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Outcomes of cancer bereavement therapeutic support groups

Submission date 31/08/2018	**Recruitment status** No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/09/2018	**Overall study status** Completed	☐ Statistical analysis plan ☐ Results
Last Edited 04/06/2021	**Condition category** Mental and Behavioural Disorders	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

The loss of a loved one to cancer is associated with negative bereavement outcomes such as higher levels of depression, anxiety, and sleep difficulties, and can place individuals at greater risk of developing complicated grief responses. People who have lost a loved one to cancer may require more than informal support provided by friends and family in order to help them adapt to their bereavement. Group bereavement interventions are a popular treatment format for bereavement support. Their popularity can be attributed to their effective use of resources, social acceptability, and therapeutic factors that often meet the needs of bereaved individuals (e.g. reducing social isolation).

Group bereavement interventions tend to be either self-help groups (sometimes referred to as mutual support groups), or more formalised therapeutic bereavement groups. Self-help groups are usually informal, self-governing, support network focused, and are usually open to anyone who has experienced a loss. Members of bereavement self-help groups report many positive aspects, such as social support, emotional expression, reciprocity within the group, exchanging of information and advice, and sharing of hope. Few studies have used objective measures to examine the effectiveness of self-help groups for cancer bereavement. The research that has been conducted presents consistent findings that participants report self-help groups as being beneficial, but changes on objective outcome measures of psychological symptoms are not found.

The second type of group intervention for bereavement are therapeutic groups, which differ from self-help groups in that they have structured content and are initiated and led by professionals. These groups are often based on theoretical knowledge and practice, and the professional facilitating the group is usually distinct from the group members. Therapeutic bereavement groups specific to a type of loss (e.g. HIV-related death) have been shown to be an effective intervention for grief reactions. Group homogeneity is associated with increased group cohesion and better outcomes.

When individuals experience the same type of bereavement there may be similar themes or symptoms in their grief reactions, which specific therapeutic support groups are well placed to address. Despite the clinical rationale for cancer-specific therapeutic bereavement groups, and some evidence that participants find them beneficial, there is little published research regarding their effectiveness. Taking part in an eight-session therapeutic group was associated with increased self-esteem and reduced role strain. Themes identified from the groups included

opportunities for change, new relationships, time and rituals.
This study evaluates a new cancer bereavement therapeutic group intervention incorporating aspects of Compassion Focused Therapy (CFT), Cognitive Behavioral Therapy (CBT), Cognitive Therapy for PTSD (CT-PTSD), and self-help groups. The aim is to test whether a 7-session cancer bereavement therapeutic group is associated with changes in grief responses, psychological symptoms and self-compassion, at intervention completion and at three-month follow-up.

Who can participate?
People aged 18 or over who have experience of bereavement by cancer over 6 months ago

What does the study involve?
The study involves taking part in a therapeutic bereavement support group, which entails attending 7 sessions over 10 weeks. The groups run in the evening and are facilitated by psychologists. The groups are aimed at helping people who are bereaved by cancer to learn more about loss and how to cope with all that arises from it, as well as help them make stronger connections with those in a similar situation. The groups are free to attend, and participants are randomly allocated to one of three groups (one starting in October 2018 and two starting in January 2019). Participants are asked to complete some questionnaires before the group begins and after it ends (these take about 25 minutes), as well as before each meeting (these take about 10 minutes each time). The questionnaires are about how participants are feeling and how the group may be helping or not. They can be completed online.

What are the possible benefits and risks of participating?
Previous testing of content from the groups showed that people taking part experienced a positive impact on their grief, lower levels of depression and anxiety, and increased self-compassion. It is hoped that the information from this study will advance knowledge about the principles of cancer bereavement support groups, and improve practice to help people who join support groups in the future. It is possible that participants could feel upset when completing the questionnaires, although they cover topics that they are likely to have talked about and been supported with during the group sessions. If participants were to become upset, they could discuss this with facilitators of the group, and they will have the option of stopping participation.

