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Supporting cancer family caregivers: The FAMily Strengths Oriented Therapeutic Conversation intervention study

Submission date	Recruitment status	[_] Prospectively registered
17/08/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/08/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/09/2023	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

Family caregivers caring for a family member with advanced cancer are at risk for emotional distress and other long-term health problems. Supportive interventions may enhance emotional well-being and perceived support of family members who are caring for their close relative with cancer. The FAM-SOTC (FAMily Strengths Oriented Therapeutic Conversation) intervention focuses on supporting the family to become more resourceful in dealing with their present and future challenges. The therapeutic conversation which takes place between the nurse and family members may help balance this complicated situation within the family and their ability to cope. This study aims to evaluate the effectiveness of a family therapeutic conversation (FAM-SOTC) intervention for families. The intervention was developed to address the various needs and conerns of home-based family caregivers and other members of the family when facing advanced and final stage cancer of a close relative.

Who can participate?

Family caregivers of patients with cancer in the late palliative phase and are over 18, receiving care from a specialized palliative home-care unit.

What does the study involve?

The intervention is delivered at the home of the family, with two home visits per participant (each session lasts for 45-90 minutes). The family caregiver and the patient decide together which other family members participate in the conversation with the nurse.
The family caregivers answer a set of questionnaires before the first session of the intervention. After receiving two sessions of the intervention with a week interval, the family caregivers answer the same questionnaires. The caregivers answer the same questionnaires again 2-4 weeks later. These questionnaires include questions that assess perceived support from nurses, emotional states of depression, anxiety and stress, and questions about the caregivers´emotional states due to the illness of his or her close relative and the caregivers level of agreement with self-care statements.

What are the possible benefits and risks of particpating?
A potential benefit of participating in the FAM-SOTC is that the participants may perceive an increased understanding of the illness experience, enhanced emotional well-being and perceived support. This approach may enable family members' needs and concerns to be identified and procedures put into actions that will address the requirement of each family. There are no known risks to the participants taking part in this study.

Where is the study run from?
Palliative home-care unit, Landspitali – The National University Hospital, Kopavogsgerdi 10, 200 Kopavogur, Iceland

When is the study starting and how long is it expected to run for?
February 2014 to August 2016

Who is funding the study?
1. The LUH Scientific Fund (Iceland)
2. The Scientific Fund of the Nurses Association in Iceland (Iceland)
3. The Research Fund of Ingibjorg R. Magnusdottir (Iceland)

Who is the main contact?
Asta B. Petursdottir
astabp@landspitali.is
abp5@hi.is

Contact information

Type(s)
Scientific

Contact name
Mrs Asta B Petursdottir

ORCID ID
http://orcid.org/0000-0001-5234-4620

Contact details
Eirberg, Eiríksgata 34
Reykjavik
Iceland
101

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

VSN50/2013

Study information

Scientific Title
The effectiveness of a therapeutic conversation intervention to ease emotional suffering and strengthening family functioning among cancer family caregivers in palliative home-care: A quasi-experimental study

Acronym
FAM-SOTC

Study objectives
The aim of this study is to evaluate the effectiveness of a family therapeutic conversation (FAM-SOTC) intervention for families.
Would family caregivers of a family member with advanced/final stage cancer who received two sessions of the FAM-SOTC intervention report:
1. Significantly improved family support after the intervention compared with before receiving the intervention?
2. Significantly lower levels of psychological distress symptoms after the intervention compared with before receiving the intervention?
3. Significantly reduced caregiver burden after the intervention compared with before receiving the intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Scientific Ethical Board at the National University Hospital, 24/01/2014, 50/2013
The National Data Protection Authority, 07/01/2014, S6563/2013

Study design
Interventional quasi-experimental non-randomised single-arm trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Prevention

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

Psychological distress and caregiver burden

Interventions

Family caregivers of patients in the final stage of cancer, receiving specialized palliative care from a palliative home-care unit were invited to participate in the study. Family caregivers identified by the patient/ill family member to be the one most involved in their care were approached during home visits by one of the palliative home-care nurses and invited to participate. The nurses provided information about the study and informed consent.
The family caregivers completed a self-administered set of questionnaires at baseline before the intervention. In addition, a sociodemographic questionnaire to assess sociodemographic characteristics of the family caregivers, along with information regarding the patients'/ill family members' type of cancer diagnosis and date of diagnosis.
The FAM-SOTC intervention was delivered at the home of the participants and focused on supporting the cognitive, effective, and behavioural domains of the family experience by targeting issues in these categories. The FAM-SOTC intervention is comprised of two main phases: assessment and intervention. The assessment phase is comprised of five components:
1. Asking about the illness experience
2. Creating a family tree (genogram) and drawing family relationships (ecomap)
3. Asking linear/circular/therapeutic questions
4. Identifying strengths and resources
5. Assessing the need for evidence-based information and recommendations.

The intervention phase consists of four components:
1. Drawing forward experience of illness stories
2. Asking therapeutic questions
3. Validating/acknowledging emotional responses
4. The use of commendation.

After receiving 2 sessions (each session lasting 45-90 minutes) of the FAM-SOTC intervention with a week interval, caregivers completed the same questionnaires as at baseline, which included questions about perceived support from nurses, emotional states of depression, anxiety and stress, and questions about the caregivers' emotional states due to the illness of his or her close relative and the caregivers level of agreement with self-care statements. Follow-up measurements were obtained 2-4 weeks after receiving 2 sessions of the intervention, completing the same questionnaires.

Intervention Type

Other

Primary outcome measure

The following are completed at the baseline, after receiving 2 sessions of the intervention with a week interval, and 2-4 weeks post intervention:
1. Improvement in perceived support from a healthcare provider, measured using the Iceland Family Perceived Support Questionnaire (Ice-FPSQ), a self-administered questionnaire
2. Change/improvement in psychological well-being, measured using the Depression Anxiety Stress Scale (DASS), a self-administered questionnaire
3. Burden of care when caring for a close relative with advanced/final stage cancer, measured using the Brief Assessment Scale for Caregivers of the Medically Ill (BASC), a self-administered questionnaire

Secondary outcome measures

N/A

Overall study start date
15/02/2014

Completion date
30/08/2016

Eligibility

Key inclusion criteria
1. Family caregivers of cancer patients/family members receiving palliative care from a specialised palliative home-care unit
2. Aged 18 years or older
3. Each patient could identify one primary caregiver to participate

Participant type(s)
Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48

Total final enrolment
48

Key exclusion criteria
Family caregivers of patients with illnesses other than cancer

Date of first enrolment
10/02/2014

Date of final enrolment
15/07/2016

Locations

Countries of recruitment
Iceland

Study participating centre

Pallitive home-care unit, Landspitali – The National University Hospital,
Kopavogsgerdi 10,
Kopavogur
Iceland
200

Sponsor information

Organisation
University of Iceland

Sponsor details
Eirberg, Eiríksgata 34
Reykjavik
Iceland
101
+3545254960
hjukrun@hi.is

Sponsor type
University/education

Website
https://www.hi.is/hjukrunarfraedideild

ROR
https://ror.org/01db6h964

Funder(s)

Funder type
Not defined

Funder Name
The LUH Scientific fund

Funder Name
The Scientific Fund of the Nurses Association in Iceland

Funder Name

The Research Fund of Ingibjorg R. Magnusdottir

Results and Publications

Publication and dissemination plan

1. Publication as part of PhD thesis
2. Dissemination of protocol and results in scientific peer reviewed journals
3. Dissemination of results in national and international professional conferences

Intention to publish date

31/07/2019

Individual participant data (IPD) sharing plan

The datasets analysed during this study will be available upon request from Asta B. Petursdottir by e-mail (abp5@his.is OR astabp@landspitali.is). The anonymised raw dataset will be available from February 2019 to February 2025. The dataset will be available to health professionals with an interest in supportive care for family caregivers requiring data for meta-analysis or in response to requests generated from publication of results in scientific journals/presentations at conferences. Consent from participants was obtained via informed consent procedures and a signed informed consent document.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/08/2019	06/09/2023	Yes	No