).

This statistical plan will be performed with the following statistical tests:

2. Univariate analysis:

In the univariate analysis, variables will be defined as qualitative or quantitative:

- For quantitative variables and covariables, we will use mean, standard deviation, medians and interquartile range.

- For qualitative variables, the results will be expressed in percentages, proportions or frequencies.

3. Bivariate analysis:

Comparison of the qualitative covariables proportions will be carried out using Chi-square or Fisher's exact Test.

Comparison of the dependent variable and quantitative variables' mean and median of the independent variable will be carried out using Student-t test and Mann-Whitney U respectively.

4. Multivariate analysis:

A multivariate analysis will be performed to adjust the result of the outcome variable for the covariables, trying to avoid potential confounders that could modify the results.

To analyze the relationship between the sexual satisfaction and the independent variable, a lineal regression model will be used, adjusting for the covariables.

WORK PLAN AND CHRONOGRAM.

1. Work plan:

The study is expected to last around 3 years. All the activities included in this study and carried out during this period of time will be organized in 5 stages.

STAGE 1: Preparation – 1month.

- Activity 1: protocol elaboration. We will design the protocol and once done we will review it in order to identify possible mistakes.
- Activity 2: presentation of protocol to the Clinical Research Ethical Committee (CEIC) for approval.
- Activity 3: Recruitment of professionals interested in participating and coordination of the centers involved.

STAGE 2: Coordination – 1 week.

- Activity 4: informative meeting. The objective of this meeting is to reunite the entire team participating in this study to explain the procedure, the working plan and how we are going to perform it, and which is the main objective. This reunion will help us to conduct the study accurately.

STAGE 3 -Participant recruitment and data collection – 12 months.

- Activity 5: pregnant patients attending Gynaecology and Obstetrics Department of the participating centers who fulfil the inclusion criteria and none of the exclusion criteria will be offered to enter the study. They will be included after giving them the explanatory sheet (see ANNEX 1-2) once we confirm they understand the objective of the study and after signing the informed consent (see ANNEX 3-4).
- Activity 6: in the first pregnancy control, the midwife or gynecologist will provide both questionnaires, the FSFI (see ANNEX 5-7) for sexual satisfaction and the WHOQOL-BREF (see ANNEX 8-9) for quality of life. We

intend to collect this data before the effects of pregnancy affects the sexual activity of the patient.

- Activity 7: After delivery (approximately 6 weeks) when the patient is to be discharged, the second batch of questionnaires will be provided, both the FSFI and the WHOQOL-BREF, to collect information on the effects of delivery in sexual satisfaction and life quality in short term.
- Activity 8: one year after birth we will contact by phone with the patients to inform that we will send them by e-mail a link to the questionnaires that they will have to answer. With this we want to know if changes in sexual satisfaction still present in a long term and how they can affect life quality of patients.

STAGE 4 – Data analysis and interpretation – 1 month.

- Activity 9: once data collection is finished the whole data will be organized and after that the necessary statistical analysis will be performed by a statistician.
- Activity 10: the statistical results obtained will be analysed and discussed by the research team.

STAGE 5 – Publication and dissemination of the research finding – 3 months.

- Activity 11: we will edit the results obtained and redact an article with the appropriate structure.
- Activity 12: once the article is finished we will send it to different journals for its publication.
- Activity 13: dissemination of the findings. The team will attempt to display our results in conferences and congresses related with health and sexuality.

2. Members of the team:

Main investigator/General coordinator (GC): responsible for, elaboration of the protocol, overseeing the study, coordination and formation of the research team, results interpretation, writing of the conclusions and results publication and dissemination.

Study coordinators: Responsible for overseeing the study (according to the study protocol). There will be a study coordinator in each of the centers participating.

Co-investigators:

- Gynecologists/midwives: Responsible for providing the questionnaires to the patients if they agree to participate and meet the inclusion criteria and none of the exclusion criteria.
- Expert statistician: Responsible for the statistical analysis of the study.

3. Chronogram:

		2019		2020						2021						2022					
ACTIVITY	PERS	Sep-Oct	Nov-dec	Jan-Feb	March-April	May-June	July - Aug	Sep-Oct	Nov-Dec	Jan-Feb	March-April	May-June	July-Aug	Sep-Oct	Nov-Dec	Jan-Feb	March April	May-June	July-aug	Sep-Oct	Nov dec
STAGE 1: Preparation																					
Protocol elaboration																					
Ethical approval																					
Recruitment of team and centers coordination																					
STAGE 2: Coordination																					
Informative meeting																					
STAGE 3: patients recruitment and data collection																					
Recruitment																					
First quest.																					
Second ques.																					
Third ques.																					
STAGE 4: Data analysis and interpretation																					
Stat analysis																					

Discussion of results																					
STAGE 5: Publication and dissemination of the research findings																					
Article elaboration																					
Article publication																					
Dissemination																					

FEASIBILITY.

This prospective observational study will take place in the Gynecology and Obstetrics Department of HUDJT and the ASSIR Gironés - Pla de l'Estany (Primary Care Centers of Güell, Sarrià de Ter, Celrà and Banyoles).

The gynecologists and the midwives will receive their habitual salaries in the hospital or the Primary Care Center. The only task that will be paid is the one conducted by the statistical specialist.

This study does not need a lot of material so it realization has a low cost. The consult where the first and second round of questionnaires are going to be answered are part of the habitual control of pregnancy which don't imply any extra cost. The questionnaires will be printed at the consult at the moment with the cost of 3 cents/page. The third round of questionnaires are going to be done online and we will use a free application.

The number of patients we need for its realization is affordable with the centers that are going to participate in this study.

In conclusion, this project seems to be a feasible study, which can be performed taking into account the location, the economic cost and the number of patients needed.

ETHICAL AND LEGAL ASPECTS.

This research protocol will be presented to the CEIC of HUJT for its assessment and approval. Moreover, the recommendations given by the committee will be taken into account to carry out the study.

A patient will not enter the study until she has been properly informed. All the patients included in this study will sign a informed consent that includes the permission of telephoning them during their follow-up, that is expected to be approximately for 17 months.

Each member of the research team must sign a statement attesting to having read and approved the final protocol and that they agree with the national and international ethical aspects of research.

This study will be conducted according to the requirements expressed in the *Declaration of Helsinki of Ethical Principles for Medical Research Involving Human Subjects* signed by the World Health Association in October 2013, and to *ministerial order SAS/3470/2009* defined in the current legislation in Spain related with the conduct of observational studies.

The processing of personal data required in this study, the personal data cession of all the patients and their confidentiality will obey the *Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 in the protection of natural persons with regard to the processing of personal data and the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) and the Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y Garantía de los derechos digitales.*

Patients data including names, surnames, telephones, addresses and clinical history information will remain anonymous after their introduction and processing into a database which will also be handled according to the mentioned Law and

exclusively used for the development of the study. The data access will only be available for the research team. The access to this information for a third person will not be allowed.

LIMITATIONS OF THE STUDY.

1. Internal validity:

- As we use a consecutive sampling method, we could have a selection bias that we will try to avoid using inclusion and exclusion criteria. Only the patients that fulfill the inclusion criteria and none of the exclusion criteria will be invited to participate in our study.

- Withdrawal and losses during the follow-up period could cause a selection bias. They will be registered. To avoid this bias the sample size has been calculated with expectations of future losses and withdrawals. Where we think we a bigger proportion of patients can be lost is in the realization of the third questionnaire. To try to minimize that lost we are going to perform this part of the study online so patients can do it at home without the need to come the consult.

- The impossibility to randomize the patients of the study. We have tried to minimalize the effects of possible confounding bias by defining the plausible confounding factors described in the literature as covariables, with the use of multivariate logistic regression analyses.

2. External validity:

- Regarding external validity, we believe that the results of this study can be extrapolated to general population in our country, but that there may be some limitation for other countries. These limitations can occur mostly out of the Western Civilization mainly due to cultural and religious differences (vision of sexuality) and clinical practices regarding the time of delivery.

BUDGET.

The budget of this study includes all the possible expenses that will be needed to realize it. We won't take into account the expenses of the clinical practice that is normally performed in the control of pregnancy and post-partum.

1. Personnel expenses:

The selection of patients included according to the inclusion and exclusion criteria will be performed by the midwives and gynecologists that participate in the study. The first and second round of questionnaires will be done at the consult of the hospital or the Primary Care Center. This cost will not be included, as the consult are part of the normal medical practice during pregnancy. The third round of questionnaires will be done online with any additional cost.

The personnel extra expense will consist in hiring a statistical analyst. We have estimated approximately 20 hours of work will we needed to perform the statistical analysis. We will pay 40€/h so we estimate a cost of 800€.

2. Execution expenses:

The articles and publications consulted for the development of this study have not entailed an additional cost.

Additional costs include the printing of the questionnaires that the patients will perform. Each page of the questionnaire printing will cost 3 cents. The cost of one FSFI questionnaire is 12 cents and the cost of the WHOQOL-BREF questionnaire is 15 cents. The total amount of questionnaires needed will cost 81 €. For the last round questionnaires, one year after birth won't be needed an extra consultation because we are going to do it online to avoid increasing the cost of the study and to decrease losing patients.

3. Publication expenses:

We will like to publish the study as a journal article. We estimate that the revision, edition, formatting layout and preparation of the digital data will cost approximately 2000€.

TYPE OF COST	UNIT COST	HOURS/UNITS	TOTAL
	PERSONNEL EXPENSES		
Statistical analyst	40€	20 hours	800 €
	EXECUTION EXPENSES		
Printing FSFI questionnaire	0,03 cents/page 4 pages	300	36 €
Printing WHOQOL questionnaire	0,03 cents/page 5 pages	300	45 €
	PUBLICATION EXPENSES		
Article publication			2000€
TOTAL			2881 €

IMPACT ON THE NATIONAL SYSTEM.

Sexual health is an important part of the actual concept of health. In spite of that, it is a topic that has not been properly dealt with at the social, educational and health levels. Sexuality remains a taboo subject whose approach leaves much to be desired despite the fact that sexual dysfunctions have a high prevalence and a high impact on our society.

Currently, the sexual alterations that can occur as a result of pregnancy and childbirth are well known, as are the main factors involved in these alterations. However, this knowledge is not used as it should in order to reduce such sexual dysfunctions.

Nowadays, in spite of its little approach, sexuality has a high importance in our society. Therefore, we believe that this study can have a high impact since it is intended to reduce the difficulty that both patients and health professionals have when it comes to consulting about problems related to sexual intercourses.

Thus, this study aims to verify the change in female sexual satisfaction that occurs after pregnancy and determine the possible factors related to this dysfunction through questionnaires in order to make it easier to ask about these issues. In addition, as a long-term objective and based on the results obtained, it is intended to establish measures to prevent, reduce or if they could not be avoided, to treat the alterations that occur in female sexual satisfaction following pregnancy.

In conclusion, we believe that this study can have a great impact on our society as it will provide a useful tool for treating sexuality in the daily medical practice and, in the future it can help to implement measures to improve the sexual satisfaction of patients and thereby also improve their life quality over which sexuality has an important role.

BIBLIOGRAPHY.

1. World Health Organization. (2014). Basic documents, 48th ed. World Health Organization. Available at: https://apps.who.int/iris/handle/10665/151605.

2. Ahumada, S., Lüttges, C., Molina, T. y Torres, S. (2014). Satisfacción sexual: revisión de los factores individuales y de pareja relacionados. *Revista Hospital Clínico Universidad de Chile, 25(1),* 278-284.

3. World Health Organization. (2006). *Defining sexual health: Report of a technical consultation on sexual health, 28-31 January 2002, Geneva*. Geneva: World Health Organization.

4. Douglas, J. M., Jr, & Fenton, K. A. (2013). Understanding sexual health and its role in more effective prevention programs. *Public health reports (Washington, D.C. : 1974)*, *128 Suppl 1*(Suppl 1), 1–4. doi:10.1177/00333549131282S101.

5. Potki, R., Ziaei, T., Faramarzi, M., Moosazadeh, M., & Shahhosseini, Z. (2017). Bio-psycho-social factors affecting sexual self-concept: A systematic review. *Electronic physician*, *9*(9), 5172–5178. doi:10.19082/5172.

6. World Health Organization. (2010). Measuring sexual Health: Conceptual and Practical considerations and related indicators.

7. The WAS Declaration of Sexual Rights was originally proclaimed at the 13th World Congress of Sexology in Valencia, Spain in 1997 and then, in 1999, a revision was approved in Hong Kong by the WAS General Assembly and then reaffirmed in the WAS Declaration: Sexual Health for the Millennium (2008). This revised declaration was approved by the WAS Advisory Council in March, 2014.

8. Banaei, M., Torkzahrani, S., Ozgoli, G., Azad, M., Mahmoudikohani, F., & Pormehr-Yabandeh, A. (2018). Addressing the Sexual Function of Women During First Six Month After Delivery: Aquasi-Experimental Study. *Materia socio-medica*, *30*(2), 136–140. doi:10.5455/msm.2018.30.

9. Alcoba Valls, S. L., García-Giralda Ruiz, L., & San Martín Blanco, C. (2004). Guía de Buena Práctica Clínica en disfunciones sexuales.

10. CIMOP. (2006). La educación y promoción de la salud sexual. Problemas y pautas de intervención con vistas a reducir los embarazos no deseados. El punto de vista de los profesionales.

11. Harper, Kyle (2013). *From Shame to Sin: The Christian Transformation of Sexual Morality in Late Antiquity*. Cambridge, Massachusettes: Harvard University Press. p. 4,7. ISBN 978-0-674-07277-0.

12. González Labrador, Ignacio, Miyar Pieiga, Emilia, & González Salvat, Rosa María. (2002). Mitos y tabúes en la sexualidad humana. *Revista Cubana de Medicina General Integral*, *18*(3), 226-229. Available at: http://scielo.sld.cu/scielo.php?script=sci_arttext&pid=S0864-21252002000300012&lng=es&tlng=es.

13. Luque López, M. C. (2008). Mujer y sexualidad. Evolución desde el puritanismo del siglo XVIII a la medicina sexual del siglo Xxi | Revista Internacional de Andrología. Available at: https://www.elsevier.es/es-revista-revista-internacional-andrologia-262-articulo-mujer-sexualidad-evolucion-desde-el-13129603.

14. Rathus, S. A., Nevid, J. S., Fichner-Rathus, L., Ortega, R. L., & Sánchez, F. L. (2005) *Sexualidad humana*. Pearson Educación.

15. González Labrador, Ignacio, & Miyar Pieiga, Emilia. (2001). Sexualidad femenina durante la gestación. *Revista Cubana de Medicina General Integral*, *17*(5), 497-501. Available at:http://scielo.sld.cu/scielo.php?script=sci_arttext&pid=S0864-21252001000500015&lng=es&tlng=es.

16. Cuba. Ministerio de Salud Pública. (1997).Manual de diagnóstico y tratamiento en Obstetricia y Perinatología. La Habana: Editorial Ciencias Médicas:14, 9-15.

17. González Labrador, Ignacio. (2002). Ginecología y sexualidad. *Revista Cubana de Medicina General Integral*, *18*(5), 349-351. Available at: http://scielo.sld.cu/scielo.php?script=sci_arttext&pid=S0864-21252002000500011&lng=es&tlng=es.

18. Alvear, L., & Tarragato, S. (s.f.). Salud sexual y reproductiva. OIT.

19. Banaei, M., Azizi, M., Moridi, A. *et al.* (2019) Sexual dysfunction and related factors in pregnancy and postpartum: a systematic review and meta-analysis protocol. *Syst Rev* **8,** 161, doi:10.1186/s13643-019-1079-4.

20. Zamani, M., Latifnejad Roudsari, R., Moradi, M., & Esmaily, H. (2019). The effect of sexual health counseling on women's sexual satisfaction in postpartum period: A randomized clinical trial. *International journal of reproductive biomedicine (Yazd, Iran)*, *17*(1), 41–50. doi:10.18502/ijrm.v17i1.3819.

21. Banaei, M., Moridi, A., & Dashti, S. (2018). Sexual Dysfunction and its Associated Factors After Delivery: Longitudinal Study in Iranian Women. *Materia socio-medica*, *30*(3), 198–203. doi:10.5455/msm.2018.30.198-203.

22. Baumeister, Roy & Twenge, Jean. (2002). Cultural Suppression of Female Sexuality. Review of General Psychology. 6. 166-203. 10.1037//1089-2680.6.2.166.

23. Carpenter, J. S., Jones, S. M., Studts, C. R., Heiman, J. R., Reed, S. D., Newton, K. M., … Shifren, J. L. (2016). Female Sexual Function Index Short Version: A MsFLASH Item Response Analysis. *Archives of sexual behavior*, *45*(8), 1897–1905. doi:10.1007/s10508-016-0804-5.

24. Manterola, Carlos, & Otzen, Tamara. (2014). Estudios Observacionales: Los Diseños Utilizados con Mayor Frecuencia en Investigación Clínica. *International Journal of Morphology*, *32*(2), 634-645. https://dx.doi.org/10.4067/S0717-95022014000200042.

25. Van Brummen, H. , Bruinse, H. , Van De Pol, G. , Heintz, A. and Van Der Vaart, C. (2006), Which factors determine the sexual function 1 year after childbirth?. BJOG: An International Journal of Obstetrics & Gynaecology, 113: 914-918. doi:10.1111/j.1471-0528.2006.01017.x.

26. Carrobles, J. A., Gámez-Guadix, M. & Almendros, C. (2011). Funcionamiento sexual, satisfacción sexual y bienestar psicológico y subjetivo en una muestra de mujeres españolas. Anales de Psicología, 27(1). ISSN: 0212-9728.

27. Fernández Laveda, E. M. (2014). Histeria: historia de la sexualidad femenina. http://rua.ua.es/dspace/handle/10045/40068.

28. Iglesias Campos, P. (2018). Satisfacción sexual femenina: influencia de la edad y variedad de prácticas sexuales. Available at: https://dialnet.unirioja.es/servlet/articulo?codigo=643214.

29. Figueroa-Martín, Laura, Duarte-Clíments, Gonzalo, Sánchez-Gómez, María Begoña, & Ruyman Brito-Brito, Pedro. (2015). Abordaje de la

sexualidad en atención primaria: ¿qué valorar? *Ene*, *9*(2). Available at: https://dx.doi.org/10.4321/S1988-348X2015000200006.

30. Borrás Valls, J.J. (2004). Diseño y validación del cuestionario de Función Sexual de la mujer (FSM).

31. WHOQOL Group. (1993). Study Protocol for the World Health Organization Project to develop a Quality of Life Assessment Instrument (WHOQOL) Qual Life Res, 2: 153-159.

32. Rosen R., Brown C., Heiman J., Leiblum S., Meston C., Shabsigh R., Ferguson D. & D'agostino R. (2000). The Female Sexual Function Index (FSFI): A Multidimensional Self-Report Instrument for the Assessment of Female Sexual Function. Journal of Sex & Marital Therapy 26: 191-208.

33. Elliot, S. A. & Watson, J. P. (1985). Sex during pregnancy and the first postnatal year. Available at: https://www.sciencedirect.com/ science/article /abs/pii/0022399985900881?via%3Dihub.

34. Reamy, K. J. & White S.E. (1987). Sexuality in the puerperium: a review.

35. Barret, G., Pendry, E., Peacock, J., & Victor, C. (1999). Women's sexuality after childbirth: a pilot study. - PubMed – NCBI. Available at: https://www.ncbi.nlm.nih.gov/pubmed/10483509.

36. Woraniltat, W. & Taneepanichshul, s. (1990). Sexual function during the postpartum period. Available at: https://www.ncbi.nlm.nihgov/pubmed/17 957914.

37. Brtnicka, H., Weiss, P. & Zverina, J. (2009). Human sexuality during pregnancy and the postpartum period. Available at: https://www.ncbi.nlm.nih.gov/pubmed/19711831.

38. Mazouni, C., Bretelle, F., Collette, E., Henkenroth, H., Bonnier, P. & Gamberre, M. (2005), Maternal and neonatal morbidity after first vaginal delivery using Thierry's spatulas. Australian and New Zealand Journal of Obstetrics and Gynaecology, 45: 405-409.

39. Amiri, F. N., Omidvar, S., Bakhtiari, A., & Hajiahmadi, M. (2017). Female sexual outcomes in primiparous women after vaginal delivery and cesarean section. *African health sciences*, *17*(3), 623–631. doi:10.4314/ahs.v17i3.4.

40. Kahramanoglu, I., Baktiroglu, M., Hamzaoglu, K. et al. Arch Gynecol Obstet (2017) 295: 907. https://doi.org/10.1007/s00404-017-4299-7.

41. Ryding, E. (1984), Sexuality During and After Pregnancy. Acta Obstetricia et Gynecologica Scandinavica, 63: 679-682.

42. Dabiri, F., Yabandeh, A. P., Shahi, A., Kamjoo, A., & Teshnizi, S. H. (2014). The effect of mode of delivery on postpartum sexual functioning in primiparous women. *Oman medical journal*, *29*(4), 276–279. doi:10.5001/omj.2014.72.

ANNEXES

ANNEX 1: Explanatory sheet for the patient. Spanish version.

HOJA INFORMATIVA PARA LA PARTICIPANTE

Buenos días/tardes,

Nos dirigimos a usted para informarle sobre un estudio en que nos gustaría que participase. Le informamos también de que este estudio ha sido previamente aprobado por el Comité Ético y de Investigación Clínica (CEIC).

Con este documento nuestra intención es que usted reciba la información correcta y suficiente para que pueda evaluar y decidir por usted misma si desea o no participar en este estudio. Para ello, lea este documento con atención y después le aclararemos las dudas que le hayan podido surgir.

1. **Título del estudio:**

Comparación de la satisfacción sexual femenina antes y después del embarazo y su impacto en la calidad de vida de las pacientes.

2. **Lugar de realización:**

Servicios de Ginecología y Obstetricia de los siguientes centros:

- Hospital Universitario Doctor Josep Trueta.
- ASSIR Gironès – Pla de l'Estany:
    - Centro de Atención Primaria de Banyoles.
    - Centro de Atención Primaria de Celrà.
    - Centro de Atención Primaria de sarrià de Ter.
    - Centro de Atención Primaria Güell.

3. **Participación voluntaria:**

Usted ha de saber que su participación en este estudio es voluntaria y puede decidir no participar o cambiar su opinión una vez haya aceptado y retirar su consentimiento en cualquier momento. Esto no supondrá ningún prejuicio para usted ni para su atención sanitaria.

4. Objetivos del estudio:

Este estudio pretende valorar la satisfacción sexual antes y después del embarazo en mujeres primíparas. Esta valoración se hará mediante un cuestionario que se realizará en tres tiempos, en el primer control del embarazo, seis semanas postparto (momento de alta de la paciente) y un año después del parto. Una vez recogidos estos datos lo que se pretende es comparar la satisfacción sexual antes y después del parto y así determinar el impacto de este en la vida sexual de las pacientes.

Al mismo tiempo, junto con los cuestionarios de salud sexual se realizará un cuestionario de calidad de vida (también en tres tiempos). Con estos además de ver el cambio en la satisfacción sexual, se pretende determinar su impacto en la calidad de vida.

5. Descripción del estudio:

Este estudio tiene una duración aproximada de tres años. El seguimiento de cada paciente se realizará una vez se haya confirmado el embarazo hasta un año después del parto.

Para poder participar en el estudio se deberá cumplir una serie de criterios de selección que se evaluarán una vez haya aceptado participar.

Se utilizarán dos cuestionarios, uno para evaluar la satisfacción sexual femenina y otro para valorar la calidad de vida. Estos cuestionarios se rellenarán en tres tiempos. El primero en el primer control del embarazo, el segundo seis semanas después del parto y el tercero un año después del parto. Los dos primeros se contestarán en la misma consulta, mientras que el último se realizará online para facilitar su realización.

Una vez se hayan recogido todos los datos de necesarios para la realización del estudio estos se describirán y analizarán estadísticamente. Por ultimo, el equipo de investigación evaluará la información obtenida a fin de determinar su relevancia y utilidad de cara a la implementación de mejoras o nuevas conductas en pacientes embarazadas durante el parto o en el postparto.

Si usted acepta participar en el estudio adquirirá las responsabilidades necesarias para poder implementar los cuestionarios (consultas físicas y cuestionarios online), igual que deberá seguir las instrucciones del protocolo. También deberá notificar cualquier acontecimiento adverso que ocurra por el cual no pueda contestar los pertinentes cuestionarios.

Finalmente, si acepta, deberá contestar los cuestionarios de forma veraz y con el tiempo requerido durante las consulta y online.

6. **Beneficios y riesgos derivados de su participación en el estudio:**

Es posible que en este estudio usted no obtenga un beneficio inmediato pero es importante su participación de caras a implementar posibles medidas de mejora de la satisfacción sexual o de prevención de su empeoramiento en un futuro. Dado que no se realiza ninguna intervención sobre las participantes no se prevén riesgos ni inconvenientes para participar en este estudio.

7. **Confidencialidad/Protección de datos personales:**

Solicitamos su permiso para realizarle la entrevista y los cuestionarios pertinentes y utilizar los datos obtenidos únicamente por la realización de este estudio, de forma totalmente confidencial y sin acceso a las mismas por parte de terceros de acuerdo con la legalidad vigente (Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y Garantía de los Derechos digitales). Los datos recogidos en el estudio estarán identificadas mediante un código, que no incluya información que pueda identificarlo, y sólo su médico del estudio/colaboradores podrán relacionar estos datos con usted y con su historia clínica.

Si usted decide retirar el consentimiento para participar en este estudio, ningún dato suyo será añadido al estudio.

8. **Gastos y compensación económica:**

En caso de que participe en el estudio, no tendrá ningún gasto ocasionado por participar. También le informamos de que no está prevista ninguna compensación económica por su participación en el estudio.

Le agradecemos su participación.

ANNEX 2: : Explanatory sheet for the patient. Catalan version.

FULL INFORMATIU PER A LA PARTICIPANT

Bon dia/tarda,

Ens dirigim a vostè per informar sobre un estudi en què ens agradaria que participés. L'informem també que aquest estudi ha estat prèviament aprovat pel Comitè Ètic i d'Investigació Clínica (CEIC).

Amb aquest document la nostra intenció és que vostè rebi la informació correcta i suficient perquè pugui avaluar i decidir per vostè mateixa si vol participar en aquest estudi. Per a això, llegiu aquest document amb atenció i després li aclarirem els dubtes que li hagin pogut sorgir.

1. Títol de l'estudi:

Comparació de la satisfacció sexual femenina abans i després de l'embaràs i el seu impacte en la qualitat de vida de les pacients.

2. Lloc de realització:

Serveis de Ginecologia i Obstetrícia dels següents centres:

- Hospital Universitari Doctor Josep Trueta.
- ASSIR Gironès - Pla de l'Estany:
    - o Centre d'Atenció Primària de Banyoles.
    - o Centre d'Atenció Primària de Celrà.
    - o Centre d'Atenció Primària de Sarrià de Ter.
    - o Centre d'Atenció Primària Güell.

3. Participació voluntària:

Vostè ha de saber que la seva participació en aquest estudi és voluntària i pot decidir no participar o canviar la seva opinió un cop hagi acceptat i retirar el seu consentiment en qualsevol moment. Això no suposarà cap prejudici per a vostè ni per la seva atenció sanitària.

4. Objectius de l'estudi:

Aquest estudi pretén valorar la satisfacció sexual abans i després de l'embaràs en dones primípares. Aquesta valoració es farà mitjançant un qüestionari que es realitzarà en tres temps, en el primer control de l'embaràs, sis setmanes postpart (moment d'alta de la pacient) i un any després del part. Un cop recollides

aquestes dades el que es pretén és comparar la satisfacció sexual abans i després del part i així determinar l'impacte d'aquest en la vida sexual de les pacients.

Al mateix temps, juntament amb els qüestionaris de salut sexual es realitzarà un qüestionari de qualitat de vida (també en tres temps). Amb aquests més de veure el canvi en la satisfacció sexual, es pretén determinar el seu impacte en la qualitat de vida.

5. Descripció de l'estudi:

Aquest estudi té una durada aproximada de tres anys. El seguiment de cada pacient es realitzarà un cop s'hagi confirmat l'embaràs fins a un any després del part.

Per poder participar en l'estudi s'haurà de complir una sèrie de criteris de selecció que s'avaluaran un cop hagi acceptat participar.

S'utilitzaran dos qüestionaris, un per a avaluar la satisfacció sexual femenina i un altre per valorar la qualitat de vida. Aquests qüestionaris s'ompliran en tres temps. El primer en el primer control de l'embaràs, el segon sis setmanes després del part i el tercer un any després del part. Els dos primers es contestaran en la mateixa consulta, mentre que l'últim es realitzarà en línia per facilitar la seva realització.

Un cop s'hagin recollit totes les dades de necessaris per a la realització de l'estudi aquests es descriuran i analitzaran estadísticament. Per últim, l'equip d'investigació avaluarà la informació obtinguda per tal de determinar la seva rellevància i utilitat de cara a la implementació de millores o noves conductes en pacients embarassades durant el part o en el postpart.

Si vostè accepta participar en l'estudi adquirirà les responsabilitats necessàries per poder implementar els qüestionaris (consultes físiques i qüestionaris online), igual que haurà de seguir les instruccions del protocol. També ha de notificar qualsevol esdeveniment advers que passi pel qual no pugui contestar els pertinents qüestionaris.

Finalment, si accepta, haurà de contestar els qüestionaris de forma veraç i amb el temps requerit durant les consulta i online.

6. Beneficis i riscos derivats de la seva participació en l'estudi:

És possible que en aquest estudi no obtingui un benefici immediat però és important la seva participació de cares a implementar possibles mesures de

millora de la satisfacció sexual o de prevenció del seu empitjorament en un futur. Atès que no es realitza cap intervenció sobre les participants no es preveuen riscos ni inconvenients per participar en aquest estudi.

7. Confidencialitat/Protecció de dades personals:

Sol·licitem el seu permís per a realitzar-li l'entrevista i els qüestionaris pertinents i utilitzar les dades obtingudes únicament per la realització d'aquest estudi, de forma totalment confidencial i sense accés a les mateixes per part de tercers d'acord amb la legalitat vigent (Llei Orgànica 3/2018 , de 5 de desembre, de Protecció de Dades Personals i Garantia dels Drets digitals). Les dades recollides en l'estudi estaran identificades mitjançant un codi, que no inclogui informació que pugui identificar-lo, i només el seu metge de l'estudi / col·laboradors podran relacionar aquestes dades amb vostè i amb la seva història clínica.

Si vostè decideix retirar el consentiment per participar en aquest estudi, cap dada seu serà afegit a l'estudi.

8. Despeses i compensació econòmica:

En el cas que participi en l'estudi, no tindrà cap despesa ocasionada per participar-hi. També l'informem que no està prevista cap compensació econòmica per la seva participació en l'estudi.

Li agraïm la seva participació.

ANNEX 3. Informed consent sheet for participants. Spanish version.

CONSENTIMIENTO INFORMADO DEL ESTUDIO

TÍTULO DEL ESTUDIO: Comparison of female sexual satisfaction of primiparous women before and after pregnancy and its impact in life quality.
INVESTIGADOR PRINCIPAL:……..
CENTRO/ SERVICIO:…….

Yo, Sra…… Con DNI ……

Afirmo que,

- He recibido y leído la hoja informativa que se me ha entregado.
- He podido hacer todas las preguntas necesarias respecto al estudio y han sido respondidas de manera satisfactoria.
- He recibido suficiente información acerca de las características y objetivos del estudio, los posibles riesgos y la importancia de mi contribución para el avance de la medicina.
- He estado informado por el investigador…….. de las implicaciones y la finalidad del estudio.
- Entiendo que mi participación es voluntaria.
- Estoy de acuerdo con que mis datos sean utilizados por el estudio indicado de forma anónima.
- Doy mi permiso para que los datos de mi historia clínica sean utilizados por el equipo de investigación para fines relacionados con el estudio, entendiendo que después de haberlos comprobado se eliminará del registro toda la información que me pudiese identificar.
- Sé que se mantendrá la confidencialidad de mis datos.
- Otorgo mi consentimiento de manera voluntaria y sé que soy libre de retirarme del estudio en cualquier momento del mismo.

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(Fecha)	(Nombre y apellidos de la participante)	(Firma de la participante)

Confirmo que he explicado a la paciente el carácter y el propósito del estudio.

ANNEX 4: Informed consent sheet for participants. Catalan version.

CONSENTIMENT INFORMAT DE L'ESTUDI

TÍTOL DE L'ESTUDI: Comparison of femalee sexual satisfaction of primiparous women before and after pregnancy and its impact in life qaulity.
INVESTIGADOR PRINCIPAL: .....
CENTRE / SERVEI: .....

Jo, la Sra ..... Amb DNI .....

Afirmo que,

- He rebut i llegit el full informatiu que se m'ha lliurat.
- He pogut fer totes les preguntes necessàries respecte a l'estudi i han estat respostes de manera satisfactòria.
- He rebut suficient informació sobre les característiques i objectius de l'estudi, els possibles riscos i la importància de la meva contribució per a l'avanç de la medicina.
- He estat informat per l'investigador ..... de les implicacions i la finalitat de l'estudi.
- Entenc que la meva participació és voluntària.
- Estic d'acord amb que les meves dades siguin utilitzades per l'estudi indicat de forma anònima.
- Dono el meu permís perquè les dades de la meva història clínica siguin utilitzats per l'equip d'investigació per a fins relacionats amb l'estudi, entenent que després d'haver-los comprovat s'eliminarà del registre tota la informació que em pogués identificar.
- Sé que es mantindrà la confidencialitat de les meves dades.
- Atorgo meu consentiment de manera voluntària i sé que sóc lliure de retirar-me de l'estudi en qualsevol moment del mateix.

| --- | --- | --- |
| (Data) | (Nom i cognoms de la participant) | (Signatura de la participant) |

Confirmo que he explicat a la pacient el caràcter i el propòsit de l'estudi.

ANNEX 5: SFSI questionnaire sheets. Spanish version.

INDICE DE FUNCIÓN SEXUAL FEMENINA

Instrucciones:
Estas preguntas son sobre su sexualidad durante las últimas 4 semanas. Por favor responda las siguientes preguntas lo más honesta y claramente posible. Sus respuestas serán mantenidas completamente confidenciales.

Definiciones:
Actividad sexual: se refiere a caricias, juegos sexuales, masturbación y relaciones sexuales.
Relación sexual: se define como penetración del pene en la vagina.
Estimulación sexual: incluye juegos sexuales con la pareja, autoestimulación (masturbación) o fantasías sexuales.

Marque sólo una alternativa por pregunta:

Deseo o interés sexual es la sensación que incluye deseo de tener una experiencia sexual, sentirse receptiva a la incitación sexual de la pareja y pensamientos o fantasías sobre tener sexo.

1. En las últimas 4 semanas, ¿Cuán a menudo usted sintió deseo o interés sexual?
– Siempre o casi siempre
– La mayoría de las veces (más que la mitad)
– A veces (alrededor de la mitad)
– Pocas veces (menos que la mitad)
– Casi nunca o nunca

2. En las últimas 4 semanas, ¿Cómo clasifica su nivel (intensidad) de deseo o interés sexual?
– Muy alto
– Alto
– Moderado
– Bajo
– Muy bajo o nada

Excitación sexual es una sensación que incluye aspectos físicos y mentales de la sexualidad. Puede incluir sensación de calor o latidos en los genitales, lubricación vaginal (humedad) o contracciones musculares.

3. En las últimas 4 semanas, ¿Con cuanta frecuencia usted sintió excitación sexual durante la actividad sexual?
– No tengo actividad sexual
– Siempre o casi siempre
– La mayoría de las veces (más que la mitad)
– A veces (alrededor de la mitad)
– Pocas veces (menos que la mitad)
– Casi nunca o nunca

4. En las últimas 4 semanas, ¿Cómo clasifica su nivel de excitación sexual durante la actividad sexual?
_ No tengo actividad sexual
_ Muy alto
_ Alto
_ Moderado
_ Bajo
_ Muy bajo o nada

5. En las últimas 4 semanas, ¿Cuánta confianza tiene usted de excitarse durante la actividad sexual?
– No tengo actividad sexual
– Muy alta confianza
– Alta confianza
– Moderada confianza
– Baja confianza
– Muy baja o nada de confianza

6. En las últimas 4 semanas, ¿Con qué frecuencia se sintió satisfecho con su excitación durante la actividad sexual?
– No tengo actividad sexual
– Siempre o casi siempre
– La mayoría de las veces (más que la mitad)
– A veces (alrededor de la mitad)
– Pocas veces (menos que la mitad)
– Casi nunca o nunca

7. En las últimas 4 semanas, ¿Con cuanta frecuencia usted sintió lubricación o humedad vaginal durante la actividad sexual?
– No tengo actividad sexual
– Siempre o casi siempre
– La mayoría de las veces (más que la mitad)
– A veces (alrededor de la mitad)
– Pocas veces (menos que la mitad)
– Casi nunca o nunca

8. En las últimas 4 semanas, ¿le es difícil lubricarse (humedecerse) durante la actividad sexual?
– No tengo actividad sexual
– Extremadamente difícil o imposible
– Muy difícil
– Difícil
– Poco difícil
– No me es difícil

9. En las últimas 4 semanas, ¿Con qué frecuencia mantiene su lubricación (humedad) vaginal hasta finalizar la actividad sexual?
– No tengo actividad sexual
– Siempre o casi siempre la mantengo
– La mayoría de las veces la mantengo (más que la mitad)

– A veces la mantengo (alrededor de la mitad)
– Pocas veces la mantengo (menos que la mitad)
– Casi nunca o nunca mantengo la lubricación vaginal hasta el final

10. En las últimas 4 semanas, ¿Le es difícil mantener su lubricación (humedad) vaginal hasta finalizar la actividad sexual?
– No tengo actividad sexual
– Extremadamente difícil o imposible
– Muy difícil
– Difícil
– Poco difícil
– No me es difícil

11. En las últimas 4 semanas, cuando usted tiene estimulación sexual o relaciones, ¿Con qué frecuencia alcanza el orgasmo o clímax?
– No tengo actividad sexual
– Siempre o casi siempre
– La mayoría de las veces (más que la mitad)
– A veces (alrededor de la mitad)
– Pocas veces (menos que la mitad)
– Casi nunca o nunca

12. En las últimas 4 semanas, cuando usted tiene estimulación sexual o relaciones, ¿Le es difícil alcanzar el orgasmo o clímax?
– No tengo actividad sexual
– Extremadamente difícil o imposible
– Muy difícil
– Difícil
– Poco difícil
– No me es difícil

13. En las últimas 4 semanas, ¿Cuan satisfecha está con su capacidad para alcanzar el orgasmo (clímax) durante la actividad sexual?
– No tengo actividad sexual
– Muy satisfecha
– Moderadamente satisfecha
– Ni satisfecha ni insatisfecha
– Moderadamente insatisfecha
– Muy insatisfecha

14. En las últimas 4 semanas, ¿Cuan satisfecha está con la cercanía emocional existente durante la actividad sexual entre usted y su pareja?
– No tengo actividad sexual
– Muy satisfecha
– Moderadamente satisfecha
– Ni satisfecha ni insatisfecha
– Moderadamente insatisfecha
– Muy insatisfecha

15. En las últimas 4 semanas, ¿Cuan satisfecha está con su relación sexual con su pareja?
– Muy satisfecha
– Moderadamente satisfecha
– Ni satisfecha ni insatisfecha
– Moderadamente insatisfecha
– Muy insatisfecha

16. En las últimas 4 semanas, ¿Cuan satisfecha está con su vida sexual en general?
_ Muy satisfecha
_ Moderadamente satisfecha
_ Ni satisfecha ni insatisfecha
_ Moderadamente insatisfecha
_ Muy insatisfecha

17. En las últimas 4 semanas, ¿Cuan a menudo siente discomfort o dolor durante la penetración vaginal?
– No tengo actividad sexual
– Siempre o casi siempre
– La mayoría de las veces (más que la mitad)
– A veces (alrededor de la mitad)
– Pocas veces (menos que la mitad)
– Casi nunca o nunca

18. En las últimas 4 semanas, ¿Cuan a menudo siente discomfort o dolor después de la penetración vaginal?
– No tengo actividad sexual
– Siempre o casi siempre
– La mayoría de las veces (más que la mitad)
– A veces (alrededor de la mitad)
– Pocas veces (menos que la mitad)
– Casi nunca o nunca

19. En las últimas 4 semanas, ¿Cómo clasifica su nivel (intensidad) de discomfort o dolor durante o después de la penetración vaginal?
– No tengo actividad sexual
– Muy alto
– Alto
– Moderado
– Bajo
– Muy bajo o nada

ANNEX 6: SFSI questionnaire sheets. Catalan version.

INDEX DE FUNCIÓ SEXUAL FEMENINA

Instruccions:
Aquestes preguntes són sobre la seva sexualitat durant les últimes 4 setmanes. Si us plau respongui les següents preguntes el més honesta i clarament possible. Les seves respostes seran mantingudes completament confidencials.

Definicions:
Activitat sexual: es refereix a carícies, jocs sexuals, masturbació i relacions sexuals.
Relació sexual: es defineix com penetració del penis a la vagina.
Estimulació sexual: inclou jocs sexuals amb la parella, autoestimulació (masturbació) o fantasies sexuals.

Marqueu només una alternativa per pregunta:

Desig o interès sexual és la sensació que inclou desig de tenir una experiència sexual, sentir-se receptiva a la incitació sexual de la parella i pensaments o fantasies sobre tenir sexe.

1. En les últimes 4 setmanes, Com de sovint vostè va sentir desig o interès sexual?
- Sempre o gairebé sempre
- La majoria de les vegades (més que la meitat)
- A vegades (al voltant de la meitat)
- Poques vegades (menys que la meitat)
- Gairebé mai o mai

2. En les últimes 4 setmanes, Com classifica el seu nivell (intensitat) de desig o interès sexual?
- Molt alt
- Alt
- Moderat
- Sota
- Molt baix o res

Excitació sexual és una sensació que inclou aspectes físics i mentals de la sexualitat. Pot incloure sensació de calor o batecs en els genitals, lubricació vaginal (humitat) o contraccions musculars.

3. En les últimes 4 setmanes, ¿Amb quanta freqüència vostè va sentir excitació sexual durant l'activitat sexual?
- No tinc activitat sexual
- Sempre o gairebé sempre
- La majoria de les vegades (més que la meitat)
- A vegades (al voltant de la meitat)
- Poques vegades (menys que la meitat)
- Gairebé mai o mai

4. En les últimes 4 setmanes, Com classifica el seu nivell d'excitació sexual durant l'activitat sexual?
_ No tinc activitat sexual
_ Molt alt
_ Alt
_ Moderat
_ Sota
_ Molt baix o res

5. En les últimes 4 setmanes, Quanta confiança té vostè d'excitar-durant l'activitat sexual?
- No tinc activitat sexual
- Molt alta confiança
- Alta confiança
- Moderada confiança
- Baixa confiança
- Molt baixa o gens de confiança

6. En les últimes 4 setmanes, amb quina freqüència es va sentir satisfet amb la seva excitació durant l'activitat sexual?
- No tinc activitat sexual
- Sempre o gairebé sempre
- La majoria de les vegades (més que la meitat)
- A vegades (al voltant de la meitat)
- Poques vegades (menys que la meitat)
- Gairebé mai o mai

7. En les últimes 4 setmanes, ¿Amb quanta freqüència vostè va sentir lubricació o humitat vaginal durant l'activitat sexual?
- No tinc activitat sexual
- Sempre o gairebé sempre
- La majoria de les vegades (més que la meitat)
- A vegades (al voltant de la meitat)
- Poques vegades (menys que la meitat)
- Gairebé mai o mai

8. En les últimes 4 setmanes, ¿li és difícil lubricar-se (humitejar) durant l'activitat sexual?
- No tinc activitat sexual
- Extremadament difícil o impossible
- Molt difícil
- Difícil
- Poc difícil
- No m'és difícil

9. En les últimes 4 setmanes, amb quina freqüència manté la seva lubricació (humitat) vaginal fins a finalitzar l'activitat sexual?
- No tinc activitat sexual
- Sempre o gairebé sempre la mantinc
- La majoria de les vegades la mantinc (més que la meitat)

- De vegades la mantinc (al voltant de la meitat)
- Poques vegades la mantinc (menys que la meitat)
- Gairebé mai o mai mantinc la lubricació vaginal fins al final

10. En les últimes 4 setmanes, Li és difícil mantenir la seva lubricació (humitat) vaginal fins a finalitzar l'activitat sexual?
- No tinc activitat sexual
- Extremadament difícil o impossible
- Molt difícil
- Difícil
- Poc difícil
- No m'és difícil

11. En les últimes 4 setmanes, quan vostè té estimulació sexual o relacions, Amb quina freqüència arriba al orgasme o clímax?
- No tinc activitat sexual
- Sempre o gairebé sempre
- La majoria de les vegades (més que la meitat)
- A vegades (al voltant de la meitat)
- Poques vegades (menys que la meitat)
- Gairebé mai o mai

12. En les últimes 4 setmanes, quan vostè té estimulació sexual o relacions, Li és difícil arribar a l'orgasme o clímax?
- No tinc activitat sexual
- Extremadament difícil o impossible
- Molt difícil
- Difícil
- Poc difícil
- No m'és difícil

13. En les últimes 4 setmanes, ¿Quan satisfeta està amb la seva capacitat per arribar a l'orgasme (clímax) durant l'activitat sexual?
- No tinc activitat sexual
- Molt satisfeta
- Moderadament satisfeta
- Ni satisfeta ni insatisfeta
- Moderadament insatisfeta
- Molt insatisfeta

14. En les últimes 4 setmanes, ¿Quan satisfeta està amb la proximitat emocional existent durant l'activitat sexual entre vostè i la seva parella?
- No tinc activitat sexual
- Molt satisfeta
- Moderadament satisfeta
- Ni satisfeta ni insatisfeta
- Moderadament insatisfeta
- Molt insatisfeta

15. En les últimes 4 setmanes, ¿Quan satisfeta està amb la seva relació sexual amb la seva parella?
- Molt satisfeta
- Moderadament satisfeta
- Ni satisfeta ni insatisfeta
- Moderadament insatisfeta
- Molt insatisfeta

16. En les últimes 4 setmanes, ¿Quan satisfeta està amb la seva vida sexual en general?
_ Molt satisfeta
_ Moderadament satisfeta
_ Ni satisfeta ni insatisfeta
_ Moderadament insatisfeta
_ Molt insatisfeta

17. En les últimes 4 setmanes, ¿Quan sovint sent desconfort o dolor durant la penetració vaginal?
- No tinc activitat sexual
- Sempre o gairebé sempre
- La majoria de les vegades (més que la meitat)
- A vegades (al voltant de la meitat)
- Poques vegades (menys que la meitat)
- Gairebé mai o mai

18. En les últimes 4 setmanes, ¿quan sovint sent desconfort o dolor després de la penetració vaginal?
- No tinc activitat sexual
- Sempre o gairebé sempre
- La majoria de les vegades (més que la meitat)
- A vegades (al voltant de la meitat)
- Poques vegades (menys que la meitat)
- Gairebé mai o mai

19. En les últimes 4 setmanes, Com classifica el seu nivell (intensitat) de desconfort o dolor durant o després de la penetració vaginal?
- No tinc activitat sexual
- Molt alt
- Alt
- Moderat
- Sota
- Molt baix o res

ANNEX 7: Punctuation of FSFI.

Domain	*Questions*	*Punctuation*	*Factor*	*Minimum*	*Maximum*
Desire	1-2	1-5	0,6	1,2	6
Excitation	3-6	0-5	0,3	0	6
Lubrication	7-10	0-5	0,3	0	6
Orgasm	11-13	0-5	0,4	0	6
Satisfaction	14-16	0-5	0,4	0,8	6
Pain	17-19	0-5	0,4	0	6
			Total	2	36

ANNEX 8: WHOQOL-BREF questionnaire sheets. Spanish version.

CUESTIONARIO WHOQOL-BREF: sobre calidad de vida

Este cuestionario sirve para conocer su opinión acerca de su calidad de vida, su salud y otras áreas de su vida. Por favor, conteste a todas las preguntas. Si no está seguro qué respuesta dar a una pregunta, escoja la que le parezca más apropiada. A veces, ésta puede ser su primera respuesta.

Tenga presente su modo de vivir, expectativas, placeres y preocupaciones. Le pedimos que piense en su vida durante las últimas dos semanas.

Por favor lea cada pregunta, valore sus sentimientos y haga un círculo en el número de la escala de cada pregunta que sea su mejor respuesta.

1.¿Cómo puntuaría su calidad de vida?

9. Muy mal.
10. Poco.
11. Lo normal.
12. Bastante bien.
13. Muy bien.

2.¿Cuán satisfecho está con su salud?

1. Muy insatisfecha.
2. Poco satisfecha.
3. Lo normal.
4. Bastante satisfecha.
5. Muy satisfecha.

Las siguientes preguntas hacen referencia a cuánto ha experimentado ciertos hechos en las últimas dos semanas.

3.¿Hasta que punto piensa que el dolor (físico) le impide hacer lo que necesita?

1. Nada.
2. Un poco.
3. Lo normal.
4. Bastante.
5. Extremadamente.

4.¿Cuánto necesita de cualquier tratamiento médico para funcionar en su vida diaria?

1. Nada.
2. Un poco.
3. Lo normal.
4. Bastante.
5. Extremadamente.

5.¿Cuánto disfruta de la vida?

1. Nada.
2. Un poco.
3. Lo normal.

4. Bastante.
5. Extremadamente.

6.¿Hasta que punto siente que su vida tiene sentido?

1. Nada.
2. Un poco.
3. Lo normal.
4. Bastante.
5. Extremadamente.

7.¿Cuál es su capacidad de concentración?

1. Nada.
2. Un poco.
3. Lo normal.
4. Bastante.
5. Extremadamente.

8. ¿Cuánta seguridad siente en su vida diaria?

1. Nada.
2. Un poco.
3. Lo normal.
4. Bastante.
5. Extremadamente.

9. ¿Cuán saludable es el ambiente físico a su alrededor?

1. Nada.
2. Un poco.
3. Lo normal.
4. Bastante.
5. Extremadamente.

Las siguientes preguntas hacen referencia a "cuan totalmente" usted experimenta o fue capaz de hacer ciertas cosas en las últimas dos semanas.

10. ¿Tiene energía suficiente para su vida diaria?

1. Nada.
2. Un poco.
3. Moderado
4. Bastante.
5. Totalmente.

11. ¿Es capaz de aceptar su apariencia física?

1. Nada.
2. Un poco.
3. Moderado
4. Bastante.
5. Totalmente.

12. ¿Tiene suficiente dinero para cubrir sus necesidades?

1. Nada.
2. Un poco.
3. Moderado
4. Bastante.
5. Totalmente.

13. ¿Qué disponible tiene la información que necesita en su vida diaria?
    1. Nada.
    2. Un poco.
    3. Moderado
    4. Bastante.
    5. Totalmente.

14. ¿Hasta qué punto tiene oportunidad para realizar actividades de ocio?
    1. Nada.
    2. Un poco.
    3. Moderado
    4. Bastante.
    5. Totalmente.

15. ¿Es capaz de desplazarse de un lugar a otro?
    1. Nada.
    2. Un poco.
    3. Lo normal.
    4. Bastante.
    5. Extremadamente.

Las siguientes preguntas hacen referencia a "cuan satisfecha o bien" se ha sentido en varios aspectos de su vida en las últimas dos semanas.

16. ¿Cuán satisfecha está con su sueño?
    1. Nada satisfecha.
    2. Poco satisfecha.
    3. Lo normal.
    4. Bastante satisfecha.
    5. Muy satisfecha.

17. ¿Cuán satisfecha está con su habilidad para realizar sus actividades de la vida diaria?
    1. Nada satisfecha.
    2. Poco satisfecha.
    3. Lo normal.
    4. Bastante satisfecha.
    5. Muy satisfecha.

18. ¿Cuán satisfecha está con su capacidad de trabajo?
    1. Nada satisfecha.
    2. Poco satisfecha.
    3. Lo normal.
    4. Bastante satisfecha.

5. Muy satisfecha.

19. ¿Cuán satisfecho está de sí misma?
    1. Nada satisfecha.
    2. Poco satisfecha.
    3. Lo normal.
    4. Bastante satisfecha.
    5. Muy satisfecha.

20. ¿Cuán satisfecha está con sus relaciones personales?
    1. Nada satisfecha.
    2. Poco satisfecha.
    3. Lo normal.
    4. Bastante satisfecha.
    5. Muy satisfecha.

21. ¿Cuán satisfecha está con su vida sexual?
    1. Nada satisfecha.
    2. Poco satisfecha.
    3. Lo normal.
    4. Bastante satisfecha.
    5. Muy satisfecha.

22. ¿Cuán satisfecha está con el apoyo que obtiene de sus amigos?
    1. Nada satisfecha.
    2. Poco satisfecha.
    3. Lo normal.
    4. Bastante satisfecha.
    5. Muy satisfecha.

23. ¿Cuán satisfecho está de las condiciones del lugar donde vive?
    1. Nada satisfecha.
    2. Poco satisfecha.
    3. Lo normal.
    4. Bastante satisfecha.
    5. Muy satisfecha.

24. ¿Cuán satisfecho está con el acceso que tiene a los servicios sanitarios?
    1. Nada satisfecha.
    2. Poco satisfecha.
    3. Lo normal.
    4. Bastante satisfecha.
    5. Muy satisfecha.

25. ¿Cuán satisfecho está con su transporte?
    1. Nada satisfecha.
    2. Poco satisfecha.
    3. Lo normal.
    4. Bastante satisfecha.
    5. Muy satisfecha.

La siguiente pregunta hace referencia a la frecuencia con que Ud. Ha sentido o experimentado ciertos sentimientos en las últimas dos semanas.

26. ¿Con que frecuencia tiene sentimientos negativos , tales como tristeza, desesperanza, ansiedad, depresión?

1. Nunca.
2. Raramente.
3. Medianamente.
4. Frecuentemente.
5. Siempre.

ANNEX 9: WHOQOL-BREF questionnaire sheets. Catalan version.

QÜESTIONARI WHOQOL-BREF: sobre qualitat de vida

Aquest qüestionari serveix per conèixer la seva opinió sobre la seva qualitat de vida, la seva salut i altres àrees de la seva vida. Si us plau, contesti a totes les preguntes. Si no sabeu quina resposta donar a una pregunta, trïi la que li sembli més apropiada. De vegades, aquesta pot ser la seva primera resposta.

Tingui present la seva manera de viure, expectatives, plaers i preocupacions. Li demanem que pensi en la seva vida durant les últimes dues setmanes.

Si us plau llegiu cada pregunta, valori seus sentiments i faci un cercle en el nombre de l'escala de cada pregunta que sigui la seva millor resposta.

1. Com puntuaria la seva qualitat de vida?
    1. Molt malament.
    2. Poc.
    3. El normal.
    4. Bastant bé.
    5. Molt bé.

2.Quant satisfet està amb la seva salut?
    1. Molt insatisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

Les següents preguntes fan referència a quant ha experimentat certs fets en les últimes dues setmanes.

3.Fins quin punt pensa que el dolor (físic) li impedeix fer el que necessita?
    1. Res.
    2. Una mica.
    3. El normal.
    4. Bastant.
    5. Extremadament.

4.Quant necessita de qualsevol tractament mèdic per a funcionar en la seva vida diària?
    1. Res.
    2. Una mica.
    3. El normal.
    4. Bastant.
    5. Extremadament.

5.Quánto gaudeix de la vida?
    1. Res.
    2. Una mica.

3. El normal.
4. Bastant.
5. Extremadament.

6.Fins quin punt sent que la seva vida té sentit?
1. Res.
2. Una mica.
3. El normal.
4. Bastant.
5. Extremadament.

7.Quina és la seva capacitat de concentració?
1. Res.
2. Una mica.
3. El normal.
4. Bastant.
5. Extremadament.

8. Quanta seguretat sent en la seva vida diària?
1. Res.
2. Una mica.
3. El normal.
4. Bastant.
5. Extremadament.

9. Com de saludable és l'ambient físic al seu voltant?
1. Res.
2. Una mica.
3. El normal.
4. Bastant.
5. Extremadament.

Les següents preguntes fan referència a "quant totalment" vostè experimenta o va ser capaç de fer certes coses en les últimes dues setmanes.

10. Té energia suficient per a la seva vida diària?
1. Res.
2. Una mica.
3. Moderat
4. Bastant.
5. Totalment.

11. És capaç d'acceptar la seva aparença física?
1. Res.
2. Una mica.
3. Moderat
4. Bastant.
5. Totalment.

12. Té prou diners per cobrir les seves necessitats?
    1. Res.
    2. Una mica.
    3. Moderat
    4. Bastant.
    5. Totalment.

13. Què disponible té la informació que necessita en la seva vida diària?
    1. Res.
    2. Una mica.
    3. Moderat
    4. Bastant.
    5. Totalment.

14. Fins a quin punt té oportunitat per realitzar activitats de lleure?
    1. Res.
    2. Una mica.
    3. Moderat
    4. Bastant.
    5. Totalment.

15. És capaç de desplaçar-se d'un lloc a un altre?
    1. Res.
    2. Una mica.
    3. El normal.
    4. Bastant.
    5. Extremadament.

Les següents preguntes fan referència a "quant satisfeta o bé" s'ha sentit en diversos aspectes de la seva vida en les últimes dues setmanes.

16. Com de satisfeta està amb el seu somni?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

17. Com de satisfeta està amb la seva habilitat per realitzar les seves activitats de la vida diària?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

18. Com de satisfeta està amb la seva capacitat de treball?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.

4. Bastant satisfeta.
5. Molt satisfeta.

19. Com de satisfeta està de si mateixa?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

20. Com de satisfeta està amb les seves relacions personals?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

21. Com de satisfeta està amb la seva vida sexual?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

22. Com de satisfeta està amb el suport que obté dels seus amics?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

23. Com de satisfeta està de les condicions del lloc on viu?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

24. Com de satisfeta està amb l'accés que té als serveis sanitaris?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

25. Com de satisfeta està amb el seu transport?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.

5. Molt satisfeta.

La següent pregunta fa referència a la freqüència amb que vostè ha sentit o experimentat certs sentiments en les últimes dues setmanes.

26. Amb quina freqüència té sentiments negatius, com ara tristesa, desesperança, ansietat, depressió?

14. Mai.
15. Rarament.
16. Mitjanament.
17. Freqüentment.
18. Sempre.