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Addressing the effectiveness of an intervention to improve mental adjustment to breast cancer

Submission date
20/10/2023

Recruitment status
No longer recruiting

Registration date
27/10/2023

Overall study status
Completed

Last Edited
15/04/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
The process of adaptation to the disease understood as mobilization of resources and development of coping strategies, is related to the patient's quality of life and well-being. Starting from this general hypothesis, the present research project has the following goal to evaluate the effectiveness of an individualized psychosocial intervention based on the management of resources to improve adaptation to breast cancer. In this way, a quasi-experimental intervention study of repeated measures with a control group will be carried out (i.e., a randomised controlled trial). The achievement of the objectives will generate knowledge to improve the quality of life and well-being of patients and that can be transferable to clinical practice guidelines. In particular, patients in the intervention group will report (H1) fewer anxiety symptoms; (H2) fewer depressive symptoms; (H3) better quality of life; (H4) better psychological well-being; and (H5) less use of psychiatric drugs, than patients in the control group (i.e., receiving just information).

Who can participate?
Patients aged between 18 and 90 years old with a primary breast cancer tumor that requires a surgery intervention

What does the study involve?
Participation will be voluntary, among female patients with breast cancer who attend the Breast Cancer Service from the Oncology Clinical Area of two large metropolitanean Hospitals in Andalusia. These patients have been recently diagnosed with a primary tumor that requires surgery treatment. An individualized psychosocial support intervention will be offered for a duration of six months (from the diagnosis to the six-month follow-up considered in the clinical protocol for breast cancer treatment in Andalusia). Patients will be surveyed for their perceptions (self-reported measures) four times: before surgery or T1, three months after surgery or T2, six months after surgery or T3, which corresponds to the end of the intervention, and twelve months after surgery or t4, which corresponds to a six-month follow-up after finishing the intervention).

What are the possible benefits and risks of participating?
The possible benefits are improving the mental adjustment to breast cancer and therefore

reducing its potential negative effects on psychological well-being. However, these benefits are not guaranteed and may differ to a great extent depending on personal and social characteristics. Participation in the study does not have any potential risk.

Where is the study run from?
The Carmides research group (carmides.es/en) at the Social Psychology Department of the Psychology School at Universidad de Sevilla. Data collection and the intervention will be conducted in the Hospital "Virgen del Rocio" and "Virgen de Valme" (agreement through the Health Research Foundation of the Andalusian Public Healthcare System, which is the funding body) (Spain)

When is the study starting and how long is it expected to run for?
June 2017 to June 2024

Who is funding the study?
Andalusian Public Progress and Health Foundation (Spain)

Who is the main contact?
Jose M. Leon-Perez, leonperez@us.es (Spain)

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PEIBA 81/2018

Study information

Scientific Title
Addressing the effectiveness of an intervention to improve mental adjustment to breast cancer: A longitudinal and experimental study

Acronym
MEJORA

Study objectives
Patients receiving a psychosocial intervention to mentally adjust better to primary breast cancer will report (H1) less anxiety symptoms; (H2) less depressive symptoms; (H3) better quality of life; (H4) Better psychological well-being; and (H5) less use of psychiatric drugs, than patients in the control group (i.e., receiving just information).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/03/2019, Almeria Research Ethics Committee (Comité de Ética de Investigación de Almería) (Hospital Universitario Torrecárdenas, Calle Hermandad de Donantes de Sangre, s/n, Almeria, 04009, Spain; +34 950 016 531, 671 562 421; al42_cetico_cht.hto.sspa@juntadeandalucia.es), ref: PEIBA 81/2018

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Quality of life, Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Quality of life in female patients with breast cancer

Interventions

The present study is a randomised controlled trial. Adding to regular clinical services is a psychosocial intervention to facilitate mental adjustment to breast cancer and its consequences versus no treatment or control group that only receives regular clinical services and psychological information.

The study involves voluntary participation from patients (female breast cancer) attending one metropolitan hospital in Andalusia (Breast Cancer Service at Oncology Clinical Area). Inclusion criteria: 18 years old or more, primary tumor and non-psychiatric condition. All voluntary participants will be accepted (recruitment period: two months). Participants are enrolled in the study continuously. A simple randomisation method is used: throwing a die/rolling a dice. Then, numbers below and equal to 3 are assigned to the control group and over 3 to the intervention group. When 40 volunteers are reached in the intervention group (the maximum number of participants that will be offered the intervention), the next participants enrolled in the study are automatically assigned to the control group. The healthcare professionals who are recruiting and conducting the intervention are not aware of the research design (they are not part of the research team). The person who analyzes data receives a coded dataset to ensure ethical data analysis and avoid publication biases.

Intervention Type
Behavioural

Primary outcome measure
Psychological well-being measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 3, 6 and 12 months after surgery

Secondary outcome measures
1. Health-related quality of life measured using the Health-related quality of life measure EORTC-QLQ-C30 at baseline, 3 and 12 months after surgery.
Psychiatric drug use (i.e., pain killers, antidepressants, and anxiolytics) measured using self-reported measures of frequency of use (from 0 = never to 4 = almost every day) at 3, 6 and 12 months after surgery

Overall study start date
20/06/2017

Completion date
30/06/2024

Eligibility

Key inclusion criteria
2. Aged 18 years old and over
2. Diagnostic of primary breast cancer tumor that requires a surgery intervention

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Female

Target number of participants
120

Total final enrolment
132

Key exclusion criteria
Having a psychiatric disorder or under any psychological treatment at the moment of being enrolled

Date of first enrolment
01/06/2019

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
Spain

Study participating centre
Universidad de Sevilla. Facultad de Psicología
Calle Camilo Jose Cela s/n
Sevilla
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Sponsor information

Organisation
Fundación Progreso y Salud

Sponsor details
Parque Científico y Tecnológico Cartuja
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Sponsor type
Government

Website
https://www.juntadeandalucia.es/organismos/fps.html

ROR
https://ror.org/0048t7e91

Funder(s)

Funder type
Government

Funder Name
Fundación Pública Andaluza Progreso y Salud

Alternative Name(s)
Andalusian Public Progress and Health Foundation, Progreso y salud Andalusian Public Foundation, Fundación Progreso y Salud, FPS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Spain

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2025

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication and later on, will be stored in a publicly available repository (https://idus.us.es/ and https://osf.io/).

Anonymized raw data will be stored that includes participants' responses to all variables of the study in Excel (.csv) and SPSS format. Also, we will share the SPSS syntax used to compute variables and analyze data. Data will be publicly available at the moment that the first article in a peer-reviewed journal is published. Data will be available for, at least, five years. Written consent was obtained from all participants. All participants received a unique code at the moment they enrolled in the study. Such code is used in all data shared among the research team. The Excel file that allows linking anonymized raw data or codes with participants' identity (their written consent) is protected with a password and stored in an external device (USB stick or pen drive). Such Excel files together with the physical written consent are locked in the principal investigator's office. There are no legal restrictions. Data can be modified if any participant decides to delete their data (a legal right that participants have according to Spanish regulation).

IPD sharing plan summary

Stored in publicly available repository, Published as a supplement to the results publication