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A trial to study the benefits of a psychotherapeutic group intervention to facilitate post-traumatic growth (PTG) in women with nonmetastatic breast cancer

Submission date
10/10/2013

Recruitment status
No longer recruiting

Registration date
28/10/2013

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There is growing evidence of post-traumatic growth (PTG) (positive psychological change) in women with breast cancer. Several factors are related to the development of PTG. Strong thoughts, change of core beliefs, Posttraumatic Stress Disorder's (PTSD) symptoms, the emotional expression about individual reactions related to the breast cancer experience, and satisfactory social support are predictors of benefit findings. An intervention group increases the perceived social support, enhances the restructuring of brain function and the individual perception of growth, and promotes a better adjustment to the disease. With innovative nature, this group programme is designed to facilitate the development of PTG, as well as to enhance emotional, psychological and social skills to cope with the disease.

Who can participate?
Adult women diagnosed with breast cancer and fluent in Portuguese can participate in this study.

What does the study involve?
All participants attend a clinical interview that lasts for about 90 minutes and will takes place in their regular hospital. In this first interview all information about this study will be explained and they will be asked to sign the informed consent and complete a short questionnaire about the individual experience of breast cancer. There is no use of medication during the study. Interviews will be repeated two times every 6 months. Participants are randomly allocated to either the intervention group or the control group. The intervention group has subgroups of six to eight participants each, who attend the programme. This consists of eight weekly sessions, with each session lasting for 90 minutes. Each session has topic, objectives and training on psychological techniques. We not only intend to boost the individual ability to manage the negative effects of breast cancer, but also to promote a positive perspective to face future problems. Participants in the control group will receive usual care. As this is a voluntary study, they may withdraw their participation at any time.

What are the possible benefits and risks of participating?
Participants may benefit from the improvement of psychosocial adjustment to breast cancer, emotional expression and social support, as well as a more positive perspective about breast cancer. The results of this study will help us understand the best way of attending the needs of women. The findings are disclosed to health professionals of the respective hospitals where the participants are followed. There are no side effects associated with this study. Some participants may be displeased about having to make purposive visits to the hospital for interviews; however, we intend to minimize this discomfort by planning the interviews for a date that they already have an exam or a visit at the hospital.

Where is the study run from?
This study takes place at the following hospitals in Portugal:
1. Centro Hospitalar de São João, Oporto
2. Hospital de Santo António - Centro Hospitalar do Porto, Oporto
3. Hospital de São Francisco Xavier - Centro Hospitalar de Lisboa Ocidental, Lisbon
4. Hospital da Luz, Lisbon
5. Movimento Vencer e Viver, núcleo Sul da Liga Portuguesa Contra o Cancro

When is the study starting and how long is it expected to run for?
The study is recruiting participants from May 2012 until May 2015.

Who is funding the study?
This study is funded by Foundation for Science and Technology (FCT), Portugal.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Relationship between post-traumatic growth, rumination and social support in women with nonmetastatic breast cancer: the impact of an intervention program

Study objectives
1. We attempt to evaluate the efficacy of the group intervention to facilitate PTG in breast cancer patients, through the assessment of PTG, by comparing a group submitted to the intervention with a group not submitted to the intervention.
2. To study the relationship between PTG and other psychosocial variables such as core beliefs, rumination, illness perception, PTSD, distress disclosure and social support in both groups.
3. To measure the manifestation of PTG and other psychosocial variables over time in this sample.

On 20/08/2015 the following changes were made to the trial record:
1. The target number of participants was changed from 200 to 55.
2. The overall trial end date was changed from 30/09/2014 to 01/03/2016.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Commission of Data Protection (CNPD); 09/10/2012 (ref: 5731/2012); Authorization no: 8204/2012

Study design
Multicentre non-randomised interventional study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Nonmetastatic breast cancer

Interventions
According to the socio-cognitive theory which defines that Posttraumatic Growth only emerges if the individual perceives the event as traumatic, we selected the intervention group based on the PCL-C values. That is, we only integrate participants in intervention groups who have a medium or high PTSD values. But we do not indicate this detail to the participants. Between the participants already selected to the Experimental Group, we randomly allocate the participants to the two or three intervention groups that happened simultaneously, in a specific hospital or institution.

Intervention group (IG): Usual treatment + intervention program to facilitate PTG
Control group (CG): Treatment as usual
Each group is planned to have 100 patients.

The assessment of psychosocial variables is carried out with both groups and occurs before the intervention, which assesses the socio-demographic, clinic and psychosocial variables (PTG, core beliefs, rumination, illness perception, PTSD, distress disclosure and social support). The second assessment (only with the psychosocial variables) occurs after the intervention for the IG and 6 months after the baseline for the CG. This assessment is repeated for both groups at follow-up, 6 months after.

Intervention:
The intervention will occur in subgroups of six to eight participants from IG during eight weekly sessions and with an approximate duration of 90 minutes per session. The intervention was designed within a socio-cognitive theoretical basis and in accordance with the following studies, Mosher et al. (2012), Tedeschi and McNally (2011) and Zakowski et al. (2004). In this particular intervention, we intend to promote the emergence of PTG or enhance the perception that may already exist about positive changes in the aftermath of breast cancer experience. The availability of trained psychologists, capable of moderating these psychotherapeutic interventions in a group, is limited. In this study, we intend to promote training sessions for experienced therapists that want to collaborate as monitors in the intervention groups. The structure and the contents of each session will be provided as follows:

Structure of sessions: During the intervention, each one of the eight sessions is planned with a theme and a specific objective related to psychosocial adjustment to breast cancer. Psychological and physical aspects related with the definition of breast cancer, the treatments and their physical effects, the worries and concerns related to the disease and the future, the cognitive and emotional changes and the social network perceived support, are worked. Mainly, all sessions were designed to promote an adaptive cognitive reconstruction in order to promote the attribution of meaning to the breast cancer experience, which leads to the perception of PTG, according to socio-cognitive theory for the development of PTG (Calhoun & Tedeschi, 1998; Tedeschi & Calhoun, 1996; 2004). Each session comprises a theoretical exposition and psychological strategies both related to a certain theme associated with breast cancer, previously scheduled in the beginning of the intervention. It is noted that the PTG is not mentioned during the intervention due to the subjectivity of the perception of positive benefits. This approach is supported by the socio-cognitive theory, which defends that the therapist should not identify PTG or enumerate the perceived changes before the patient, once it could be counterproductive to the therapy (Calhoun & Tedeschi, 1999).

Content of therapy sessions: The group intervention to facilitate PTG will use the following approach:

1. Session 1: Psychoeducation and normalization of emotional reactions - Psychological strategies are developed to promote a better understanding about the fact that negative reactions such as fear, anxiety, anger, hopelessness, guilt, shame or confusion are natural responses to a traumatic experience, such as the diagnosis of breast cancer. Psychoeducation will be given in this session, according to the individuals needs.
2. Session 2: Facilitating emotional disclosure and communication - Through practice of communication skills, we intend to promote the understanding of the importance of assertive communication and emotional expression during the illness process. The emotional disclosure and distress disclosure index (DDI) are administered in this session.
3. Session 3: Practice emotional self-regulation skills - Learning and practicing self-regulation

skills, with the objective of promoting an adaptive coping and a better stress management of individual emotions and reactions to breast cancer. Self-regulatory strategies for stress management are introduced, such as abdominal breathing and progressive muscle relaxation.
4. Session 4: Fears and concerns related to breast cancer - Promote the expression of fears and concerns about disease and future, which leads to the understanding of personal capabilities of solving problems and making decisions. Introduction and practice of Mindfulness (Bartley, 2012). The cognitive reconstruction and strategies for the replacement of intrusive thoughts in everyday life are also given.
5. Session 5: Balance between gains and losses after breast cancer diagnosis - Promote the balance of gains and losses in several areas of women's lives (e.g. psychological, physical, social, professional, etc.), which enhance the reflective thinking and the attribution of meaning to the breast cancer experience.
6. Session 6: Construction of a coherent personal narrative - Construction of an individual narrative, to understand and integrate the experience of breast cancer in the set of the woman's life events. In this session, the expressive writing technique is used, according with the guidelines of Pennebaker (2010). The procedures are adapted from group interventions developed with cancer patients (Mosher et al., 2012; Zakowski et al. 2004).
7. Session 7: Development of new values and priorities of life - We intend to promote the cognitive processing about core beliefs and personal values to achieve the redefinition of life priorities and the re-evaluation of personal objectives, which are now consistent with the perceived identity changes.
8. Session 8: Redefinition of life goals - Reconstruction of new life goals according to the actual personal narrative. Rupture with the previous objectives might occur, to give rise to life values more adjusted to the new reality. In the last session, the questionnaires of the second assessment are applied as well as a questionnaire to evaluate the intervention program.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Post-traumatic Growth Inventory (PTGI; Tedeschi & Calhoun, 1996, 1998): This is a 21-item inventory that assesses the positive changes perceived in several areas of personal life after the subject experiences a traumatic event. The positive benefits are measured through five domains of growth: personal strength, new possibilities, relating to others, appreciation of life, and spiritual change.
2. Post-traumatic Stress Disorder Checklist Scale Civilian (PCL-C; Andrykowski et al., 1991): This is a 17-item self-report measure that evaluates the distress and the impact of breast cancer as a traumatic event through three subscales: intrusion, avoidance and hyper-arousal.

Measured at baseline, 6-month, and 12-month follow-up.

Key secondary outcome(s))
1. Rumination Scale (Calhoun et al., 2000). This scale is composed of two 10-item subscales that assess the style of rumination, intrusive and deliberate, respectively in each subscale, during the two weeks immediately after the traumatic event. Measured at baseline, 6-month and 12-month follow-up.
2. Core Beliefs Inventory (CBI; Cann et al., 2010), is a nine-item measure that assesses the degree to which the traumatic event shattered the assumptive world. Measured at baseline, 6-month

and 12-month follow-up.
3. Stressfulness of the event (Lindstrom et al., 2011). We evaluate the stressfulness of breast cancer with two questions made on the Likert scale with seven points, ranging from one (not at all stressful) to seven (extremely stressful). The questions are: "How stressful was the event for you at the time it happened?" and "How stressful is the event for you now?". Measured at baseline, 6-month and 12-month follow-up.
4. Social Support Satisfaction Scale (ESSS; Pais Ribeiro, 1994) assesses perceived social support through 15 statements that describe four social support dimensions: relationships satisfaction, intimacy, satisfaction with family and social activities. Measured at baseline, 6-month and 12-month follow-up.
5. Brief Illness Perception Questionnaire (Brief IPQ; Broadbent, Petrie, Main, & Weinman, 2006), is used to assess, in a population that has had a physical illness, the individual representations about the disease in areas such as stress, lifestyle or heredity. Disposed in nine items, this questionnaire assesses cognitive illness representations, emotional representations and illness comprehensibility. Eight of the items are rated using an analogue scale from 0 to 10 points. The last item is a causal question, which asks patients to enumerate three causal factors to the illness, in their particular case. Measured at baseline, 6-month and 12-month follow-up.
6. Distress Disclosure Index (DDI; Kahn & Hessling, 2001). This is a 12-item index to measure ones tendency to disclose individual distressing information, such as distressing thoughts, personal problems and unpleasant emotions. Measured at the second session of the intervention for IG and at the 6-month assessment for CG.
7. Emotional Disclosure (Gore, Cross, & Morris, 2006). It is five-item scale to measure the extension of which the participant talked with her spouse or other close person, between a range of several topics. Measured at the second session of the intervention for IG and at the 6-month assessment for CG.

Completion date
01/03/2016

Eligibility

Key inclusion criteria
1. Participants must have been diagnosed after January 2011 until the present
2. First breast cancer and diagnosis between stages I-III
3. Female subjects with minimum age of 18 years. No age range.
4. Able to provide informed written consent
5. Fluent written and spoken Portuguese. The questionnaires are written and validated in Portuguese.
6. Have no physical or mental disorder that compromises participation in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Another diagnosis of breast cancer or other type of cancer prior or after the first assessment
2. Psychological or physical comorbidities that make it unlikely that participants will complete the study
3. The participants who have symptoms of major depression or anxiety disorder, and also the participants who feel too distressed to be approached, will be excluded from the study
4. Participants that have substance misuse or other issues that may compromise their participation in the study

Date of first enrolment
01/05/2012

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
Portugal

Study participating centre
Centro Hospitalar de São João
Oporto
Portugal
-

Study participating centre
Hospital de Santo António - Centro Hospitalar do Porto
Oporto
Portugal
-

Study participating centre
Hospital de São Francisco Xavier - Centro Hospitalar de Lisboa Ocidental
Lisbon
Portugal
-

Study participating centre

Hospital da Luz
Lisbon
Portugal
-

Study participating centre
Movimento Vencer e Viver, núcleo Sul da Liga Portuguesa Contra o Cancro
Portugal
-

Sponsor information

Organisation
Instituto Superior de Psicologia Aplicada (ISPA) (Portugal)

ROR
https://ror.org/019yg0716

Funder(s)

Funder type
Research organisation

Funder Name
Foundation for Science and Technology (FCT) (Portugal), Ref: SFRH/BD/81515/2011

Alternative Name(s)
Portuguese Science and Technology Foundation, Foundation for Science and Technology, Fundacao para a Ciencia e a Tecnologia, The Foundation for Science and Technology (FCT), FCT

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Portugal

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/05/2016	17/12/2020	Yes	No
Basic results		27/07/2017	21/09/2017	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes