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The effectiveness of a psychological intervention targeting bereaved caregivers of cancer patients

Submission date
01/12/2024

Recruitment status
Recruiting

Registration date
04/12/2024

Overall study status
Ongoing

Last Edited
19/05/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
An increasing number of patients with advanced cancer are receiving home palliative care, provided in most cases by informal caregivers who are exposed to significant demands on their time, physical energy and mental resources. While many studies proposed interventions targeting cancer caregivers, most of them focus on caregivers' distress, overlooking positive outcomes, such as Resilience and Post Traumatic growth. This study aims to test the feasibility, acceptability and effectiveness of an adapted version of the EMPOWER (Enhancing & Mobilizing the POtential for Wellness & Emotional Resilience) intervention for protecting Cypriot bereaved cancer caregivers against distress and enhancing their positive outcomes.

Who can participate?
The participants of the study will be Greek-speaking bereaved caregivers of cancer patients. Eligible for participation will be those experienced the loss of a loved one within the last 18 months and three months have passed since the loss and at risk for Prolonged Grief. Participation is allowed regardless of gender, career orientation and family status, with the only requirement being age, meaning adults over 18 years old. Participation in the study is not allowed for individuals who lost a non-adult son/daughter to cancer, those with low grief risk, people suffering from severe mental illness (i.e. psychosis, bipolar, severe depression, personality disorder) or substance abuse disorder, or dementia (self-report of previous diagnosis), caregivers with substantial risk of suicidality and those receiving external psychological support in individual or group format

What does the study involve?
The study will be a Trial with bereaved caregivers. The intervention group will receive six weekly sessions that take approximately 45–60 min each to complete. Following the 6 weekly sessions, two booster sessions will be delivered by phone, 2 and 4 weeks after the end of the intervention. Booster sessions will focus on reviewing the skills taught in the six previous sessions and will last approximately 30 minutes each.
Participants of the control group will receive a 1.5-hour psycho-educational workshop. Caregivers will be provided information regarding bereavement characteristics, factors that

influence bereavement outcomes (risk vulnerability), common emotional-psychological reactions and thoughts after the loss, basic bereavement models and theories, adaptation to loss, and information on when to seek professional support and access to further care

What are the possible benefits and risks of participating?
Participants in the intervention group will benefit from receiving psychological support if found to be at risk for developing complicated grief, based on the screening assessment. Participants in the control group will have the opportunity to receive the intervention after completion of the study if they wish to do so, as PASYKAF's services will keep running as long as there are individuals in need. Also, participants will contribute to the knowledge around what works for bereavement.
Bereavement has not been investigated enough, especially in Greek-speaking population. In addition, the scientific knowledge and experience on the specific population is limited. As the results of the study are expected to confirm our hypotheses, regarding superiority of the intervention for decreasing distress, protecting against prolonged grief and increasing resilience, Post Traumatic Growth and experiential acceptance, bereaved cancer caregivers will benefit by having an intervention that helps in the decrease of the symptoms caused by the loss of a loved one
Considering the sensitivity of the topic, there is a possibility of emotional discomfort. Nonetheless, appropriate and necessary measures and procedure will be followed.
In case that suicidal ideation is detected during the screening process, participants will be referred to the clinical psychologists of PASYKAF for mental health first aid and further assessment to palliate real suicide risk.
In case that any of the participants feel anxiety or discomfort during the assessment or intervention, they will interrupt their participation to the study, and continue their therapeutic process with one of the psychologists of PASYKAF.
In addition, all the participants will be provided with a list including information (telephone numbers and address) of the hospitals and the Registered Clinical and Counselling Psychologists all over Cyprus.

Where is the study run from?
The study will take place at the premises of the Cyprus Association of Cancer Patients and Friends (PASYKAF) all over Cyprus (Nicosia, Larnaca, Limassol, Ammochostos, and Paphos). PASYKAF is an association offering Supportive and Home Palliative Care, supporting cancer patients and caregivers at all stages of the illness. It provides medical and nursing home care services, psychological, social support, rehabilitation services, physiotherapy during treatment, remission, and particularly, during the palliative and end of life care stage.

When is the study starting and how long it is expected to run for?
November 2024 to June 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Eleni Petkari, epetkari@uma.es

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effectiveness of a psychological intervention targeting bereaved caregivers of cancer patients: study protocol for the EMPOWER-Cancer-Grief RCT

Acronym
EMPOWER-Cancer-Grief

Study objectives
The primary hypotheses of the study are:
1. The intervention will be feasible and show good levels of acceptability among the Cypriot cancer caregivers
2. Compared to usual care, intervention group caregivers will report reduced distress (i.e. depression and anxiety symptoms) and reduced risk for prolonged grief after the intervention.
3. Caregivers in the intervention group will also show higher levels of experiential acceptance, resilience and post Traumatic Growth (PTG) after the intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 18/11/2024, Cyprus National Bioethics Committee (22 Laertou Street, Nicosia, 2365, Cyprus; +357 22-809038; cnbc@bioethics.gov.cy), ref: EEBK/EP/2024/69

Study design
Phase 1: open interventional trial, Phase 2: multisite randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life, Treatment

Health condition(s) or problem(s) studied
Bereaved caregivers of cancer patients

Interventions
The study will consist of two phases. Phase 1 will involve two steps: an open trial with 10 bereaved caregivers who will receive the intervention and then provide feedback on their experience; and a manual refinement process that will involve 5 caregivers and 5 mental health clinicians. They will be provided with the manual and asked for feedback on the content, format, and language of the EMPOWER-Cancer-Grief Intervention. The feedback given in phase 1, will be used to adjust the intervention.

Phase 2 will involve a multisite Randomized Controlled Trial using a 2-group design with one intervention and one control group, aiming to enroll up to 50 bereaved caregivers. The randomisation process will be carried out using an online tool.

The EMPOWER-Cancer-Grief intervention will be administered by four trained psychologists, one for each city. The intervention aims to reduce experiential avoidance (i.e., the tendency to avoid unpleasant feelings) and protect caregivers from negative outcomes, such as prolonged grief disorder or Post Traumatic Stress disorder (PTSD) following the patient's death. It is a blended intervention combining techniques from Cognitive behavioural and Acceptance and commitment Therapy, aiming to teach coping skills that will help caregivers tolerate, minimize, and deal with the death of their loved one.
The intervention includes active listening, breathing techniques and mindfulness, experiential exercises, psychoeducation on trauma, common reactions and emotional functioning. It uses imaginal dialogue and teaches coping techniques such as problem-focused strategies and meaning making.

It consists of six weekly sessions that take approximately 45–60 min each to complete. Following the 6 weekly sessions, two booster sessions will be delivered by phone, 2 and 4 weeks after the end of the intervention. Booster sessions will focus on reviewing the skills taught in the six previous sessions and will last approximately 30 minutes each.
Participants of the control group will receive a 1.5-hour psycho-educational workshop. Caregivers will be provided information regarding bereavement characteristics, factors that influence bereavement outcomes (risk vulnerability), common emotional-psychological reactions and thoughts after the loss, basic bereavement models and theories, adaptation to loss, and information on when to seek professional support and access to further care.

Intervention Type

Behavioural

Primary outcome(s)
1. Demographics are measured using an ad-hoc questionnaire at Screening, pre-intervention
2. Grief is measured using the Texas Revised Inventory of Grief (TRIG) at Screening, pre-intervention, post-intervention, one-month follow-up, and three-month follow-up
3. Prolonged grief is measured using the Prolonged Grief/PG-13 (Prigerson et al., 2009) at Screening, pre-intervention, post-intervention, one-month follow-up, and three-month follow-up
4. Suicide risk is measured using the Suicide Risk Scale (SRS) at Screening
5. Depression and anxiety are measured using the Depression-Anxiety-Stress Scale (DASS-21) at pre-intervention, post-intervention, one-month follow-up, and three-month follow-up
6. Resilience is measured using the CD-RISC (Connor & Davidson, 2003) at pre-intervention, post-intervention, one-month follow-up, and three-month follow-up
7. Post-traumatic growth is measured using the PTGI (Tedeschi & Calhoun, 1996) at pre-intervention, post-intervention, one-month follow-up, and three-month follow-up
8. Experiential avoidance is measured using the AAQ II (Bond et al., 2011) at pre-intervention, post-intervention, one-month follow-up, and three-month follow-up

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Having lost a loved one within the last 18 months and three months have passed since the loss
2. Cancer-related loss
3. Aged from 18 years
4. Being at risk for Prolonged Grief based on the PG-13-R scores (Prolonged Grief Disorder Revised; Prigerson et al.,2021) and on the TRIG scores (Texas Revised Inventory of Grief Greek version; Christodoulou et al. under preparation)
5. Able to communicate fluently in Greek.

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Having lost a non-adult son/daughter to cancer
2. Low grief risk based on PG-13-R scores and TRIG scores
3. Suffering from severe mental illness (i.e. psychosis, bipolar, severe depression, personality disorder) or substance abuse disorder, or dementia (self-report of previous diagnosis)
4. Substantial risk of suicidality (Based on SRS Suicide Risk Scale; Plutchik et al, 1989)
5. Receiving external psychological support in individual or group format

Date of first enrolment
02/06/2025

Date of final enrolment
30/03/2026

Locations

Countries of recruitment
Cyprus

Study participating centre
EUROPEAN UNIVERSITY OF CYPRUS
6, Diogenes 2404 Engomi
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P.O. Box: 22006, 1516

Sponsor information

Organisation
European University Cyprus

ROR
https://ror.org/04xp48827

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
IPD will be uploaded at the osf.io platform

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		14/05/2025	19/05/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes