

Brief group interventions with breast cancer survivors

Submission date 03/10/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/12/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/12/2013	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Scientific research has found that cancer survivors face worries about the future, depression, post-traumatic symptoms and lower quality of life. Most studies provide support using cognitive-behavioural therapy (CBT) strategies. However, this is not studied in detail for breast cancer survivors especially in Portugal. The current study aims to find out how acceptable and effective the two brief group intervention programs are for breast cancer survivors.

Who can participate?

Women aged 18 years or older who were diagnosed and received treatment for breast cancer in the past and do not have the disease at present.

What does the study involve?

Participants were randomly allocated to one of three groups: a control group, a psychoeducational intervention group or a cognitive-behavior therapy group. Participants were followed up at two different occasions.

What are the possible benefits and risks of participating?

Participants in the intervention groups may have improved quality of life. Participants in the control group will not receive any direct benefit from participation. We do not anticipate any risks, side effects or discomforts as a result of participation.

Where is the study run from?

The study is run from the Portuguese Cancer League and from Hospital of Braga, both in Portugal.

When is study starting and how long is it expected to run for?

The study started in April 2009 and ran until March 2013.

Who is funding the study?

Portuguese Foundation of Science and Technology (Fundação ciência e tecnologia [FCT]) (Portugal).

Who is the main contact?

Dr Natália Amaral

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The effect of brief group interventions on psychosocial adjustment of breast cancer survivors

Study objectives

1. Participants treated with brief group interventions will present better psychosocial adjustment and quality of life than the control group.
2. Participants treated with a psychoeducational intervention will present different outcomes to those who participated in cognitive-behaviour group therapy.
3. Participants treated with brief group interventions will present effects until 6 months and there is interference of psychosocial variables on the outcomes of the interventions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Portuguese Cancer League, 2008

Study design

Multi-site quasi-experimental trial with equivalent control group

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Breast cancer survivors

Interventions

Subjects of the Reach to Recovery Movement of the Portuguese Cancer League were invited to participate in the study, as well as cancer survivors followed up in Senology Unit of the Hospital of Braga. Pre-existent groups were randomly allocated to one of three groups:

1. Control group
2. Psychoeducational intervention
3. Cognitive-behavioral therapy

Psychoeducational intervention and cognitive-behavioral therapy are group interventions, which are weekly structured sessions of 2 hours during 8 weeks.

The Portuguese Cancer League of the centre of Portugal has groups in extensions (the main is in the city of Coimbra, but there are also extensions in another cities: Viseu, Castelo Branco, Guarda, Leiria, Covilhã and Aveiro); these are pre-existent groups that were randomly allocated to the study conditions. The Hospital of Braga also had a pre-existent group, a sample available to the study, who was also allocated to a study condition.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Acceptability and feasibility will be measured:

1. Participant uptake of the intervention
2. Intervention session attendance
3. Rates of participant drop-out

Measured at pre-test, baseline, post-test: final intervention, 3 months follow-up and 6 months follow-up

Secondary outcome measures

1. Cancer Coping Questionnaire (CCQ)
2. Courtauld Emotional Control Scale (CEC)
3. Hospital Anxiety and Depression Scale (HADS)
4. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire with the Supplementary Questionnaire Breast Cancer Module (EORTC QLQ - C30 and BR -23)
5. Self-Concept Clinical Inventory (ICAC)
6. Life Orientation Test - Revised (LOT-R)
7. Patient Health Questionnaire (PHQ-9)
8. Profile of Mood States (POMS)
9. Personal Growth subscale of the Scale of Psychological Well-Being (EBEP)
10. Sub-scale of Spirituality
11. Inventory of State - Trait anxiety (STAI)

Measured at baseline, after 8 weeks, 3 months and 6 months

Overall study start date

01/04/2009

Completion date

31/03/2013

Eligibility

Key inclusion criteria

1. Over 18 years old
2. Received breast cancer diagnosis and treatment
3. Does not present currently signals of disease

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

62

Key exclusion criteria

1. Younger than 18 years old
2. Inability to participate in groups
3. Conflicts with other members of group
4. History of other psychiatric disorders prior to illness
5. Suicidal ideation
6. Dependence on psychoactive substances (such drugs and alcohol)
7. Organic brain disorders

Date of first enrolment

01/04/2009

Date of final enrolment

31/03/2013

Locations

Countries of recruitment

Portugal

Study participating centre

Campus Universitário of Santiago

Aveiro

Portugal

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Sponsor information

Organisation

Portuguese Foundation of Science and Technology (Fundação ciência e tecnologia) (FCT)
(Portugal)

Sponsor details

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Sponsor type

Research organisation

ROR

<https://ror.org/00snfq58>

Funder(s)

Funder type

Research organisation

Funder Name

Portuguese Foundation of Science and Technology (Fundação ciência e tecnologia [FCT]) (Portugal)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/03/2011		No	No
Abstract results		01/06/2012		No	No
Other publications	Torres, A., Pereira, A. & Monteiro, S. (). [Cognitive-behaviour group therapy for breast cancer survivors: description of a program and preliminar evaluation of efficacy] Terapia de grupo cognitivo-comportamental para sobreviventes de cancro da mama: descrição de um programa e avaliação preliminar da sua eficácia. Psychology, Community and Health, 1(3):300-312.	27/11/2012		Yes	No