ISRCTN22231701 https://doi.org/10.1186/ISRCTN22231701

PREPARE – A clinical trial on a group treatment for distressed caregivers of cancer patients

Submission date
31/03/2016

Recruitment status
Stopped

Registration date
07/04/2016

Overall study status
Stopped

Last Edited
13/02/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Being a caregiver for someone with cancer can be very difficult emotionally. For many the patient is a family member or friend, and so this can cause the caregiver a great deal of psychological distress. There are currently very few studies looking into the effectiveness of psychological treatments for distressed caregivers of cancer patients. This study is looking at tailored group therapy program for carers of cancer givers. The aim of this study is to find out whether this program can help to lower levels of distress in cancer caregivers and help them to better cope with caring for someone with the illness.

Who can participate?
Adult carers of patients who have been diagnosed with cancer in the last six months.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in the tailored group therapy program, over a course of five sessions spread over eight weeks. The sessions are structured group talks and discussions which revolve around pre-specified themes: coping and acceptance, distress, handling cancer-related stressful situations, self-care and a final session for stabilisation. Those in the second group receive a leaflet containing brief information about what individual counselling services are available. One week after the eight week treatment period and again six months later, participants in both groups complete a number of questionnaires in order to find out if their distress levels are lower as well as how well they are coping.

What are the possible benefits and risks of participating?
It is possible that caregivers who take part in the tailored group therapy program will benefit from lower levels of distress and improved coping. There are no notable risks involved with taking part in this study.

Where is the study run from?
Heidelberg University Hospital (Germany)

When is the study starting and how long is it expected to run for?
February 2016 to August 2017

Who is funding the study?
Heidelberg University (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02739243

Protocol serial number
S-655/2015

Study information

Scientific Title
Addressing the hidden patient - A randomised-controlled trial of a tailored group intervention for caregivers of cancer patients

Acronym
PREPARE

Study objectives

A caregiver-specific group intervention is significantly more effective in reducing disease-related distress than treatment as usual that includes brief information and individual referral to the local outpatient counselling centre.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the Medical Faculty Heidelberg, 08/02/2016, ref: S-129/2015

Primary study design
Interventional

Study design
Randomised controlled pilot trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Disease-specific distress in caregivers of cancer patients

Interventions
Gender-stratified 1:1 randomisation with allocation concealment (computed-assisted randomisation in RANDI2 by a blinded data manager). Total treatment duration is eight weeks for both groups. Follow-up for both study arms is at 1-week and 6-months post treatment.

Experimental condition: Participants take part in the tailored group intervention which consists of five 90-minute group sessions over eight weeks. The sessions are in the form of structured group talk/discussions following specific themes:
Session 1 - Coping and acceptance: identification of common themes from participants' feedback, provision of information about support services, mindfulness practices
Session 2 - Distress: introduction of the distress model, identification of resources, breathing practices
Session 3 - Handling of stressful situations: individual identification in tandems, discussion of common pitfalls in the group
Session 4 - Self-care: inspection of individual daily routines, group collects positive experiences with „windows" for self-care
Session 5 - Feedback and outlook: stabilisation, retrospective reflection on the group experience and its benefits and, if applicable, potential adverse events

Control condition: Participants are provided with brief information in a leaflet, about the possibilities for individual counselling including referral to the local outpatient cancer counselling centre providing client-centred counselling and financial social work.

Participants in both groups are followed up 1 week and 6 months post-treatment.

Intervention Type
Behavioural

Primary outcome(s)
Distress is measured using the Questionnaire on Stress in Caregivers of Cancer Patients Revised version (QSC-R10C) at baseline, 1 week, and 6 months post treatment.

Key secondary outcome(s)
1. Depression is measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline, 1 week, and 6 months post treatment
2. Anxiety is measured using the Generalized Anxiety Disorder-7 (GAD-7) at baseline, 1week, and 6 months post treatment
3. General distress is measured using the Distress Thermometer (NCCN DT) at baseline, 1week, and 6 months post treatment
4. Unmet needs are measured using the Supportive Care Needs Survey – Partners & Caregivers (SCNS-P&C-G) at baseline, 1 week, and 6 months post treatment
5. Self-effficacy in coping with the cancer disease is measured using the adapted General Perceived Self-Efficacy Scale, Positive Bonding Scale of the Group Questionnaire (GQ-D) at baseline, 1 week, and 6 months post treatment
6. Utilisation of primary healthcare is measured via the number of visits with the individual primary care physician at baseline, 1-week, and 6-months post treatment

Completion date
30/08/2017

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Time since initial diagnosis (of patient) not longer than six months previously
2. Significant distress against the background of the cancer disease (QSC-R10C exceeding 16 points)
3. Provision of informed consent
4. Aged 18 or over, either gender

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria

1. Inability to give informed consent
2. Insufficient German language knowledge
3. Cognitive impairment impeding handling of questionnaires
4. Severe psychiatric disease (acute psychosis or acute suicidality)

Date of first enrolment
15/04/2016

Date of final enrolment
14/05/2016

Locations

Countries of recruitment
Germany

Study participating centre
Heidelberg University Hospital
Department of General Internal Medicine and Psychosomatics
Im Neuenheimer Feld 410
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Germany
D-69120

Sponsor information

Organisation
Department of General Internal Medicine and Psychosomatics

ROR
https://ror.org/013czdx64

Funder(s)

Funder type
University/education

Funder Name
Heidelberg University

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository