UNIVERSITAT DE BARCELONA

Cognitive emotional and social aspects in breast cancer

Laura Ciria Suárez

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UNIVERSITAT DE BARCELONA

Facultat de Psicologia

COGNITIVE, EMOTIONAL AND SOCIAL ASPECTS IN BREAST CANCER

Thesis presented by

Laura Ciria Suárez

To qualify for the degree of

Ph.D of Psychology

Doctoral Program in **Clinical and Health Psychology.** University of Barcelona

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University of Barcelona

Directed by

Dra. Caterina Calderón Garrido

Dra. Paula Jiménez Fonseca

UNIVERSITAT DE BARCELONA

Facultat de Psicologia

Caterina Calderón Garrido, Doctor in Psychology and Associate Professor at the Faculty of Psychology of the University of Barcelona.

Paula Jiménez Fonseca, Doctor of Medicine and Surgery. Department of Medical Oncology. Central University Hospital of Asturias, Oviedo.

CERTIFY:

That the work entitled "**Cognitive, Emotional and Social Aspects in Breast Cancer**" has been made entirely by Laura Ciria Suárez under our supervision. This work has been completed and, in our opinion, it meets all the necessary merits to qualify for the Doctorate Degree from the University of Barcelona.

And for the record for the appropriate purposes, we sign this certification in June 2021:

Sgd.	Sgd.
Caterina Calderón Garrido	Paula Jiménez Fonseca

This thesis is dedicated to my grandmother Ignacia.

My gratitude to all those who have supported me throughout this time, especially Caterina Calderon, for having always been my guide and reference.

I would also like to thank all those patients and healthcare professionals who have selflessly collaborated in this research.

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Abstract

Background: Breast cancer is one of the most prevalent diseases in women. Prevention and treatments have lowered mortality; nevertheless, the impact of diagnosis and treatment continue to affect all aspects of patients' lives (physical, emotional, cognitive, social, and spiritual). The presence of psychological distress, anxiety and depression are still very prevalent. Cancer treatment often involves surgery, radiotherapy, chemotherapy, or hormonal therapy, treatment options that must be assessed and decided, and where patients have a relevant role. Shared decision-making (SDM) regarding adjuvant systemic therapy is based on both properly conveying information about the prognosis of the disease and the benefits and risks of adjuvant treatment, as well as the patient's ability to understand this information.

Aims: This research has two objectives: 1) Describe breast cancer patient's experiences throughout all the stages of their disease with a journey model, and 2) Examine doctor-patient coincidence with respect to the estimation of relapse with/without adjuvant chemotherapy and regarding the risk of treatment toxicity.

Methods: To meet the first objective, a qualitative study was designed. Twenty-one women with breast cancer or survivors were recruited at 9 large hospitals in Spain and intentional sampling methods were applied. Data were collected using a semi-structured interview that was elaborated with the help of medical oncologists, nurses, and psycho-oncologists. Data were processed by adopting a thematic analysis approach.

To attain the second objective, cross-sectional, multicenter study was conducted. It involved 281 breast cancer patients and 23 oncologists employed at 11 Spanish hospitals. Prognosis (risk of recurrence with and without chemotherapy and risk of severe toxicity with chemotherapy) and SDM questionnaires were completed by oncologists and breast cancer patients. These last ones also filled out the 18-item Brief Symptom Inventory scale (BSI-18).

Results: The diagnosis and treatment of breast cancer entails a radical change in patients’ day-to-day that linger in the mid-term. Seven stages have been defined that correspond to the different medical processes: diagnosis/unmasking stage, surgery/cleaning out, chemotherapy/loss of identity, radiotherapy/transition to normality, follow-up care/the “new” day-to-day, relapse/starting over, and metastatic/time-limited chronic breast cancer. The most relevant aspects of each of the states are highlighted, as are the various cross-sectional aspects that manifest throughout the patient´s journey.

The results of the second objective indicate that oncologists' prediction of risk of relapse without and with chemotherapy (30.4 and 13.3%) and risk of severe toxicity (9.8%) were more optimistic than those of breast cancer patients (78.6, 29.6, and 61.0%, respectively). The greater the severity, the higher the risk of relapse according to the oncologists ($p = 0.001$); not so for the patients. Older physicians and more experienced ones predicted lower risk of relapse with and without chemotherapy and less severe toxicity than younger doctors and those with less experience ($p < 0.001$). Oncologists' SDM and their prediction of risk of relapsing with chemotherapy correlated negatively with patients' SDM and their prediction of risk of severe toxicity ($p < 0.01$). There is a positive correlation between psychological distress (BSI-18) and the estimated risk of recurrence with chemotherapy in breast cancer patients ($p < 0.001$). These results stress the importance of improving doctor-patient communication in SDM.

Conclusions: An in-depth understanding of breast cancer patients' experiences favor patient-centered care, which facilitates a better adjustment of the healthcare professional as well as the detection of risk situations, helping to identify the key moments when more precise information and support should be offered. Similarly, preparing women for the process they have to face and for the sequelae of treatments would contribute to reduce their uncertainty and concern, and improve their quality-of-life.

In breast cancer patients undergoing treatment with curative intent, enhancing doctor-patient communication to coincide more the respect to risk of relapse and toxicity would raise expectations of cure, decrease treatment-related anxiety, and achieve a more realistic estimate of the risk of relapse and toxicity.

Keywords: Patient journey, Breast cancer, Patient voice, Prognosis, Shared decision making, Doctor-patient communication.

Resumen

Antecedentes: El cáncer de mama es una de las enfermedades más prevalentes en la mujer. La prevención y los tratamientos han reducido la mortalidad; sin embargo, el impacto del diagnóstico y el tratamiento continúa afectando todos los aspectos de la vida de los pacientes (físico, emocional, cognitivo, social y espiritual). La presencia de angustia psicológica, ansiedad y depresión sigue siendo muy frecuente. El tratamiento del cáncer a menudo implica cirugía, radioterapia, quimioterapia u hormonoterapia, opciones de tratamiento que deben evaluarse y decidirse, y donde los pacientes tienen un papel relevante. La toma de decisiones compartida (TDC) con respecto a la terapia sistémica adyuvante se basa en la transmisión adecuada de información sobre el pronóstico de la enfermedad, los beneficios y los riesgos del tratamiento adyuvante, así como en la capacidad del paciente para comprender esta información.

Objetivos: Esta investigación tiene dos objetivos: 1) Describir las experiencias de las pacientes con cáncer de mama a lo largo de todas las etapas de su enfermedad con un "patient journey", y 2) Examinar la coincidencia médico-paciente con respecto a la estimación de la recaída con / sin quimioterapia adyuvante y con respecto al riesgo de toxicidad del tratamiento.

Métodos: Para cumplir con el primer objetivo se diseñó un estudio cualitativo. Se reclutaron 21 mujeres con cáncer de mama o supervivientes en 9 grandes hospitales de España y se aplicaron métodos de muestreo intencional. Los datos se recolectaron mediante una entrevista semiestructurada que se elaboró con la ayuda de médicos oncólogos,

enfermeras y psicooncólogos. Los datos se procesaron adoptando un enfoque de análisis temático.

Para alcanzar el segundo objetivo, se realizó un estudio transversal y multicéntrico. En él participaron 281 pacientes con cáncer de mama y 23 oncólogos de 11 hospitales españoles. Los oncólogos y los pacientes con cáncer de mama completaron los cuestionarios de pronóstico (riesgo de recurrencia con y sin quimioterapia y riesgo de toxicidad grave con quimioterapia) y los cuestionarios de TDC. Estos últimos también cumplimentaron la escala de Inventario Breve de Síntomas de 18 ítems (BSI-18).

Resultados: El diagnóstico y tratamiento del cáncer de mama conlleva un cambio radical en el día a día de las pacientes que perdura a medio plazo. Se han definido siete etapas que corresponden a los diferentes procesos médicos: etapa de diagnóstico / desenmascaramiento, cirugía / “limpieza”, quimioterapia / pérdida de identidad, radioterapia / transición a la normalidad, atención de seguimiento / el “nuevo” día a día, recaída / comienzo de nuevo, y cáncer de mama crónico metastásico / limitado en el tiempo. Se destacan los aspectos más relevantes de cada uno de los estados, así como los diversos aspectos transversales que se manifiestan a lo largo del recorrido del paciente.

Los resultados del segundo objetivo indican que la predicción de los oncólogos del riesgo de recaída sin y con quimioterapia (30,4 y 13,3%) y el riesgo de toxicidad grave (9,8%) fueron más optimistas que las de las pacientes con cáncer de mama (78,6, 29,6 y 61,0 %, respectivamente). A mayor gravedad, mayor riesgo de recaída según los oncólogos ($p = 0,001$); no así para los pacientes. Los médicos de mayor edad y los más experimentados predijeron un menor riesgo de recaída con y sin quimioterapia y una toxicidad menos grave que los médicos más jóvenes y

aquellos con menor experiencia (p <0,001). La TDC de los oncólogos y su predicción del riesgo de recaída con la quimioterapia se correlacionaron negativamente con la TDC de los pacientes y su predicción del riesgo de toxicidad grave (p <0,01). Existe una correlación positiva entre la angustia psicológica (BSI-18) y el riesgo estimado de recurrencia con quimioterapia en pacientes con cáncer de mama (p <0,001). Estos resultados subrayan la importancia de mejorar la comunicación médico-paciente en la TDC.

Conclusiones: Un conocimiento profundo de las vivencias de los pacientes de cáncer de mama favorece la atención centrada en el paciente, lo que facilita un mejor ajuste del profesional de la salud, así como la detección de situaciones de riesgo, ayudando a identificar los momentos clave en los que se debe ofrecer información y apoyo más preciso. Asimismo, preparar a las mujeres para el proceso que deben afrontar y las secuelas de los tratamientos contribuiría a reducir su incertidumbre e inquietud y mejorar su calidad de vida.

En pacientes con cáncer de mama que se someten a un tratamiento con intención curativa, mejorar la comunicación médico-paciente para que se ajuste más al riesgo de recaída y al de toxicidad aumentaría las expectativas de curación, disminuiría la ansiedad relacionada con el tratamiento y lograría una estimación más realista del riesgo de recaída y toxicidad.

Palabras clave: “Patient journey”, Cáncer de mama, Voz del paciente, Pronóstico, Toma de decisiones compartida, Comunicación médico-paciente.

1. Presentation

This work is being submitted to obtain the degree of Doctor in Psychology from the University of Barcelona. It is the result of the work conducted between 2018 and 2021 at the University of Barcelona.

It is submitted as a compendium of three original research articles published in 2020 and 2021, indexed in the Journal Citation Reports (sections Science Citation Index -SCI- and Social Science Citation Index -SSCI-).

The present doctoral project is part of the research group led by Dr. Caterina Calderón and Dr. Paula Jiménez Fonseca in the "Continuous care group" of the Spanish Society of Medical Oncology (SEOM) that I have participated in as researcher as 2017. For the NEOcoping work, we had the ONVIDA grant from the FSEOM group in 2015. Recently, two more grants have been obtained for the NEOetic study (FSEOM 2018 and ASTRAZENECA 2020).

The references of the three articles are listed below, along with the order in which they will be referred to throughout the document:

Study 1: **Ciria-Suárez-L.;** Jiménez-Fonseca, P., Palacín-Lois, M.; Antoñanzas-Basa, M.; Fernández-Montes, A.; Manzano-Fernández, A.; Castelo, B.; Asensio-Martínez, E.; Hernando-Polo, S., Calderón, C. (2020). Ascertaining breast cancer patient experiences through a journey map: a qualitative study protocol. *PLOS ONE,* 15(12): e0244355. https://doi.org/10.1371/journal.pone.0244355

Study 2: **Ciria-Suárez, L.;** Jiménez-Fonseca, P., Palacín-Lois, M.; Antoñanzas-Basa, M.; Fernández-Montes, A.; Manzano-Fernández, A.; Castelo, B.; Asensio-Martínez, E.; Hernando-Polo, S., Calderón, C. (2021). Breast cancer patient experiences through a journey map: a qualitative study. *PLOS ONE,* 16(9): e0257680. https://doi.org/10.1371/journal.pone.0257680

Study 3: **Ciria-Suárez, L.;** Jiménez-Fonseca, P.; Hernández, R.; Rogado, J.; Calderón, C. (2020). Estimation of risk of recurrence and toxicity among oncologist and patients with resected breast cancer: a quantitative study. *Frontiers in Psychology,* 11:540083. https://doi.org/10.3389/fpsyg.2020.540083

2. Introduction

Breast cancer is the most common cancer that associates the highest mortality rates among Spanish women, with 32,953 new cases estimated to be diagnosed in Spain in 2020 (SEOM, 2020). Thanks to early diagnosis and therapeutic advances, survival has increased in recent years (Clèries et al., 2018). The 5-year survival rate is currently around 85% (Baeyens-Fernández et al., 2018; Gómez-Acebo et al., 2020).

Though high, this survival rate is achieved at the expense of multiple treatment modalities, such as surgery, chemotherapy, radiotherapy, and hormone therapy, the side effects and sequelae of which can impair quality-of-life (Engelhardt et al., 2020). Added to this is the uncertainty surrounding prognosis; likewise, life or existential crises are not uncommon, requiring great effort to adjust and adapt (Muzzatti et al., 2020). This will not only affect the patient psychologically, but will also impact their ability to tolerate treatment and their socio-affective relations (Campbell-Enns & Woodgate, 2017).

2.1 Epidemiology

The number of cases of cancer continues to grow around the worldwide, thanks to population screening and the progress and extension of diagnostic testing, as well as to the increase in the risk factors we are currently exposed to, in particular, aging (Bray, Jemal, Grey, Ferlay, & Forman, 2012). Cancer continues to be one of the main causes of morbidity and mortality in the world. The International Agency for Research on Cancer (IARC) estimated that in 2018, 18.1 million cancers were diagnosed in the world, and that in the year 2020, approximately 19.3 million new cases were diagnosed (SEOM, 2021). The World Health Organization (WHO) estimates that, by 2030, the number of new cancer cases can be expected to raise by 40% in high-income countries and by more than 80% in low-income countries. Both cancer survival and mortality are also projected to increase (WHO, 2018). Today, one in 5 people worldwide will develop cancer during their lifetime (WHO, 2021). In Spain, REDECAN (the Spanish Network of Cancer Registries) calculate that 276,239 cases of cancer will be diagnosed in 2021 (SEOM, 2021).

WHO experts have stated that the global cancer landscape is changing and the prevalence of the different types of cancer has varied. Statistics published by the IARC (International Agency for Research on Cancer) in December 2020 reveal that breast cancer has surpassed lung cancer as the most diagnosed cancer in the world (WHO, 2021), becoming the most common cancer in general. It is estimated that in Spain, the year 2021 will witness 33 thousand new breast cancer diagnoses (SEOM, 2021). Nevertheless, due to therapeutic advances and early diagnosis, survival have improved in recent years (Clèries et al., 2018). These data evidence that prevention and screening, treatment, follow up and palliative care are key and that an interdisciplinary attention is essential to deal with this critical social problem (Grassi, 2020).

2.2 Psycho-social involvement in breast cancer

Cancer diagnosis appears as a threat to life, triggering a complex set of issues as managing physical symptoms, looking to cope with the new situation, facing the existential dimension of the illness, re-adjusting the relationship with the family, and dealing with the philosophical, spiritual or religious beliefs to give meaning to life and death (Ciria-Suarez et al., 2021; Holland, 2002).

The majority of the patient diagnosed with breast cancer tend to be women who are relatively young, around 55 years of age (Harding et al., 2015). Once diagnosed, for a non-metastatic cancer, surgery is the therapy of choice, with chemotherapy and radiotherapy as adjuvant treatments that reduce the risk of recurrence (Harding et al., 2015). Breast cancer patients, because of the treatment side effects and sequelae, are three times more likely to experience physical symptoms and psychological disorders than patients with other kinds of tumors (Purkayastha, Venkateswaran, Nayar, & Unnikrishnan, 2017; Zainal, Nik-Jaafar, Baharudin, Sabki, & Ng, 2013). Comparing with colon cancer, breast cancer patients react worse to the diagnosis, showing symptoms of anxiety, depression and somatization and in the beginning of the adjuvant treatment they need more information and involvement of the oncologist in shared decision-making (SDM) and more medical and psychological support (García-García et al., 2019). These patients suffer physical and psychological distress as depression, fatigue and pain (Fradelos et al., 2017; Shin et al., 2017), which cause a huge impact on physical, psychological, social, and quality-of-life aspects (Calderon et al., 2019). Their feminine identity and fertility are also affected, causing in a high number of cases a feeling of vulnerability and an affectation in their self-esteem (Esplen & Trachtenberg, 2020; Triberti et al., 2019). Family of these patients gets involved in the disease situation, being the majority of the times an indispensable support, but being in other moments a source of conflict (Namkoong, Shah, & Gustafson, 2017; Stephens, Westmaas, Kim, Cannady, & Stein, 2016). Most patients receive social support from their physicians and friends/family (Finck, Barradas, Zenger, & Hinz, 2018), being the effects of social support positively correlated with spiritual coping (Ciria-Suarez et al., 2021).

2.3 Patient's experiences throughout all their journey

In order to detail the patient experiences, the term "patient voice" has become more common in healthcare context and allows the patient to explain how they have experienced the events (Hall, Kunz, Davis, Dawson,

& Powers, 2015). Knowing these experiences would enable us to know their affectations in all aspects, both physical and emotional as well as cognitive and social. With the objective of structure all this information in a temporal narrative, they can be depicted as a “cancer journey”, which is a map of the different phases of the disease patients go through (Blows, Bird, Seymour, & Cox, 2012), describing from early diagnosis, treatment, follow up, to terminal stages (Kristjanson & Ashcroft, 1994).

Despite the growing importance of the patient’s role in the course of the disease and in medical decision-making, little research has focused on the their experiences (Cherif, Martin-Verdier, & Rochette, 2020; Rapport et al., 2019). Moreover, Sanson-Fisher et al. (2019) concluded that recently published studies had examined limited segments of patients’ experiences of cancer care and remarked the importance of having a greater focus on patients’ experiences across multiple components and into the whole care pathway.

Portraying breast cancer patients’ experiences as they move through all the stages of the disease, from diagnosis to treatment and follow-up, would enable us to understand better patients diagnosed with this disease, allowing health professionals to depict a more integral picture of the person. This information can aid in shifting the focus of health care toward those key moments, improving the quality of life of patients.

2.4 Patient’s expectations regarding prognosis

One of the most important and frequent concerns of the breast cancer patient throughout the journey is the prognosis, it means the estimation of what will happen during their illness, wondering about the severity of their situation and about their chances of survival. Prognostic awareness helps patients and family to make informed decisions related to treatment and prepare for the future, planning and coping with what is ahead (Mack, Fasciano, & Block, 2018).

In recent years, doctors have added new parameters (such as tumor grade, estrogen- and progesterone-receptor, HER2 overexpression, and genomic profiles) to the prognostic value of TNM with the objective of becoming more robust and precise (Piñeros et al., 2019). Studies comparing physicians’ and cancer patients’ expectations are developed in advanced stages of the disease, detailing that patients tend to be more optimistic than physicians (Gramling et al., 2016; Malhotra et al., 2019; Robinson et al., 2008). Studies in early stage breast cancer are few and old (Ravdin, Siminoff, & Harvey, 1998; Siminoff, Fetting, & Abeloff, 1989), being difficult to extrapolate their results to nowadays due to the tremendously change that therapies, survival and doctor-patient communication have suffered over time.

Coincidence between patients and oncologists estimations is important to reduce confusion, adjust patients' expectations, boost treatment compliance and greater involvement in SDM, as well as to plan medical care and healthcare services that patients may need, thereby improving their quality of life (Lobb, Butow, Kenny, & Tattersall, 1999).

2.5 The role of the psycho-oncologist

The improvement of general living conditions, the medical progress, and the increase in life expectancy have led to rise of the prevalence of oncologic disease. In addition, more and more patients survive cancer or live with the disease for long periods of time. Whereas the fight for survivorship is continuously being battle, improving patients' quality of life has come to the fore. Psychosocial aspects have a deep impact on patients' physical and mental wellbeing and may even modulate the course of the illness. Psycho-oncology appears as a relatively new interdisciplinary field with the objective of providing support to oncological patients who has to confront numerous challenges during the stages of the disease (Lang-Rollin & Berberich, 2018). Psycho-oncology incorporates the psychological, social, spiritual and existential dimensions and seeks to help the cancer patient find a tolerable meaning to the presence of the unwelcome serious illness that threat the life itself (Holland, 2002).

