

# Brief group interventions with breast cancer survivors

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

Prof Anabela Pereira

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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

3810-193

## **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?
<a href="#">Abstract results</a>		01/03/2011		No	No
<a href="#">Abstract results</a>		01/06/2012		No	No
<a href="#">Other publications</a>	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