Where is the study run from?
The Loss Foundation (UK)

When is the study starting and how long is it expected to run for?
August 2018 to June 2019

Who is funding the study?
1. The Loss Foundation (UK)
2. Postcode Community Trust (UK)

Who is the main contact?
Dr Erin Thompson

Study website
https://www.thelossfoundation.org/therapy-groups/

Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
180829TLF

Study information

Scientific Title
A randomised controlled trial exploring outcomes of 7-session cancer bereavement therapeutic support groups for adults

Study objectives
The present study hypothesises that a 7-session cancer bereavement therapeutic group intervention for adults will be associated with changes in grief responses, psychological symptoms and self-compassion, at intervention completion and at 3-month follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Chair of The Loss Foundation Board (registered number 1147362) and The Loss Foundation Research Committee, 29/08/2018, Project ID No: 180829TLF

Study design
Randomised controlled longitudinal study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Community

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Cancer bereavement

Interventions
Participants will be randomised using a computer randomisation tool. Participants are randomly allocated to one of three groups (one starting in October 2018 and two starting in January 2019).

The 7-session therapeutic bereavement group intervention incorporates aspects of psychoeducation, Compassion Focused Therapy (CFT), Cognitive Behavioural Therapy (CBT), Cognitive Therapy for PTSD (CT-PTSD: Ehlers & Clark, 2000), and self-help groups. Groups will be run by Psychologists trained in the intervention content.

Quantitative data will be collected using a range of self-report outcome measures. Specific outcome measures will be collected at the first and last sessions (pre-post), whilst others will be collected weekly. All groups will be followed up 3-months post the intervention.

Intervention Type
Behavioural

Primary outcome measure
All outcome measures will be collected online using Qualtrics, a professional survey software. The following questionnaires will be collected at baseline (registering to the groups), prior to every group session, post the intervention, and at 3 months follow up:

1. The Prolonged Grief Disorder Inventory (PG-13). (Prigerson & Maciejewski, 2008) The PG-13 assesses the prevalence and severity of PGD symptoms (e.g. yearning for the deceased, feelings of emotional numbness/detachment from others, feeling that a part of oneself died along with the deceased). The PG-13 is a subset of 13 items from the Inventory of Complicated Grief (ICG; Prigerson et al., 1995). The ICG has very good internal consistency (α=.85), test-retest reliability (.80), and has excellent incremental validity in predicting a variety of grief-related functional impairments, controlling for depression and anxiety.

2. The Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer, & Williams, 2001) is a 9-item self-report questionnaire that measures the severity of depressive symptoms. A sample item is “Feeling tired or having little energy”. Each item is scored on a 4-point scale with response categories of “0=Not at all” to “3=Nearly every day”; this provides a 0 to 27 severity score. The measure has strong psychometric properties (Kroenke et al., 2001).

3. The Generalized Anxiety Disorder-7 (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006) is a 7-item self-report questionnaire that measures the severity of anxiety symptoms. A sample item is

“Feeling nervous, anxious or on edge”. Each item is scored on a 4-point scale with response categories of “0=Not at all” to “3=Nearly every day”; this provides a 0 to 21 severity score. The measure has strong psychometric properties (Spitzer et al., 2006).

4. The Self-Compassion Scale-Short Form (SCS-SF; Raes, Pommier, Neff, & Van Gucht, 2011: Appendix I) is a 12-item self-report questionnaire that measures self-compassion. A sample item is “I’m disapproving and judgmental about my own flaws and inadequacies”. Each item is scored on a 5-point scale with response categories of “1=Almost Never” to “5=Almost Always”; this provides a total score of 12-60. The measure has strong psychometric properties (Raes et al., 2011). Cronbach’s alpha in the present study was 0.81.

Secondary outcome measures

The following questionnaire will be collected after each group session:

The Helpful Aspects of Therapy (HAT; Llewelyn, 1988) is a post-session self-report questionnaire that asks about perceptions of key change processes in therapy. It is partly qualitative and captures perceptions of helpful and unhelpful aspects of the previous session. An example item is “Of the events which occurred in the last group session, which one do you feel was the most helpful or important for you personally? Please describe what the event was.” Each event is then scored as to how helpful or unhelpful it was on a 5-point scale with response categories of “0=Not at all” to “4=Extremely”. Two questions ask participants to identify, describe and then rate first a helpful and second an unhelpful event. In addition, there are two optional questions for participants to identify, describe and then rate other helpful and unhelpful events.

The following questionnaires will be collected at baseline (registering for the group), prior to the start of the intervention, at the end of the intervention, and at 3 months follow up:

1. The PTSD Checklist for DSM-5 (PCL-5; Weathers et al., 2013) is a 20-item self-report questionnaire that assesses symptoms of PTSD. A sample item is “In the past month, how much were you bothered by repeated, disturbing, and unwanted memories of the stress experience?” Each item is scored on a 5-point scale with response categories of “0=Not at all” to “4=Extremely”; this provides a total severity score of 0-80. The measure has strong psychometric properties (Blanchard, Jones-Alexander, Buckley, & Forneris, 1996).

2. Loss-related memory characteristics (OG-M). This 27-item questionnaire asks participants to rate on a 5-point scale (0 – not at all to 4 – very strongly) the extent to which each statement regarding their memory of the loss applied to them during the last month. Twenty-three items probed memory triggers and their consequences (e.g. ‘I am reminded of the loss for no apparent reason’), qualities of memory (e.g. ‘Memories of things we did together are painful’), the poor availability of positive memories (e.g. ‘I struggle to remember positive times without [-]’), and the physical impact of loss-related memories (e.g. ‘The memories of [-] 's death make my body ache with overwhelming fatigue’). Four further items, taken from the intrusiveness scale of the Trauma Memory Questionnaire (Halligan et al., 2003), asked about unintentional memories of the loss (frequency in the last week, distress, how much they seemed to be happening now instead of in the past, and the extent to which they felt as though they were reliving the memory). These items were originally rated on a different rating scale and rescored to 0 to 4 for equivalency. Factor analyses revealed a unidimensional structure. The total loss-related memory characteristics scale demonstrated excellent internal consistency (ω = .98).

3. Negative grief appraisals (OG-A). This 35-item questionnaire asks participants to indicate on a 7-point scale (1 - totally disagree to 7 - totally agree) the extent to which they agree with the statement. Items pertain to five content domains: 1. Hopelessness of self and life (e.g. Without [-

] I can never be strong again), 2. Regret (e.g. I blame myself for things I did or did not do when [-] was alive), 3. Negative interpretation of grief (e.g. If I start to cry I won't be able to stop), 4. Loss of relationships and future (e.g. I cannot maintain previous relationships without [-]), 5. Fear of losing connection to the deceased (e.g. Letting go of my grief would mean betraying [-]). Factor analyses confirmed these content domains as latent factors and supported a higher order latent factor of total appraisals. The total negative appraisals scale demonstrated excellent internal consistency (ω = .98).

4. Maladaptive coping strategies (OG-CS). This 23-item questionnaire asks participants on a 5-point scale (1 - never to 5–always) to indicate how often they used particular strategies to cope with their loss. Items pertain to four content domains: 1. Avoidance (e.g. I avoid places we went together), 2. Proximity seeking (e.g. I feel compelled to surround myself with things that they liked), 3. Grief rumination (e.g. I dwell on moments that could have changed the outcome), and 4. Injustice rumination (e.g. I think about the unfairness of the loss). Factor analyses confirmed these content domains as latent factors and supported a higher order latent factor of total coping strategies. The total maladaptive coping strategies scale demonstrated excellent internal consistency (ω = .96).

5. Social disconnection (OG-SD). This 15-item questionnaire asks participants to indicate on a 7-point scale (1 - totally disagree to 7 - totally agree) the extent to which they agree with the statement. Items pertain to three content domains: 1. Negative interpretation of others' reactions (e.g. 'Others would judge me if I were to speak openly about my grief'), 2. Negative interpretation of social situations (e.g. 'I can't be myself around other people the way I used to'), 3. Safety in solitude (e.g. 'It is easier to be alone than to have to pretend to feel ok'). The total social disconnection scale demonstrated excellent internal consistency (α = .96).

Overall study start date
06/08/2018

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Experience of bereavement by cancer
3. Time since bereavement greater than six months, so as not to interfere with a natural recovery process (Schut & Stroebe, 2010)
4. Not undergoing any other psychological treatment during participation in the intervention
5. Self-referral to the charity or via a related organization

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
Significant substance or alcohol misuse, which would interfere with ability to participate

Date of first enrolment
01/09/2018

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Loss Foundation
34b York Way
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Sponsor information

Organisation
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Sponsor type
Charity

Website
https://www.thelossfoundation.org/#mytop

Funder(s)

Funder type
Charity

Funder Name
The Loss Foundation

Funder Name
Postcode Community Trust

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal, with expected publication date around June 2020.

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date