The evaluation and understanding of the psychosocial aspects of cancer and its treatment has appeared in the literature since the 1950s, but it was not until the 1980s that psycho-oncology is institutionalized. During that time, researcher Jimmie Holland established the first psychiatric service specialized in cancer patients and relatives at Memorial Sloan Kettering Cancer Center in New York, the International Psycho-oncology Society was created, and the description of the first cancer study plan appeared. Psycho-oncology was born with the objective that patients and relatives receive adequate psychological care during the different stages of the disease and survival. From this moment on, reports, practice guides and territorial recommendations begin to be generated that echo the relevance of implementing adequate measures to support this need in a specialized way (Echarte, Fuster, Roda, & Velasco, 2019)

Psychological care for patients and their families has now been established as a relevant clinical practice and discipline and is incorporated into national and international cancer control standards and policies. In Spain, psychological care for patients and their families is established in the National Cancer Strategy, with declines in the case of child and adolescent patients and palliative care. Psychological care for people with cancer is considered in 100% of regional cancer plans, and care for family members in 70%. Thus, it can be concluded that regional cancer policies generally incorporate the need to satisfy this demand for psychological care, however, the level of formalization and implementation of policies, instruments, and resources to provide psychological care in cancer is uneven and generally insufficient. According to the Spanish Association Against Cancer (AECC), there is a great distance between the official documentation and the reality on the ground, observing that in 16 of the 17 Spanish autonomous communities, the personnel of the national health system are unable to meet the psychological care needs of cancer patients. In fact, in almost half (48%) of the hospitals with oncology departments, there is not even a specialized psychiatry or psychology human resource dedicated to this need. In the case of family members and companions, the situation worsens, observing a lack of coverage of psychological care for them in 70% of the hospitals (Echarte, Fuster, Roda, & Velasco, 2019).

3. Justification of current research

Although the patient's role within the course of the disease and in SDM is increasingly important, little research has focused on the patient´s experiences (Cherif et al., 2020; Rapport et al., 2019) . Moreover, there are few studies that show a general perspective of the patients' experience from diagnosis to terminal stages. Because of this reason, the objective is to describe the experience of breast cancer patients throughout the different stages of the disease, through a journey model. For this, a qualitative study with semi-structured individual interviews is proposed. The results of this study are expected to provide new insights into the experiences of breast cancer patients, offering guidance to improve the care of these patients. In addition, portraying breast cancer patients' experiences as they move through all the stages of the disease, from diagnosis to treatment and follow-up would enable us to understand these patients' experiences in detail. Moreover, comprehending the transition phases and having a holistic perspective would allow for a more integral picture of the person.

On the other hand, since there is practically no scientific evidence on patients' and physicians' estimation of risk of recurrence and toxicity, the aim is to provide insights into the comparison of these perceptions. For this, a quantitative study is proposed by means of tests to patients and oncologists that allows the comparison of different variables. The results of this study are expected to clarify the expectations of the patients comparing them with the oncologists' ones, providing knowledge about the agreement between them, and deepening into the SDM and communication.

4. Objectives

The objective of the present thesis is to broaden knowledge about cognitive, emotional, and social aspects in breast cancer patient with the purpose of contributing to the improvement of their quality of life, both during treatment and in their recovery.

Each of the studies that compose the current thesis focuses on the following aspects:

- The first study seeks to describe the protocol to detail breast cancer patients' experience over the course of their illness. The outcomes of the research will afford new insights into breast cancer patients' experiences, providing guidance to improve the care given to these individuals.
- The second study focused to describe breast cancer patient experiences through a journey map. We expect that the psychological discomfort will be determined by the different phases of the process, specifically by the diagnosis and type of treatment; aspects such as femininity, motherhood and the couple relationship will appear altered; and the family and the social environment will be protective factors that will help patients better cope with the disease.
- The third study focuses on the perception of oncologists and patients with breast cancer on the risk of recurrence with and without chemotherapy and the risk of toxicity. We expect that oncologists will be more realistic in their estimations of these two situations than patients, and the greater the patient-perceived risk of relapse and treatment-related toxicity, the less their satisfaction with SDM.

The research of this first and second study is presented in two articles published in the PLOS ONE journal. The first outlines the protocol for describing breast cancer patient's experiences. The second one details breast cancer patients' experience over the course of the various stages of illness by means of a journey model. The content of the research is described in "5. Study 1" and "6. Study 2" of this document.

The research of the third study is presented in a published article in the Frontiers of Psychology journal. The content of the research is detailed in "7. Study 3" of this document.

5. Study 1. Ascertaining breast cancer patient experiences through a journey map: a qualitative study protocol.

This study has been published as:

> Ciria-Suárez, L.[1], Jiménez-Fonseca, P[2]., Palacín-Lois, M[3].; Antoñanzas-Basa, M[4].; Fernández-Montes, A[5].; Manzano-Fernández, A[4].; Castelo, B[6].; Asensio-Martínez, E[7].; Hernando-Polo, S[8]., Calderón, C[1]. (2020). Ascertaining breast cancer patient experiences through a journey map: a qualitative study protocol. *PLOS ONE,* 15(12): e0244355. https://doi.org/10.1371/journal.pone.0244355

Affiliations:

1 Clinical Psychology and Psychobiology Department, Faculty of Psychology, University of Barcelona, Spain.

2 Medical Oncology Department, Hospital Universitario Central of Asturias, Oviedo, Spain.

3 Social Psychology and Quantitative Psychology Department, Faculty of Psychology. University of Barcelona, Spain.

4 Medical Oncology Department, Hospital Universitario Clínico San Carlos, Madrid, Spain.

5 Medical Oncology Department, Complejo Hospitalario Universitario de Orense, Orense, Spain.

6 Medical Oncology Department, Hospital Universitario La Paz, Madrid, Spain.

7 Medical Oncology Department, Hospital General Universitario de Elche, Elche, Spain.

8 Medical Oncology Department, Hospital Universitario Fundación Alcorcón, Madrid, Spain.

5.1 Introduction

The number of cases of cancer continues to grow around the world, thanks to populational screening and the progress and extension of diagnostic testing, as well as to the increase in the risk factors we are currently exposed to, in particular, aging (Bray et al., 2012). Breast cancer (BC) is currently the second most common cancer overall and the leading cancer in women, with more than 2 million new cases diagnosed in 2018 (Bray et al., 2018). It is estimated that in Spain, the year 2020 will witness almost 33 thousand new cases in women (Sociedad Española de Oncologia Médica, n.d.). Nevertheless, due to therapeutic advances and early diagnosis, survival and mortality have improved in recent years (Clèries et al., 2018).

Breast cancer patients tend to be diagnosed when they are relatively young, around 55 years of age (Harding et al., 2015). These individuals, given treatment side effects and sequelae, are three times more likely to experience physical symptoms and psychological disorders than patients with other kinds of tumors (Purkayastha et al., 2017; Zainal et al., 2013). Once diagnosed, they go through different phases. If we are to support and accompany them in this process, we must have a profound understanding of their experiences. As put forth by Hall et al. (Hall et al., 2015), “patient voice” is a term that has become more common in healthcare contexts and serves to describe the whole of the patient’s experiences, encompassing thoughts, emotions, feelings, worries, and concerns, amongst others. Thus, we can ascertain how cancer affects patients -- physically, emotionally, cognitively, socially, and spiritually. This “patient voice” can be depicted as a journey, an experiential map of the different stages of disease subjects go through (Blows et al., 2012). Like all cancers, the person receives a diagnosis, prognosis, and treatment; they recover, and, in the event of relapse, develop metastases, undergo palliative care, and even, find themselves at life’s end. This care continuum is what is known as a “cancer journey”.

To a greater or lesser extent, each cancer diagnosis conceals the story of a life or existential crisis (Krouse & Krouse, 1982) that necessitates a major effort to adjust and adapt that will entail psychological repercussions for the individual (Fawzy, Fawzy, Arndt, & Pasnau, 1995). This diagnosis is generally unexpected and psychological distress ensues in practically all patients, including feelings of uncertainty, disbelief, hopelessness, vulnerability, anger, fear, anxiety, and sadness (Cameron, Booth, RJ, Schlatter, M, Ziginskas, & Harman, 2007; Spiegel et al., 1999). All of this implies a drastic change that, on occasion, compels the person to assume a new identity as a cancer patient who must also confront employment, economic, and psychosocial effects. Their lifestyle and self-perception change and their families are also affected (Krouse & Krouse, 1982). The most common physical and psychological symptoms in patients during and following breast cancer treatment include fatigue, pain, and depression (Fradelos et al., 2017; Galiano-Castillo et al., 2014; Shin et al., 2017; So et al., 2010), in addition to fear of relapse (Mirošević, Prins, Selič, Zaletel Kragelj, & Klemenc Ketiš, 2019) and of treatment side effects (Dooley, Slavich, Moreno, & Bower, 2017a). These symptoms undermine their psychological wellbeing and quality of life after diagnosis, when initiating therapy, and following surgery or systemic treatment (Galiano-Castillo et al., 2014).

Qualitative studies are gaining relevance to better comprehend specific aspects, such as willingness (or not) to participate in these studies (Habersack & Luschin, 2013); breast cancer symptom recognition and evaluation (Bonsu & Ncama, 2019; Gebremariam et al., 2019); the importance of social support (Adam & Koranteng, 2020) or physical exercise (Avancini et al., 2020) on survival and quality of life of these individuals.

Nevertheless, to the best of our knowledge, there are no studies that analyze patients’ experience from diagnosis to treatment and follow up. Therefore, the aim of this study is to portray breast cancer patients’ experiences as they travel through all the stages of the disease. Although the patient's role in the course of the disease and in medical decision making is increasingly important, little research has focused on the patient´s experiences (Cherif et al., 2020; Rapport et al., 2019).

A breast cancer patient journey map will enable health care professionals to gain first-hand knowledge about their patients’ personal experiences, enhance communication and understanding in the physician-patient relationship, thereby creating a better, more person-centered system. Moreover, the journey information may aid in redesigning the service, improving quality, planning changes more effectively, and in shifting the focus of care toward activities most valued by the patient (Trebble, Hansi, Hydes, Smith, & Baker, 2010). We hope that this protocol will encourage researchers to create more patient journey maps.

5.2 Methods

5.2.1 Study design

In this study, a qualitative method will be used to explore the pathway of standard care for women with breast cancer and to develop a schematic map of their journey process based on their experiences (Trebble et al., 2010). As Sandelowski comments (Sandelowski, 2000), by means of this approach, the experience is detailed from the person’s perspective and, following analysis, an in-depth description of patient experiences is presented. Healthcare Process Mapping is an important new form of clinical audit that examines how we organize the patient´s journey, using the patient’s perspective to identify problems and suggest improvements

(Antonacci, Reed, Lennox, & Barlow, 2018). It allows us to understand the patient's experience by separating the management of a specific condition or treatment into a series of consecutive events or steps (e.g., diagnostic procedures, therapeutic interventions, staff interactions, activities). Process Mapping has shown clinical benefit across a variety of specialties, multidisciplinary teams, and healthcare systems (Trebble et al., 2010).

This study will be performed in accordance with the ethical standards of the Declaration of Helsinki and its later amendments. This study was approved by the Research Ethics Committee of University of Barcelona (Institutional Review Board: IRB00003099) and supported by the Bioethic Group of the Spanish Society of Medical Oncology (SEOM) 2018 grant.

The study will be conducted in four large hospitals in three geographical areas in Spain. Each study site has more than 100 beds and reference and tertiary oncology services.

5.2.2 Participants

The presence of women with breast cancer and breast cancer survivors with a team of medical oncologists, oncology nurses and psycho-oncologists as consultants is anticipated. Study participants will comprise women with breast cancer who go to the sites for follow-up between December 2019 and January 2021. Inclusion criteria will be having been diagnosed with a histologically confirmed adenocarcinoma of the breast in the last 5 years and being over the age of 18 years. Those who are not in good physical/ mental state during the study period will be excluded. Medical oncologists and nurses who work at the centers will help to identify patients who meet the inclusion criteria, develop the written material, and interpret and clinically contextualize the results of the interview, but will not actively participate in the interviews.

An intentional sampling procedure will be used to recruit participants for the study based on age, marital status, level of education, employment status, having children, as well as clinical data, such as the stage of the disease and type of cancer treatment received. Therefore, patients will be interviewed with different cancer stages and who find themselves at different moments in their journey. The aim is to access the various experiences and promote transferability of the findings. Participation will be voluntary, and all participants will be asked about their own experiences.

5.2.3 Data collection

A bibliographic search will be conducted on Medline and Scopus Electronic Database for the terms “breast cancer”, “wellbeing”, “mental health”, and “patient voice”, since 2015, with the aim of delving into the theoretical and conceptual framework of the topic. Based on this review, an interview guide will be created for data collection. A pilot test will be conducted in a public university hospital to evaluate the acceptability and ease of the interview process. The interview guide will be reviewed by two oncologists, three nurses (a day hospital cancer nurse, a case manager nurse who liaises with the different services, and the nurse in charge of explaining postoperative care and treatment), as well as two psycho-oncologists to make the necessary modifications prior to conducting the final interviews included in the analysis (supplementary file). The interview will cover four main blocks. First, patients’ sociodemographic and medical information will be gathered. Second, daily activities, family, and support network will be discussed. Third, participants will be asked about their overall perception of breast cancer and their coping mechanisms. Finally, physical, emotional, cognitive, spiritual, and medical aspects related to diagnosis, treatment, and side effects will be probed. Additionally, patients will be encouraged to express their thoughts should they have more to say about the subject.

All the interviews will be performed by the fist author of the manuscript in a private space on the hospital grounds; if that is not possible, it will be conducted online. All the interviews will be recorded with the consent of the study subjects. Relevant notes will also be taken during the interview to document key issues and observations. The interviews will continue until the point of relative saturation is reached as regards the issues being discussed, lasting between 60 and 75 minutes. In general, a single interview will be carried out, although the contact will be saved, in case clarification is need for any aspect of the interview that had not been clearly recorded. To avoid bias arising from the timing of the interview, patients are three different time points will be represented: 1) after surgery, 2) during systemic treatment, and 3) at some point during the year following treatment completion.

5.2.4 Data analysis

The data will undergo a qualitative content analysis. To assure trustworthiness, the analysis will be based on the system put forth by Graneheim and Lundman (Graneheim & Lundman, 2004). First, transcribing the interviews for analysis and reading them over several times so as to be familiar with the material and gain a broad understanding of the experiences of patients with breast cancer. This will be followed by a more deductive analysis of those aspects of patient´s experiences that are of primary interest to the research team (i.e., knowledge and experience of their cancer and treatment, risk awareness, experiences of cancer care services, overall health status, satisfaction with cancer services, and perceived health care needs). Next, it will continue dividing the text into different content areas; obtaining units of meaning and putting them into each content area; extracting and adding a unit of meaning code; categorizing codes in terms of differences and similarities, and creating themes to link underlying meanings in the categories. Key aspects of cancer-patient´s knowledge and experience will be identified. A subject analysis approach will be used to categorize the codes by means of several iteration. This will be done by the authors of the manuscript. Team members will review the data and triangulate the outcomes between two sources of data: qualitative data from the interview and non-modifiable information, such as sociodemographic (i.e., age, marital status, having children) and clinical (i.e., cancer stage, and surgery type) data. The categories will be discussed at length and validated by all the authors to guarantee that the issues put forth are cogent.

5.2.5 Informed consent materials

All participants will receive a written informed consent form that they will sign prior to commencing with the interviews and after receiving information about the study. Said consent form will guarantee that they have received clear and sufficient information about the study; that their decision is voluntary, and that they understand that they can withdraw at any time. Likewise, they consent to the collection, analysis, and release of the information they share, to recording of the interview, and to the use of their own words in future publications.

5.3 Discussion

5.3.1 Contribution

So far as we are aware, this study will be the first qualitative research that will describe the experience of patients with breast cancer throughout the various stages of the disease using a journey model.

The knowledge garnered will enable us to comprehend breast cancer patients' experiences in detail, as well as the reasons for them. Furthermore, having first-person information from these patients will promote greater understanding of their situation, their emotional state, and the empathy of all the stakeholders, supporting sufferers and their families in receiving holistic cancer care. In addition, this information is subject to being used at a micro level (for instance, giving knowledge to healthcare professionals so that they can better understand and communicate with their patients, or shedding more light on key aspects of breast cancer patients' experiences, such as the impact of diagnosis, questioning their own identity and femininity, their approach to family communication – especially between mother and children-, repercussions for their partner and in the workplace, their feelings and thoughts about the treatment, or the significance they attached to the disease and the personal changes it brings), as well as at a macro level (for example, redesigning care or integrating specific services provided by the healthcare system) to enhance these women's experiences. In this way, the current paradigm that advocates for a patient-based healthcare system will continue to be fostered.

This protocol offers a clear methodological guide for patients' journey in healthcare. Journey maps, which originate in the field of service design (Howard, 2014), have been used in various areas to illustrate complex processes or interactions that would otherwise be difficult to apprehend. In the field of healthcare, journey maps can be used to depict service from the perspective of different stakeholders, like the patient, giving them a central role (McCarthy, S, O'Raghallaigh, P, Woodworth, S, Lim, YY, Kenny, LC, and Adam, F, 2020). Healthcare process mapping is considered a new and important form of clinical auditing that examines how the patient journey is managed (Kollberg, Dahlgaard, & Brehmer, 2006; Trebble et al., 2010). This protocol seeks to encourage the realization of Patient Journeys, a highly useful tool that is still uncommon in investigation, giving researchers greater confidence, as well as improving study reliability.

There is a clear need to prepare patients facing this diagnosis for prolonged, multimodal treatment (surgery, chemotherapy, hormonotherapy, radiotherapy) and to confront physical and psychological sequelae, in addition to the fear surrounding an uncertain prognosis. It’s important to manage their expectations; similarly, identifying and addressing the issues that arise at different time points during treatment for their disease could improve the patient’s experience.

5.3.2 Study limitations

This study will be conducted with Spanish participants, which is why certain aspects cannot reflect the experiences of breast cancer patients from other countries, both because of the particularities of the Spanish healthcare system and Spanish culture. Likewise, the data attained will be specific to women with breast cancer, which can scarcely be extrapolated to men with breast cancer and individuals with other cancers. Finally, the findings do not reflect men's experiences with breast cancer and research with this group would enrich the field further.

5.4 Additional file 1: Semi-structured interview guide to breast cancer patients/survivals.

Introduction

Thank you for agreeing to take participate in this interview. We are conducting these interviews with the objective of understanding the experiences that people who are diagnosed with breast cancer go through, and in this way to be able to improve their experiences. Please, note that there are no right or wrong answers; we are only interested in your thoughts and opinions. Participation in this study is voluntary and you may withdraw from the study at any time without explanation. The interview will take approximately one and a half to two hours. With your permission, I would like to record the interview because I don't want to miss any of your comments. All answers will be confidential. Do you have any questions? May I start the interview? Thus, in order to protect your privacy, we are providing you with a **signed confidentiality agreement**. I would like you to read it carefully and sign it.

Please note that this guide only represents the main topics to be discussed with the participants and that these will be adapted to the patient's own speech and circumstances.

Initials data

1. Before starting with your experiences, I would like to ask you for sociodemographic and clinical data. Could you tell me...

- Date of birth
- Marital status
- Number of children
- Educational Level
- Current ocupational status
- Place of residence
- Year of breast cancer diagnosis
- Cancer stage
- Other relevant information about the type of cancer (location, histological subtype, hereditary...) that you know
- Health care coverage: Social Security or private insurance

The patient and the breast cancer (BC) perception

2. To begin with, I would like you to tell me a little bit about yourself, for example, about your day-to-day life, profession, hobbies, family, support network...

3. And before we go into your experiences, I would like you to describe to me in a generic way how you would describe breast cancer.

4. I would like you to imagine now that you walk into an art gallery and at the back of the room you see a painting. Imagine you walk up to it and the sign on the painting says breast cancer. What would this painting look like to you? Why? And if you had to give it a title, what would it be?

Patient Journey Mapping

5. We will now go over your entire history with breast cancer on a temporary basis. We are going to start with what your life was like before the diagnosis and we are going to gradually advance through the different stages: diagnosis, treatment alternatives, decision on surgery, complementary treatment with chemotherapy and radiotherapy, secondary effects, revisions...

The patient is asked about each of her stages. Given that the circumstances are different for each of the patients and not all of them go through the same phases (i.e. some are subjected to neo-adjuvant chemotherapy, others to adjuvant chemotherapy, others to radiotherapy, others have hormonal treatment, others suffer a recurrence...), we detail below different aspects to be covered in the different stages, asking "could you give me more information about..." or "how did you live...".

- Medical issues: diagnostic studies, treatments, relationship with referring professionals (i.e. gynecologists, oncologists, radiologists, nurses, surgeons), decisions regarding treatment or type of surgery, side effects, use of alternative and/or complementary treatments

- Physical issues: physical discomfort and pain, aesthetic changes, day-to-day affectation, early menopause, personal care

- Emotional issues: anxiety and depression, self-esteem, fear of recurrence, uncertainty of the future, fear of death, early mourning, difficulties and concerns (i.e. about motherhood), emotional support network

- Cognitive issues: previous knowledge about the disease and treatments, doubts, sources of information, construction of identity (i.e. after breast surgery, during chemotherapy with hair loss), concept of femininity, coping strategies

- Social issues: communication of the disease (i.e. to the mother, children or closed environment), relationship with the partner (i.e. sexuality), children and with the community, friendships, work situation, contact with other patients or associations.

- Needs: outstanding needs and possible solutions

6. As the last section of this journey map, I would like you to tell me, from each of the stages of the disease you have gone through, a word, phrase or feeling that summarizes it. I would ask you to tell me the first one that comes to mind.

Conclusion

7. Finally, I would like to ask you if you give any meaning to this whole process (i.e. impulse to change your life, have other values or priorities).

8. Do you think this process has transformed you in any way? If so, could you define for me what you were like before and what you are like now?

Thank you very much for your time and the information you shared today.

6. Study 2. Breast cancer patient experiences through a journey map: a qualitative study.

This study has been published as:

> **Ciria-Suárez, L**[1]**.;** Jiménez-Fonseca, P[2]., Palacín-Lois, M[3].; Antoñanzas-Basa, M[4].; Fernández-Montes, A[5].; Manzano-Fernández, A[4].; Castelo, B[6].; Asensio-Martínez, E[7].; Hernando-Polo, S[8]., Calderón, C[1]. (2021). Breast cancer patient experiences through a journey map: a qualitative study. *PLOS ONE,* 16(9): e0257680. https://doi.org/10.1371/journal.pone.0257680

Affiliations:

1 Clinical Psychology and Psychobiology Department, Faculty of Psychology, University of Barcelona, Spain.

2 Medical Oncology Department Hospital Universitario Central of Asturias, Oviedo, Spain.

3 Social Psychology and Quantitative Psychology Department, Faculty of Psychology, University of Barcelona, Spain.

4 Medical Oncology Department, Hospital Universitario Clínico San Carlos, Madrid, Spain.

5 Medical Oncology Department, Complejo Hospitalario Universitario de Ourense, Ourense, Spain.

6 Medical Oncology Department, Hospital Universitario La Paz, Madrid, Spain.

7 Medical Oncology Department, Hospital General Universitario de Elche, Elche, Spain.

8 Medical Oncology Department, Hospital Universitario Fundación Alcorcón, Madrid, Spain.

6.1 Introduction

Breast cancer is the most common cancer and the one that associates the highest mortality rates among Spanish women, with 32,953 new cases estimated to be diagnosed in Spain in 2020 (SEOM, 2020). Thanks to early diagnosis and therapeutic advances, survival has increased in recent years (Clèries et al., 2018). The 5-year survival rate is currently around 85% (Baeyens-Fernández et al., 2018; Gómez-Acebo et al., 2020).

Though high, this survival rate is achieved at the expense of multiple treatment modalities, such as surgery, chemotherapy, radiotherapy, and hormone therapy, the side effects and sequelae of which can interfere with quality-of-life (Engelhardt et al., 2020). Added to this is the uncertainty surrounding prognosis; likewise, life or existential crises are not uncommon, requiring great effort to adjust and adapt (Muzzatti, Barbara, Bomben, Francesca, Flaiban, Cristiana, Piccinin, Marika, Annunziata, 2020). This will not only affect the patient psychologically, but will also impact their ability to tolerate treatment and their socio-affective relations (Campbell-Enns & Woodgate, 2017).

Several medical tests are performed (ultrasound, mammography, biopsy, CT, etc.) to determine tumor characteristics and extension, and establish prognosis (Piñeros et al., 2019). Once diagnosed, numerous treatment options exist. Surgery is the treatment of choice for non-advanced breast cancer; chemotherapy, radiotherapy, and hormone therapy are adjuvant treatments with consolidated benefit in diminishing the risk of relapse and improving long-term survival (Waks & Winer, 2019). Breast cancer treatments prompt changes in a person’s physical appearance, sexuality, and fertility that interfere with their identity, attractiveness, self-esteem, social relationships, and sexual functioning (Triberti, Savioni, Sebri, & Pravettoni, 2019). Patients also report more fatigue and sleep disturbances

(Palesh et al., 2018). Treatment side effects, together with prognostic uncertainty cause the woman to suffer negative experiences, such as stress in significant relationships, and emotions, like anxiety, sadness, guilt, and/or fear of death with negative consequences on breast cancer patients' quality-of-life (Bower et al., 2015; Triberti et al., 2019). Once treatment is completed, patients need time to recover their activity, as they report decreased bodily and mental function (Jakobsen, Magnus, Lundgren, & Reidunsdatter, 2018), fear of relapse (Miroševič et al., 2019), and changes in employment status (van Maarschalkerweerd, Schaapveld, Paalman, Aaronson, & Duijts, 2020). After a time, there is a risk of recurrence influenced by prognostic factors, such as nodal involvement, size, histological grade, hormone receptor status, and treatment of the primary tumor (Geurts et al., 2017). Thirty percent (30%) of patients with early breast cancer eventually go on to develop metastases (Lee Mortensen, Madsen, Krogsgaard, & Ejlertsen, 2018). There is currently no curative treatment for patients with metastatic breast cancer; consequently, the main objectives are to prolong survival, enhance or maintain quality-of-life, and control symptoms (Cardoso, Harbeck, Mertz, & Fenech, 2016; Lee Mortensen et al., 2018). In metastatic stages, women and their families are not only living with uncertainty about the future, the threat of death, and burden of treatment, but also dealing with the existential, social, emotional, and psychological difficulties their situation entails (Cardoso et al., 2016; Mustafa, Carson-Stevens, Gillespie, & Edwards, 2013).

Supporting and accompanying breast cancer patients throughout this process requires a deep understanding of their experiences. To describe the patient's experiences, including thoughts, emotions, feelings, worries, and concerns, the phrase "patient voice" has been used, which is becoming increasingly common in healthcare (Hall et al., 2015). Insight into this "voice" allows us to delve deeper into the physical, emotional, cognitive, social, and spiritual effects of the patient’s life. This narrative can be portrayed as a “cancer journey", an experiential map of patients’ passage through the different stages of the disease (Blows et al., 2012) that captures the path from prevention to early diagnosis, acute care, remission, rehabilitation, possible recurrence, and terminal stages when the disease is incurable and progresses (Kristjanson & Ashcroft, 1994). The term ‘patient journey’ has been used extensively in the literature (Gualandi et al., 2020) and is often synonymous with ‘patient pathway’ (Richter, P.; and Schlieter, 2019). Richter et al. (Richter, P.; and Schlieter, 2019) state that there is no common definition, albeit in some instances the ‘patient journey’ comprises the core concept of the care pathway with greater focus on the individual and their perspective (needs and preferences) and including mechanisms of engagement and empowerment.

While the patient’s role in the course of the disease and in medical decision making is gaining interest, little research has focused on patient experiences (Cherif et al., 2020; Rapport et al., 2019). Patient-centered care is an essential component of quality care that seeks to improve responsiveness to patients’ needs, values, and predilections and to enhance psychosocial outcomes, such as anxiety, depression, unmet support needs, and quality of life (Sanson-Fisher et al., 2019). Qualitative studies are becoming more and more germane to grasp specific aspects of breast cancer, such as communication (Khoshnazar et al., 2016; Rapport et al., 2019), body image and sexuality (Fouladi, Pourfarzi, Dolattorkpour, Alimohammadi, & Mehrara, 2018; Tat, Doan, Yoo, & Levine, 2018), motherhood (Faccio et al., 2020), social support (Adam & Koranteng, 2020), survivors’ reintegration into daily life (Jakobsen et al., 2018; van Maarschalkerweerd et al., 2020), or care for women with incurable, progressive cancer (Lee Mortensen et al., 2018). Nevertheless, few published studies address the experience of women with breast cancer from diagnosis to follow-up. These include a clinical pathway approach in the United Kingdom in the early 21st century (Lindop & Cannon, 2001), a breast cancer patient journey in Singapore (Ng et al., 2020), a netnography of breast cancer patients in a French specialized forum (Cherif et al., 2020), a meta-synthesis of Australian women living with breast cancer (Rajagopal, Liamputtong, & McBride, 2019), and a systematic review blending qualitative studies of the narratives of breast cancer patients from 30 countries (Smit, Coetzee, Roomaney, Bradshaw, & Swartz, 2019). Sanson-Fisher et al. (Sanson-Fisher et al., 2019) concluded that previously published studies had examined limited segments of patients' experiences of cancer care and emphasized the importance of focusing more on their experiences across multiple components and throughout the continuum of care. Therefore, the aim of this study is to depict the experiences of Spanish breast cancer patients in their journey through all stages of the disease. To the best of our knowledge, there are no studies that examine the experience of women with breast cancer in Spain from diagnosis through treatment to follow-up of survivors and those who suffer a relapse or incurable disease presented as a journey map.

A map of the breast cancer patient's journey will enable healthcare professionals to learn first-hand about their patients' personal experiences and needs at each stage of the disease, improve communication and doctor-patient rapport, thereby creating a better, more person-centered environment. Importantly, understanding the transitional phases and having a holistic perspective will allow for a more holistic view of the person. Furthermore, information about the journey can aid in shifting the focus of health care toward those activities most valued by the patient (Trebble et al., 2010). This is a valuable and efficient contribution to the relationship between the system, medical team, and patients, as well as to providing resources dedicated to the patient's needs at any given time, thus improving their quality of life and involving them in all decisions.

6.2 Methods

6.2.1 Study design and data collection

We conducted a qualitative study to explore the pathway of standard care for women with breast cancer and to develop a schematic map of their journey based on their experiences. A detailed description of the methodology is reported in the published protocol "Ascertaining breast cancer patient experiences through a journey map: A qualitative study protocol" (Ciria-Suarez et al., 2020).

An interview guide was created based on breast cancer literature and adapted with the collaboration of two medical oncologists, three nurses (an oncology nurse from the day hospital, a case manager nurse who liaises with the different services and is the 'named' point of contact for breast cancer patients for their journey throughout their treatment, and a nurse in charge of explaining postoperative care and treatment), and two psycho-oncologists. The interview covered four main areas. First, sociodemographic and medical information. Second, daily activities, family, and support network. Third, participants were asked about their overall perception of breast cancer and their coping mechanisms. Finally, physical, emotional, cognitive, spiritual, and medical aspects related to diagnosis, treatment, and side effects were probed. Additionally, patients were encouraged to express their thoughts should they want to expand on the subject.

The study was carried out at nine large hospitals located in six geographical areas of Spain. To evaluate the interview process, a pilot test was performed. Interviews were conducted using the interview guide by the principal investigator who had previous experience in qualitative research. Due to the Covid-19 pandemic, all interviews were completed online and video recorded with the consent of the study participants for subsequent transcription. Relevant notes were taken during the interview to document key issues and observations.

6.2.2 Participant selection and recruitment

Inclusion criteria were being female, over 18 years of age, having a diagnosis of histologically-confirmed adenocarcinoma of the breast, and good mental status. To ascertain the reality of women with breast cancer, most of the patients recruited (80%) had been diagnosed in the past 5 years. Patients (20%) were added who had been diagnosed more than 5 years earlier, with the aim of improving the perspective and ascertaining their experience after 5 years.

Medical oncologists and nurses working at the centers helped identify patients who met the inclusion criteria. Participants went to the sites for follow-up between December 2019 and January 2021. Eligible women were informed of the study and invited to participate during an in-person visit by these healthcare professionals. Those who showed interest gave permission to share their contact information (e-mail or telephone number) with the principal investigator, who was the person who conducted all interviews. The principal investigator contacted these women, giving them a more detailed explanation of the study and clarifying any doubts they may have. If the woman agreed to participate, an appointment was made for a videoconference.

A total of 21 women agreed to participate voluntarily in this research. With the objective of accessing several experiences and bolstering the transferability of the findings, selection was controlled with respect to subjects' stage of cancer, guaranteeing that there would be a proportional number of women with cancer in all stages, as well as with relapses.

6.2.3 Data analysis

The data underwent qualitative content analysis. To assure trustworthiness, analyses were based on the system put forth by Graneheim, and Lundman (2004). Interviews were transcribed and divided into different content areas; units of meaning were obtained and introduced into each content area; meaning codes were extracted and added; codes were categorized in terms of differences and similarities, and themes were created to link underlying meanings in the categories. All members of the research team (core team, two medical oncologists, three nurses and two psycho-oncologists) reviewed the data and triangulated the outcomes between two sources of data: qualitative data from the interview and non-modifiable information, such as sociodemographic (i.e., age, marital status, having children) and clinical (i.e., cancer stage and surgery type) data. Following this process, we reached saturation of the interview data by the time we had completed 21 interviews.

6.2.4 Ethical considerations

This study was performed in accordance with the ethical standards of the Declaration of Helsinki, and its subsequent amendments. The study was approved by the Research Ethics Committee of University of Barcelona (Institutional Review Board: IRB00003099) and supported by the Bioethics Group of the Spanish Society of Medical Oncology (SEOM) 2018 grant. All participants received a written informed consent form that they signed prior to commencing with the interviews and after receiving information about the study.

6.3 Results

6.3.1 Patient baseline characteristics

In total, 21 women with a mean age of 47 years (range, 34 to 61) were interviewed. Most of the study population was married (66.7%), had a college education (66.7%), and had 2 or more children (42.9%). All cancer stages were represented, up to 23.8% tumor recurrence, and most of the primary cancers had been resected (95.2%) (see **Table 1**).

Table 1. Socio-demographic and clinical characteristics of study participants (N=21)

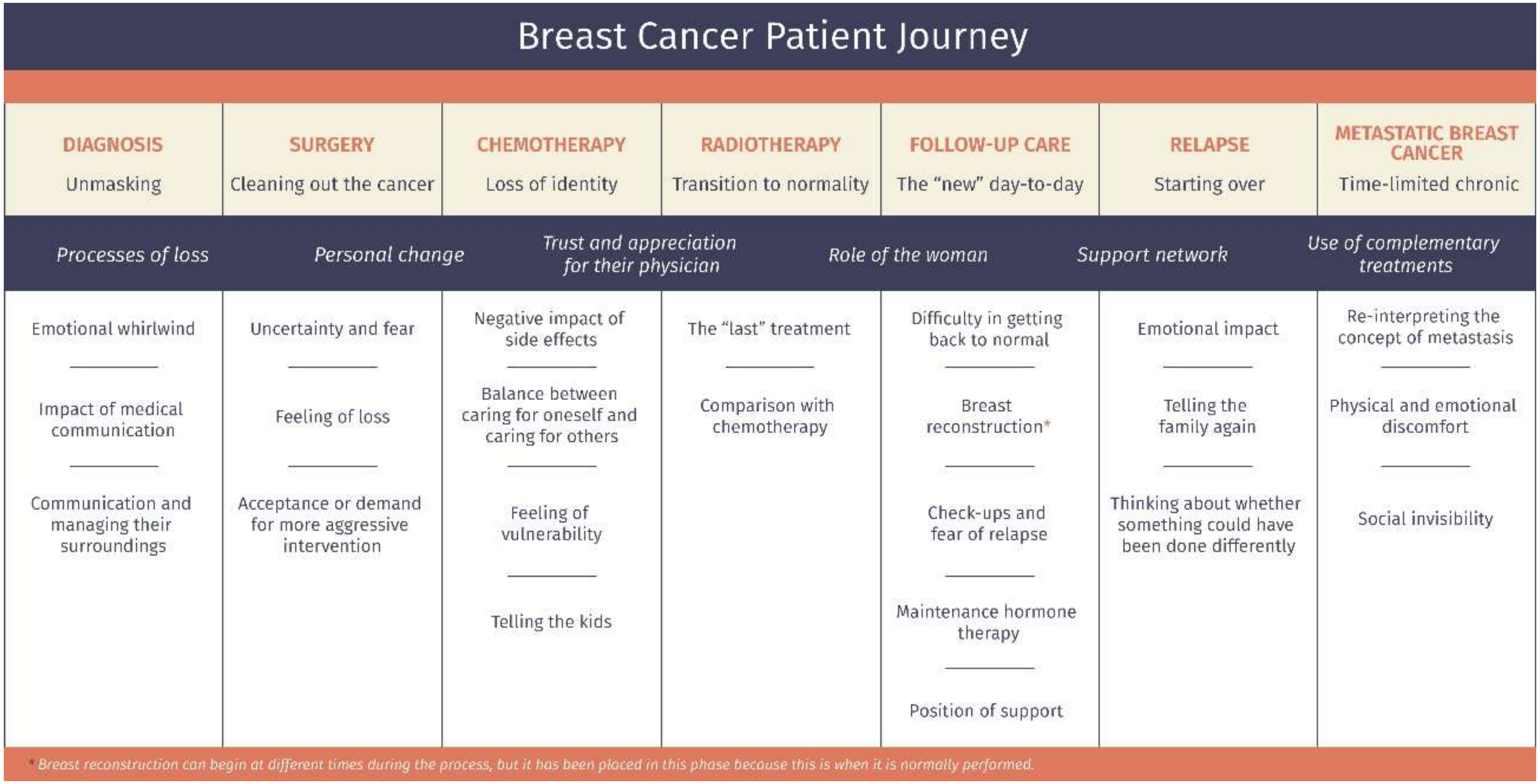
Variables	N (%)
Age	
≤45	10 (47.6%)
>46	11 (52.4%)
Educational level	
< High school	3 (14.3%)
High school graduate	4 (19.0%)
College graduate	14 (66.7%)
Marital Status	
Single	4 (19.0%)
Married	14 (66.7%)
Divorced	3 (14.3%)
Children	
0	4 (19.0%)
1	8 (38.1%)
≥2	9 (42.9%)
Employment Status	
Employed	8 (38.1%)
Unemployed/On leave	2 (9.5%)
Disability (or pending)	8 (38.1%)
Early retirement	3 (14.3%)
Cancer stage	
I	4 (19.0%)
II	4 (19.0%)
III	5 (23.8%)
IV	3 (14.3%)
Relapse	5 (23.8%)
Surgery Type	
Breast-conserving surgery	8 (38.1%)
Mastectomy	12 (57.1%)
Unresected	1 (4.8%)

6.3.2 Description of the breast cancer patient journey

The women diagnosed with breast cancer describe the journey as a process tremendously affected by the different medical stages. Each stage has its own characteristics that condition the experiences, unleashing specific physical, emotional, cognitive, and social processes. Additionally, the patients perceive this entire process as pre-established journey they must undertake to save their life, with its protocols based on the type and stage of cancer.

> *"People said to me, 'What do you think?' and I answered that there was nothing for me to think about because everything is done, I have to go on the journey and follow it and wait to see how it goes" (Patient 6)*

Figure 1 displays the various phases of the journey that patients with breast cancer go through; nevertheless, each woman will go through some or others, depending on their type of cancer.



Breast Cancer Patient Journey

DIAGNOSIS Unmasking	SURGERY Cleaning out the cancer	CHEMOTHERAPY Loss of identity	RADIOTHERAPY Transition to normality	FOLLOW-UP CARE The “new” day-to-day	RELAPSE Starting over	METASTATIC BREAST CANCER Time-limited chronic
Emotional whirlwind	Uncertainty and fear	Negative impact of side effects	The “last” treatment	Difficulty in getting back to normal	Emotional impact	Re-interpreting the concept of metastasis
Impact of medical communication	Feeling of loss	Balance between caring for oneself and caring for others	Comparison with chemotherapy	Breast reconstruction*	Telling the family again	Physical and emotional discomfort
Communication and managing their surroundings	Acceptance or demand for more aggressive intervention	Feeling of vulnerability		Check-ups and fear of relapse	Thinking about whether something could have been done differently	Social invisibility
		Telling the kids		Maintenance hormone therapy		
				Position of support		

Processes of loss · *Personal change* · *Trust and appreciation for their physician* · *Role of the woman* · *Support network* · *Use of complementary treatments*

* *Breast reconstruction can begin at different times during the process, but it has been placed in this phase because this is when it is normally performed.*

Figure 1. Breast Cancer Patient Journey

Throughout the entire patient journey

Processes of loss

What stands out the most in the process these women go through during the diagnosis and treatment of breast cancer is loss; specifically, the loss of health and of their previous identity. In the most extreme cases, the loss of health emerges with the fear of death that many women report at the time of diagnosis or during treatment, due to the distress generated. The loss of identity, above all their feminine identity, appears to be associated with treatment aggressiveness, such as surgery to remove part of or the entire breast, chemotherapy-induced baldness, and the loss of the possibility of pregnancy and, with it, of motherhood.

> *I felt a terrifying fear and thought, "You have cancer you tell yourself, you're going to die tomorrow." (Patient 6)*

> *I feel like after the hysterectomy, as a woman, I no longer have anything, only the physical. Sure, I look great, but I tell myself that it's just a shell, the shell I inhabit, because as a woman, I only have one breast left. (Patient 6)*

> *At that moment, I had to make the decision that I was no longer going to be a mother. (Patient 14)*

Personal change

Most of the women report that with the diagnosis of breast cancer, their life stands still and from that point forward, a different journey begins. The sole focus on this journey is the disease and its implications. During all those months, the patients stop working; they focus on their medical treatments, and reflect a lot on their current situation and on life. Most of the participants state, especially those who have already been discharged, that they know themselves better now; they take better care of themselves, and they enjoy their day-to-day and the small moments more, making the most of their time, with more initiatives and fewer trivial complaints.

> *Clearly, you're not the same person you were before; I don't think she'll ever come back; your mindset changes completely and I have sequelae from all the treatments. (Patient 1)*

> *I re-think wasting energy on lost causes; what's more, I've also learnt to say no. If I'm not in the mood to go somewhere, I just say no. (Patient 7)*

> *I take much more advantage of the present now, because you realize that things can change on any given day. (Patient 3)*

Trust and appreciation for their physician

Most of the interviewees stated that they fully trusted the doctors who care for them, without question or objection to the treatments proposed. They reported that, as they go forward, they discuss the tests and treatments that are going to be performed, as well as possible side effects. Several stated that they are unaware of the stage of their cancer; similarly, most also do not know the benefits expressed in X% of the treatments. A few of the participants claimed that they did talk in detail about the different types of treatments with their oncologists, that they had sought another opinion, and one of them even reported having decided to stop chemotherapy, which was very hard for her, given her physician's insistence that she continue.

> *The truth is that the oncologist didn't say much about percentages; what she told me were the steps that I had to take; I thoroughly trusted her and she gave me a lot of peace of mind. (Patient 5)*

> *I told him, "I'm going to do whatever you tell me to." It never occurred to me to dispute whatever the oncologist might tell me. I was willing to do whatever was needed. (Patient 8)*

Most of the women, at some point during the interview, state that they are grateful for the care they received and that, within the seriousness of their situation, there is a treatment for their condition.

> *I am super grateful for the treatment I've received and with the doctors assigned to me. (Patient 2)*

> *I'm very lucky; I'm only on my second line of treatment for metastasis and I've got a lot more ahead of me, but I consider myself lucky and I believe things are going very well. (Patient 20)*

Role of the woman

We can see that the women adopt a role of caregivers and managers of their surroundings. They worry about the disease negatively affecting the people around them, which is why they make an effort to manage the family's activity for when they can't do it and they try to avoid being a physical burden or cause emotional distress to the people around them.

> *I was very strong; I made everything easy for people, but making it very easy, doesn't mean that it was easy for me, but that I made it easy for everyone. (Patient 8)*

> *I didn't want to worry anyone because that's just the way I am, I push forward and that's that. (Patient 5)*

Support network

In all cases, the family appears to be one of the elements that is most involved in the disease process. Within the family, the partner deserves special mention. The testimonies in this regard reveal a wide spectrum of possibilities that range from the feeling of having had great support to a lack of attention and understanding that, in many situations, causes the relationship to be strained or to end. Friends tend to appear more occasionally.

> *I can't complain about my husband; he was up to the challenge, very attentive toward me and he fully understood how I was feeling; I felt very supported. (Patient 14)*

> *We've had a period of a lot of arguing; I've had to sit down with him and tell him that life had changed for me. (Patient 18)*

> *I had a partner I had lived with for five and a half years and he told me, literally, that he looked at me like a little sister, no longer as a woman, and he left me, and that hurt me tremendously. (Patient 6)*

On the other hand, many patients commented on the importance of social media, where they have met people in the same situation as them. They report feeling understood and in good company; likewise, they commented on the importance of being able to share their doubts and get to know about other experiences.

> *It's a situation that only someone who has gone through can understand; you can have all the good intentions in the world, but if you haven't gone through it, you can't even begin to understand. (Patient 8)*

Use of complementary treatments

Most patients follow conventional medical treatment. However, many resort to other disciplines that help them improve their quality-of-life, like dietary changes, getting more exercise than usual, visits to a psychologist or physical therapist, or using other integrative therapies, such as acupuncture, yoga, reiki, flowers of Bach, homeopathy, cannabis, or meditation.

> *I started to read a whole bunch of books to see what I could do to take care of myself in terms of nutrition and exercise; you consider everything you can do. (Patient 5)*

Diagnosis/Unmasking

This phase encompasses the time from when the woman detects some symptom or goes to a check-up until the medical diagnosis is made. For the woman, this is a time of a series of tests and results. We have observed that the procedures, especially the healthcare professionals that deal with the patients, and the timing vary, depending on the medical center where they are being cared for. Emotionally, this is one of the most complicated stages.

Emotional whirlwind

The wait to obtain test results has a huge emotional impact for the women, given that it is a time of great uncertainty and fear.

> *An entire month with all the anguish of finding out if you have something. (Patient 3)*

> *The worst part is waiting 15 days to find out the magnitude of the tragedy, if it's throughout your entire body or only in your breast; you go through a brutal emotional whirlwind; the wait is horrible because there's nothing else you can do, so that anguish that you carry inside is dreadful; it was hell for me. (Patient 10)*

Additionally, the interviewees described many other emotions that included fear of death, fear of having no time, feeling of unreality, rage, anger, sadness, avoidance, denial…

> *The first thing I thought was that I was going to die and that I wouldn't finish watching my children [grow up]; my father had died of lung cancer 25 years ago. (Patient 9)*

> *My only aim was to get back to normal, as if there were nothing wrong. (Patient 4)*

> *You have a lot of conflicting feelings; you wish this weren't happening; you want to run away, but you say, "Where am I going to run to?". (Patient 14)*

Impact of medical communication

Several women comment that, when given the diagnosis, they dissociate because of the emotional impact and that they don't listen to all the information that the medical professional is giving them.

> *I remember that she talked and talked, but I didn't know what she was saying until she said, "Isabel, you're going to be cured, okay?". (Patient 9)*

During the diagnostic testing, the women are highly sensitive to the healthcare professionals' words and gestures.

> *I looked at the face of the person who was doing the mammogram and that's when I started to imagine the worst. (Patient 20)*

> *I say to them, "But, is there a solution to this?", and they say to me, "Don't worry, I'm sure there is a solution." That "sure" is etched in my mind. (Patient 10)*

Communication and managing their surroundings

After the diagnosis, the patients feel that they have to tell the people around them about their situation, especially those closest to them, the family. They all agree on how hard it is to share. Normally, the people it's hardest to tell are their mother and their children. When they do, they try to put the most positive spin on it possible, in an attempt to keep them from worrying.

> *You no longer think only about yourself, you think, "Good grief, now I've got to tell my mother." It's hard. (Patient 16)*
>
> *I wanted to tell my kids the way I say things, always trying to look for the upside, and positive, although it was hard, but, anyway, in the end, it went well. When I finished, my husband told me, "You've convinced me that it's no big deal." (Patient 9)*
>
> *I told my son, "Son, don't cry, your mom's going to get over this, this is nothing." (Patient 1)*

During this period, the women contemplate how their situation will affect their surroundings and they try to organize it as much as possible.

> *I devoted myself to planning everything, to organizing what to do with my daughter, and to thinking about work, too, how I had left things at work. (Patient 4)*

Surgery/Cleaning out the cancer

Uncertainty and fear

The participants express that before going into surgery, they are told about the kind of procedure that will be done, but that, depending on what they find and the analysis, it may change. In light of this, they exhibit an enormous feeling of uncertainty and fear. In addition, many voice concern about how the surgery will go.

> *They tell you conservative surgery, but if we open up and see something we didn't see on the tests, then everything could change. (Patient 10)*

> *Aside from the anesthesia, that I'm terrified of, you spend several hours in surgery and you don't really know how things will go; when they clean it out, they analyze it, and you go into the operating room and you don't know what can happen. (Patient 9)*

Feeling of loss

Considering that the breast is associated with an intimate, feminine part [of their body], many women experience the operation as a loss. This loss is more acute if the operation is a mastectomy and there is no reconstruction at the same time. The loss also involves a loss of identity, compounded by the side effects of chemotherapy, such as hair loss. The interviewees who had undergone mastectomy say that following surgery, when the bandaging is removed and the scar is revealed, is one of the most critical moments, which is why they express difficulty in managing it and appreciate the caring assistance from the professionals.

> *It is identification with yourself, you know, it's what you've seen in the mirror, what you think you're like and, suddenly, you're no longer like that; there's an incredible personal crisis because you no longer recognize what you're seeing. (Patient 11)*

> *I closed my eyes and I removed the bandaging and I didn't dare look … with my eyes, I imagined the worst. (Patient 12)*

Acceptance or demand for more aggressive intervention

The patients perceive the surgery as essential to recovering their health, which is why the process is widely accepted. Some patients who demand a more invasive intervention, normally a bilateral mastectomy, do so because that way, they feel safer with respect to a possible relapse, as well as more comfortable esthetically.

> *If they have to remove my breast, let them take it; what I want is to get better. (Patient 16)*

> *They say that I am in full remission, so they only removed the lump, but at first, I said that I wanted my whole [breast] removed; then they assessed how to do it. (Patient 13)*

> *They told me that I had a genetic mutation and more possibilities of developing breast cancer and, since I felt such rejection toward my remaining breast, I decided to get rid of that one, too. (Patient 20)*

Chemotherapy/Loss of identity

The chemotherapy phase is one of the phases that affects the women's lives the most, because of its physical impact and how long it lasts. No differences have been found in how they experience chemotherapy depending on whether it was neoadjuvant or adjuvant.

Negative impact of side effects

Chemotherapy is associated with many side effects that vary from one woman to another. Many indicate that they have suffered physical discomfort, such as fatigue, dysgeusia, pain, nausea and vomiting, mucositis, diarrhea, etc.

> *One day when I didn't want to go to bed, I went to bed crying because I had the feeling that I wasn't going to wake up. That day it was because I felt awful. (Patient 1)*

Furthermore, all of the women suffer hair loss, which is one of the most-feared effects. Likewise, their body hair also falls out, especially on their face, and their weight fluctuates. All of these changes lead to a loss of identity that is experienced as taking away from their femininity. It must be remembered that oftentimes, chemotherapy is administered after surgery, further exacerbating this physical change. On top of all that, several women comment having to decide at the beginning of treatment whether to freeze their eggs or not; at that moment, many of them forfeit the possibility of becoming a mother or of becoming a mother again, which also adds to this loss of femininity.

> *Losing my hair was hard, but when it grew out again, I had an identity crisis. I didn't recognize myself; people said I was really pretty like that, with my hair so short. I looked at myself in the mirror and I said that I'm not that woman, I can see that that woman is pretty, but it's just that I don't recognize myself. That's not me or, it was like, I looked at myself and I didn't recognize myself. That's when I suffered a serious identity crisis, psychologically serious, but also serious because I sobbed because I looked at myself, but it wasn't me. (Patient 6)*

> *Where's that sexy lady, where is she?, because you don't feel good. I didn't like myself at all. I was several sizes larger and I looked at myself and said, "What a monster." I didn't feel good about myself. (Patient 1)*

Many patients say that chemotherapy decreases their libido and dries up their mucous membranes, which is why they prefer not to have sex. For those who live as a couple, this situation can strain the relationship.

> *Sexually, I just didn't feel like it, I wasn't in the mood; not only did I not feel like it, my mucous membranes were dry and, what's smore, I just couldn't, I couldn't, I felt bad for my husband, but he said, "Don't worry." (Patient 16)*

Finally, some interviewees expressed a feeling of being poisoned by the treatment. These women tend to be highly focused on taking care of their body and have a very natural attitude toward life.

> *I had to really work my awareness that I was poisoning myself; at night I was at home and I thought that all that red liquid was circulating through my veins … I think I even had nightmares. (Patient 4)*

Balance between caring for oneself and caring for others

The patients feel that it is time to take care of themselves, so they prioritize resting when they need it. Moreover, they worry about getting a haircut and, most of the times, they look for turbans and wigs. Some also learn how to put on make-up, which they rate as being very positive. On the other hand, those who have children or another person in their care, try to take care of them as much as they are able.

> *Around 11:00, I no longer felt good, so I'd go to the armchair to rest and it's like I had an angel, because I'd wake up a minute before I had to set the table and get lunch for my son who would be coming home from school. (Patient 1)*
>
> *While I was getting chemo, I went with the gadget and I told myself, "I'm going to teach you to apply make-up; for instance, your eyelashes are going to fall out. Make a line like this" and at that moment when you look in the mirror, and we look like Fester in the Addams family. (Patient 13)*

Vulnerability

The women experience great uncertainty and feelings of vulnerability the first times they receive chemotherapy, since they don't know what side effects they will suffer.

> *With chemo, I started with a lot of fear and, later on, I became familiar with it little by little until the time comes when you go to the hospital like someone who's going to pick up a bit of paper. (Patient 9)*

In addition, those participants who join a social network or who are more closely tied to the hospital setting, know about the relapses and deaths of people around them diagnosed with breast cancer, which makes them feel highly vulnerable.

> *There are some people who leave the group because… it's not like there are a lot of relapses and, geez, I think that it messes with your head. (Patient 13)*
>
> *We were almost always the same people at chemotherapy; there was one guy who was really yellow who looked terrible and, there was one time when we stopped seeing him and another lady asked and the nurse said that he had died. (Patient 15)*

At the same time, given the physical changes, especially those that have to do with body hair, many women feel observed when they leave home.

> *If I have to go out and take off my scarf because I'm hot or go straight out without any scarf on my head and whoever wants to look… let them; I think that it's up to us, the patients, to normalize the situation; unfortunately, there are more and more cases. (Patient 9)*

Telling the kids

Since when the chemotherapy stage is going to entail many physical changes, the women look for ways to talk to their children about the treatment. Most of them comment that it is a complicated situation and all of them try to talk to their children in such a way as to protect them as much as possible.

> *I asked the nurse for help before I started chemotherapy to see if she had any pointers about how to talk about this with the kids and she recommended a story, but when I saw it, I didn't like it … so, in the end, I decided to do it off the cuff. (Patient 10)*

Radiotherapy/Transition to normality

The “last” treatment

When the patient reaches radiotherapy, normally, they have already spent several months undergoing physically aggressive medical procedures, which is why they feel exhausted. There is a physical exhaustion resulting from the previous treatments and made worse by the radiation therapy. Furthermore, many women also report feeling emotionally drained by the entire process. However, this is generally accompanied by joy and relief because they feel that they are in the final stage of treatment.

> *Emotionally, it’s a marathon that has to end up at some point. (Patient 10)*

> *For me, radiotherapy was like a lull in the battle, with a winning mind-set. (Patient 4)*

Comparison with chemotherapy

There is a widespread perception that radiotherapy has fewer side effects than chemotherapy, although later, when they receive it, several patients suffer discomfort, above all fatigue and dizziness. Several report that at this point, they are mentally worn out and just want to be done with the process, which is why they have less information than about chemotherapy.

> *I feel like radiotherapy is unknown, that you think it’s more “light” and it turns out not to be so light. (Patient 13)*

Follow-up care/The “new” day-to-day

Difficulty in getting back to normal

Once the patients are discharged, many feel that they need some time to recover, that it will be slow, in order to restore a more normalized pace of life. They are still working on their emotional and personal process.

> *When they tell you that you have cancer, they make it very clear: you have a goal; you have some months of chemo, some months of radio, and when you finish, you say, "And now, what do I do?". I say that because now I have to get back to my normal life, but I don't feel normal. I still don't feel cured, I'm not 100%. And you're glad you've that you've finished it all and you're alive, but at the same time, you say, "Gosh… this is very odd." It was a very strange feeling. (Patient 8)*

Most patients report that their quality-of-life has diminished, due to the sequelae from the treatments. Lymphedema is one of the sequelae they name most often, although they also mention other symptoms, like digestive upset, weight issues, eye problems, scar pain, etc. The women who are on hormone therapy also suffer side effects, such as joint and muscle pain.

> *I have lymphedema and, although I have good mobility, I'm a little bit weak; when I go out for dinner, I generally order fish, because I can't always cut meat well. (Patient 6)*

Several interviewees also express difficulty in their affective-sexual relations. Many of them feel insecure because of all the physical changes; others have sequelae that hinder their relations, and still others are suffering symptoms of early menopause. This can cause problems in the couple and for those who don't have a partner, suffer many complications when it comes to meeting other people.

> *I haven't had sex with my husband for 2 years because, it's also really complicated to get over; I've gone for pelvic physical therapy; I've used gels, but nothing works. (Patient 8)*

> *It's taken me many months for me to have a relationship again; it's been really hard because, even though everyone told me that I looked fine, I didn't feel fine. My breast cancer had taken away all my attributes as a woman. (Patient 6)*

Some women also experience difficulties when it comes to returning to work. Several state that they had been fired when they went back. They also report that when interviewing for a job, it's complicated for them because they have to explain what happened and they mention the schedule of doctor's visits that they have. Other women comment that they've been given early retirement or disability.

> *You go to the interview and if you tell them that you've had the disease, they look at you like you're a weirdo. (Patient 13)*

Breast reconstruction

How reconstruction is experienced, as well as its timing, are highly contingent upon they type of reconstruction. Each one has its pros and cons, but the opinions collected with respect to the type of reconstruction have been positive.

> *Although it took 18 months for the entire process to be over, I'm delighted with reconstruction with the expander. (Patient 16)*

Some patients state that after the whole process, which has been long and complicated, they prefer not to undergo reconstruction immediately. In these cases, they report having felt a subtle pressure from the outside to undergo reconstruction.

> *Every time I went for my check-ups, they said, "You're the only one left [who hasn't undergone reconstruction]" and in the end, the truth is that I'm really happy because I think I look pretty. (Patient 12)*

Check-ups and fear of relapse

Check-ups are one of the times that generate most worry and insecurity. The women remark that, starting a few days before and until they receive the results of the follow-up studies, they are more anxious about the possibility of relapse.

> *At every check-up my legs start shaking again and my stomach is in knots, although at my last one, everything turned out okay and I'm thrilled. (Patient 6)*

> *During the first stage, I did everything I had to do and I got over it, but it's a lottery. You can do whatever you want, but it's the luck of the draw and when you start going for check-ups, it's like going to play Russian roulette. (Patient 8)*

Maintenance hormone therapy

Hormone therapy is understood differently depending on age and on the major decision of whether or not to be a mother or to have another child. If the woman does not want to have more children, the treatment is accepted better. The patients who take it also report effects derived from menopause, for instance, joint pain or dry mucous membranes.

> *I did notice joint pain, but since I exercised, [I felt it] much less than my fellow women, although, for instance, when it comes to getting up from a chair, you get up like an old lady. (Patient 10)*

Position of support

Several patients mention that, after discharge, they stay active on social media, they volunteer when they find out about someone or to participate in activities related to breast cancer, with the aim of being able to help other people who are in this situation.

> *It's really good to meet other people who are going through the same thing, so, now that I've finished, I like it and I always help whenever I can, because I can share what was good for me. (Patient 13)*

Relapse/Starting over

Emotional impact

The diagnosis of a relapse is experienced much the same as the initial diagnosis. All of the women report fear, although they also state that they are more familiar with the processes. Other emotions emerge, such as why me, blame, disbelief, etc.

> *Since they had told me that it wasn't going to happen again, I believed it, of course, I wanted to believe it and it totally surprised me; I couldn't stop crying and crying. (Patient 17)*

Telling the family again

Patients repeat that telling the family about it again, especially the children and parents, is tough and they try to minimize it in an attempt to protect them emotionally.

> *On the very same day that I had my mammogram, my mother says that she wants to come a see the kids. We're in the park, when she arrives, I have to tell her that everything's fine and when we get home, I tell her everything. My mother's devastated again and I tell her not to worry, that everything is going to be fine. (Patient 16)*

Thinking about whether something could have been done differently

Several women comment that, after their relapse, they think about whether the treatment was enough or there must have been something they could have done to avoid the relapse.

> *You get furious, because you say, "I wasn't supposed to get sick, because if, 2 years ago when the first microcalcifications appeared I had had them removed, then I wouldn't have metastasis, or maybe I would. (Patient 19)*

Metastatic breast cancer/Time-limited chronic

Re-interpreting the concept of metastasis

Most of the participants in this stage state that they have had to give new meaning to the word, "metastasis," since their first perception was directly related to death. In this way, they come to understand that cancer can become chronic, although they now have to take medication and go to the hospital on a regular basis. Nevertheless, they know that their life expectancy may be a few years. The women who are involved in a group point out how hard it is to see their fellow member pass away.

> *What I now call my "new normal" consists of lots of visits to the hospital and never going back to work. (Patient18)*

They also state that at this stage, they do not identify with the disease generally known socially as "breast cancer", where there is great emphasis placed on early detection and on their chances of being cured. This causes them to feel more isolated.

> *These pink ribbon campaigns hurt us because they tend to underscore that everything is going to turn out fine because breast cancer has a very high cure rate; there is huge lack of awareness. (Patient 20)*

Physical and emotional discomfort

Most of the women in this stage report side effects from the treatments, although some comment that good quality-of-life can be preserved. On an emotional level, they say that they sometimes feel a certain agony due to not knowing how much longer the treatment will be effective. They live in a state of uncertainty that they try to cope with by focusing on their day-to-day and experience the good times deeply.

> *When I'm not in pain, I try not to even remember what I have and go out and have fun with my family and live. (Patient 20)*

Several women who have children express with regret that they worry about their children enjoying them and remembering them when they were well. They are sad that they won't be able to grow up in a normal family. Some also comment the impact this diagnosis is having on their partner.

> *What I don't want is for them to carry this baggage of having a sick mother. (Patient 18)*

A conflict with disability also appears, as many women report their desire to continue working, but feel that they can't keep up with the pace of work. Additionally, several state that going through the medical board is a strenuous process, given that they look good physically.

> *It's hard to deal with, I'm a non-practicing lawyer and I have degrees galore, but I worked the first year and I couldn't continue. (Patient 21)*

> *Every year they call me again for the disability monitoring and they always threaten me. To be honest, the treatment doesn't make me sick, but I don't know how long it's going to be like this. (Patient 19)*

Social invisibility

The participants say that they do not have any physical signs of being ill, that they look fine, although they know and feel that inside, they are not well. They say that it is sometimes hard to manage socially, since on occasion, they feel misunderstood and disparaged.

> *I'm much sicker now, but people think or want to think that I'm fine. When I was doing chemo, it was like wearing a sign that said "cancer." (Patient 17)*

6.4 Discussion

This study describes the patient journey of women with breast cancer, specifying the different phases with the most relevant aspects of each, as well as the different cross-sectional features they report throughout the entire treatment process.

The results portray breast cancer as a process in which there is a striking feeling of loss of health and self-identity, changes in routines, personal and employment transformation, as well as emotional hardship during and after breast cancer treatment, aspects that are also reported in the literature

(Drageset, Lindstrøm, & Ellingsen, 2020; Zhai, Newton, & Copnell, 2019). Earlier studies state that experiencing cancer is highly stressful. It involves a major threat to life or physical integrity, in addition to mental health, interfering with the path, projects, and plans patients have for their life over the short, medium, and, on occasion, long term as well (Muzzatti, Barbara, Bomben, Francesca, Flaiban, Cristiana, Piccinin, Marika, Annunziata, 2020). Along with reporting adverse physical and psychological impacts, patients also report positive ways in which they have grown psychologically or emotionally from the experience (Campbell-Enns & Woodgate, 2017; Zhai et al., 2019). The diagnosis of breast cancer not only impacts the women individually, but also affects their surroundings. As reported in the literature, despite going through a very challenging time, the women struggle to put on a positive face and attempt to conserve the family's well-being, specifically that of their children (Campbell-Enns & Woodgate, 2017). At the same time, the family is a fundamental source of support and usually provide indispensable support; however, it is not always effective, because family members do not fully understand the stresses involved in living with cancer (Namkoong et al., 2017). Previous studies also reveal that for some women, their partners are one of their most significant supports; nonetheless, research also suggests that a cancer diagnosis predicts marital breakup more strongly for female survivors than males (Stephens et al., 2016). Our results reflect that the women frequently resort to other women in the same situation, possibly because they face significant unmet supportive care needs (Khoshnazar et al., 2016).The need for social support may lead patients to seek social support groups consisting of people who are experiencing similar health crises, because such groups allow them to interact with those who best understand their suffering (Namkoong et al., 2017). Another aspect that appears across the board is the relationship the participants have with the medical team. In this study, we have noted their trust in the medical team and acceptance of the treatments proposed without going into the clinical data of the disease and without needing to know the benefit provided by the treatment. Cancer patients are confronted with a potentially life-threatening [condition], feeling vulnerable, and need to rely heavily on their care providers, expecting the physician to act in their best interests (Engelhardt et al., 2020). Therefore, they need to have a close relationship, as well as comprehensive care (Khoshnazar et al., 2016). Patients' trust in a physician has been associated with a reduction of their fears and anxiety and [increased] satisfaction and adherence to treatment (Engelhardt et al., 2020; Khoshnazar et al., 2016). We believe that it would be important to provide patients with accurate information, so as to avoid misunderstandings (such as cancer being synonymous with death, regardless of stage) as several participants in this study have reported, which can lead them to believe that the risk of relapse with and without chemotherapy is much greater than the oncologists estimate (Ciria-Suarez et al., 2020). We believe that in future studies that it would be worthwhile to examine the peculiarities of each kind of patient information with the aim of determining how to break it up and make it both comprehensible and tolerable to promote patients' well-being.

A breast cancer diagnosis is generally unexpected and practically all patients suffer psychological distress, such as feelings of uncertainty, disbelief, hopelessness, vulnerability, anger, fear, anxiety, and sadness (Cameron et al., 2007; Cordova, Riba, & Spiegel, 2017). The literature has reported that many women experience peritraumatic distress or dissociation during the medical conversation in which they are given their diagnosis of cancer (Gieseler, Gaertner, Thaden, & Theobald, 2018), which might account for the reactions of the respondents. Given that, when they receive their diagnosis, additional information is generally given to them, such as clinical aspects and preferred treatments. Repeating this information at subsequent appointments could contribute to improving communication with patient, since several participants stated that they found it hard to pay attention to the physician, given the emotional impact. Additionally, breast cancer patients tend to be diagnosed when they are relatively young, and often when they are in the middle furthering their career or raising children (Bower et al., 2015). In spite of everything, the women try to put on as brave a face as they can and focus on maintaining their children's well-being (Campbell-Enns & Woodgate, 2017). Telling children about their diagnosis is reportedly one of the biggest challenges; parents are usually unsure of how to tell them, because at the same time that they want it to be open and honest and cover their children's developmental needs, they also want to protect them children (Sinclair et al., 2019).

Once diagnosed, breast cancer patients go through different treatments. The most salient experiences of these phases pertain to the impact of side effects on physical quality-of-life and psychological well-being, which is consistent with the literature (Palesh et al., 2018). Moreover, cancer therapy entails physical changes that affect their feminine identity, fertility, self-esteem, sexual functioning, and makes them more vulnerable (Esplen & Trachtenberg, 2020; Triberti et al., 2019). Women described their inner self as being on an emotional rollercoaster with highs and lows throughout the various phases of treatment (Campbell-Enns & Woodgate, 2017). Given treatment side effects and sequelae, these women are more likely to experience physical symptoms and psychological disorders than patients with other kinds of tumors (Purkayastha et al., 2017). The side effects involve an acute sense of loss of health and quality-of-life, as well as identity and femininity. It would be interesting for future research to explore the therapies used in grief counseling with cancer patients, as understanding and exploring this perspective could comprise an additional clinical aid.

Once the women have completed their treatments, they gradually get back to normal and many contemplate returning to work. However, in line with our results, the literature reveals that even though they want to normalize their lives, female breast cancer survivors feel that they will never return to their baseline status (Campbell-Enns & Woodgate, 2017). A significant number of patients experience difficulties in physical, cognitive, and emotional functioning after their treatment, such as symptoms like lymphedema, fatigue, pain, sleep disorders, cancer-related cognitive impairment, emotional stress, symptoms of depression and anxiety, problems with relationships, reduced sexual identity, fertility problems, and fear of cancer relapse (Jakobsen et al., 2018; Miroševič et al., 2019). Furthermore, patients with hormone therapy suffer hot flashes, sweats, joint pain, weight gain, decreased libido, and low energy (Lin, Chao, Bickell, & Wisnivesky, 2017). A sizeable number of these women also experience changes in employment status which can happen even 5-10 years following diagnosis (van Maarschalkerweerd et al., 2020). Given that all these changes alter the structure of the woman's everyday life, personalized care and treatment plans in cancer survivors are highlighted in the literature with extended specialized support being proposed that enables them to make a better psychosocially adjusted transition from treatment to follow-up (Matthews & Semper, 2017) and advocating for the patient's participation in all decisions that affect her during this period (de Ligt, van Egdom, Koppert, Siesling, & van Til, 2019). Further research is needed concerning how to structure the follow-up and support offered to these women during this stage so as to meet their needs and help them adjust to their new reality with the chronic sequelae caused by cancer and its treatment. On the other hand, the personal transformation of the initial stages of the journey are best seen during this phase. The literature shows that women who have had breast cancer report changes in their philosophy of life, such as embarking on a new life path, changing their priorities in life, as well as valuing life in general (Zhai et al., 2019). Most of the participants in our study place special emphasis on appreciating life, enjoying it more, and living each day to the fullest. Cancer survivors report being aware of how precarious life is, while also feeling the joy of being alive (Santos, ATCd, Silva, RPd, Almeida, LMd, Bosi, MLM, Menezes, MdFBd, Skaba, Nigenda, Arruda, CAM, Pinheiro, González-Robledo, & Knaul, 2020). Similarly, they have been found to be more resilient and better able to repair their mood than healthy women (Guil, Rocio; Ruiz-González, Paula; Merchán-Clavellino, Ana; Morales-Sánchez; Lucía; Zayas, Antonio; Gómez-Molinero, 2020).

About 5% of all patients with breast cancer are diagnosed when the disease is metastatic, whereas some 30% have suffered a relapse of an early breast cancer (Lee Mortensen et al., 2018). We saw that some women suffering a relapse after initial treatment with curative intent tend to wonder if the treatment was sufficient or if they should have done something more to prevent the relapse. Metastatic breast cancer is uncurable, which is why these women’s main psychosocial challenges are not the same as those who are diagnosed in early stages (Cardoso et al., 2016). Faced with incurability, the women react with shock and fear of imminent death, but this anxiety diminishes once they begin treatment and learn that there are more treatment options (Lee Mortensen et al., 2018). During this phase, the interviewees reported impaired physical QoL and functioning, being hindered by pain, fatigue, or menopausal symptoms. Emotionally, they report suffering bouts of depression and anxiety, as well as fear because of the spread of their cancer. As for their relational QoL, their children's welfare is their number one concern, especially for mothers of young children (Lee Mortensen et al., 2018; Vila, Barco Berron, Gil-Gil, Ochoa-Arnedo, & Vázquez, 2020). What's more, these women felt isolated from society in general and, more specifically, from the non-advanced breast cancer community, inasmuch as they feel that nobody understands what they are going through (Cardoso et al., 2016). A psychosocial approach is especially important in this phase to help these women to continuously adapt to the changes of their individual clinical situation and to the progression of the disease, thereby improving their coping.

6.4.1 Clinical implications

Having first-person information enables us to comprehend in detail the experiences of breast cancer patients, their situation, and emotional state, which favors holistic cancer care for health professionals.

Healthcare professionals should prepare women for a changed life situation, as well as to face prolonged, multimodal treatment (surgery, chemotherapy, hormone therapy, radiotherapy), and to confront physical and psychological sequelae, as well as the fear surrounding an uncertain prognosis. It is important to help them manage their expectations and fears and, to identify and address the issues and concerns that arise at different time points during treatment. The information and support offered should be adjusted to each woman's individual needs, her life situation, her coping style, and the time and stage of their cancer. This more empathic, understanding outlook can also contribute to improving the physician-patient rapport, promoting communication, understanding, and shared decision-making.

Finally, a comprehensive understanding of the women's psychosocial support endorses their belonging to groups of women with breast cancer, in which there is a relationship among equals. Further research is needed to specify the type needed so as to decrease both the impact of the death of women in the group, as well as the vast amount of information that they may end up obtaining, without needing it or requesting it.

6.4.2 Limitations

This study was performed with Spanish participants, which is why certain aspects cannot reflect the experiences of breast cancer patients from other countries, given the particularities of both the Spanish healthcare system and Spanish culture. Likewise, the data attained were specific to women with breast cancer, which can scarcely be extrapolated to individuals with other cancers. Moreover, the findings do not reflect men's experiences with breast cancer and research with this group would enrich the field further. In addition, the age of our participants ranged from 34 to 61 years; hence the results should be interpreted for a middle-aged population and do not reflect the experiences of women diagnosed at very early or very old ages. Finally, we believe that there may be a bias regarding the women who agree to participate, as this group has probably accepted their condition more, as well as having worked on it more.

Despite these limitations, we hope that our findings can contribute to better understanding the experiences of women with breast cancer.

7. Study 3. Estimation of risk of recurrence and toxicity among oncologist and patients with resected breast cancer: a quantitative study

This study has been published as:

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Affiliations:

1 Department of Clinical Psychology and Psychobiology, Faculty of Psychology, University of Barcelona, Barcelona, Spain.

2 Department of Medical Oncology, Central University Hospital of Asturias, Oviedo, Spain.

3 Department of Medical Oncology, Canary University Hospital, Santa Cruz de Tenerife, Spain.

4 Department of Medical Oncology, Infanta Leonor University Hospital, Madrid, Spain.

7.1 Introduction

Breast cancer is the second most common cancer overall and the leading cancer in women, with over 2 million new cases diagnosed in 2018 (Fitzmaurice et al., 2018). Surgery is the treatment of choice for non-advanced breast cancer; chemotherapy, radiotherapy, and hormone therapy are adjuvants with consolidated benefit in diminishing the risk of relapse and improving long-term survival (Waks & Winer, 2019). These treatments provoke fear surrounding side effects such as alopecia, body changes, pain, fatigue… (Dooley, Slavich, Moreno, & Bower, 2017b) that add to their fear of recurrence (Mirošević et al., 2019). In recent years, other factors such as tumor grade, estrogen- (ER) and progesterone-receptor (PR) status, HER2 overexpression, and, in some cases, genomic profiles have been added to the prognostic value of TNM staging based on tumor size (T), number of regional lymph nodes affected (N), and the presence or absence of distant metastases (M), yielding more robust and precise prognostic information (Piñeros et al., 2019; Schönherr et al., 2012). Physicians estimate risk of adjuvant treatment-associated toxicity on the rates of side effects reported in clinical trials. Nevertheless, these trials are conducted in a highly selected population; thus, their data can scarcely be extrapolated to clinical practice where patients are more fragile, older, and present more comorbidities, all of which can modify patients' risk of toxicity (Piñeros et al., 2019; Schönherr et al., 2012). Knowing the prognosis of the disease and risk of adjuvant treatment-related toxicity is relevant to doctor-patient shared decision making, tailoring treatment to risk, as well as helping the patient to cope better and lessening psychological distress (Lobb, Kenny, Butow, & Tattersall, 2001). Nevertheless, little is known about the effectiveness of communicating this kind of information in the oncologist's office in a situation in which the effect of recent cancer surgery and emotional stress affect the ability to comprehend the language being used, thereby casting doubt on the validity of this shared decision making between patient and oncologist as to the advisability of receiving adjuvant treatment, its benefits, and risks. Furthermore, several factors influence how the patient participates in shared decision making (Bakker et al., 2001; Ingersoll, et a., 2019; Janz et al., 2004; Maly et al., 2004; Street et al., 1995). Low-educated and older patients are often associated with a passive role (Street et al., 1995) with education being more consistent than age as a factor impinging on patient-physician communication (Janz et al., 2004). Additionally, doctors may provide less informative to individuals with lower levels of education (high school or less) and lower incomes (Bakker et al., 2001). As for race, fewer consultations for information concerning prognosis have been reported in the black and Latino populations, as well as unrealistic optimism regarding this prognosis (Ingersoll et al., 2019). In North American studies, ethnic minority women (i.e., African American and Latino breast cancer patients) were considerably less likely than white patients to perceive themselves as the chief treatment decision-makers, while at the same time, they were more likely to question their physician about their treatment, possibly due to mistrust of the healthcare system (Maly et al., 2004).

Most of the literature comparing doctors' and patients' expectations is founded on research in more advanced stages of the disease, concluding that patients tend to be more optimistic than doctors (Gramling et al., 2016; Malhotra et al., 2019; Robinson et al., 2008). Few publications address this issue in early stage breast cancer (Ravdin, Siminoff, & Harvey, 1998; Siminoff, Fetting, & Abeloff, 1989). The few studies found reveal that agreement between patients and oncologists regarding the benefits and risks involved with adjuvancy is poor (Siminoff et al., 1989) and that patients are apt to overestimate the curative value of adjuvant therapy in 70-80% of the cases with respect to non-treatment (Ravdin et al., 1998). The optimistic confidence in treatment may reflect trouble in physician-patient communication (Mackillop, Stewart, Ginsburg, & Stewart, 1988), the influence of other sources of information (Adamson, Cotoc, Choi, & Notaro, 2019), or to patients' minimizing or denying that cancer can be life-threatening (Mackillop et al., 1988; Wakiuchi, Marcon, Oliveira, & Sales, 2019).

Coincidence between patients and oncologists in estimating risk of disease relapse and chemotherapy-associated toxicity is important to reduce confusion, adjust patients' expectations, boost treatment compliance and involvement in shared decision making, as well as to plan medical care and healthcare services that patients may need, thereby improving their quality of life (Lobb et al., 1999). So far as we know, in the setting of resected, non-metastatic breast cancer, there are no recent studies that examine doctor-patient coincidence with respect to the estimation of relapse with/without adjuvant chemotherapy and regarding the risk of treatment toxicity, which is the main objective of our study. Secondarily, we seek to explore the sociodemographic and psychological factors associated with estimating risk of recurrence and toxicity. We postulate that oncologists will be more realistic in their estimations of these two situations than patients and that the greater the patient-perceived risk of relapse and treatment-related toxicity, the less their satisfaction with shared decision making.

7.2 Methods

7.2.1 Study

This is a prospective, cross-sectional, multicenter study involving oncologists and non-metastatic breast cancer patients from all over Spain. Inclusion criteria were: >18 years of age; histologically confirmed, non-advanced, resected solid tumor; eligible for adjuvant treatment. Exclusion criteria consisted of adjuvant treatment with hormone therapy alone and patients with dementia or any other serious mental illness that, in the investigator's opinion, impeded survey comprehension or hampered the patient's ability to participate in the study. Of the 310 breast cancer patients screened, 29 were ineligible (5 failed to meet inclusion criteria; 9 met an exclusion criterion, and 15 had incomplete data).

7.2.2 Ethics Statements

The study was approved by the Research Ethics Committee of the Principality of Asturias (19 January 2015) and by the Spanish Agency of Medicines and Medical Devices (AEMPS) (4 April 2015). All participants signed an informed consent form prior to participation. Participation was voluntary, anonymous, and would not affect patient care. Subjects completed questionnaires following their first appointment with the oncologist, approximately one month after surgery. The physician had informed them of the risk of relapse with and without treatment suited to their stage of cancer, risk factors, molecular subtype, and possible side effects of chemotherapy. Data were collected and updated by medical oncologist, specifically trained to meet the study requirements, through a web-based platform (www.neocoping.es

7.2.3 Data and Questionnaires

Sociodemographic and clinical data were collected during the first visit to the Medical Oncology department during which the advisability of receiving adjuvant treatment was discussed. Oncologists had to indicate their age and years of experience and both clinicians and patients had to predict risk of relapse with and without chemotherapy, and the risk of toxicity using a 0-100 numerical rating scale. Participants completed questionnaires (SDM-Q-9 and BSI-18) at home between the first visit and the start of adjuvant chemotherapy and oncologists filled in the SDM-Q-Doc after the first consultation.

Doctors had to answer the SDM Questionnaire-Physician's version (SDM-Q-Doc) (Scholl, Kriston, Dirmaier, Buchholz, & Härter, 2012) to express their perspective on SDM and how well they followed it with their patients. The questionnaire consists of 9 items, each of which describes one step of the SDM process; it was adapted and subsequently validated with good internal consistency in Spain (alpha=0.90) (Calderon et al., 2017). Clinicians had to rate each item on a five-point Likert scale, yielding a summary score from 0 to 36; the higher the score, the greater the physician's satisfaction with the information provided.

Participants completed the SDM Questionnaire-patient's version (SDM-Q-9). This questionnaire was published by Kriston et al. (Kriston et al., 2010), adapted to Spanish and has proven good internal consistency in Spain (alpha=0.90) (Calderon et al., 2018). It consists of 9 items, each portraying one step of the SDM process (Kriston et al., 2010) and is appraised on a five-point Likert scale with a summary score of 0 to 36; the higher the score, the greater the patient's satisfaction with the information received.

Patients also answered the Brief Symptom Inventory-18 (BSI-18) (Derogatis, 1993) that contains 18 items assessing somatization, depression, and anxiety. Respondents were asked to answer based on how they had felt over the previous seven days; each item was rated on a five-point Likert scale. Participants whose T-score was ≥67, as per cutoff values recommended by Derogatis (1993), were deemed "probable anxiety or depression". The higher the score, the greater the psychological distress in the previous month. Alpha coefficients ranged between 0.75 and 0.88 in Spain sample (Calderon et al., 2020)

7.2.4 Statistical methods

We used descriptive statistics for breast cancer patients' clinical data, as well as for participants' and oncologists' demographic information. T-test was used for quantitative variables and chi-square test for qualitative variables to appraise the degree of contrast between prognosis and toxicity estimations made by patients and oncologists. We used ANOVAs to assess variations in doctors' and patients' estimation by stage and age; Pearson correlation coefficients analyzed the relationships between estimations and demographic variables, SDM, and psychological distress. Given the large study sample size, the F-ratio could incorrectly detect statistically significant differences. We therefore included the effect size (eta squared, $\eta 2$) using the classic formula proposed by Fisher (1928) to adjust effect estimate, avoiding bias sample. The interpretation of effect size is straightforward: values $\leq$0.20 indicate a very small or insignificant magnitude of effect; 0.20-0.49, a small effect size; 0.50-0.79, a moderate effect size, and values $\geq$0.80 indicate a large effect size. We set a statistical significance level of 0.05. Statistics were performed using the IBM-SPSS software package for Windows, version 23.0 (SPSS, INC., Chicago, IL).

7.3 Results

7.3.1 Participants' characteristics

The physicians' sample comprised 23 medical oncologists (5 males and 13 females) employed at 11 Spanish hospitals. They have a mean age of 36.3 years (*SD*=8.1, range, 28-59) and 12.9 years (*SD*=9.8, range, 4-38) of experience. Sixty-five percent are super-specialists and 56.5% work at a public university hospital.

The breast cancer patient sample consisted of 281 subjects. Cancers were stage IB (38.4%), II (52.3%), or III (9.3%). All subjects had undergone curative surgery in the previous month (56.5% partial resection vs 46.5 complete resection), were treated with adjuvant chemotherapy (64.2% conventional and 35.8% modified treatment), and 66.4% received sequential radiotherapy.

Mean age was 53.2 years (*SD*=10.8, range, 26-77); 72% were married or partnered; 77.8% had primary or secondary education, and 44.4% were retired.

7.3.2 Estimation of risk of recurrence and toxicity

Oncologists' prognosis of risk of breast cancer relapse without chemotherapy was 30.4% (45.3% deemed risk to be low), while the estimated risk of recurrence with chemotherapy-related chemotherapy was 13.3% (91.4% calculated that it would be very low). The risk of severe toxicity was estimated to be 9.8% (96.6% of the oncologists thought it was very low) (see Table 1).

Breast cancer patients' prediction of risk of recurrence without chemotherapy was 78.6% (40.2% felt it was high), while they estimated a

29.6% risk of relapse with chemotherapy (72.5% thought it was very low). The estimated risk of suffering severe toxicity was 61% (40% of patients deemed that it was low).

Oncologists and patients differed significantly in their prediction of relapse without chemotherapy (χ^2=15.901, p=0.006), with chemotherapy (χ^2=9.702, p=0.021), and in their estimation of severe toxicity (χ^2=-12.120, p=0.007). For all three situations, patients believed they were at higher risk than did oncologists, overestimating the risk of recurrence with and without chemotherapy, as well as their risk of severe side effects if they received chemotherapy.

Table 1. Prognostic predictions about risk of relapse and toxicity

Variables	M (SD)	Very low	Low	High	Very high
Oncologists' prediction		0-25%	26-50%	51-75%	76-100%
Risk of relapse without chemotherapy	30.4 (16.2)	43.4	**45.3**	10.1	1.1
Risk of relapse with chemotherapy	13.3 (8.4)	**91.4**	8.6	--	--
Risk of severe toxicity	9.8 (7.4)	**96.6**	3.4	--	--
Breast Cancer Patients' prediction					
Risk of relapse without chemotherapy	78.6 (20.4)	1.7	19.1	**40.2**	39.0
Risk of relapse with chemotherapy	29.6 (20.4)	**72.5**	22.9	2.1	2.5
Risk of severe toxicity	61.0 (22.8)	14.2	**40.0**	32.5	13.3

Bold, $p < 0.05$

7.3.3 Estimation of risk of recurrence and toxicity by stage

For patients with stages IB, II, and III, oncologists' prognoses regarding risk of relapse without chemotherapy was 25.8%, 31.7%, and 42%, respectively. They estimated risk of recurrence with chemotherapy to be 10.3%, 13.6%, and 23.9%, respectively. The risk of severe toxicity with chemotherapy was believed to be 9.1%, 10.2%, and 9.9%, respectively.

Patients with breast cancer stages IB, II, and III predicted their risk of recurrence without chemotherapy to be 72.4%, 81.8%, and 86.9%, respectively. They estimated their risk of relapse with chemotherapy to be 29.1%, 28.4%, and 38%, respectively, and of suffering severe toxicity to be 58.5%, 61.9%, and 65.2%, respectively (see Table 2).

Clinicians predicted risk of relapse differently depending on tumor stage, estimating greater risk without chemotherapy (F=11.529, *p*=0.001, η2=0.080) and with chemotherapy (F=30.852, *p*=0.001, η2=0.189) for individuals with higher stages. The same trend was apparent in patients' prediction of risk of relapse without chemotherapy by stages (F=7.958, *p*=0.001, η2=0.063). No significant stage-based differences were observed in patients' predictions of risk of relapse with chemotherapy or of severe toxicity.

Table 2. Prognostic predictions about risk of relapse and toxicity by stage

Variables	Stage I	Stage II	Stage III	F	*p*	Effect size η2
	M (SD)	M (SD)	M (SD)			
Oncologists’ prediction						
Risk of relapse without chemotherapy	25.8 (13.1)	31.7 (17.1)	42.0 (15.2)	11.529	**0.001**	**0.080**
Risk of relapse with chemotherapy	10.3 (5.7)	13.6 (8.4)	23.9 (9.5)	30.852	**0.001**	**0.189**
Risk of severe toxicity	9.1 (5.5)	10.2 (9.0)	9.9 (3.5)	0.778	0.460	---
Breast Cancer Patients’ prediction						
Risk of relapse without chemotherapy	72.4 (21.0)	81.8 (19.5)	86.9 (16.6)	7.958	**0.001**	**0.063**
Risk of relapse with chemotherapy	29.1 (20.9)	28.4 (19.7)	38.0 (21.1)	2.224	0.110	---
Risk of severe toxicity	58.5 (22.0)	61.9 (22.5)	65.2 (22.8)	1.000	0.369	---

Bold, $p < 0.05$

7.3.4 Factors modulating estimated risk

There is a significant correlation between oncologists' age and years of experience and their risk prediction. Young doctors and those with fewer years of experience prognosticate greater risk of relapse than older, more veteran physicians both without chemotherapy (r=-0.267, *p*<0.001; r=-0.256, *p*<0.001, respectively) and with chemotherapy (r=-0.273, *p*<0.001; r=-0.256, *p*<0.001, respectively). The same was seen with respect to risk of severe toxicity (r=-0.213, *p*<0.001; r=-0.188, *p*<0.001, respectively). However, participants' risk prediction did not correlate with doctors' age, years of experience, or patients' age (see Table 3).

SDM-Q-Doc and Q-9 correlated significantly with some predictions. The higher the estimated risk of relapse with chemotherapy, the less satisfied the oncologist was with SDM (r=-0.160, *p*<0.01). Similarly, patients were less satisfied with SDM when their risk of severe toxicity was higher (r=-0.228, *p*<0.01).

There is a positive, significant correlation between psychological distress (BSI-18) and patient prognosis of greater risk of recurrence with chemotherapy (r=0.206, *p*<0.001).

Table 3. Correlations between prognostic prediction and sociodemographic variables

	Oncologists' prediction			Breast Cancer Patients' prediction		
Variables	Relapse without chemo	Relapse with chemo	Toxicity	Relapse without chemo	Relapse with chemo	Toxicity
Oncologists' age	-0.267**	-0.273**	-0.213**	0.076	-0.088	-0.013
Years of experience	-0.256**	-0.256**	-0.188**	0.064	-0.083	-0.012
Patient's age	-0.011	-0.054	-0.070	0.101	0.099	-0.022
SDM Oncologist	-0.079	-0.160*	-0.029	---	---	---
SDM Patient	---	---	---	0.035	-0.054	-0.228*
BSI Psychological distress	---	---	---	0.026	0.206**	0.096

*$p < 0.01$; **$p < 0.001$

7.4 Discussion

Overall, patients' predictions of risk their cancer recurring with and without chemotherapy tended to be higher than oncologists'. Moreover, while physicians estimated greater risk of relapse as disease stage increased, patients only exhibited this tendency when they predicted risk of recurrence without chemotherapy, trusting in their treatment regardless of their initial medical situation. In general, doctors considered that the risk of relapse with and without chemotherapy was low and very low, respectively, whereas patients felt that their risk with chemotherapy was very low and high without chemotherapy, respectively. The same trend was observed for risk of toxicity. The literature points toward oncology patients being more optimistic than oncologists in the context of advanced cancer (Robinson et al., 2008); nonetheless, we have only found one study that examines doctors' and cancer patients' perceptions in the early stages of the disease. An old study reports that while patients and oncologists coincided insofar as risk of recurrence without adjuvant treatment is concerned, such was not the case with adjuvant treatment (60% patients overestimated their possibilities of being cured with adjuvant treatment by 20% or more versus their oncologists) nor with respect to treatment-associated risks. These results, which differ from ours, are not directly comparable, given that therapies, survival, and physician-patient communication have changed tremendously over time. Focusing on the patients, we detected a sizable difference between the perception of risk of relapse with chemotherapy (high) and without (very low). Patients' perception of less risk of relapse with or without adjuvant treatment is disproportionate, unrealistic in terms of the expected benefit, and is also seen in a classic study, where expectations of a 79% decrease in the risk of recurrence with adjuvant chemotherapy were observed (Ravdin et al., 1998). We believe that three different factors may influence our results: 1) doctor-patient communication, which we consider should be less paternalistic and more patient-focused; 2) patients' knowledge about cancer, and 3) interpersonal relations with other agents, notably the media and patient associations.

Several studies refer to the importance of physician-patient communication (Bon-van de Hoek et al., 2019; Gramling et al., 2016 and Trant et al., 2019). Likewise, some classic studies have determined that the discrepancy between doctors' and patients' expectations may be due to physicians failing to provide quantitative data (Loprinzi, Ravdin, De Laurentiis & Novotny, 1994; Siminoff et al., 1989). Although doctors are increasingly furnishing more quantitative data regarding the disease (Belkora et al., 2009; Zikmund-Fisher et al., 2016), most patients continue to estimate their risk of recurrence and treatment-associated risk inaccurately (Belkora et al., 2009). Consequently, variables such as level of education, psychological status, or patients' familiarity with medical concepts may affect their estimations. Similarly, some authors suggest that it is difficult for patients to understand the technical and scientific aspects of chemotherapy (Wakiuchi et al., 2019), which ultimately leads to knowledge based on their own experience in which aspects such as their vision of the disease, their relatives' and acquaintances' experiences in the same circumstance, their own coping style, or the confidence they have in themselves to confront their cancer all take precedence (Bon-van de Hoek et al., 2019; Slevin et al., 1990; Wakiuchi et al., 2019). The lack of information concerning the medical condition and/ or treatment is one of the leading causes of patients' dissatisfaction (Calderon et al., 2018). In fact, at present, most want to receive more information, as well as to participate more in the decision-making process, albeit the proportion of people who prefer a more active role differs across countries (Calderon et al., 2018). A survey conducted in eight European countries revealed that patients wanted to participate in decision making, although their expectations about their involvement in healthcare decisions differed significantly across countries; for example, in Spain, participants preferred a more paternalistic model than in Switzerland or Germany (Elwyn, et al., 2014).

As for cognitive aspects, the fact that they had only learned of their cancer diagnosis a few weeks earlier may have led society's fear of cancer to prevail, as it is generally associated with death (Wakiuchi et al., 2019), as well as the feeling that their very survival was at stake (Mackillop et al., 1988). In our study, we believe that the scenario of tremendous uncertainty and possible physical discomfort due to recent surgery and current recovery, together with initiating a new treatment, may have magnified patients' estimation of risk of relapse and toxicity.

Other studies also point to the effect of other sources of information, such as relatives, cancer survivors, support groups, non-physician healthcare personnel, and educational material that could modify patients' perception of risk of relapse (Adamson et al., 2019).

Turning our attention to the physician cohort, prediction of risk of relapse, with and without chemotherapy, and of severe toxicity was related to oncologists' age and years of experience. This is consistent with other studies, where these doctor-related variables contribute to shaping their prognosis (Taniyama et al., 2014). On the other hand, they feel that SDM is more difficult when they perceive a higher risk of relapse. Smith et al. report that discussing uncertainty and risks challenges patient-clinician communication (Smith, Street Jr, Volk, & Fordis, 2013); therefore, when the physician finds themself in a complex situation, they may feel more uncomfortable with SDM.

As for patients, those suffering greater psychological distress predicted higher risk of relapse with chemotherapy. This reveals a negative, defeatist attitude, without losing sight of the numerous studies that indicate that depression and anxiety correlate with a higher risk of mortality in cancer patients (Shim et al., 2020). This illustrates the need to detect and support these individuals to relieve their psychological distress, which will not only affect their quality of life, but may also improve their prognosis. In contrast, patients who are more satisfied with SDM estimated a lower risk of severe toxicity, which may indicate that a good interview bolsters their confidence in treatment and gives them a greater perception of safety. Hjerl et al. found that treatment side effects influence patients' acceptance of treatment (Hjerl et al., 2003). As previously laid out, most patients were willing to accept intensive chemotherapy for even a slight chance of benefit (Slevin et al., 1990).

This study's findings should be considered in conjunction with its limitations. First, the present study was cross-sectional in nature; therefore, it was not possible to determine the directionality of the relationships observed. Future studies should explore perceptions of risk of relapse and severe toxicity after adjuvant chemotherapy is completed, with an end to assessing whether these perceptions are changing over time and how variables relate to one another. Second, patients' and oncologists' responses have been collected by means of questionnaires, which, on the one hand, may have limited the spectrum of answers and, on the other, hindered delving into personal motivations and comprehension. Third, the results obtained in this study are specific for patients who underwent surgery with curative intent for stage I, II, or III breast cancer, making it difficult to extrapolate to metastatic disease and other types of cancer given the specificities of this patient cohort. Fourth, in all cases, the indication for adjuvant chemotherapy was based on international clinical guidelines and all agreed to receive it; consequently, we do not know to what degree this decision may have influenced patients' predictions of their risk of relapse without chemotherapy, as a variable they may not have deemed realistic. Finally, it would be advisable to enlarge the sample of oncologists in the future.

As for the clinical implications of these findings, shared decision making about adjuvant treatment and patients' understanding of cancer prognosis are complex issues; hence, it may be necessary to ascertain each individual's perception and communicate information over consecutive visits. Furthermore, improving physician-patient communication in pursuit of more realistic expectations regarding risk of relapse and toxicity could lessen anxiety, depression, and fear of treatment, thereby enhancing patients' quality of life.

8. General discussion

The prevalence of breast cancer is increasing and is expected to continue rising in the coming years (WHO, 2021). It is important to note that breast cancer became the most common cancer in general, surpassing lung cancer as the most diagnosed cancer in the world (WHO, 2021), according with the statistics published by the IARC (International Agency for Research on Cancer) in December 2020. Despite this increment, early diagnosis due to screening campaigns and innovation in treatment has led to improved survival of the disease; however, the diagnosis and treatment is having a high impact in physical, emotional, cognitive, social and spiritual aspects of breast cancer patients (Ciria-Suarez et al., 2021; Holland, 2002). Having an in depth understanding of all these aspects and adjusting to them will contribute to enhance breast cancer patients' quality of life.

The patient's role in the healthcare process is gaining a growing interest (Cherif et al., 2020). The patient-centered care movement has positioned raised importance on monitoring healthcare, patient engagement in SDM, and legitimizing health policy through consumer input (Rapport et al., 2019). To assess the quality of care of these patients, both measuring clinical quality and safety, and knowing the views of the patients is key (Lombarts, Rupp, Vallejo, Suñol, & Klazinga, 2009). Patient-centered care is an essential component of quality care that search for improving the responsiveness of care to needs, values and preferences of the patients; improving their psychosocial outcomes, as anxiety, depression, unmet supportive care needs and quality of life (Sanson-Fisher et al., 2019).

The results obtained in these studies show the *journey* of the breast cancer patient across all the different stages of the disease. In each of them it is possible to appreciate which are the most significant experiences for the patients, as well as the impact that the situation generates on their day to day. The affectation is observed in all the aspects of their life: physical, mental, emotional, and social.

With regard to physical impact, patients reported pain and fatigue, which are two of the most cited symptoms of the treatment in the literature (Caterina Calderon et al., 2019a; Sanson-Fisher et al., 2019). On the other hand, patients detailed the high impact of the surgery and chemotherapy on their body aspect, where they may lose all the hair of their body, change their weigh and/or stay with less or no breast. Moreover, the impossibility of become mother is also a physical repercussion that appears often due to the treatments.

Regarding cognitive and emotional aspects, the first impact that patients report is the emotional rollercoaster that suffer while the diagnosis. In the same way that concluded in these studies, feelings of uncertainty, hopelessness, anger, fear and anxiety are detailed (Cameron et al., 2007; Spiegel et al., 1999). Body alterations described in the previous paragraph have a high affectation in the patients, concretely in their self-image and self-esteem, as well as in their identity. As Esplen and Trachtenberg (2000) detail, the construct of body image is more frequently recognized as complex and multifaceted, being a critical psychosocial issue for cancer patients. While the patients are advancing in their treatments, patients process their situation and they get into a personal change that concludes with a different perspective of their life. The literature details different manifestations of posttraumatic growth which are synthesized in new perception of self, relatedness to others, new life philosophy, and spiritual and religious growth (Zhai et al., 2019). This personal change sometimes makes it difficult to return to their “normal life”, where they have to come back to their “old life” but they feel different now. During this period, the medical check-ups cause a high level of stress due to fear of relapse, being the relapse one of the most feared situations (Miroševič et al., 2019). For those patients who are in the metastatic breast cancer stage, they report a huge impact due to the consideration of “metastasis” world which is linked with dead, therefore, they have to re-interpret the concept of this world due breast cancer patients may live for years with this diagnosis. Moreover, they suffer a huge emotional discomfort due the uncertainty of the time of life that they have left. Literature remarks that these patients feel medically well-treated but a multidisciplinary approach to care including psychological support is lacked (Lee Mortensen et al., 2018).

With respect social impact, patients report different situation. First of them is the difficulty of communicating to their surroundings, specially to their family. Breast cancer patients are usually woman that try to protect their closer people, specially their children, taking care of the way they express the situation and managing the new tasks of the situation. Literature reports that despite the challenging time, women puts on their positive face and attempt to conserve the family’s well-being (Campbell-Enns & Woodgate, 2017). Moreover, it is not only the patient who is affected, but the disease affects the whole family (Krouse & Krouse, 1982), often causing either imbalances or a feeling of greater closeness. One of the roles that appears in a marked way is the peer support offered by other patients who have gone through the same situation. At first, they are a fundamental guide in their support, since they feel understood among them; and more forward, as people to guide with the own experiences. Interestingly, literature reports that breast cancer patient are inclined to use computer-mediated social support group for developing interpersonal relationships (Namkoong et al., 2017). Metastasis patients reports a feeling of isolation and lack of understanding by the society due to their “normal” physical aspect, which does not reflect their disease (Cardoso et al., 2016).

During all this process, health professionals have a key role. Patients report being really grateful to the development of medicine and knowledge and support of professionals. These agents are key along all the first stages, which goes from diagnoses to the end of the treatments. In the same way as in the literature, patients express strong trust in their oncologists (Engelhardt et al., 2020). In the setting of resected, non-metastatic breast cancer, there are no recent studies that examine doctor-patient coincidence with respect to the estimation of relapse with/without adjuvant chemotherapy and regarding the risk of treatment toxicity. Our study concludes that patient’s predictions (both with and without chemotherapy) tend to be higher than oncologists’, overestimating the risks. Moreover, it was observed that the risk of relapse estimated by patients is *high* without chemotherapy and *very low* with chemotherapy. These results could be examined together with those described by Calderon et al. (2020b) where only 7.6% cancer patients evaluated upon completion of adjuvant chemotherapy expressed regret over having opted to receive this treatment, despite many of the patients reported fatigue, insomnia and pain. In addition, patients trust in their treatment regardless of their initial medical situation, while physicians estimate greater risks of relapse as disease stage increase. These data could suggest that the baseline level of concern of patients is high, and that situations that appear during their *journey* are faced under a worried feeling. Literature supports that pessimism and depression are two significant characteristics in breast cancer (Calderon et al., 2019b). It is important to remark the importance of physician-patient communication; for patients undergoing treatment with curative intent, treatment-related anxiety would decrease and expectations of being cured would increase by enhancing this communication.

These research’s findings have to be considered in conjunction with its limitations. First of all, all the patients who participated received assistance in Spain, therefore, the results cannot reflect the experiences and prognosis of breast cancer patient from other countries, both because the Spanish healthcare system and Spanish culture. Second, the experiences (study 1 and 2) were analyzed from middle aged women (34-61), being scarcely extrapolated to younger or older, men and other types of cancer. Third, estimations were analyzed with questionnaires with a cross-sectional study (study 3), which difficult to determine the directionality of the relationships and extrapolate them to patients who did not go to surgery or who are in a metastatic stage. Despite these limitations, we hope that the findings can contribute to improve the quality of life of breast cancer patients.

9. Final conclusions

9.1 Main contributions

After the completion of the doctoral thesis, the following conclusions have been obtained.

From the **first objective** "Describe breast cancer patient's experiences throughout all the stages of their disease with a journey model":

- The diagnosis and treatment of breast cancer entails a radical change in patients' day-to-day that linger in the mid-term.
- Seven stages have been defined through this process that correspond to the different medical moments: diagnosis/unmasking stage, surgery/cleaning out, chemotherapy/loss of identity, radiotherapy/transition to normality, follow-up care/the "new" day-to-day, relapse/starting over, and metastatic/time-limited chronic breast cancer.
- Through the diagnosis phase, patients feel an emotional whirlwind that includes fear, uncertainty, and other negative feelings. During the diagnostic testing, patients are extremely sensitive to the healthcare professionals' words and gestures; while in the diagnosis moment, some of the patients dissociate because of the emotional impact. All of them agree on how hard is to share their situation to their surroundings, which try to do it in the most positive spin possible.
- During the surgery phase, they feel uncertainty and fear. Because breast is associated with a feminine part, many women experience a feeling of loss. But because it is perceived as essential to

recovering their health, patients accept it and some of them demand a more invasive intervention.

- Through the chemotherapy phase, side effects as physical discomfort and hair loss are the worst impact, living it as a loss of health and femininity, and feeling highly vulnerable. Patients need to balance between caring for oneself and for others and experience as a hard moment explaining the situation to their children, whom they want to protect.
- During the radiotherapy phase, patients live it as the last treatment: exhausted but with joy and relief. There is a widespread perception that radiotherapy has fewer side effects than chemotherapy.
- In the follow-up phase, patients have difficulty returning to normal day-to-day life. Some are still working on their personal process, most have sequelae from the treatments, as lymphedema, some express difficult for their affective-sexual relations, and some for returning to work. Medical check-ups are living with worry and insecurity because a fear of relapse. Hormone therapy is accepted different depending on the age and the decision of having children. Patients want to support other patients in the early disease.
- Women have positive opinions regard the breast reconstruction. Those who prefer not to undergo reconstruction immediately feel a subtle pressure to do it.
- During the relapse phase, patients feel negative emotions such as fear. Some of them think about whether it could have been done differently in order not to have a recurrence. Communicating the new situation to the family is one of the toughest parts, which they try to minimize to protect others.

- In the metastatic breast cancer phase, patients must re-interpreting the concept to metastasis from death to chronic with a limited time. They stop identifying with the rest of breast cancer patients and feel difficult to manage their situation socially because the lack of physical signs. Patients feel physical and emotional discomfort because side effects, uncertainty about the effectiveness of the treatment, their children, and the impossibility to work.
- Throughout the entire patient journey stands out a process of loss of health and identity as well as a personal change that materializes in a self-knowledge and a greater focus in the day to day.
- Family and other patients with the same clinical condition are key as social support for breast cancer patients.

From the **second objective** "Examine doctor-patient coincidence with respect to the estimation of relapse with/without adjuvant chemotherapy and regarding the risk of treatment toxicity":

- Oncologists' prediction of risk of relapse with and without chemotherapy and risk of severe toxicity were more optimistic than those of breast cancer patients. Doctors considered that the risk of relapse with and without chemotherapy was very low and low, respectively, whereas patients felt that their risk with chemotherapy was very low and high without chemotherapy, respectively. Oncologists predicted risk of severe toxicity as very low while patients predicted it as low.
- It is key to improve doctor-patient communication in SDM for offering some more realistic expectations.

- The higher the tumor stage, the higher the risk of relapse without and with chemotherapy according to the oncologists. For the patients, the higher the tumor stage, the higher risk of relapse without chemotherapy, not with chemotherapy.
- Older physicians and more experienced ones predicted lower risk of relapse with and without chemotherapy and less severe toxicity than younger doctors and those with less experience.
- The higher the estimated risk of relapse with chemotherapy, the less satisfied the oncologist was with SDM. Similarly, patients were more satisfied with SDM when their risk of severe toxicity was lower.
- Psychological distress of the patient and their prognosis of greater risk of recurrence with chemotherapy are positively correlated.

9.2 Implications for clinical practice

As psychologists, our gaze is always focused on understanding our users to, from their own perspective, accompany them on their way. The research carried out in this thesis allows us to delve into the feelings and lives of people diagnosed with breast cancer, and in this way, understand the reason for their experiences. Knowing the journey, they go through (from the time they are diagnosed to the more advanced stages), helps the professionals who deal with these patients to have a closer look at their experiences and to be able to adapt to each of them. Moreover, it facilitates the detection of situations of risk and helps to identify key moments when more precise information should be offered. Similarly, preparing the women for the process they must confront and for the sequelae of medical treatments would contribute to decreasing their uncertainty and concern, and to improving their quality-of-life. In addition to the qualitative study of the patient´s journey, having developed a quantitative study at a specific time, just before starting chemotherapy, has allowed us to establish a baseline in terms of the severity perceived by patients in relation to oncologists, and consequently of the health system. All the information obtained highlights the important and necessary work of the psychologist in the oncological context, a task that, given medical advances, will have to continually adjusted to reality, although without forgetting the burden of so many years of hopelessness in the face of this diagnosis.

Knowing in depth the needs of patients diagnosed with breast cancer leads to reflection on how to best accompany them. On the one hand, regarding patients, this need for support is observed, which is reflected in each of the stages of the journey. In addition to counselling in individual sessions, community accompaniment appears to be essential, especially with other patients, since it is with other people who have gone through the same situation that they feel most understood and supported. On the other hand, it is observed the essential role that health professionals have in the experiences of patients, how their work can help them improve their quality of life. The results indicate that enhancing physician-patient communication for some more realistic expectations with respect the risk of relapse and toxicity could lessen anxiety, depression, and fear of treatment.

It is for all these reasons that, together with other researchers from the NEOcoping study, we have created an association, called HealthyOnco, with the aim of creating an integrative space, of quality and scientific rigor, where to share knowledge and promote health-related quality of life (HRQoL) of cancer patients. We are currently developing a web platform for both cancer health professionals and people diagnosed with cancer and their families with the aim of sharing scientific evidence, disseminating good practices, collecting doubts, offering support to patients, and continuing to jointly research on cancer. It is the way we have found to transfer information from our research, with the aim that it really has an impact on the lives and HRQoL of all these patients. In addition, specifically for patients with breast cancer, an app is planned where patients have both a personal space and a space for interaction with other people who are going through the same situation. The most appropriate way for patients to find a small group is currently being developed; the goal is to offer them a space where they can find support while reducing the amount of negative interactions (such as treatment failures and tumor recurrence) from large groups.

9.3 Future work

The field of psycho-oncology is a field with a wide projection, there are more people diagnosed with a long survival, and the number of professionals integrated in health teams is currently low despite the exposed needs and the high demand (Echarte, Fuster, Roda, & Velasco, 2019). Because of that, more professionals with specific knowledge about this pathology integrated into the health system are needed.

At the research level, the discipline of psycho-oncology is recent, and, despite the fact that resources have been allocated to its knowledge, there is still a wide range of research to be carried out, such as long time clinical-controlled studies, effective interventions for the consequences of cancer and its treatments, methodologically high quality psychotherapies studies in oncology and palliative care, prevention research in cancer, or health care services research in psycho-oncology (as barriers and favorable conditions for the implementation of psycho-oncology interventions, evaluation of the effectiveness and efficiency and quality standards) (Goerling & Mehnert, 2018).

Regarding the research developed in this thesis, as a continuation of the first objective “describing breast cancer patient’s experiences throughout all the stages of their disease with a journey model”, it is expected to continue working on the HealthyOnco web platform and in the app for patients with breast cancer. In this way, it will be possible to continue knowing their experiences and investigate the impact of technologies as support for cancer patients. Due to the pandemic situation we are going through, virtual tools are becoming more and more relevant, which is why it is key to continue delving in this field.

Regarding to the second objective “examining doctor-patient coincidence with respect to the estimation of relapse with/without adjuvant chemotherapy and regarding the risk of treatment toxicity”, it is expected to continue investigating SDM and doctor-patient communication. In the study in which I participated, "NEOCOPING: coping, quality of life and communication focused on the patient with early-stage cancer treated with adjuvant chemotherapy", data were collected on perceptions of the risk of recurrence at six months, data pending to be analyzed and compared with the currently published study.

Finally, it is also important to note that, as shown in the first study, the experiences of the patients are related to the medical treatments to which they are subjected. In addition to classical treatments, such as chemotherapy, radiation therapy, and surgery, there are currently other systemic treatments as immunoterapy and antitargeted drugs. In this regard, I am currently participating in the “NEOETIC Study: coping, quality of life, psychological effects and shared decision-making during the treatment of adjuvant cancer in immunotherapy” where risk and prevention factors (sociodemographic, clinical, and psychological) that influence cancer coping, quality of life, doctor-patient communication, and expectations regarding immunotherapy are identified. This research is expected to deepen the experiences of patients with these treatments.

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11. Annexes

11.1 Other articles published

Other articles published during the doctoral thesis period are listed below:

1. Carmona-Bayonas, A.; Calderón, C.; Hernández, R., Fernández-Montes, A.; Castelo, B.; **Ciria-Suárez, L.;** Antoñanzas-Baza, M.; Rogado, J.; Pacheco-Barcia, V.; Asensio-Martinez, E.; Ayala de la Peña, F., Jiménez-Fonseca, P. (2021). Prediction of quality of life in early breast cancer upon completion of adjuvant chemotherapy. *NPJ Breast Cancer,* 7. **JCR, IF: 6,0 Q1** *Oncology* 41/244. **SJR, IF:** 3,545 **Q1** Oncology, **Q1** Pharmacology (medical), **Q1** Radiology, Nuclear Medicine and Imaging. ISSN: 23744677. https://doi.org/10.1038/s41523-021-00296-8

2. **Ciria-Suárez, L.;** Calderon, C.; Fernández-Montes, A.; Antoñanzas, M.; Hernández, R.; Rogado, J.; Pacheco-Barcia, V.; Asensio-Martinez, E.; Palacin-Lois.; Jiménez-Fonseca, P. (2021). Optimism and Social Support as contributing Factors to Spirituality in Cancer Patients. *Supportive Care in Cancer,* 29, 3367–3373. **JCR, IF: 2,698 Q1,** *Rehabilitation* 12/65. **Q2** *Health Care Science & Services* 24/90, **Q2**. *Oncology* 124/217. ISSN: 0941-4355. https://doi.org/10.1007/s00520-020-05954-4

3. Calderón, C.; Ferrando, P.J.; Lorenzo-Seva, U.; Gómez-Sánchez, D.; Ferreira, E.; **Ciria-Suárez, L.;** Oporto, M.; Jímenez-Fonseca, P. (2021). Factor structures and psychometric properties of Spanish version of the Mini-Mental Adjustment to Cancer Scale. *International Journal of Clinical and Health Psychology,* 21 (1). **JCR, IF: 3,9 Q1** Psychology, Clinical 22/130. **SJR, IF:** 1.345 **Q1** *Clinical Psychology*.ISSN : 1697-2600. https://doi.org/10.1016/j.ijchp.2020.06.001

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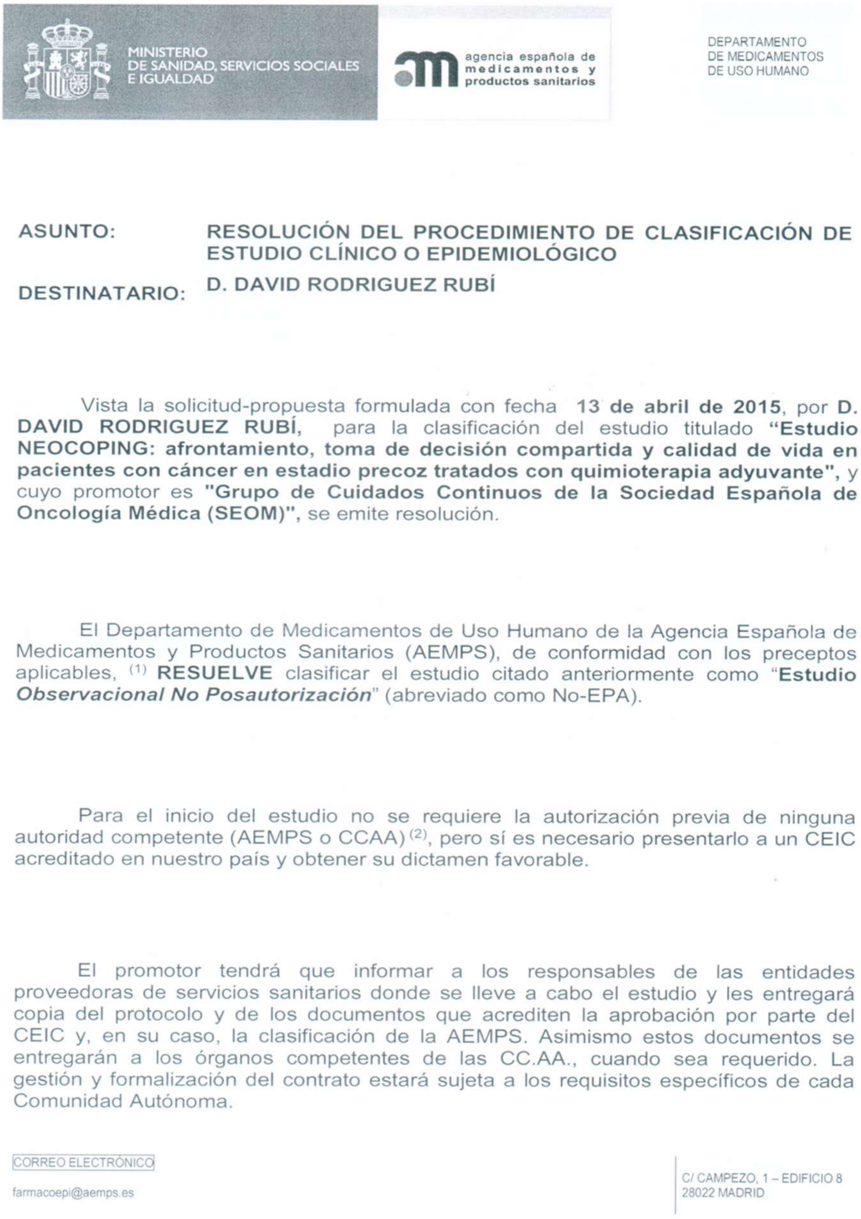
11.2 AEMPS classification of the NEOcoping study.



MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

DEPARTAMENTO
DE MEDICAMENTOS
DE USO HUMANO

ASUNTO: **RESOLUCIÓN DEL PROCEDIMIENTO DE CLASIFICACIÓN DE ESTUDIO CLÍNICO O EPIDEMIOLÓGICO**

DESTINATARIO: **D. DAVID RODRIGUEZ RUBÍ**

Vista la solicitud-propuesta formulada con fecha **13 de abril de 2015**, por **D. DAVID RODRIGUEZ RUBÍ**, para la clasificación del estudio titulado **"Estudio NEOCOPING: afrontamiento, toma de decisión compartida y calidad de vida en pacientes con cáncer en estadio precoz tratados con quimioterapia adyuvante"**, y cuyo promotor es **"Grupo de Cuidados Continuos de la Sociedad Española de Oncología Médica (SEOM)"**, se emite resolución.

El Departamento de Medicamentos de Uso Humano de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), de conformidad con los preceptos aplicables, (1) **RESUELVE** clasificar el estudio citado anteriormente como "***Estudio Observacional No Posautorización***" (abreviado como No-EPA).

Para el inicio del estudio no se requiere la autorización previa de ninguna autoridad competente (AEMPS o CCAA) (2), pero sí es necesario presentarlo a un CEIC acreditado en nuestro país y obtener su dictamen favorable.

El promotor tendrá que informar a los responsables de las entidades proveedoras de servicios sanitarios donde se lleve a cabo el estudio y les entregará copia del protocolo y de los documentos que acrediten la aprobación por parte del CEIC y, en su caso, la clasificación de la AEMPS. Asimismo estos documentos se entregarán a los órganos competentes de las CC.AA., cuando sea requerido. La gestión y formalización del contrato estará sujeta a los requisitos específicos de cada Comunidad Autónoma.

CORREO ELECTRÓNICO
farmacoepi@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID

Contra la presente resolución que pone fin a la vía administrativa podrá interponerse Recurso Potestativo de Reposición, ante la Directora de la Agencia, en el plazo de un mes a contar desde el día siguiente a aquel en que tenga lugar la notificación de la presente resolución. (3)

Madrid, a 14 de abril de 2015

EL JEFE DE DEPARTAMENTO DE
MEDICAMENTOS DE USO HUMANO

agencia española de
medicamentos y
productos sanitarios
Departamento de Medicamentos de Uso Humano
División de Farmacoepidemiología y Farmacovigilancia

César Hernández García

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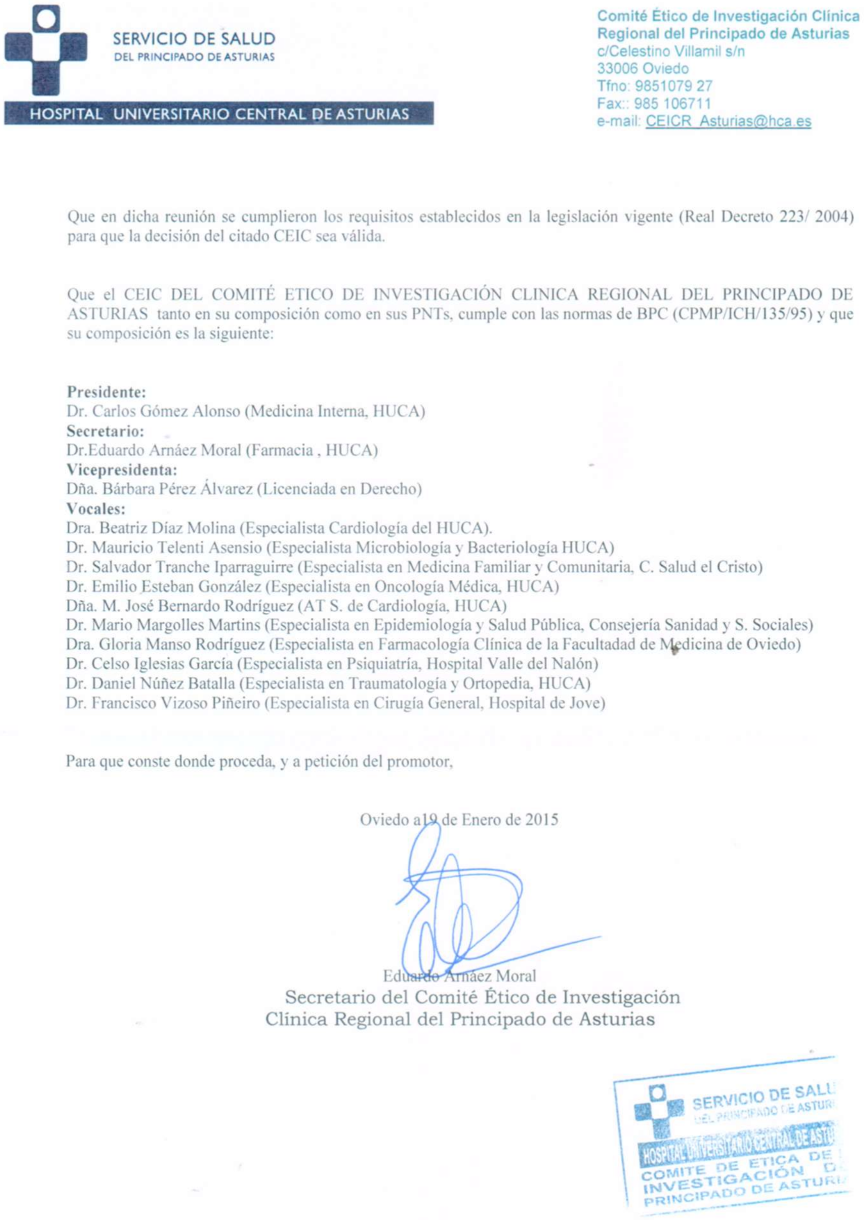
[1] Son de aplicación al presente procedimiento la Ley 30/1992, de 26 de noviembre, de Régimen Jurídico de las Administraciones Públicas y del Procedimiento Administrativo Común; la Ley 12/2000, de 29 de diciembre, de medidas fiscales, administrativas y de orden social; la Ley 29/2006, de 26 de julio, de Garantías y Uso Racional de los Medicamentos y Productos Sanitarios; el Real Decreto 223/2004, de 6 de febrero, por el que se regulan los ensayos clínicos con medicamentos; el Real Decreto 1275/2011, de 16 de septiembre, por el que se crea la Agencia estatal "Agencia Española de Medicamentos y Productos Sanitarios" y se aprueba su estatuto; el Real Decreto 577/2013, de 26 de julio, por el que se regula la farmacovigilancia de medicamentos de uso humano y la Orden SAS/3470/2009, de 16 de diciembre, por la que se publican las directrices sobre estudios posautorización de tipo observacional para medicamentos de uso humano.

[2] De acuerdo con la Orden SAS/3470/2009, de 16 de diciembre

[3] De conformidad con lo dispuesto en los artículos 116 y 117 de la Ley 30/1992, de 26 de noviembre, o Recurso Contencioso-Administrativo ante el Juzgado Central de lo Contencioso-Administrativo de Madrid, en el plazo de dos meses contados desde el día siguiente al de la notificación de la presente resolución, de conformidad con la Ley 29/1998, de 13 de Julio, reguladora de la Jurisdicción Contencioso-Administrativa, sin perjuicio de poder ejercitar cualquier otro recurso que se estime oportuno. En caso de interponerse recurso de reposición no podrá interponerse recurso contencioso-administrativo hasta la resolución expresa o presunta del primero.

11.3 Bioethics commission approvals.



SERVICIO DE SALUD
DEL PRINCIPADO DE ASTURIAS
HOSPITAL UNIVERSITARIO CENTRAL DE ASTURIAS

Comité Ético de Investigación Clínica
Regional del Principado de Asturias
c/Celestino Villamil s/n
33006 Oviedo
Tfno: 9851079 27
Fax:: 985 106711
e-mail: CEICR_Asturias@hca.es

Que en dicha reunión se cumplieron los requisitos establecidos en la legislación vigente (Real Decreto 223/ 2004) para que la decisión del citado CEIC sea válida.

Que el CEIC DEL COMITÉ ETICO DE INVESTIGACIÓN CLINICA REGIONAL DEL PRINCIPADO DE ASTURIAS tanto en su composición como en sus PNTs, cumple con las normas de BPC (CPMP/ICH/135/95) y que su composición es la siguiente:

Presidente:
Dr. Carlos Gómez Alonso (Medicina Interna, HUCA)
Secretario:
Dr.Eduardo Arnáez Moral (Farmacia , HUCA)
Vicepresidenta:
Dña. Bárbara Pérez Álvarez (Licenciada en Derecho)
Vocales:
Dra. Beatriz Díaz Molina (Especialista Cardiología del HUCA).
Dr. Mauricio Telenti Asensio (Especialista Microbiología y Bacteriología HUCA)
Dr. Salvador Tranche Iparraguirre (Especialista en Medicina Familiar y Comunitaria, C. Salud el Cristo)
Dr. Emilio Esteban González (Especialista en Oncología Médica, HUCA)
Dña. M. José Bernardo Rodríguez (AT S. de Cardiología, HUCA)
Dr. Mario Margolles Martins (Especialista en Epidemiología y Salud Pública, Consejería Sanidad y S. Sociales)
Dra. Gloria Manso Rodríguez (Especialista en Farmacología Clínica de la Facultadad de Medicina de Oviedo)
Dr. Celso Iglesias García (Especialista en Psiquiatría, Hospital Valle del Nalón)
Dr. Daniel Núñez Batalla (Especialista en Traumatología y Ortopedia, HUCA)
Dr. Francisco Vizoso Piñeiro (Especialista en Cirugía General, Hospital de Jove)

Para que conste donde proceda, y a petición del promotor,

Oviedo a19 de Enero de 2015

Eduardo Arnáez Moral
Secretario del Comité Ético de Investigación
Clínica Regional del Principado de Asturias

SERVICIO DE SALU
DEL PRINCIPADO DE ASTUR
HOSPITAL UNIVERSITARIO CENTRAL DE ASTU
COMITE DE ETICA DE
INVESTIGACIÓN D
PRINCIPADO DE ASTURI

SERVICIO DE SALUD
DEL PRINCIPADO DE ASTURIAS

HOSPITAL UNIVERSITARIO CENTRAL DE ASTURIAS

Comité de Ética de la Investigación del Principado de Asturias
C/ Celestino Villamil s/n
33006.-Oviedo
Tfno: 985.10.79.27/985.10.80.28
e-mail: celcr_asturias@hca.es

Área Sanitaria IV

Oviedo,19 de Enero de 2015

El Comité Ética de la Investigación del Principado de Asturias ha evaluado el Estudio nº 10/15, titulado "NEOCOPING: AFRONTAMIENTO, TOMA DE DECISIÓN COMPARTIDA Y CALIDAD DE VIDA EN PACIENTES CON CÁNCER EN ESTADIO PRECOZ TRATADOS CON QUIMIOTERAPIA ADYUVANTE", versión 1.15 de 12 de enero 2015.Promotor Grupo de cuidados Continuos SEOM. Investigadores Principales Dra. Paula Fonseca Jiménez y Dr. David José Rodríguez Rubí. S. Oncología Médica del HUCA.

El Comité ha tomado el acuerdo de considerar que el citado estudio reúne las condiciones éticas necesarias para poder realizarse y, en consecuencia, emite su autorización.

Le recuerdo que deberá guardar la máxima confidencialidad de los datos utilizados en este estudio.

Le saluda atentamente.

Fdo: Eduardo Arnáez Moral
Secretario del Comité Ético de Investigación
Clínica Regional del Principado de Asturias

UNIVERSITAT DE BARCELONA

Oficina de Gestió de la Recerca
Pavelló Rosa (recinte Maternitat) primer pis
Travessera de les Corts, 131-159 93-4035398
08028 Barcelona

Comisión de Bioética
de la Universitat de Barcelona

Certificado de aprobación
Sobre experimentación en humanos o en muestras de origen humano

---

Don Albert Royes Qui, Secretario de la Comisión de Bioética de la Universitat de Barcelona.

CERTIFICA:

Que la Dra. **Caterina Calderon Garrido** presentó el proyecto titulado "APP para pacientes oncológicos con tratamiento de inmunoterapia para conocimiento, evaluación y control de los efectos secundarios por medio de inteligencia artificial" La Comisión de Bioética de la Universitat de Barcelona analizó toda la documentación presentada por la Dra. **Caterina Calderon Garrido** y, por acuerdo de fecha 14 de noviembre de 2019, aprobó informar favorablemente desde el punto de vista bioético el proyecto de investigación de referencia.

Y para que conste y a los efectos que corresponda, firmo este documento con el visto bueno del presidente de la Comisión en Barcelona a 14 de noviembre de 2019.

Universitat de Barcelona
Comissió de Bioètica

Vº Bº El presidente de la Comisión de Bioética de la Universitat de Barcelona

Domènec Espriu Climent

UNIVERSITAT DE BARCELONA
Oficina de Gestió de la Recerca

11.4 Patient information sheet for battery tests

Título: Estudio NEOCOPING: afrontamiento, toma de decisión compartida y calidad de vida en pacientes con cáncer en estadio precoz tratados con quimioterapia.

Promotor: Grupo de Cuidados Continuos de la Sociedad Española de Oncología Médica (SEOM).

En el Servicio de Oncología Médica del centro……………………………………………….. se está realizando un estudio en el que se le invita a participar después de que haya leído la información que se le facilita en estas páginas, y haya consultado y aclarado todas las dudas. Pregunte a su médico cualquier cuestión, y solicítele cualquier aclaración que considere necesaria, para que pueda decidir de forma libre y con la información necesaria, si quiere o no participar en este estudio.

Pacientes participantes en el estudio

Se prevé una participación de unos 1000 pacientes.

Procedimientos del estudio

Recogida de datos de pacientes con un cáncer en estadio precoz, sin metástasis, que reciben quimioterapia tras una cirugía curativa. Se evaluarán las estrategias de afrontamiento de la enfermedad, la toma de decisión compartida entre paciente y médico y la calidad de vida de los pacientes al inicio y al finalizar el tratamiento. Además, se correlacionarán con datos psicosociales y clínicos.

Beneficios y riesgos de la participación en el estudio

Usted será tratado según la práctica clínica habitual de su médico. No existen beneficios específicos relacionados con su participación, ni tampoco tendrá un riesgo adicional diferente al que de por sí tiene su enfermedad. El beneficio del estudio proviene de la obtención de datos que completarán el conocimiento de su enfermedad. Este hecho podrá ser usado por la comunidad científica y médica, para establecer nuevas investigaciones, nuevas formas de abordaje psicosocial y de comunicación, que redundará, finalmente, en una mejora asistencial de los pacientes y en la ayuda para afrontar la enfermedad.

Carácter voluntario de la participación

Si decide participar en este estudio se le pedirá que firme un formulario de consentimiento escrito. Si después de pensarlo, decide no participar en el estudio, o una vez que está participando posteriormente cambia de idea, por favor, informe a su médico. Es usted quien tiene que decidir libremente si participar o no, y su médico no tomará partido respecto a su decisión, ni la juzgará. Si elige abandonar el estudio después de decidir su participación (incluida la posibilidad de que sus datos se destruyan y no resulten analizados), no tendrá que explicar los motivos que le han llevado a tomar esa decisión, y se le ofrecerá el tratamiento que su médico piense que se adecua mejor y la misma calidad asistencial.

Su participación, por tanto, es de carácter voluntario y si decide retirarse del estudio no se alterará su relación con los médicos, ni se producirá ningún perjuicio en su seguimiento clínico ni en su tratamiento. También el promotor podrá terminar el estudio, durante el desarrollo de este.

Confidencialidad de los datos personales

Toda la información relativa al paciente será tratada de forma estrictamente confidencial. El paciente sólo será identificado por un número. El tratamiento de los datos de carácter personal requeridos en este ensayo se rige por la Ley Orgánica 15/1999. De acuerdo con lo que establece la legislación mencionada, usted puede ejercer el derecho de acceso, modificación, oposición y cancelación de datos, para lo cual deberá dirigirse a su médico del estudio. La información obtenida de este estudio no podrá ser revelada a ninguna persona sin su consentimiento por escrito, excepto a su médico o sus colaboradores, al promotor del estudio o sus representantes, a los coordinadores, a los Comités Éticos de Investigación Clínica de los hospitales donde se esté realizando el estudio y, en el caso de que se requiera, a las autoridades competentes de las Comunidades Autónomas.

Los expertos autorizados del promotor podrán supervisar la realización del estudio a través de la denominada monitorización o auditoria, para que puedan confirmar que la información recogida durante el estudio es exacta. Estos expertos, así como los miembros de las autoridades, tienen el derecho de inspeccionar los datos médicos originales (historia médica, datos de laboratorio, etc.) del paciente. Pero siempre se mantendrá la confidencialidad de los datos según la legislación vigente.

En la práctica, la transmisión de la información se hará de forma que no permita identificar al paciente. El médico y sus colaboradores en el estudio transmitirán la información a través de un CRD electrónico al servidor dispuesto para tal fin.

Los resultados obtenidos en este estudio se usarán para presentaciones o publicaciones científicas. En el caso de que los resultados de este estudio se publicasen, el nombre del paciente no será nunca mencionado. En dichas publicaciones o presentaciones se mantendrá la confidencialidad de los datos, de acuerdo con la Ley Orgánica de protección de datos de carácter personal 15/1999, de 13 de diciembre.

Debe saber que este estudio ha sido aprobado por el Comité Ético y que se realizará cumpliendo la legislación europea y española vigente para este tipo de estudios.

Persona de contacto

Durante todo el estudio podrá formular cualquier pregunta que tenga. Si surge algún problema o más preguntas sobre el estudio, póngase en contacto con la persona indicada a continuación:

Nombre: ……………………………………………………………………………………
Dirección: ……………………………………………………………………………………
Teléfono: ……………………………………………………………………………………

11.5 Patient informed consent

Título: Estudio NEOCOPING: afrontamiento, toma de decisión compartida y calidad de vida en pacientes con cáncer en estadio precoz tratados con quimioterapia

Promotor: Grupo de Cuidados Continuos de la Sociedad Española de Oncología Médica (SEOM).

Yo,…………………………………………………………………………….. (nombre y apellidos del paciente)

He recibido la información contenida en la hoja de información al paciente sobre el estudio titulado: "Estudio NEOCOPING: afrontamiento, toma de decisión compartida y calidad de vida en pacientes con cáncer en estadio precoz tratados con quimioterapia".

He podido hacer preguntas sobre el estudio.

- He recibido suficiente información sobre el estudio.
- He hablado con el doctor ……………………………………………………………………………

Comprendo que mi decisión sobre la participación en el estudio es voluntaria.

Comprendo que puedo retirarme del estudio:

- Cuando quiera.
- Sin tener que dar explicaciones.
- Sin que esto repercuta en sus cuidados médicos.

Entiendo que, al acceder a participar en este estudio, consiento en la recogida, tratamiento, cesión y transferencia (si procede) de mis datos personales, con respeto del anonimato para fines de atención sanitaria y/o investigación médica.

Presto libremente mi conformidad para participar en el estudio y que mis datos puedan ser utilizados con fines de investigación.

Recibiré una copia firmada de la hoja de información y del consentimiento informado.

Nombre y apellidos del paciente (en mayúsculas)

………

Firma del paciente:

Fecha

_____/_____/_____

Nombre y apellidos del investigador (en mayúsculas)

………………………………………………………………………………………………………

Firma del investigador: Fecha
_____/_____/_____

Título: Patient Journey de pacientes con Cáncer de Mama
Yo,……………………………………………………………………………. (nombre y apellidos del paciente)

He recibido la información referente al estudio sobre el "Patient journey de pacientes con cáncer de mama" y he podido realizar las preguntas necesarias sobre el mismo.

Comprendo que mi decisión sobre la participación en el estudio es voluntaria. Entiendo que puedo retirarme del estudio en el momento que quiera y sin necesidad de tener que dar explicaciones.

Entiendo que, al acceder a participar en este estudio, consiento en la recogida, tratamiento, cesión y transferencia (si procede) de la información obtenida en las entrevistas.

Presto libremente mi conformidad en la grabación de la entrevista y en la utilización de las propias palabras para futuras publicaciones.

Recibiré una copia firmada del consentimiento informado.
Firma del paciente:

Fecha
_____/_____/_____
Nombre y apellidos del investigador (en mayúsculas)

………………………………………………………………………………………………………

Firma del investigador: Fecha
_____/_____/_____

11.6 List of study centers and principal investigators

1. CCAA PAÍS VASCO: Hospital Galdakao-Asunsolo, Galdácano. Dra Montserrat Mangas
2. CCAA ASTURIAS: Hospital Universitario Central de Asturias de Oviedo. Dra Paula Jiménez-Fonseca
3. CCAA CANTABRIA: Hospital Universitario Marqués de Valdecilla, Santander. Dra Eva Martínez de Castro
4. CCAA CASTILLA LA MANCHA: Hospital General Virgen de la Luz, Cuenca. Dra María del Mar Muñoz
5. CCAA MADRID: Hospital Universitario La Paz, Madrid. Dra Beatriz Castelo
6. CCAA MADRID: Hospital Universitario La Princesa, Madrid. Dra Olga Donnay
7. CCAA MADRID: Hospital Universitario Fundación Alcorcón, Madrid. Dr Carlos Jara
8. CCAA CATALUÑA: Hospital Universitari Santa Creu i San Pau, Barcelona. Dra Margarita Majem
9. CCAA MURCIA: Hospital Universitario Morales Meseguer, Murcia. Dr Alberto Carmona -Bayonas
10. CCAA ANDALUCÍA: Hospital Quirónsalud de Sevilla. Dra Carmen Beato
11. CCAA CANARIAS: Hospital Universitario de Canarias, Tenerife. Dra Raquel Hernández