

***Patson Approach versus the
Standard Approach for increasing
breast reconstruction rates in
women undergoing mastectomy***

A randomized, controlled, open-label clinical trial

FINAL DEGREE PROJECT

Department of Plastic Surgery, Hospital Universitari de Girona Dr. Josep Trueta

Author: Sonia Viu Duran

Tutor: Oscar Huc Grasa

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*La vida tiene tu nombre, mujer de las mil batallas.
Per a tu, per ser tan forta i lluitadora, per ser la millor padrina que podria tenir.*

INDEX

1. SUMMARY.....	4
2. INTRODUCTION.....	5
2.1 BACKGROUND.....	5
2.1.1 Epidemiology of breast cancer.....	5
2.1.2 Breast reconstruction after mastectomy.....	5
2.1.3 Breast reconstruction outcomes: patient’s satisfaction and quality of life	9
2.1.4 Patient involvement in the decision-making process.....	12
2.1.5 Other factors that influence patient decision-making regarding reconstruction.....	13
2.2 JUSTIFICATION.....	15
3. BIBLIOGRAPHY.....	16
4. HYPOTHESES.....	19
4.1 MAIN HYPOTHESIS.....	19
4.2 SECONDARY HYPOTHESES.....	19
5. OBJECTIVES.....	20
5.1 MAIN OBJECTIVE.....	20
5.2 SECONDARY OBJECTIVES.....	20
6. METHODS.....	21
6.1 STUDY DESIGN.....	21
6.2 STUDY POPULATION.....	21
6.2.1 Inclusion criteria.....	21
6.2.2 Exclusion criteria.....	21
6.3 SAMPLE SIZE AND SAMPLING.....	21
6.4 INTERVENTIONS.....	22
6.4.1 Randomization.....	22
6.4.2 Description of the approaches.....	22

6.5 VARIABLES	26
6.5.1 Independent variable.....	26
6.5.2 Dependent variable	26
6.5.3 Secondary dependent variables.....	26
6.5.4 Co variables	26
6.6 MEASURE INSTRUMENTS	27
6.7 DATA COLLECTION.....	28
7 STATISTICAL ANALYSIS.....	31
8 ETHICAL CONSIDERATIONS.....	32
9 STUDY LIMITATIONS	33
10 WORK PLAN	34
11 FEASIBILITY.....	36
12 BUDGET	37
13 IMPACT ON THE NATIONAL HEALTH SYSTEM	38
14 ANNEXES	39
14.1 ANNEX 1. QUESTIONNAIRES	39
14.2 ANNEX 2. CASE REPORT FORM (CRF).....	47
14.3 ANNEX 3. INFORMATION SHEET FOR PARTICIPANTS.....	50
14.4 ANNEX 4. INFORMED CONSENT FOR PARTICIPANTS	62
14.5 ANNEX 5. CHRONOGRAM.....	65

1. SUMMARY

Background: breast cancer is the most prevalent neoplasm among women in the majority of countries worldwide. Breast cancer treatment include mastectomy which is associated to strong impact in women. Breast reconstruction is an option for many women to re-establish their body image and also to decrease psychological impact. However, breast reconstruction rates are low and many factors are involved in not undergoing breast reconstruction. Patient involvement in the decision-making process increases breast reconstruction rates and is associated to higher satisfaction and less anxiety and depression symptoms. More physician-patient relation and more education in terms of breast reconstruction are needed to achieve our objective. A new approach of medical care, called Patson Approach, is created in order to meet our goal with more patient involvement, as well as, physician and psychological counselling.

Objective: to increase breast reconstruction rates in women who are candidates for breast reconstruction after mastectomy and are included in the Patson Approach compared to women included in the Standard Approach.

Methods: the study design will be a randomized, controlled, open-label clinical trial. 62 patients will be recruited during two years and randomly divided in two groups, 31 will be included in the Standard Approach and 31 will be included in the Patson Approach. Preoperative and postoperative appointments are established in order to do a follow-up of the patients and collect all the data.

Keywords: breast cancer; mastectomy; breast reconstruction; patient involvement; decision-making process; physician-patient relationship; medical care; psychological counselling, psycho-oncology.

2. INTRODUCTION

2.1 BACKGROUND

2.1.1 Epidemiology of breast cancer

Breast cancer is the most prevalent neoplasm among women in the majority of countries worldwide. Bray et al estimated this prevalence in 145 of 184 countries with 5.2 million cases globally. Even when they combine both sexes in their study, breast cancer was still the most prevalent cancer in 112 of 184 countries worldwide¹.

Breast cancer prevalence and survival in Girona is similar to the worldwide prevalence. Breast cancer is included in the five most prevalent cancers in Girona with an incidence of 380 new cases every year. Breast cancer survival in Girona is one of the highest with 84.6% of relative survival in 5 years. Data collected in 2007, 2008 and 2009, calculated incidence rates of 28.1%, 26.5% and 27.5%, respectively².

2.1.2 Breast reconstruction after mastectomy

Mastectomy is a breast cancer surgical treatment which is associated to strong psychological distress, social and sexual impact in women as it changes body image and it can lead to a feeling of loss of femininity and self-esteem. This impact can also affect woman's behaviour with her family, her partner and even affect in a social level. Women can be emotionally labile, irritable and nervous which can affect partnership relations³⁻¹². Besides, mastectomy can lead to physical complications which can also affect quality of life¹³. Sinno et al demonstrated in their study that quality of life of living with bilateral mastectomy defect could be compared to living with monocular blindness, severe facial disfigurement, HIV and diabetes mellitus type I¹⁰.

Mastectomy distress can be reduced with breast reconstruction (BR) that can be performed at the time of mastectomy, by an immediate reconstruction, taking advantage of the anaesthesia induced. Several studies have demonstrated that BR reduces psychological morbidity, as well as, an improved satisfaction and quality of life for breast cancer survivors^{4-7,14-18}.

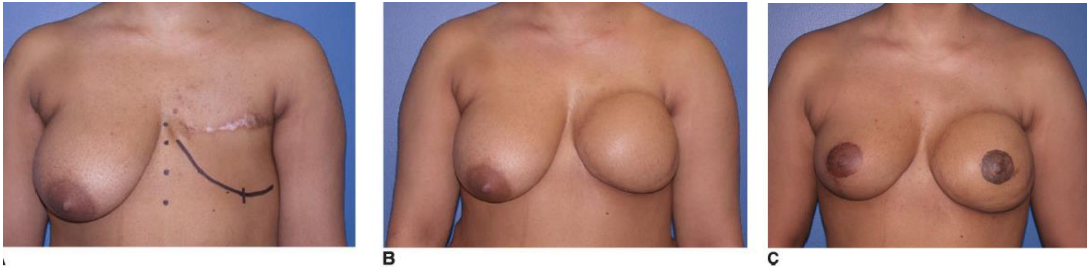
However, only approximately 20-40% of women received breast reconstruction after mastectomy^{3,6,19}. Reconstruction rates vary widely in different countries and even centres and some factors that can explain these low rates are the provider factor, limited operating time in public hospitals and not offering the option to patients. Shameem et al reported in their study that 45.5% of women were not informed about breast reconstruction³. Nowadays, breast reconstruction is becoming a part of the overall treatment of breast cancer^{4,5} in many hospitals.

Timing of breast reconstruction after mastectomy

There are three possibilities in the timing of breast reconstruction after mastectomy that are determined by a combination of different factors such as patient preference, breast cancer stage or the need for radiation therapy (RT) after mastectomy^{5,20}:

- **Immediate Breast Reconstruction (IBR):** is performed at the time of the mastectomy and it is a consideration for patients with early-stage breast cancer (0, I or IIA) which represents more than 70% of women who undergo mastectomy. Patients with a low risk of requiring RT after mastectomy are candidates for IBR. Nowadays, IBR is the most commonly elected by patients and surgeons as it has several advantages such as awakening from the surgery with a reconstructed breast. The main advantage is the possibility of preservation of the breast skin envelope as there is a less-extensive resection and, in some patients, the possibility of nipple preservation, improving the aesthetic result^{20,21}. Then, satisfaction and quality of life are higher in these patients^{4,5,13,14,20,21}.
- **Delayed Breast Reconstruction (DBR):** involves firstly performing a mastectomy and then a reconstruction after the breast cancer treatment (chemotherapy, RT) is completed. It can be performed some months or even years after mastectomy. DBR is an option for patients who are not sure of undergoing breast reconstruction and for patients with multiple medical comorbidities and potential risk factors because otherwise the surgery would take long time to be performed. DBR is usually performed using autologous tissue as the retained skinned is scarred and inflexible because of the RT. It is

important to have realistic expectations for the outcomes and to be aware of the potential complications of the DBR, especially in irradiated breasts. Some patients will need more than one surgery to achieve acceptable aesthetic results^{4,5,20-22}.



Figure²¹. Delayed reconstruction after radiation therapy. (A) The patient underwent a left mastectomy and has chosen to undergo breast reconstruction several years after RT. (B) 6 months after DBR of the left breast with a right microvascular TRAM flap. (C) 3 months later, after the patient underwent a right vertical mastectomy for symmetry and a left nipple and areola reconstruction.

- **Delayed-Immediate Breast Reconstruction (DIBR):** is usually the best option if a patient requires post-mastectomy RT or if there is an increased risk of requiring it as it allows for RT prior to definitive reconstruction. It involves placing a temporary tissue expander when the mastectomy is performed. DIBR also preserves the breast skin envelope improving aesthetic results. If a patient does not require RT, an immediate reconstruction can be performed. However, if the patient requires RT, the expander can be deflated to its 50-75% capacity to optimize radiation delivery. Then, after RT, the preserved breast skin is expanded again in order to perform the reconstruction (similar to a DBR). It is known that BR after RT can lead to short and long-term complications such as problems with wound healing, fat necrosis and capsular contracture.^{20,21,23}

Breast reconstruction techniques

Patient's anatomy is an important factor when choosing the best breast reconstruction technique, as well as, patient preference, availability of donor tissues and health conditions^{16,21}. It is important to select the best option to optimise aesthetic outcomes and to reduce potential complications²¹. There are many breast reconstruction techniques¹⁴, the most common ones are the explained below:

- **Expander placement followed by exchange for a permanent breast implant:** involves placing a tissue expander in a submuscular position which has an integrated saline-filling port with a magnet that is used to localise the expander. Once the expander is localised, it is accessed by a needle through the skin in order to fill it with saline during multiple postoperative appointments. Three to six months are required to complete the expansion process depending on the desired breast size, patient's tolerance and thickness of the mastectomy skin flaps. The process is not usually painful but it can cause some discomfort after each expansion. The main advantage is the rapid surgical and recovery time (1-2 hours of surgery and 7-10 days of recovery). The main disadvantage is that it is often a 2-stage approach so a second surgical will be needed to remove the expander and place a permanent breast implant. It is also more difficult to achieve a natural appearance breast shape and symmetry with the contralateral breast (in unilateral mastectomies) requiring sometimes a contralateral mastopexy ^{11,18,21}.
- **Latissimus dorsi flap plus a breast implant:** a skin island, including a muscle flap, is displaced from the back to the chest wall preserving its thoracodorsal vessels. It can be placed either an implant in the immediate setting (1-stage approach) or an expander which will be exchanged later to an implant (2-stage approach). Even though is a more complex technique (3-6 hours of surgery) and is associated with a longer recovery period (4 weeks), its aesthetic outcomes are better than reconstruction with an expander/implant. It is a good option for obese patients and patients who are not candidates for a TRAM flap. A disadvantage of this technique is that the latissimus muscle tends to atrophy over the years worsening aesthetic results ^{18,21}.
- **Transverse rectus abdominis muscle (TRAM) flap:** an abdominal skin pedicle is placed in the chest by two different techniques:
 - *Pedicled TRAM flap:* the lower abdominal fatty tissue with attached underlying rectus abdominis muscle is tunnelled to the chest wall.
 - *Microvascular TRAM flap* is freed from the rectus abdominis muscle, the blood supply is based inferiorly directly off the deep inferior epigastric vessels. The flap is not tunnelled to the chest wall so discomfort is lower but the technic is more complex.

It is a good option for patients with a body mass index $<30\text{kg/m}^2$ because obesity, as well as, smoking are risk factors for complications (fat necrosis and wound-healing problems in the donor site). The recovery is long and tough (4-6 weeks) but it requires fewer follow-up appointments and fewer surgeries and has more satisfaction reported than expander/implant reconstruction^{12,21}. TRAM flap has natural aesthetic outcomes and breast size tends to change with body weight²¹.

- **Deep inferior epigastric artery perforator (DIEP) flap:** it offers potential functional benefits of the abdominal wall as avoids the need of harvesting the rectus abdominis muscle. Aesthetic outcomes are similar to the ones achieved with the microvascular TRAM flap. However, it has been associated with an increased incidence of fat necrosis. It is an option in selected patients as it is longer and more complex than the microvascular TRAM flap^{11,21}.
- **Gluteal artery perforator (GAP) flap:** it is a second-line option autologous tissue reconstruction that includes only the skin and the subcutaneous tissue with the superior or inferior gluteal artery and vein (no muscle is removed)²¹.

2.1.3 Breast reconstruction outcomes: patient's satisfaction and quality of life

Overall satisfaction rates are higher when undergoing mastectomy followed by breast reconstruction than mastectomy alone which have more negative impact. Satisfaction includes better body image, physical attractiveness and sexuality. It has also been described less psychological morbidity (anxiety and depression symptoms) in women who undergo breast reconstruction^{3-5,11-13,15,18}.

IBR vs DBR vs No reconstruction

Several studies have shown that patients with IBR are more likely to be more satisfied, to report a better quality of life and to be less associated with depression and anxiety than with DBR^{4,5,13,14,20,22}. Quality of life over the 1st postoperative year in IBR can be compared with normal population¹². Moreover, IBR is superior to DBR in cost-effectiveness as the reconstruction is performed at the time of the mastectomy⁵.

Fernández-Delgado et al demonstrated that 87.27% of women undergoing DBR and 56.14% of women no-reconstructed wished they had undergone IBR. What is more, they found that only 22.8% of the no-reconstruction were satisfied while 54.38% were very unsatisfied with the aesthetic results achieved⁴.

Some studies reported that patients who have undergone mastectomy and were not offered breast reconstruction, may have no interest in DBR as they are emotionally and physically exhausted after all the process^{20,23}.

Nipple preservation mastectomy

Nipple-sparing mastectomies are also reported to have higher levels on patient's satisfaction²⁰. If the nipple cannot be preserved, nipple reconstruction or tattooing also increase patient's satisfaction¹².

Postoperative complications

Complications after BR have a significant impact on patient's short-term satisfaction and women can experience serious levels of distress, anxiety and depression. Distress before the surgery can lead to postoperative nausea, fatigue and discomfort. Doctors should inform patients about possible complications and their impact on mood and stress levels¹⁷.

Patients who have received RT have higher complication rates and poorer aesthetic outcomes, especially when using expander/implant prostheses. The most common complications are risk of capsular contracture and impaired wound healing due to radiation effects^{11,12,14,15,17,19,23}.

Sexuality

Sexual satisfaction has been shown to be improved in patients undergoing mastectomy followed by breast reconstruction than mastectomy alone⁷. Women seeking BR for sexuality reasons such as feeling less self-conscious during sexual intercourses tend to choose IBR rather than DBR²². Partnership relations in women not offered breast reconstruction tend to deteriorate and women usually have a decreased sexual interest. However, it is related to changes in sexual function or satisfaction after breast cancer more than undergoing or not BR. Partners play a really important role in woman's adaptation to the breast cancer diagnosis. Partner support and understanding has a positive impact on patients^{8,9}.

Involvement in the decision-making process

Several studies have demonstrated that patients are more satisfied with their outcomes, report better quality of life and are more adherent to treatment recommendations if they are involved in the decision-making process^{6,13,19,20,23}.

Psychological support

It has been reported that adequate psychological support during the breast cancer treatment could be useful for patients in order to improve their loss in quality of life in the overwhelming diagnosis of breast cancer^{7,8}.

Questionnaires to evaluate breast reconstruction outcomes

There are some questionnaires that are useful to evaluate patient's psychological impact due to breast reconstruction after mastectomy. The three questionnaires below are the ones that will be used as measure instruments.

- The **Breast Reconstruction Satisfaction Questionnaire (BRECON-31)** is a specific questionnaire for BR. It is composed by 31 items in 8 different subscales which are self-image (feelings of normalcy, femininity and attractiveness), arm concerns (shoulder function, arm pain and swelling), intimacy (impact of BR on intimate relationships), satisfaction (overall satisfaction with the outcome of the BR and whether the patient would choose the surgery again for herself or recommend it to others), recovery (intrusiveness of the surgery and the perception of the length of recovery), self-consciousness (comfort with having her breasts seen by others), expectations (preparation and information about the BR) and appearance (size and appearance of the new breast). It also includes two additional subscales: a 4-item nipple subscale (appearance of the nipple and its function in BR) and a 10-item abdominal subscale (effects on abdominal shape, healing, strength and appearance)^{24,25}. The original BRECON-31 questionnaire is attached in Annex 1 which will have to be translated to Catalan and Spanish.
- The **Hospital Anxiety and Depression Scale (HADS)** is a 14-item scale divided in two groups, one subscale for anxiety and one for depression, with 7 questions each one. HADS is a brief questionnaire with high consistency which

was initially used for psychiatric disorders but it can be also used for surgical and oncology patients^{4,26-28}. The scale has been adapted and validated for use with the Spanish population^{4,27}. HADS English Version²⁶ and Spanish Version²⁸ are attached in Annex 1.

- The **Short-Form 36 Health Status Questionnaire (SF-36)** is a generic scale which is useful to evaluate health related quality of life. It is composed by 36, both positive and negative, health items. It has 8 subscales about physical functioning, physical role functioning, bodily pain, general health perceptions, vitality, social role functioning, emotional role functioning and mental health²⁹. Elder et al demonstrated that 1 year postoperatively, patients reported quality of life was comparable with that of reference population, though lowest scores were for emotional role functioning and mental health¹². The Spanish validated version of the SF-36 is attached in Annex 1²⁹.

2.1.4 Patient involvement in the decision-making process

Breast cancer diagnosis can overwhelm many patients and treatment decisions such as breast reconstruction can be really complex and intimidating. It is of vital importance that physicians counsel patients about surgery, as well as, involve patients in the decision-making process^{6,22,23,30}.

Taking part of the decision-making process has been shown to influence in reconstruction rates³¹, patient satisfaction and quality of life. Moreover, increasing patient autonomy increases patient's trust and compliance with future clinical recommendations while not being included has the opposite outcomes. Woman's values and preferences should be taken into account, using an informed or shared opinion approach and avoiding a paternalistic role^{6,19}, always exploring patient's expectations¹⁶. Lack of information can lead to dissatisfied patients while giving too detailed information may frighten other patients¹⁸.

Physician counselling is of vital importance for patients and it should be individualised according to patient's needs and expectations¹⁶. It is essential that doctors guide and give adequate counselling about breast reconstruction specially about IBR, which can

prevent or reduce psychological impact and unsatisfactory outcomes^{5,20,30}. Doctors have to educate and be frank with patients so they have realistic expectations of the outcomes and the possible complications and sequels^{12,14,18,30,31}. Plastic surgeons should explore patient's expectations in order to detect unrealistic expectations or misconceptions as patient's education may improve long-term quality of life and satisfaction. Some patients may have high expectations and may be, then, disappointed with the outcome while patients with inappropriate low expectations may not consider the option of BR^{16,18}.

Physician-patient relationship is really important in the breast cancer counselling as it has an impact in patient's evaluations. Many patients with acceptable cosmetically outcomes may evaluate the procedure negatively because of a bad relationship with their physician while patients with poor cosmetically results, may be satisfied because they trusted and felt valued by her physician³⁰. Therefore, patient perceptions may differ from physician perceptions in many different ways³¹.

2.1.5 Other factors that influence patient decision-making regarding reconstruction

- **Fear of not detecting a cancer recurrence:** it has been established by many studies that breast reconstruction is oncologically safe, which means that has no impact on the risk of cancer recurrence or on the prognosis, even in locally advanced breast cancer^{3,4,14,20,22}. However, there are some patients and even physicians that may be worried about remaining viable cells in the mastectomy bed or the ability to detect a cancer recurrence²⁰. Physician counselling should include that BR does not affect detection of cancer recurrence and survival outcomes.
- **Fear of additional surgery and fear of complications:** anxiety is a normal response to surgery and breast cancer patients are often overwhelmed with the diagnosis and treatment options. It is essential that physicians provide appropriate information about breast reconstruction to reduce anxiety and distress among pre-operative patients^{3,22,26}.
- **Low priority:** some patients may regard breast reconstruction as an extra treatment for breast cancer so they decide not to undergo breast

reconstruction or to delay it as it is not a priority and they want to be focused on treating the cancer²².

- **Regain normal life:** patients reported that they seek reconstruction for many reasons: to recover their life before cancer as a way of putting the illness behind them, to decrease negative feeling, to feel whole again, to improve self-esteem, to regain femininity, to feel more balanced, to avoid wearing external prosthesis and to have fewer clothing limitations^{3,12,13,18,20,22}.
- **Mood and personality:** it has been reported that a better physical health, an optimistic personality, giving more importance on body image and sexuality, and being less afraid of surgery are factors for choosing reconstruction^{13,20} while mood disturbance, such as depression, and cancer-related fatigue may be factors for not choosing BR²³.
- **Age:** it can influence in regarding BR as it has been reported that women younger than 50 years old are more likely to undergo BR after mastectomy^{3,18-20,22}.
- **Marital status:** in some studies, it was demonstrated that women who undergo breast reconstruction were more likely to be married or live with a companion^{3,19}. However, women seem to choose reconstruction for themselves and not for their partners^{3,12}.

2.2 JUSTIFICATION

The main objective of this clinical trial is to increase breast reconstruction rates as only 20-40% of women undergo reconstruction^{3,6,19}. Breast reconstruction has been shown as beneficial for women in terms of psychological impact improving overall satisfaction and decreasing depression and anxiety levels^{4-7,14-18}. Therefore, if breast reconstruction rates were higher, more women would be satisfied and would need less psychological support to recover from the big impact of mastectomy.

There are several articles about the importance of involving the patient in the decision-making process^{6,16,19,22,23,30,31} as a factor that influence patient's final decision. Lack of information, misconceptions and bad physician-patient relationship can influence patients to not choose breast reconstruction^{16,18,30}. A new approach is needed to improve patient involvement and to avoid negative factors about the decision of undergoing breast reconstruction.

The **Patson Approach** has been created in order to prove if a new approach increases breast reconstruction rates. The Patson Approach includes more patient involvement in the decision-making process, as well as, physician counselling involving gynaecologists, oncologists, plastic surgeons and psycho-oncologists. The aim is that patients consider breast reconstruction as a part of the whole process of breast cancer treatment and not as an extra step just for "feeling whole again". Breast reconstruction is part of breast cancer treatment and patients should be aware of it. Physicians will educate patients in terms of breast reconstruction specially on Immediate Breast Surgery as the psychological impact is lower and satisfaction rates are higher^{4,5,13,14,20-22}. What is more, IBR is performed at the time of mastectomy^{20,21} so it is cost-effectiveness⁴. Physicians will inform patients with the appropriate information about BR and will decide with them the best option in each case. Physician-patient discussion will lead to a shared opinion, avoiding a paternalistic role^{6,19} and without persuading or forcing the patient to undergo breast reconstruction.

In conclusion, a multidisciplinary team will be involved in the Patson Approach in order to increase breast reconstruction rates by improving patient involvement in the decision-making and counselling so they can give their opinions about breast reconstruction. This process should be individualised according to their preferences. Then, the outcomes of the Patson Approach will be compared to the outcomes of the Standard Approach which is the one performed in the hospital. Both approaches are described in detail in the Methods section (pages 22-26).

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4. HYPOTHESES

4.1 MAIN HYPOTHESIS

The Patson Approach will achieve higher rates of breast reconstruction than the Standard Approach.

4.2 SECONDARY HYPOTHESES

- a. Satisfaction rates of breast reconstruction will be higher in the Patson Approach than in the Standard Approach.

- b. Less depression and anxiety symptoms will be reported in the Patson Approach compared to the Standard Approach.

- c. Quality of life will be better in the Patson Approach than in the Standard Approach.

5. OBJECTIVES

5.1 MAIN OBJECTIVE

To compare the effectiveness of the Patson Approach versus the Standard Approach in increasing breast reconstruction rates in women who are candidates of breast reconstruction after mastectomy.

5.2 SECONDARY OBJECTIVES

- a. To compare the effectiveness of the Patson Approach versus the Standard Approach in increasing patient's satisfaction rates with breast reconstruction in women who are candidates of breast reconstruction after mastectomy.

- b. To compare the effectiveness of the Patson Approach versus the Standard Approach in decreasing depression and anxiety severity and rates in women who are candidates of breast reconstruction after mastectomy.

- c. To compare the effectiveness of the Patson Approach versus the Standard Approach in increasing quality of life, in women who are candidates of breast reconstruction after mastectomy.

6. METHODS

6.1 STUDY DESIGN

The study will be a randomized, controlled, open-label clinical trial. The patients will be randomly divided in two groups. The first group will be included in the **Standard approach** and, the second group in the new approach, called **Patson Approach**.

6.2 STUDY POPULATION

The patients of the study would be women who undergo mastectomy and are offered breast reconstruction between the years 2015 and 2017 in Hospital Universitari Doctor Josep Trueta de Girona and in Hospital Santa Caterina de Salt.

6.2.1 Inclusion criteria

- Women diagnosed of breast cancer that will be treated either with unilateral or bilateral mastectomy and are candidates for BR.
- Women aged 18 or older.
- Women who have read the Information sheet for participants (Annex 3) and have signed the Informed consent form (Annex 4).
- Women who are willing to attend to the appointments and to answer the three questionnaires (BRECON-31, HAD, SF-36).

6.2.2 Exclusion criteria

- Lumpectomy.
- Short life expectancy (less than a year, by physician criteria).
- Women not able or not willing to attend to the appointments and to answer the questionnaires.

6.3 SAMPLE SIZE AND SAMPLING

A non-probabilistic and consecutive sampling will be done in a period of two years.

Accepting an alpha risk of 0,05 and a beta risk of 0,2 in a two-sided test, 31 subjects will be needed in the standard approach and 31 in the Patson Approach (62 subjects in total) to recognize a statistically significant relative risk greater than or equal to 2. It is thought that the drop-out rate will be 10%. The sample size has been obtained with the program GRANMO Calculator. The POISSON approximation has been used.

In the first appointment, a trial doctor will give the Information sheet for participants (Annex 3) of the project and if the patient agrees with it, she will sign the Informed consent form (Annex 4).

Randomization will be done by SPSS after the patient has signed the Informed consent form. Therefore, the patient will be randomly assigned to one of the approaches.

6.4 INTERVENTIONS

6.4.1 Randomization

Randomization will be done by a statistical specialist once the patient has signed the Informed consent form (Annex 4). Patients will be randomly assigned to an approach using the software SPSS. After that, assignments will be known by the investigation team as it is an open trial but nobody in the team will have decided in which approach the patient should have been included. Each patient will be given an identification number obtained by a number code generator to maintain personal data confidentially.

Plastic surgeons will be also randomized in order to decrease inter-surgeon variation.

6.4.2 Description of the approaches

The study will include two different approaches:

- The **standard approach** is the one that is been doing in the hospital.
- The **new approach**, called **Patson approach**, will include more patient-involvement in the decision-making process, as well as, psycho-oncologist's appointments and counselling. Both approaches will have common steps such as the first appointment, the postoperative follow-up and appointments 3 months, 6 months and on 1-year post-op.

The first appointment will include the explanation of the project and giving her the information sheet for participants (Annex 3). If she agrees with the project, she will sign the Informed consent form (Annex 4) and, after that, randomization will be done. In the following days, all women included in the standard approach will receive a letter or a text message with the date of plastic surgeon's appointment. On the other hand, women included in the Patson Approach will receive a letter or a text message with the date of plastic surgeon and psycho-oncologist's appointment. The two approaches are described in detail below:

The Standard Approach

- Appointment 1: gynaecologist/oncologist's appointment to explain the severity of the breast cancer and treatment options including breast reconstruction. In this appointment, the doctor will offer the patient to participate in the project. If the patient agrees with it, then the doctor will give her the information sheet (Annex 3) and the patient will sign the Informed consent form (Annex 4).
- Appointment 2: preoperative plastic surgeon's appointment to explain breast reconstruction options and agree a technique with the patient.
- Surgery: it will include unilateral or bilateral mastectomy following or not breast reconstruction.
- Appointment 3: postoperative gynaecologist/oncologist or plastic surgeon's appointment to do the follow-up of the surgery's outcomes. All patients who have opted for breast reconstruction will be visited by a plastic surgeon. Otherwise, patients who decided not to undergo a breast reconstruction will be visited by her gynaecologist/oncologist.
Patients will be offered a psycho-oncologist's appointment only when is needed and asked by either the patient or the doctor.
- Appointment 4 (3-months post-op): the gynaecologist/oncologist or plastic surgeon will give the questionnaires to the patient (BRECON-31, HAD and SF-36) and she will answer them during the appointment and give them back to the doctor. The BRECON-31 questionnaire will only be answered if the patient has undergone breast reconstruction.
- Appointment 5 (6-months post-op): same routine as the appointment 4.
- Follow-up appointments: the number of appointments will depend on the patient, her needs and her recovery from the surgery.
- Appointment 6 (1-year post-op): same routine as the appointments 4 and 5.

The Patson Approach

- Appointment 1: this appointment will be performed as in the standard approach. Although, a first preoperative psycho-oncologist's appointment will be scheduled. This appointment will be a non-structured clinical interview that has to include the following topics (the order of the interview should be decided by the professional):
 - Anamnesis including family support and marital status.

- Knowledge of the disease and treatments.
 - Acceptance of the disease.
 - Adaptive status.
 - Primary concern.
 - Other kind of difficult circumstances and knowing how she react to them (other own diseases or family diseases, deaths,...).
- Appointment 2: preoperative gynaecologist/oncologist and plastic surgeon's appointment to explain the whole treatment of breast cancer including chemotherapy, radiotherapy, hormonal therapy, mastectomy and breast reconstruction options (depending on the breast cancer of the patient) in order to increase patient involvement in the decision-making process and improve doctor's communication abilities with the patient. The aim of this appointment will be showing the patient that breast reconstruction is just another step in the breast cancer treatment.
- A second psycho-oncologist's appointment will be scheduled before the surgery, following the scheme of the first appointment, a non-structured clinical interview, depending on the patient's needs.
- Surgery: as in the **standard approach**, it will include unilateral or bilateral mastectomy following or not breast reconstruction.
- Appointment 3: this appointment will be performed as in the **standard approach**. Besides, it will be scheduled a postoperative psycho-oncologist's appointment, also following the scheme of a non-structured clinical interview, depending on the patient's needs.
- Appointment 4 (3 months post-op): as in the **standard approach**, the patient will answer the questionnaires (BRECON-31, HAD and SF-36) during the appointment and give them back to the doctor. The BRECON-31 questionnaire will only be answered if the patient has undergone breast reconstruction.
- Appointment 5 (6-months post-op): as in the **standard approach**, same routine as the appointment 4.
- Follow-up appointments: as in the **standard approach**, the number of appointments will depend on the patient, her needs and her recovery from the surgery.
- Appointment 6 (1-year post-op): as in the **standard approach**, same routine as the appointments 4 and 5.

	STANDARD APPROACH	PATSON APPROACH
Appointment 1	Gynaecologist or oncologist's appointment	Gynaecologist or oncologist's appointment
		First preoperative psycho-oncologist's appointment
Appointment 2	Preoperative plastic surgeon's appointment	Preoperative plastic surgeon + gynaecologist/oncologist's appointment
		Second preoperative psycho-oncologist's appointment
Surgery	Mastectomy +/- reconstruction	Mastectomy +/- reconstruction
Appointment 3	Postoperative gynaecologist/oncologist or plastic surgeon's appointment	Postoperative gynaecologist/oncologist or plastic surgeon's appointment
	Psycho-oncologist's appointment only if needed	Postoperative psycho-oncologist's appointment
Appointment 4 3-months post-op	Gynaecologist/oncologist or plastic surgeon's appointment to answer the questionnaires	Gynaecologist/oncologist or plastic surgeon's appointment to answer the questionnaires
Appointment 5 6-months post-op	Gynaecologist/oncologist or plastic surgeon's appointment to answer the questionnaires	Gynaecologist/oncologist or plastic surgeon's appointment to answer the questionnaires
Follow-up appointments	Depending on the patient	Depending on the patient
Appointment 6 1-year post-op	Gynaecologist/oncologist or plastic surgeon's appointment to answer the questionnaires	Gynaecologist/oncologist or plastic surgeon's appointment to answer the questionnaires

6.5 VARIABLES

All the variables will be included in the Case Report Form (CRF, Annex 2).

6.5.1 Independent variable: it will be the *exposition to the Standard Approach or to the Patson Approach*. As it is a qualitative nominal dichotomous variable, it will be expressed in proportions or percentages.

6.5.2 Dependent variable: it will be *whether or not women undergo breast reconstruction* depending on each approach. As it is a qualitative nominal dichotomous variable, it will be expressed in proportions or percentages.

6.5.3 Secondary dependent variables:

- **Grade of satisfaction with the breast reconstruction:** It will be measured with the BRECON-31 questionnaire and administered to patients who have undergone breast reconstruction. It is a quantitative discrete variable.
- **Depression and anxiety severity:** It will be measured with the Hospital and Anxiety and Depression Scale (HADS). It will be administered to patients from both approaches. It is a quantitative discrete variable.
- **Quality of life:** It will be measured with the SF-36 questionnaire and administered to patients from both approaches. It is a quantitative discrete variable.

6.5.4 Co variables:

- **Related to the patient:**
 - **Age:** 50 or younger, 51 or older. Age is a quantitative discrete variable but it has been turned into a categorical nominal dichotomous variable to facilitate the analysis.
 - **Height and weight:** both are quantitative continuous variables.
 - **Body Mass Index (BMI):** <30 or >30. BMI is a quantitative continuous variable that has been turned into a categorical nominal dichotomous variable to facilitate the analysis.
 - **Marital status:** single, in a relationship/married, divorced, widowed. It is a categorical nominal variable.

- **Related to the surgery:**
 - **Unilateral or bilateral mastectomy:** it is a categorical nominal dichotomous variable.
 - **Timing of the reconstruction:** immediate, deferred or delayed-immediate reconstruction. It is a categorical nominal variable.
 - **Reconstruction technique:** expander/implant, latissimus dorsi flap or TRAM flap. It is a categorical nominal variable. DIEP and GAP flaps are not included as they are not performed in the Hospital.
 - **Nipple preservation:** yes or no. It is a categorical nominal dichotomous variable.
 - **Lymph nodes dissection:** yes or no. It is a categorical nominal dichotomous variable.
 - **Surgeon:** surgeon 1, surgeon 2, surgeon 3 or surgeon 4. It is a categorical nominal variable.
 - **Postoperative complications (in the 7 days after the surgery):** yes or no. It is a categorical nominal dichotomous variable.

- **Related to the medical care:**
 - **Total follow-up appointments in one year:** it is a quantitative discrete variable.
 - **Radiation therapy:** yes or no. It is a categorical nominal dichotomous variable.

6.6 MEASURE INSTRUMENTS

The measure instruments that will be used in the study are the following ones:

- **BRECON-31:** it has 31 items with five possible answers which are *strongly agree (1), disagree (2), agree (3), strongly agree (4)* and *not applicable (N/A)*. Each item is given a number that has to be calculated with the other items of the subscale with a formula which is basically summing the scores of the items, dividing it by the number of items of the subscale and then, multiplying it by 25. Each subscale has to be scored separately. If a subscale is missing or if more than one item is scored "N/A" or is missing, then the subscale cannot be scored. Subscales are scored out of 100 and the higher scores indicate higher satisfaction²⁴.

- **HADS:** each item of the questionnaire is scored in a scale of 4 grades of frequency from 0 to 3. All the scores are summed with a maximum possible score of 21. Scoring 11 or more is considered as a morbidity indicative, from 8-10 as a borderline risk and from 0-7 as absence of significant morbidity (normal range)^{26,28}.
- **SF-36:** each subscale has different number of items that have to be codified, attached and transformed into a 0 to 100 scale. The higher the score, the better quality of life. Therefore, 0 would be the maximum disability and 100 would be no disability²⁹.

6.7 DATA COLLECTION

All the patient data will be collected in a **Case Report Form** (CRF, Annex 2) that will include all the variables (independent, dependent and secondary dependent) and co variables.

Before using the CRF as a method for data collection, a pilot experiment will be carried out in order to prove the reliability and quality of the CRF, as well as, the difficulties in collecting data. This pilot experiment will be useful to remake and improve the CRF. A statistical specialist will be responsible for evaluating data quality and consistence.

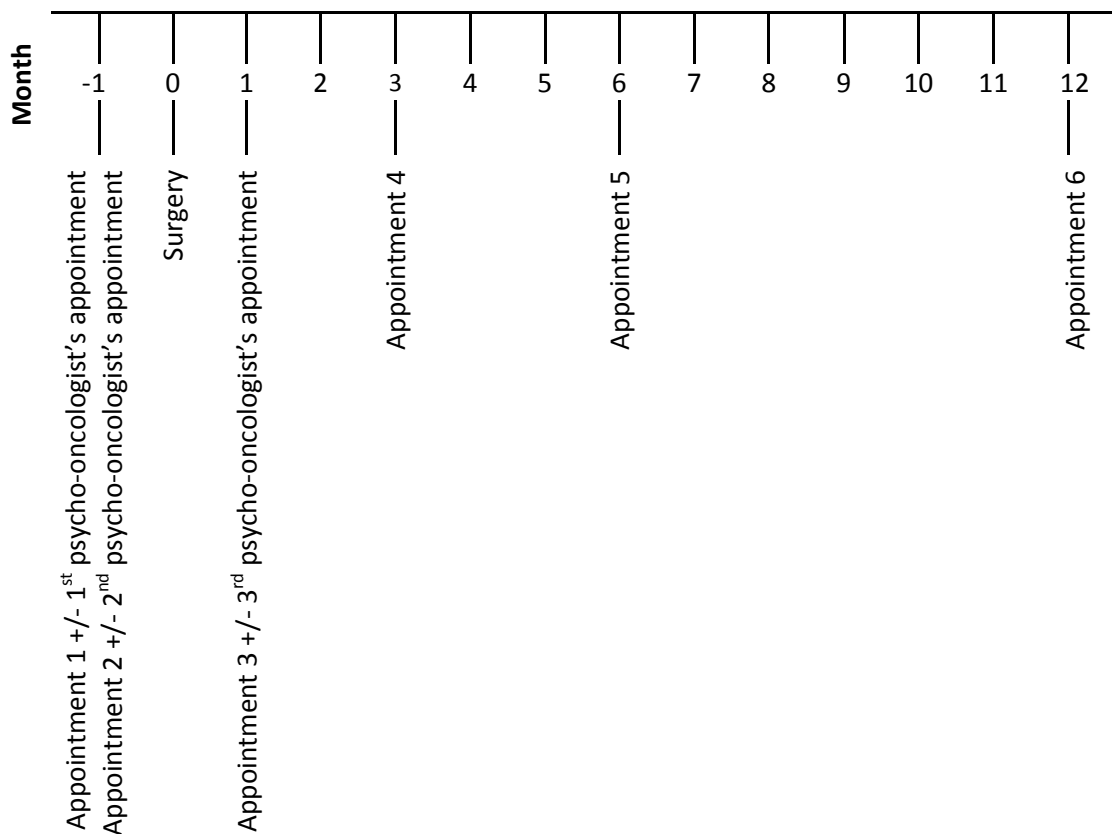
The CRF will include different sections, each one for each appointment in which specific data will be collected. In each appointment, the person who will collect the data will have to write his/her surname and the date when the data is collected. All data should be introduced to a computer database after each appointment in order to have two copies of the patient's CRF.

Data will be collected by the study team that will include one gynaecologist, one oncologist, four plastic surgeons and one psycho-oncologist's. Each member will be previously taught and trained so to know the questionnaire, the methodology of collecting data and how and when each item should be collected. The following table summarises when and which data will be collected and who will collect it.

Month	Appointment	Collected data	Study member
-1	Appointment 1	<ul style="list-style-type: none"> Attendance to the appointment Reading the Information sheet Signature of the Informed consent 	<ul style="list-style-type: none"> Gynaecologist Oncologist
-1	1 st psycho-oncologist's appointment	<ul style="list-style-type: none"> Attendance to the appointment 	<ul style="list-style-type: none"> Psycho-oncologist's
-1	Appointment 2	<ul style="list-style-type: none"> Attendance to the appointment Standard or new approach Age Height Weight BMI Marital status 	<ul style="list-style-type: none"> Plastic surgeon
-1	2 nd psycho-oncologist's appointment	<ul style="list-style-type: none"> Attendance to the appointment 	<ul style="list-style-type: none"> Psycho-oncologist's
0	Surgery	<ul style="list-style-type: none"> Attendance to the appointment Surgeon number Unilateral or bilateral mastectomy Breast reconstruction Timing of the reconstruction Reconstruction technique Nipple preservation Lymph nodes dissection 	<ul style="list-style-type: none"> Gynaecologist (if the woman has not opted for BR) Plastic surgeon (if the woman has opted for breast reconstruction)
1	Appointment 3	<ul style="list-style-type: none"> Attendance to the appointment Postoperative complications 	<ul style="list-style-type: none"> Gynaecologist/oncologist (if the woman has not opted for BR) Plastic surgeon (if the woman has opted for BR)
1	3 rd psycho-oncologist's appointment	<ul style="list-style-type: none"> Attendance to the appointment 	<ul style="list-style-type: none"> Psycho-oncologist's
3	Appointment 4	<ul style="list-style-type: none"> Attendance to the appointment Answering and punctuation of the questionnaires: BRECON-31, HADS and SF-36. 	<ul style="list-style-type: none"> Gynaecologist/oncologist (if the woman has not opted for BR) Plastic surgeon (if the woman has opted for BR)

6	Appointment 5	<ul style="list-style-type: none"> • Attendance to the appointment • Answering and punctuation of the questionnaires: BRECON-31, HADS and SF-36. 	<ul style="list-style-type: none"> • Gynaecologist/oncologist (if the woman has not opted for BR) • Plastic surgeon (if the woman has opted for BR)
12	Appointment 6	<ul style="list-style-type: none"> • Attendance to the appointment • Total number of follow-up appointments • Radiation therapy • Answering and punctuation of the questionnaires: BRECON-31, HADS and SF-36. 	<ul style="list-style-type: none"> • Gynaecologist/oncologist (if the woman has not opted for BR) • Plastic surgeon (if the woman has opted for BR)

The study scheme for each patient will be the following:



7 STATISTICAL ANALYSIS

In the *univariate analysis*, we will define variables as categorical or continuous.

- **Categorical variables** are exposition to one approach, undergoing breast reconstruction, marital status, unilateral or bilateral mastectomy, timing of the reconstruction, reconstruction technique, nipple preservation, lymph nodes dissection, surgeon, postoperative complications and radiation therapy. Each categorical variable will be described as percentages and proportions.
- **Quantitative variables** are age, height, weight, BMI, BRECON-31 punctuation, HADS punctuation, SF-36 punctuation and total number of follow-up appointments. Each quantitative variable will be described as means +/- standard deviation assuming a normal distribution.

In the *bivariate analysis*, the comparison between the independent and the dependent variables, as they are both categorical, will be realised with the relative risk or with a Chi-Square test or a Fisher's exact test. For the comparison between the independent and the secondary dependent variables, Student's t-test will be used as the independent is a categorical variable and the secondary dependent variables are quantitative.

In the *multivariate analysis*, we will use a type of probabilistic statistical classification model such a logistic regression adjusted for all the co variables.

IBM SPSS Statistics will be the software package that will be used for statistical analysis. To manage computed data, Microsoft Excel tool will be used.

We will considerate all variables statistically significant if p value <0.05.

8 ETHICAL CONSIDERATIONS

One ethical consideration that should be taken into account is that the new approach, called Patson Approach, is more likely to increase patient's satisfaction in all aspects. Improving the involvement in the decision-making process of their treatment and receiving psychological counselling may lead to a better medical care referred by some patients. Both approaches are ethically right and approved but it is something that should be considered. To avoid a doctor's paternalistic role, randomization will be done after the patient has signed the informed consent (Annex 4) in order to not make a selection bias in the sample.

This study has being designed in accordance with the medical ethics defined in the WMA Declaration of Helsinki, as a statement of ethical principles for medical research involving human subjects.

All the collected information during the course of the research will be kept strictly confidential ensuring the compliance of the Organic Law 15/1999 of 13 December on the Protection of Personal Data, intended to guarantee and protect the public liberties and fundamental rights of natural persons. What is more, to maintain confidentiality of personal data, an identification number will be used instead of the woman's name.

The study protocol will be reviewed and approved by the Clinical Research Ethics Committee (CEIC) of the Hospital Universitari de Girona Doctor Josep Trueta and Hospital Santa Caterina de Salt.

Before participants are included in the trial, they will be given an Information sheet for participants (Annex 3), in which the study will be explained, and they will have to sign an informed consent (Annex 4).

9 STUDY LIMITATIONS

The main limitation of the study is that it is an open-label trial. That means the patient, doctors and the study team will know in which approach is the patient include. To avoid being paternalistic with certain patients, randomization will be done after the patient has signed the informed consent (Annex 4) and no patients could be changed to the other group. Although, the standard approach is properly designed and this fact should be explained to the patient because they may think that the approach is poor built and that is the reason for creating a new one. For this reason, patients may desire to be in the Patson approach and, once they know they belong to the standard one, they may want to be changed or may want to withdraw from the study. Doctors have to explain to these patients that they are not able to change patients from one approach to the other one and that if they are not taking part in the study, they will also follow the standard approach. The fact is that the study involves answering the questionnaires three times in one year, so patients may decide not to answer them.

Data collection may be another limitation as seven study members are involved in it. To avoid mistakes and missing data, all members will be previously trained to use the CRF correctly. What is more, a pilot experiment of the CRF will be carried out to make sure it is reliable.

Four plastic surgeons will participate in the surgeries so it may be a limitation as the surgeon experience and technique can be a factor that may be determinant of the results. To avoid inter-surgeon variation, they will be randomly assigned and they will perform a similar amount of surgeries.

Lost to follow-up may be a limitation in the study but we expected it will be minimum as most of the appointments are part of the medical care. The only appointments which are extra are the psycho-oncologist's ones so it will have to be considered, as well as, appointments 4, 5 and 6 in which the patient will have to answer the questionnaires. If the patient does not attend to the appointment, the hospital will try to contact her via phone or text message during the following days. Intention-to-treat analysis will be used for missing data.

The study will be performed in a small Health Area of Catalunya with a small number of patients which may be difficult to extrapolate to other regions or countries. However, randomization of patients and using validated questionnaires increases reliability to extrapolate outcomes to other regions or countries.

10 WORK PLAN

10.5 PERSONNEL OF THE RESEARCH TEAM

The research team will be composed by a gynaecologist (GY), an oncologist (ON), four plastic surgeons (PS1, PS2, PS3 and PS4), a psycho-oncologist (PO), a computer engineer (CE) and a statistical specialist (SS).

10.6 STUDY STAGES

The study has been designed in four stages that are described below:

- **Stage 1. Coordination (3 months):**
 - Activity 1: obtaining the ethical approval from the Clinical Research Ethics Committee (CREC). The general coordinator of the study (PS1) will be the responsible of this activity.
 - Activity 2: informative meeting. The PS1 will explain all the objectives to the rest of the research team. The chronogram of the study will be done and tasks will be distributed.
 - Activity 3: training for using the CRF. The PS1 will teach the other members how to collect data in the CRF.
 - Activity 4: database elaboration. The CE will be in charge to create a database in order to ease data extraction and data management.

- **Stage 2. Study conduct (36 months):**
 - Activity 5: research team meetings. There will be three meetings:
 - Before collecting data: the aim will be discussing if there are any doubts about data collection or other parts of the study in order to solve them before start collecting data.
 - One year after data collection: the aim will be solving problems and interpreting the preliminary results, as well as, quantifying the number of patients recruited in one year.
 - Two years after data collection: the aim will be solving problems and starting analysis of data and quantifying patients in order to determine if we have achieved the sample size estimated.

- Activity 6: *pilot experiment of the CRF during the two first months of data collection*. Problems or mistakes will be identified and a definitive CRF will be created.
- Activity 7: *patient recruiting, randomization, coding and data collection*. Doctors will recruit patients during two years and after that, the SS will randomize and give a code to each one of them. Data will be introduced in the database after each appointment.
- Activity 8: *data cleansing from database and data quality assurance and control*. The CE and the SS will be responsible for maintaining a good quality of data and make sure all the information of each patient is correctly introduced in the database.

- **Stage 3. Data analysis and interpretation (6 months):**
 - Activity 9: *statistical analysis*. Data will be analysed using the appropriate statistical tests by the SS.
 - Activity 10: *interpretation and discussion of the results*. The results will be interpreted and discussed by the GY, ON, PS1, PO and SS.

- **Stage 4. Publication and dissemination of the research findings (6 months):**
 - Activity 11: *publication of the results*. Articles will be written and we will also attempt to publish them in a plastic surgery journal.
 - Activity 12: *dissemination of the findings*. We will attempt to assist to conferences about breast reconstruction to present the results.

The chronogram is attached in Annex 5.

11 FEASIBILITY

The research study will be carried out at Hospital Universitari de Girona Doctor Josep Trueta and Hospital Santa Caterina de Salt in which almost all the study members are working. We will need to hire a statistical specialist, a computer engineer and a freelance clinical research professional which will be included in the budget. The psycho-oncologist will be also hired for the extra hours in the Patson Approach.

The hospital will provide all the necessary means such as personnel salaries, surgeries and cures, and also computer devices and programs to elaborate the database and to carry out the statistical analysis.

It is estimated that in the Hospital Universitari de Girona Doctor Josep Trueta and Hospital Santa Caterina de Salt about more than 30 patients per year will be diagnosed of breast cancer and will be candidates for breast reconstruction after mastectomy. In the last four years, only in the Hospital Universitari de Girona Doctor Josep Trueta, 121 patients (mean = 30 patients/year) underwent mastectomy with a mean reconstruction rate of 53%. It is estimated that in the future years, more patients will be include in the database as patients from Hospital Santa Caterina will be included in it. To find the main hypotheses relevant, it was estimated that the sample size should be 62 patients so we expected than in 2 years of data collection we will meet our goal.

12 BUDGET

The appointments and surgeries will not be included in the budget because they are part of the National Health System. Psycho-oncologist's appointments of the Patson Approach will be included as they are not part from the standard medical care. The psycho-oncologist estimated salary will be 35€ per hour. Each woman in the Patson approach (31 women) will attend to 3 sessions of 30 minutes each one (1,5h) which represents 46.5 hours. Then, psycho-oncologist's salary will be about 1627.5€.

We will hire a statistical specialist in order to randomize and code patients, do data quality control, statistical analysis, discussion and publication of the results. The estimated salary will be 35€ per hour and approximately 30 hours of statistical support will be needed. Then, the estimated cost will be 1050€.

We will hire a computer engineer so as to create the database and to do the data quality control with the statistical specialist. The salary will be 35€ per hour and approximately 20 hours will be needed. Then, the estimated cost will be 700€.

We will also hire a freelance clinical research professional with a master's degree in Clinical Trial Monitoring and Management who will be responsible for study registration, clinical trial notification, data quality control and final report preparation. The salary will be about 35€ per hour and approximately 30 hours to be needed. Then, the estimated cost will be 1050€.

Translation of the BRECON-31 questionnaire to Catalan and Spanish will have a cost of 70€.

Personnel costs	
• Psycho-oncologist	1627.5€
• Statistical specialist	1050€
• Computer engineer	700€
• Freelance clinical research professional	1050€
• Translator (BRECON-31 questionnaire)	70€
Publication costs	
• Approximated cost of publication	1000€
Travel expenses	
• International journey to disseminate the findings	2000€
TOTAL = 7497.5€	

13 IMPACT ON THE NATIONAL HEALTH SYSTEM

If the results are relevant and our hypotheses are validated, the foreseeable impact on the National Health System (NHS) is that it will be a new way to treat patients during their medical care process. The new approach, called Patson Approach, which includes more patient involvement and psychological therapy, may lead to a change in the healthcare process, not just physically but mentally. Patients need to be listened and to be treated in a way that they are comfortable with it. Paternalistic role has almost disappeared but there is still little communication between the patient and doctors and it should be improved. Breast cancer has a great impact in women and breast reconstruction can help them to recover psychologically faster. If the main hypothesis is statistically relevant, it may change the way we treat patients with breast cancer and that will have an impact on the NHS and maybe not only for breast cancer but also other cancers or other diseases that should be approached with psychological therapy and counselling.

If secondary hypotheses (satisfaction, depression and anxiety symptomatology and quality of life) are also proved to be relevant, it will also impact on the NHS in terms of preventing psychological and psychiatric diseases in patients undergoing mastectomy and it may also be extrapolated to other cancers and diseases.

14 ANNEXES

14.1 ANNEX 1. QUESTIONNAIRES

BRECON-31

BRECON-31: Breast RECONstruction Satisfaction Questionnaire

We are interested to know how satisfied you are with your breast reconstruction. Women who have had breast reconstruction helped write the sentences below. Consider your own feelings about your breast reconstruction within the past two weeks. Please mark the box that best describes how much you agree with each sentence.

	Strongly Disagree (1)	Disagree (2)	Agree (3)	Strongly Agree (4)	Not Applicable (N/A)
1. I feel attractive.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. I feel good about myself.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I feel feminine.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. I feel normal.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. I have trouble moving my shoulder.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. My arm hurts.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. My arm is swollen.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. My shoulder is sore.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. My husband/partner is comfortable with my new breast(s).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. My intimate life is good.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. My husband/partner and I have a stable relationship.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. My husband/partner and I are happy together.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. My husband/partner supported me during my breast reconstruction.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. I am satisfied with my breast reconstruction.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. If I had to do it all over again, I would choose this type of reconstruction.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. I would recommend my type of breast reconstruction to a friend.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. The breast reconstruction turned out the way I thought it would.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. It took me longer than expected to recover.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. The surgery was a lot to go through.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. The surgery was complex.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. The surgery was long.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22. I hide from my family when I change my clothes at home.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. I prevent others from seeing my chest.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. I feel comfortable nude in front of my husband/partner.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25. My plastic surgeon prepared me well.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
26. I knew just what I wanted from the plastic surgeon.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
27. What I wanted from the surgery was realistic.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28. The plastic surgeon told me what I needed to know.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
29. It is difficult to find a bra that fits.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
30. My reconstructed breast(s) is the right size for me.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
31. My reconstructed breast(s) looks better than my original breast(s) .	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Some women have had their nipple(s) remade. Only rate the next 4 questions if this was the case for you.

	Strongly Disagree (1)	Disagree (2)	Agree (3)	Strongly Agree (4)	Not Applicable (N/A)
32. My nipple(s) does not stick out enough.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
33. My nipple(s) feels numb.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
34. My nipple(s) has a nice shape.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
35. My reconstructed nipple(s) made my new breast(s) look better.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

In some breast reconstructions, tissue is used from the belly. Only rate the next 10 questions if this was the case for you.

	Strongly Disagree (1)	Disagree (2)	Agree (3)	Strongly Agree (4)	Not Applicable (N/A)
36. I have a heavy feeling in my abdomen.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
37. I have trouble getting up from lying down.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
38. My abdomen is weak.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
39. My abdomen took a long time to heal.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
40. My abdomen keeps me from exercising as much as I would like.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
41. My belly button looks good.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
42. The shape of my abdomen is better now than before my reconstruction.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
43. My abdomen looks even.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
44. My abdomen sticks out under my belly button.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
45. My abdomen sticks out above my belly button.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

HADS QUESTIONNAIRE

English Version

Hospital Anxiety and Depression Scale (HADS)			
A	I feel tense or wound up		
	Most of the time	3	
	A lot of the time	2	
	From time to time, occasionally	1	
	Not at all	0	
D	I still enjoy the things I used to enjoy		
	Definitely as much	0	
	Not quite so much	1	
	Only a little	2	
	Hardly at all	3	
A	I get a sort of frightened feeling as if something awful is about to happen		
	Very definitely and quite badly	3	
	Yes, but not too badly	2	
	A little, but it doesn't worry me	1	
	Not at all	0	
D	I can laugh and see the funny side of things		
	As much as I always could	0	
	Not quite so much now	1	
	Definitely not so much now	2	
	Not at all	3	
A	Worrying thoughts go through my mind		
	A great deal of the time	3	
	A lot of the time	2	
	From time to time, but not too often	1	
	Not at all	0	
D	I feel cheerful		
	Not at all	3	
	Not often	2	
	Sometimes	1	
	Most of the time	0	
A	I can sit at ease and feel relaxed		
	Definitely	0	
	Usually	1	
	Not often	2	
	Not at all	3	
D	I feel as if I am slowed down		
	Nearly all the time	3	
	Very often	2	
	Sometime	1	
	Not at all	0	
A	I get a sort of frightened feeling like butterflies in the stomach		
	Not at all	0	
	Occasionally	1	
	Quite often	2	
	Very often	3	
D	I have lost interest in my appearance		
	Definitely	3	
	I don't take as much care as I should	2	
	I may not take quite as much care	1	
	I take just as much care as ever	0	
A	I feel restless as if I have to be on the move		
	Very much indeed	3	
	Quite a lot	2	
	Not very much	1	
	Not at all	0	
D	I look forward with enjoyment to things		
	As much as I ever did	0	
	Rather less than I used to	1	
	Definitely less than I used to	2	
	Hardly at all	3	
A	I get sudden feelings of panic		
	Very often indeed	3	
	Quite often	2	
	Not very often	1	
	Not at all	0	
D	I can enjoy a good book, radio or television programme		
	Often	0	
	Sometimes	1	
	Not often	2	
	Very seldom	3	

(Zigmond and Snaith 1983)

Spanish Version

HOSPITAL ANXIETY AND DEPRESSION SCALE Versión original de Zigmond y Snaith, 1983

Este cuestionario ha sido diseñado para ayudarnos a saber cómo se siente usted. Lea cada frase y marque la respuesta que más se ajusta a cómo se sintió durante la semana pasada. No piense mucho las respuestas. Lo más seguro es que si responde de prisa sus respuestas se ajustarán mucho más a cómo realmente se sintió.

- | | |
|--|--|
| 1. Me siento tenso o nervioso.
<input type="checkbox"/> Todos los días
<input type="checkbox"/> Muchas veces
<input type="checkbox"/> A veces
<input type="checkbox"/> Nunca | 8. Me siento como si cada día estuviera más lento.
<input type="checkbox"/> Por lo general, en todo momento
<input type="checkbox"/> Muy a menudo
<input type="checkbox"/> A veces
<input type="checkbox"/> Nunca |
| 2. Todavía disfruto con lo que antes me gustaba.
<input type="checkbox"/> Como siempre
<input type="checkbox"/> No lo bastante
<input type="checkbox"/> Sólo un poco
<input type="checkbox"/> Nada | 9. Tengo una sensación extraña, como si tuviera mariposas en el estómago.
<input type="checkbox"/> El Nunca
<input type="checkbox"/> En ciertas ocasiones
<input type="checkbox"/> Con bastante frecuencia
<input type="checkbox"/> Muy a menudo |
| 3. Tengo una sensación de miedo, como si algo horrible me fuera a suceder.
<input type="checkbox"/> Definitivamente y es muy fuerte
<input type="checkbox"/> Sí, pero no es muy fuerte
<input type="checkbox"/> Un poco, pero no me preocupa
<input type="checkbox"/> Nada | 10. He perdido interés en mi aspecto personal.
<input type="checkbox"/> Totalmente
<input type="checkbox"/> No me preocupo tanto como debiera
<input type="checkbox"/> Podría tener un poco más de cuidado
<input type="checkbox"/> Me preocupo al igual que siempre |
| 4. Puedo reírme y ver el lado divertido de las cosas.
<input type="checkbox"/> Al igual que siempre lo hice
<input type="checkbox"/> No tanto ahora
<input type="checkbox"/> Casi nunca
<input type="checkbox"/> Nunca | 11. Me siento inquieto, como si no pudiera parar de moverme.
<input type="checkbox"/> Mucho
<input type="checkbox"/> Bastante
<input type="checkbox"/> No mucho
<input type="checkbox"/> Nada |
| 5. Tengo mi mente llena de preocupaciones.
<input type="checkbox"/> La mayoría de las veces
<input type="checkbox"/> Con bastante frecuencia
<input type="checkbox"/> A veces, aunque no muy a menudo
<input type="checkbox"/> Sólo en ocasiones | 12. Me siento optimista respecto al futuro.
<input type="checkbox"/> Igual que siempre
<input type="checkbox"/> Menos de lo que acostumbraba
<input type="checkbox"/> Mucho menos de lo que acostumbraba
<input type="checkbox"/> Nada |
| 6. Me siento alegre.
<input type="checkbox"/> Nunca
<input type="checkbox"/> No muy a menudo
<input type="checkbox"/> A veces
<input type="checkbox"/> Casi siempre | 13. Me asaltan sentimientos repentinos de pánico.
<input type="checkbox"/> Muy frecuentemente
<input type="checkbox"/> Bastante a menudo
<input type="checkbox"/> No muy a menudo
<input type="checkbox"/> Rara vez |
| 7. Puedo estar sentado confortablemente y sentirme relajado.
<input type="checkbox"/> Siempre
<input type="checkbox"/> Por lo general
<input type="checkbox"/> No muy a menudo
<input type="checkbox"/> Nunca | 14. Me divierto con un buen libro, la radio, o un programa de televisión.
<input type="checkbox"/> A menudo
<input type="checkbox"/> A veces
<input type="checkbox"/> No muy a menudo
<input type="checkbox"/> Rara vez |

SF-36

CUESTIONARIO DE SALUD SF-36

1.- En general, usted diría que su **salud** es:

- 1 Excelente
- 2 Muy buena
- 3 Buena
- 4 Regular
- 5 Mala

2.- ¿Cómo diría que es su **salud actual**, comparada con la de hace un año?

- 1 Mucho mejor ahora que hace un año
- 2 Algo mejor ahora que hace un año
- 3 Más o menos igual que hace un año
- 4 Algo peor ahora que hace un año
- 5 Mucho peor ahora que hace un año

Las siguientes preguntas se refieren a actividades o cosas que usted podría hacer en un día normal.

3.- Su salud actual, ¿le limita para hacer **esfuerzos intensos**, tales como correr, levantar objetos pesados, o participar en deportes agotadores?

- 1 Sí, me limita mucho
- 2 Sí, me limita un poco
- 3 No, no me limita nada

4.- Su salud actual, ¿le limita para hacer **esfuerzos moderados**, como mover una mesa, pasar la aspiradora, jugar a los bolos o caminar más de una hora?

- 1 Sí, me limita mucho
- 2 Sí, me limita un poco
- 3 No, no me limita nada

5.- Su salud actual, ¿le limita para **coger o llevar la bolsa de la compra**?

- 1 Sí, me limita mucho
- 2 Sí, me limita un poco
- 3 No, no me limita nada

6.- Su salud actual, ¿le limita para **subir varios pisos** por la escalera?

- 1 Sí, me limita mucho
- 2 Sí, me limita un poco
- 3 No, no me limita nada

7.- Su salud actual, ¿le limita para **subir un solo piso** por la escalera?

- 1 Sí, me limita mucho
- 2 Sí, me limita un poco
- 3 No, no me limita nada

8.- Su salud actual, ¿le limita para **agacharse o arrodillarse**?

- 1 Sí, me limita mucho
- 2 Sí, me limita un poco
- 3 No, no me limita nada

9.- Su salud actual, ¿le limita para caminar **un kilómetro o más**?

- 1 Sí, me limita mucho
- 2 Sí, me limita un poco
- 3 No, no me limita nada

10.- Su salud actual, ¿le limita para caminar **varias manzanas** (varios centenares de metros)?

- 1 Sí, me limita mucho
- 2 Sí, me limita un poco
- 3 No, no me limita nada

11.- Su salud actual, ¿le limita para caminar **una sola manzana** (unos 100 metros)?

- 1 Sí, me limita mucho
- 2 Sí, me limita un poco
- 3 No, no me limita nada

12.- Su salud actual, ¿le limita para **bañarse o vestirse por sí mismo**?

- 1 Sí, me limita mucho
- 2 Sí, me limita un poco
- 3 No, no me limita nada

Las siguientes preguntas se refieren a problemas en su trabajo o en sus actividades cotidianas.

13.- Durante las 4 últimas semanas, ¿tuvo que **reducir el tiempo** dedicado al trabajo o a sus actividades cotidianas, a causa de su salud física?

- 1 Sí
- 2 No

14.- Durante las 4 últimas semanas, ¿**hizo menos** de lo que hubiera querido hacer, a causa de su salud física?

- 1 Sí
- 2 No

15.- Durante las 4 últimas semanas, ¿tuvo que **dejar de hacer algunas tareas** en su trabajo o en sus actividades cotidianas, a causa de su salud física?

- 1 Sí
- 2 No

16.- Durante las 4 últimas semanas, ¿tuvo **dificultad** para hacer su trabajo o sus actividades cotidianas (por ejemplo, le costó más de lo normal), a causa de su salud física?

- 1 Sí
- 2 No

17.- Durante las 4 últimas semanas, ¿tuvo que **reducir el tiempo** dedicado al trabajo o a sus actividades cotidianas, a causa de algún problema emocional (como estar triste, deprimido, o nervioso)?

- 1 Sí
- 2 No

18.- Durante las 4 últimas semanas, ¿**hizo menos** de lo que hubiera querido hacer, a causa de algún problema emocional (como estar triste, deprimido, o nervioso)?

- 1 Sí
- 2 No

19.- Durante las 4 últimas semanas, ¿no hizo su trabajo o sus actividades cotidianas tan **cuidadosamente** como de costumbre, a causa de algún problema emocional (como estar triste, deprimido, o nervioso)?

- 1 Sí
- 2 No

20.- Durante las 4 últimas semanas, ¿hasta qué punto su salud física o los problemas emocionales han dificultado sus actividades sociales habituales con la familia, los amigos, los vecinos u otras personas?

- 1 Nada
- 2 Un poco
- 3 Regular
- 4 Bastante
- 5 Mucho

21.- ¿Tuvo **dolor** en alguna parte del cuerpo durante las 4 últimas semanas?

- 1 No, ninguno
- 2 Sí, muy poco
- 3 Sí, un poco
- 4 Sí, moderado
- 5 Sí, mucho
- 6 Sí, muchísimo

22.- Durante las 4 últimas semanas, ¿hasta qué punto el dolor le ha dificultado su trabajo habitual (incluido el trabajo fuera de casa y las tareas domésticas)?

- 1 Nada
- 2 Un poco
- 3 Regular
- 4 Bastante
- 5 Mucho

Las siguientes preguntas se refieren a cómo se ha sentido y cómo le han ido las cosas durante las 4 últimas semanas. En cada pregunta responda lo que se parezca más a cómo se ha sentido usted.

23.- Durante las 4 últimas semanas, ¿cuánto tiempo se sintió lleno de **vitalidad**?

- 1 Siempre
- 2 Casi siempre
- 3 Muchas veces
- 4 Algunas veces
- 5 Sólo alguna vez
- 6 Nunca

24.- Durante las 4 últimas semanas, ¿cuánto tiempo estuvo muy **nervioso**?

- 1 Siempre
- 2 Casi siempre
- 3 Muchas veces
- 4 Algunas veces
- 5 Sólo alguna vez
- 6 Nunca

25.- Durante las 4 últimas semanas, ¿cuánto tiempo se sintió tan **bajo de moral** que nada podía animarle?

- 1 Siempre
- 2 Casi siempre
- 3 Muchas veces
- 4 Algunas veces
- 5 Sólo alguna vez
- 6 Nunca

26.- Durante las 4 últimas semanas, ¿cuánto tiempo se sintió **calmado y tranquilo**?

- 1 Siempre
- 2 Casi siempre
- 3 Muchas veces
- 4 Algunas veces
- 5 Sólo alguna vez
- 6 Nunca

27.- Durante las 4 últimas semanas, ¿cuánto tiempo tuvo **mucha energía**?

- 1 Siempre
- 2 Casi siempre
- 3 Muchas veces
- 4 Algunas veces
- 5 Sólo alguna vez
- 6 Nunca

28.- Durante las 4 últimas semanas, ¿cuánto tiempo se sintió **desanimado y triste**?

- 1 Siempre
- 2 Casi siempre
- 3 Muchas veces
- 4 Algunas veces
- 5 Sólo alguna vez
- 6 Nunca

29.- Durante las 4 últimas semanas, ¿cuánto tiempo se sintió **agotado**?

- 1 Siempre
- 2 Casi siempre
- 3 Muchas veces

- 4 Algunas veces
- 5 Sólo alguna vez
- 6 Nunca

30.- Durante las 4 últimas semanas, ¿cuánto tiempo se sintió **feliz**?

- 1 Siempre
- 2 Casi siempre
- 3 Muchas veces
- 4 Algunas veces
- 5 Sólo alguna vez
- 6 Nunca

31.- Durante las 4 últimas semanas, ¿cuánto tiempo se sintió **cansado**?

- 1 Siempre
- 2 Casi siempre
- 3 Muchas veces
- 4 Algunas veces
- 5 Sólo alguna vez
- 6 Nunca

32.- Durante las 4 últimas semanas, ¿con qué frecuencia la salud física o los problemas emocionales le han dificultado sus actividades sociales (como visitar a los amigos o familiares)?

- 1 Siempre
- 2 Casi siempre
- 3 Algunas veces
- 4 Sólo alguna vez
- 5 Nunca

Por favor, diga si le parece cierta o falsa cada una de las siguientes frases.

33.- Creo que me pongo enfermo más fácilmente que otras personas.

- 1 Totalmente cierta
- 2 Bastante cierta
- 3 No lo sé
- 4 Bastante falsa
- 5 Totalmente falsa

34.- Estoy tan sano como cualquiera.

- 1 Totalmente cierta
- 2 Bastante cierta
- 3 No lo sé
- 4 Bastante falsa
- 5 Totalmente falsa

35.- Creo que mi salud va a empeorar.

- 1 Totalmente cierta
- 2 Bastante cierta
- 3 No lo sé
- 4 Bastante falsa
- 5 Totalmente falsa

36.- Mi salud es excelente.

- 1 Totalmente cierta
- 2 Bastante cierta
- 3 No lo sé
- 4 Bastante falsa
- 5 Totalmente falsa

14.2 ANNEX 2. CASE REPORT FORM (CRF)

CASE REPORT FORM																
Project title: <i>Patson Approach versus the Standard Approach for increasing breast reconstruction rates in women undergoing mastectomy</i>				Patient's identification number												
<p>Instructions:</p> <ul style="list-style-type: none"> - Please write the patient's identification number in the boxes above. - Mark "x" in appropriate boxes. Do not forget to mark any box. - Make sure you have marked the right box and that the "x" is clear and understandable. - Before collecting the data, write your surname and the date when the data is collected next to each appointment as it is indicated. - Mark "x" in the box next to each appointment's name only if the patient has attended to it. The psycho-oncologist's appointments are only for patients who belong to the Patson approach. Mark "x" if the patient has attended to the appointment. - If you are not sure of the answer or you have problems with some item, please contact with Dr. Viu by phone at 687060477. 																
APPOINTMENT 1		<input type="checkbox"/>	Doctor's surname: Date:													
The patient has read the Information sheet		<input type="checkbox"/>														
The patient has signed the Informed consent		<input type="checkbox"/>														
1st PSYCHO-ONCOLOGIST'S APPOINTMENT		<input type="checkbox"/>	Psycho-oncologist's surname: Date:													
APPOINTMENT 2		<input type="checkbox"/>	Doctor's surname: Date:													
Standard approach		<input type="checkbox"/>	New approach		<input type="checkbox"/>											
Age (years)		<table style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: center; padding: 5px;">Marital status</th> </tr> <tr> <td style="padding: 5px;">Single</td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">In a relationship/married</td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">Divorced</td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">Widowed</td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> </tr> </table>					Marital status		Single	<input type="checkbox"/>	In a relationship/married	<input type="checkbox"/>	Divorced	<input type="checkbox"/>	Widowed	<input type="checkbox"/>
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Height (m)																
Weight (kg)																
BMI (kg/m²)																

2nd PSYCHO-ONCOLOGIST'S APPOINTMENT <input style="float: right;" type="checkbox"/>	Psycho-oncologist's surname: Date:												
SURGERY <input style="float: right;" type="checkbox"/>	Doctor's surname: Date:												
<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> Unilateral mastectomy <input type="checkbox"/> Bilateral mastectomy <input type="checkbox"/> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> Breast reconstruction Yes <input type="checkbox"/> No <input type="checkbox"/> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> Nipple preservation Yes <input type="checkbox"/> No <input type="checkbox"/> </div> <div style="border: 1px solid black; padding: 5px;"> Lymph nodes dissection Yes <input type="checkbox"/> No <input type="checkbox"/> </div>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> Timing of the reconstruction Immediate <input type="checkbox"/> Delayed <input type="checkbox"/> Delayed-immediate <input type="checkbox"/> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> Reconstruction technique Expander/implant <input type="checkbox"/> Latissimus dorsi flap <input type="checkbox"/> TRAM flap <input type="checkbox"/> </div> <div style="border: 1px solid black; padding: 5px;"> Surgeon number <input type="checkbox"/> </div>												
APPOINTMENT 3 <input style="float: right;" type="checkbox"/>	Doctor's surname: Date:												
Postoperative complications <input type="checkbox"/> Yes <input type="checkbox"/> No													
3rd PSYCHO-ONCOLOGIST'S APPOINTMENT <input style="float: right;" type="checkbox"/>	Psycho-oncologist's surname: Date:												
APPOINTMENT 4 <input style="float: right;" type="checkbox"/>	Doctor's surname: Date:												
<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;"></th> <th style="width: 20%; text-align: center;"><u>Answered</u></th> <th style="width: 20%; text-align: center;"><u>Punctuation</u></th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">BRECON-31</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td style="text-align: center;">HADS</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td style="text-align: center;">SF-36</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input style="width: 100%;" type="text"/></td> </tr> </tbody> </table>			<u>Answered</u>	<u>Punctuation</u>	BRECON-31	<input type="checkbox"/>	<input style="width: 100%;" type="text"/>	HADS	<input type="checkbox"/>	<input style="width: 100%;" type="text"/>	SF-36	<input type="checkbox"/>	<input style="width: 100%;" type="text"/>
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HADS	<input type="checkbox"/>	<input style="width: 100%;" type="text"/>											
SF-36	<input type="checkbox"/>	<input style="width: 100%;" type="text"/>											

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14.3 ANNEX 3. INFORMATION SHEET FOR PARTICIPANTS

English Version

INFORMATION SHEET FOR PARTICIPANTS

Project title: Patson Approach versus the Standard Approach for increasing breast reconstruction rates in women undergoing mastectomy

You are being invited to take part in a research study about the medical care of patients diagnosed of breast cancer and being treated surgically.

Please take time to read the following information about the study carefully. It is important for you to understand why the research is being done and what it will involve. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

Why have I been chosen to participate in this study?

You have been invited to participate in a comparison study of two approaches in the medical care of patients diagnosed of breast cancer that will last 1 year. It will be compared the standard approach with a new one, called Patson Approach, which has been approved for patients diagnosed of breast cancer that will be treated with mastectomy and are candidates for breast reconstruction.

What is the purpose of the study?

The aim of the study is to compare two approaches of medical care, in patients diagnosed of breast cancer that will be treated surgically with mastectomy. It will be compared the standard approach with a new one that will pretend to increase the number of women who undergo breast reconstruction. Others aims of the study are to find out if that new approach increases satisfaction of breast reconstruction, if it increases quality of life and if it decreases depression and anxiety symptoms.

How many women will participate in this study?

Approximately 62 women diagnosed of breast cancer of the Hospital Universitari de Girona Doctor Josep Trueta and Hospital Santa Caterina de Salt will take part in the study.

What will happen to me if I take part?

If you signed the informed consent, you will be randomly assigned to one of the two approaches of medical care. Both approaches will involve 6 doctor's appointments (and the ones you need) during the period of 1 year. If you belong to the new approach, it is also involved three psycho-oncologist's appointments.

In your first appointment, you will be asked to give some information about your personal data and oncological medical history to prove if you satisfy the requirements to be included in the study. If you meet the criteria and you sign the informed consent, you will be informed in the following days about the second preoperative appointment with a plastic surgeon who will explain you the breast reconstruction options. After the surgery, having or not opted for reconstruction, there will be the third appointment to evaluate your status after the intervention.

The fourth, fifth and sixth appointment will take place 3 months, 6 months and one year after the surgery respectively, and you will be asked to answer some questionnaires. Filling the questionnaires will take less than 1 hour, depending on the number of available questionnaires in your native language. These questionnaires will ask your opinion about some life aspects as the satisfaction if you have had breast reconstruction, your quality of life and your mood.

You will receive all the follow-up appointments that you need.

Will being in a study conflict with my care?

Your participation in the study will not conflict with your medical care. Both approaches are quality tested and personalised. The differences are the number of appointments that involves each of the approaches without affecting to the medical care quality.

What are my responsibilities if I take part in the study?

- To go to all the study's appointments and other appointments asked by the study team.
- To follow all the study's instructions.
- To inform about any problem or doubt during the study.
- To answer all the questionnaires when asked by the study team during the appointments.

Can I stop once I start, or change my mind about being in the study?

Your participation in this study is optional. You can decide to withdraw from the study at any time without affecting the standard of care you will receive in the future. Before withdrawing from the study, you should tell your study's doctor about your decision.

The study's doctor can withdraw you from the study at any time. You can also be withdrawn because of the following reasons: if you decide not to take part in the study after giving the consent, if you do not follow the study's instructions, if you do not attend to all the appointments or if there are medical or personal reasons that lead you to withdraw from the study.

What are the possible benefits of taking part?

The information we get from this study may help us to treat future patients with a similar condition better. However, it is not guaranteed that your condition will be better as a consequence of participating in the study.

What are the foreseeable risks or inconveniences of taking part?

There are no risks or inconveniences foreseen for taking part in the study.

What happens when the research study stops?

Once the study has finished, you will receive the medical care you need depending on your condition without affecting having or not participate in the study.

Will I be paid?

We will repay all the reasonable travel expenses because of your participation in the study.

Will my taking part in this study be kept confidential?

If you consent to take part in the research, the study's team will collect information about you during the course of the research (like your name and other personal data, surgery data and the study's results). All information which is collected about you will not be identified with your name but with a code that only your study's doctor/collaborators will have access to and will be able to relate the data with you and your clinical history. Your name will not appear in any study's report and these reports will be used only for research purposes. You have the right to consult all the collected information about you in the study and to rectify any wrong data.

All the information which is collected about you during the course of the research will be kept strictly confidential ensuring the compliance of the Organic Law 15/1999 of 13 December on the Protection of Personal Data. You can exercise at any time your rights of access, rectification, elimination or opposition to your personal data. However, if you decide to withdraw your consent for the use and divulgation of you recognisable medical data, you will not be able to be part of the study. All the collected or used recognisable medical data before the day you decide to formally withdraw your consent can be still used and divulgate for the study members for research purposes.

What will happen to the results of the research study?

Once the study has finished, we planned to publish the results always keeping all the personal data confidential.

Who has reviewed the study?

The study has been reviewed by the Clinical Research Ethics Committee (CREC) of Hospital Universitari de Girona Doctor Josep Trueta and Hospital Santa Caterina de Salt.

Who can I contact to for Further Information or problems?

If you have any questions about the study please contact Dr. Viu by phone 687060477 or by e-mail u1904918@campus.udg.edu

If you have any questions about your rights as a research subject, about your participation in the study or any complains about the study, please contact with your research doctor.

Catalan version

FULL D'INFORMACIÓ PER AL PACIENT

Títol de l'estudi: L'enfocament Patson versus l'enfocament Estàndard en l'augment de les taxes de reconstrucció en dones candidates a mastectomia.

Vostè ha estat convidada a participar en un estudi d'investigació sobre el maneig d'atenció mèdica de les pacients en el tractament quirúrgic del càncer de mama.

Per a participar s'haurà de prendre el temps necessari per a llegir aquest formulari en el qual s'inclou un resum de la informació sobre l'estudi. És important que entengui perquè s'està realitzant la recerca i que inclou. La convidem a preguntar-nos tot allò que no li hagi quedat clar o si li agradaria rebre més informació. Prengui's el seu temps per a decidir si desitja o no participar en l'estudi.

Gràcies per llegir el formulari.

Per què se m'ha demanat que participi en aquest estudi?

Se li ha sol·licitat que participi en un estudi de comparació de dos enfocaments en l'atenció mèdica de pacients amb càncer de mama durant 1 any. Es compararà l'enfocament actual amb un nou enfocament d'atenció mèdica, anomenat enfocament Patson, el qual està aprovat per a pacients amb càncer de mama que seran tractades amb mastectomia i són candidates a reconstrucció mamària.

Per què es realitza aquest estudi?

El propòsit d'aquest estudi consisteix en comparar dos enfocaments d'atenció mèdica, en pacients amb diagnòstic de càncer de mama i que rebran tractament quirúrgic amb mastectomia. Es compararà l'enfocament actual amb un nou enfocament en el qual es pretén que s'augmenti el número de dones que opten per la reconstrucció mamària com a part del tractament. Altres propòsits d'aquest estudi són esbrinar si aquest nou enfocament augmenta la satisfacció en la reconstrucció mamària, si augmenta la qualitat de vida i si disminueix el símptomes de depressió i ansietat.

Quantes dones participaran en aquest estudi?

En aquest estudi participaran aproximadament 62 dones amb càncer de mama de l'Hospital Universitari de Girona Doctor Josep Trueta i Hospital Santa Caterina de Salt.

Què passarà si participo en aquest estudi?

Si vostè accepta participar en l'estudi, se li assignarà aleatòriament a un dels dos enfocaments d'atenció mèdica. En els dos enfocaments haurà de realitzar 6 visites programades (més les visites que vostè necessiti) a la consulta durant el transcurs d'1 any. Si vostè pertany al nou enfocament, rebrà, a més a més, tres visites amb un psicòleg especialista en oncologia.

En la seva primera visita programada a la consulta, se li sol·licitarà que ens faciliti informació sobre les seves dades personals i antecedents oncològics amb la finalitat de comprovar si compleix els requisits per a participar en l'estudi. Si vostè compleix tots els requisits de l'estudi i si firma el consentiment informat, se li informarà en els dies posteriors de la segona visita preoperatòria amb el cirurgià plàstic en la qual se li explicarà les opcions de reconstrucció mamària. Després de la cirurgia, hagi optat o no per la reconstrucció, tindrà lloc la tercera visita programa per a avaluar el seu estat després de la intervenció.

La quarta, cinquena i sisena visites programades tindran lloc 3 mesos, 6 mesos i 1 any després de la intervenció respectivament, i se li demanarà que complimenti una sèrie de qüestionaris. Pot tardar menys d'1 hora en complimentar els qüestionaris, depenent del número de qüestionaris que estiguin disponibles per a complimentar en el seu idioma local. Aquests qüestionaris li preguntaran la seva opinió sobre varis aspectes de la seva vida, com el grau de satisfacció si vostè opta per la reconstrucció mamària, la qualitat de vida i l'estat anímic.

A part de les visites programades, vostè rebrà totes les visites de seguiment que necessiti.

Participar en l'estudi afectarà a la meva atenció mèdica?

La seva participació en l'estudi no afectarà a la seva atenció mèdica. Si vostè pertany a un enfocament o un altre, rebrà una atenció de qualitat i personalitzada. Les diferències recauen en el número de visites a les quals vostè haurà d'assistir sense que això afecti a la qualitat de l'assistència.

Quines són les meves responsabilitats si participo en aquest estudi?

- Assistir a la consulta per a totes les visites de l'estudi i altres visites sol·licitades pel personal de l'estudi.
- Seguir totes les instruccions del protocol de l'estudi.
- Informar al personal de l'estudi sobre qualsevol problema o dubte que presenti durant l'estudi.
- Complimentar tots els qüestionaris quan sigui sol·licitat pel personal de l'estudi durant les seves visites a la consulta.

Puc retirar-me o canviar d'opinió una vegada iniciat l'estudi?

La seva participació en aquest estudi és voluntària. Pot decidir abandonar l'estudi en qualsevol moment i sense que afecti la seva atenció en el futur. Abans de fer-ho, haurà de parlar amb el metge de l'estudi sobre la seva decisió.

El metge de l'estudi pot decidir retirar-la d'aquest estudi en qualsevol moment. També se la retirarà d'aquest estudi per qualsevol de les següents raons: si vostè retira el seu consentiment, si no segueix les normes de l'estudi, si vostè no assisteix a les visites programades o si existeixen raons mèdiques o personals que fan necessari que deixi l'estudi.

Participar en aquest estudi implica algun benefici?

Els resultats de l'estudi podrien ajudar a persones que tinguin una afecció semblant en el futur. No obstant, no hi ha garanties que la seva condició millori com a conseqüència de la seva participació en aquest estudi.

Quins són els possibles riscos o inconvenients de participar en aquest estudi?

No es preveuen riscos ni inconvenients per participar en aquest estudi.

Què passarà quan finalitzi l'estudi?

Una vegada finalitzat l'estudi, vostè rebrà l'atenció mèdica que necessiti segons la seva condició sense afectar que vostè hagi participat o no en l'estudi.

Se'm pagarà per participar?

L'hospital en el qual es realitza l'estudi li reemborsarà les despeses de desplaçament raonables degut a la seva participació en l'estudi.

Com es mantindrà la confidencialitat de la meva informació personal?

Si participa en aquest estudi, el personal de l'estudi recopilarà informació sobre vostè (com el seu nom i altres dades personals, dades sobre la cirurgia i els resultats de l'estudi). Aquesta informació recopilada no l'identificarà pel seu nom sinó únicament per un codi i només el seu metge de l'estudi/col·laboradors podran relacionar aquestes dades amb vostè i amb la seva història clínica. No s'utilitzarà el seu nom en cap informe de l'estudi i aquests informes s'utilitzaran únicament amb finalitats de recerca. Té dret a consultar tota la informació recopilada sobre vostè en aquest estudi i a rectificar qualsevol dada errònia.

Tota la informació recopilada durant aquest assaig clínic es mantindrà confidencial garantint en tot moment el compliment de les disposicions de la Llei Orgànica 15/1999, de 13 de desembre, sobre la protecció de dades de caràcter personal. Pot exercir en qualsevol moment els seus drets d'accés, rectificació, eliminació i oposició a les seves dades personals. No obstant, si retira la seva autorització (consentiment) per a l'ús i divulgació de la seva informació mèdica identificable, no podrà seguir participant en aquest assaig d'investigació clínic. Qualsevol informació mèdica identificable recopilada o utilitzada abans de la data en la qual va retirar formalment la seva autorització pot seguir essent utilitzada o divulgada pels investigadors per als fins descrits en aquesta secció.

Què passarà amb els resultats de l'estudi?

Una vegada finalitzat l'estudi es preveu publicar els resultats sempre mantenint la confidencialitat de les seves dades.

Qui ha revisat l'estudi?

L'estudi ha estat revisat pel Comitè d'Ètica i Investigació Clínica (CEIC) de l'Hospital Universitari de Girona Doctor Josep Trueta i Hospital Santa Caterina de Salt.

Amb qui puc contactar si tinc preguntes o problemes?

Pot trucar a la Dra. Viu al 687060477 o enviar un correu a u1904918@campus.udg.edu si té alguna pregunta sobre aquest estudi.

Si té preguntes sobre els seus drets com a subjecte d'una investigació, sobre la seva participació en l'estudi o queixes sobre l'estudi, pot posar-se en contacte amb el seu metge de l'estudi.

Spanish version

HOJA DE INFORMACIÓN PARA EL PACIENTE

Título del estudio: El enfoque Patson versus el enfoque Estándar en el incremento de las tasas de reconstrucción de mama en mujeres candidatas a mastectomía.

Usted ha sido invitada a participar en un estudio de investigación sobre el manejo de atención médica de las pacientes en el tratamiento quirúrgico del cáncer de mama.

Para participar debe usted tomarse el tiempo necesario para leer este formulario en el que se incluye un resumen de la información sobre el estudio. Es importante que entienda porqué se está realizando la investigación y que incluye. Le invitamos a preguntarnos todo aquello que no le ha quedado claro o si le gustaría recibir más información. Tómese su tiempo para decidir si quiere o no participar en el estudio.

Gracias por leer el formulario.

¿Por qué se me ha pedido que participe en este estudio?

Se le ha solicitado que participe en un estudio de comparación de dos enfoques en la atención médica de pacientes con cáncer de mama durante el transcurso de 1 año. Se comparará el enfoque actual con un nuevo enfoque de atención médica, nombrado enfoque Patson, el cual está aprobado para pacientes con cáncer de mama que serán tratadas con mastectomía y son candidatas a reconstrucción mamaria.

¿Por qué se realiza este estudio?

El propósito de este estudio consiste en comparar dos enfoques de atención médica, en pacientes con diagnóstico de cáncer de mama y que recibirán tratamiento quirúrgico con mastectomía. Se comparará el enfoque actual con un nuevo enfoque en el que se pretende que aumente el número de mujeres que optan por la reconstrucción mamaria como parte del tratamiento. Otros propósitos de este estudio son averiguar si este nuevo enfoque aumenta la satisfacción en la reconstrucción mamaria, si aumenta la calidad de vida y si disminuye los síntomas de depresión y ansiedad.

¿Cuántas mujeres participarán en este estudio?

En este estudio participarán aproximadamente 62 mujeres con cáncer de mama del Hospital Universitari de Girona Doctor Josep Trueta y Hospital Santa Caterina de Salt.

¿Qué sucederá si participo en este estudio?

Si usted acepta participar en el estudio, se le asignará aleatoriamente uno de los dos enfoques de atención médica. En los dos enfoques deberá realizar 6 visitas programadas (más las que usted precise) a la consulta durante el transcurso de 1 año. Si usted pertenece al nuevo enfoque, recibirá además tres visitas con un psicólogo especialista en oncología.

En su primera visita programada a la consulta, se le solicitará que nos facilite información sobre sus datos personales y antecedentes oncológicos con el fin de comprobar si cumple los requisitos para participar en el estudio. Si usted cumple todos los requisitos del estudio y firma el consentimiento informado, se le informará en los días posteriores de la segunda visita preoperatoria con el cirujano plástico en la que le explicará las opciones de reconstrucción mamaria. Después de la cirugía, haya optado por la reconstrucción o no, tendrá lugar la tercera visita programada para evaluar su estado después de la intervención.

La cuarta, quinta y sexta visita programadas tendrán lugar a los 3 meses, 6 meses y 1 año después de la intervención respectivamente, y se le pedirá que cumplimente una serie de cuestionarios. Puede tardar menos de 1 hora en cumplimentar los cuestionarios, dependiendo del número de cuestionarios que estén disponibles para cumplimentar en su idioma local. Estos cuestionarios le preguntarán su opinión sobre varios aspectos de su vida, como el grado de satisfacción si usted opta por la reconstrucción mamaria, su calidad de vida y su estado anímico.

Además de las visitas programadas usted recibirá todas las visitas de seguimiento que precise.

¿Participar en el estudio afectará a mi atención médica?

Su participación en el estudio no afectará a su atención médica. Si usted pertenece a un enfoque o a otro, recibirá una atención de calidad y personalizada. Las diferencias recaen en el número de visitas a las cuáles usted deberá asistir sin que esto afecte a la calidad de la asistencia.

¿Cuáles son mis responsabilidades si participo en este estudio?

- Acudir a la consulta para todas las visitas del estudio y otras visitar solicitadas por el personal del estudio.
- Seguir todas las instrucciones del protocolo del estudio.
- Informar al personal del estudio sobre cualquier problema o duda que presente durante el estudio.

- Complimentar todos los cuestionarios según lo solicitado por el personal del estudio durante sus visitas a la consulta.

¿Puedo retirarme o cambiar de opinión una vez empezado el estudio?

Su participación en este estudio es voluntaria. Puede decidir abandonar el estudio en cualquier momento y sin que afecte a su atención en el futuro. Antes de hacerlo, debe hablar con el médico del estudio de su decisión.

El médico del estudio puede decidir retirarla de este estudio en cualquier momento. También la retiraremos de este estudio por cualquiera de las siguientes razones: si usted retira su consentimiento, si no sigue las normas del estudio, si usted no asiste a las visitas programadas o si existen razones médicas o personales que hacen necesario que deje el estudio.

¿Participar en este estudio implica algún beneficio?

Los resultados del estudio podrían ayudar a personas que tengan una afección similar en el futuro. No obstante, no hay garantías de que su condición mejore como consecuencia de su participación en este estudio.

¿Cuáles son los posibles riesgos o inconvenientes de participar en este estudio?

No se prevén riesgos ni inconvenientes por participar en este estudio.

¿Qué pasará cuando finalice el estudio?

Una vez finalizado el estudio, usted recibirá la atención médica que precise según su condición sin afectar que usted haya participado o no en el estudio.

¿Se me pagará por participar?

El hospital en el que se realiza el estudio le reembolsará los gastos de desplazamiento razonables por su participación en el estudio.

¿Cómo se mantendrá la confidencialidad de mi información personal?

Si participa en este estudio, el personal del estudio recopilará información acerca de usted (como su nombre y otros datos personales, datos sobre la cirugía y los resultados del estudio). Esta información recopilada no le identificará por su nombre, sino únicamente por un código y solo su médico del estudio/colaboradores podrán relacionar dichos datos con usted y con su historia clínica. No se utilizará su nombre en ningún informe del estudio y estos informes se

utilizarán únicamente con fines de investigación. Tiene derecho a consultar toda la información recopilada sobre usted en este estudio y a rectificar cualquier dato erróneo.

Toda información recopilada durante este ensayo clínico se mantendrá confidencial garantizando en todo momento el cumplimiento de las disposiciones de la Ley Orgánica 15/1999, de 13 de diciembre, sobre la protección de datos de carácter personal. Puede ejercer en cualquier momento sus derechos de acceso, rectificación, eliminación y oposición a sus datos personales. Sin embargo, si retira su autorización (consentimiento) para el uso y divulgación de su información médica identificable, no podrá seguir participando en este ensayo de investigación clínica. Cualquier información médica identificable recopilada o usada antes de la fecha en que retiró formalmente su autorización puede seguir siendo utilizada o divulgada por los investigadores para los fines descritos en esta sección.

¿Qué pasará con los resultados del estudio?

Una vez finalizado el estudio se prevé publicar los resultados siempre manteniendo la confidencialidad de sus datos.

¿Quién ha revisado el estudio?

El estudio ha sido revisado por el Comité de Ética e Investigación Clínica (CEIC) del Hospital Universitari de Girona Doctor Josep Trueta y Hospital Santa Caterina de Salt.

¿Con quién puedo comunicarme si tengo preguntas o problemas?

Puede llamar a la Dra. Viu al 687060477 o mandar un correo a u1904918@campus.udg.edu si tiene alguna pregunta sobre este estudio.

Si tiene preguntas acerca de sus derechos como sujeto de una investigación, sobre su participación en el estudio o quejas sobre el estudio, puede ponerse en contacto con su médico del estudio.

14.4 ANNEX 4. INFORMED CONSENT FOR PARTICIPANTS

English Version

INFORMED CONSENT FORM		
<p>Project title: <i>Patson Approach versus the Standard Approach for increasing breast reconstruction rates in women undergoing mastectomy</i></p>		
<hr/>		
<ul style="list-style-type: none">• I have read the Information sheet for participants and the Informed consent form. I understand that I can keep a copy of both.• I understand what I will be ask to do during the study and I have had enough time to think about what the study will mean to me.• I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.• I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.• I give permission for the study's members to have access to my clinical history with verifying purposes and to my study's records always ensuring the compliance of the Organic Law 15/1999 of 13 December on the Protection of Personal Data.• I consent voluntarily to participate as a participant in this research.		
Participant:		
_____	_____	_____
Name of Participant	Signature	Date
Researcher:		
_____	_____	_____
Name of Researcher	Signature	Date

Catalan Version

FORMULARI DE CONSENTIMENT INFORMAT

Títol de l'estudi: *L'enfocament Patson versus l'enfocament Estàndard en l'augment de les taxes de reconstrucció en dones candidates a mastectomia*

- He llegit el Full d'informació per al pacient i el Formulari de consentiment informat. Entenc que podré conservar una còpia d'ambdós.
- Entenc què se'm sol·licitarà que faci durant aquest estudi i he tingut temps per a pensar en la implicació que té l'estudi per mi.
- He parlat sobre l'estudi amb el metge o el personal de l'estudi i han respòs a les meves preguntes de forma satisfactòria.
- Entenc que la decisió de participar o no en l'estudi depèn de mi, que puc canviar d'idea més endavant i que, independentment de la meva decisió, la meva atenció mèdica i els meus drets legals no es veuran afectats.
- Dono permís al personal de l'estudi perquè consultin la meva història clínica amb finalitats de verificació de dades i la meva informació recopilada en l'estudi. Sempre en conformitat amb la Llei Orgànica 15/1999, de 13 de desembre, sobre protecció de dades de caràcter personal.
- Accepto voluntàriament participar en aquest estudio d'investigació.

Participant:

Nom del Participant

Firma

Data

Investigador:

Nom de l'investigador

Firma

Data

Spanish Version

FORMULARIO DE CONSENTIMIENTO INFORMADO

Título del estudio: *El enfoque Patson versus el enfoque Estándar en el incremento de las tasas de reconstrucción de mama en mujeres candidatas a mastectomía*

- He leído la Hoja de información para el paciente y el Formulario de consentimiento informado. Entiendo que podré conservar una copia de ambos.
- Entiendo lo que se me solicitará que haga durante este estudio y he tenido tiempo para pensar en lo que el estudio implica para mí.
- He hablado sobre el estudio con el médico o el personal del estudio y han respondido a mis preguntas de forma satisfactoria.
- Entiendo que la decisión de participar o no en el estudio depende de mí, que puedo cambiar de idea más adelante y que independientemente de lo que decida, mi atención médica y mis derechos legales no se verán afectados.
- Otorgo permiso al personal del estudio para que consulten mi historia clínica con fines de verificación de datos y mi información recopilada en el estudio. Siempre en conformidad con la Ley Orgánica 15/1999, de 13 de diciembre, sobre protección de datos de carácter personal.
- Acepto voluntariamente participar en este estudio de investigación.

Participante:

Nombre del Participante Firma Fecha

Investigador:

Nombre del investigador Firma Fecha

14.5 ANNEX 5. CHRONOGRAM

			2014	2015				2016				2017				2018	
			Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun
STAGE 1	Obtaining ethical approval (CREC)	PS1															
	Informative meeting	ALL															
	Training for using the CRF	ALL															
	Database elaboration	CE															
STAGE 2	Research team meetings	ALL															
	Pilot experiment of the CRF	ALL															
	Recruiting, randomization, coding and data collection	ALL															
	Data cleansing, quality assurance and control	CE, SS															
STAGE 3	Statistical analysis	SS															
	Interpretation and discussion of the results	GY, ON, PS1, PO, SS															
STAGE 4	Publication of the results	ALL															
	Dissemination of the findings	PS1															

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