

Randomized controlled trial of the program 'my story as informal care-giver'.

Published: 16-01-2007

Last updated: 09-05-2024

The goal of this project is to develop and evaluate the effects of a new and promising theoretically founded intervention focused on preventing psychological problems among adult children who provide informal care for their parents. Questions1. Does...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON29973

Source

ToetsingOnline

Brief title

My story as informal care-giver

Condition

- Other condition

Synonym

depressive symptoms, stress

Health condition

psychische klachten

Research involving

Human

Sponsors and support

Primary sponsor: Trimbos-instituut

Source(s) of monetary or material Support: zonmw

Intervention

Keyword: burnout, effectiveness, informal care-givers, prevention

Outcome measures

Primary outcome

- Depressive symptoms (Centre of Epidemiological Studies - Depression scale, CES-D, Bouma, Ranchor, Sanderman and van Sonderen 1995). This is a widely used measuring instrument in the Netherlands as well as abroad with twenty items for the existence and extent of depressive symptoms..
- Perceived stress. The Self-Perceived Pressure by Informal Care (SPPIC) questionnaire was especially developed to monitor the results of the care-provider*s appraisal of the care situation (Pot et al. 1995, 1998). It consists of nine items in a one-dimensional hierarchic scale varying from less to more pressure. In addition to this quantitative classification, a qualitative classification can also be observed in the items. The pressure first manifests itself in the care-providers* thoughts and then in their interaction with the environment as well.
- Mastery (Pearlin Mastery Scale, Pearlin and Schooler 1978) This questionnaire consists of seven items about the extent to which people have their lives under control.
- Affective relationship between the parent and child (Positive Affect Index, Bengtson and Mangen 1988). This questionnaire consists of ten items, five about

the child's feelings towards the parent and five about the parent's feelings towards the child as perceived by the child.

Secondary outcome

nvt

Study description

Background summary

Approximately 750,000 people provide informal care in the Netherlands for more than three months and more than eight hours a week. These informal care-givers run a high risk of psychological problems such as depression or burnout. At the moment, however, no preventive interventions with proven effectiveness are available to informal care-givers in the Netherlands. On the basis of a scientific theoretical model that explains the development of psychological problems among informal care-givers, a new preventive intervention - the informal care-givers in Balance course - has been developed for adult children who provide informal care for their parents. The life review method, a systematic evaluation of one's own life, plays a central role in the intervention. This method is being used for the first time to address the problems of informal care-givers. An initial regional pilot project demonstrates the positive result of the intervention, i.e. a significant decrease in the perceived stress of informal care-givers. The proposal is to now develop the intervention nation-wide and on a larger scale and to more comprehensively examine the effects.

Study objective

The goal of this project is to develop and evaluate the effects of a new and promising theoretically founded intervention focused on preventing psychological problems among adult children who provide informal care for their parents.

Questions

1. Does the Informal care-givers in Balance course lead to a significant decrease in psychological problems and perceived stress, an improvement in the quality of life of the informal care-givers and the quality of their relationships with the care recipients and a reinforcement of the mastery of the adult children providing informal care for their parents as compared with a waiting list control group?
2. Are there any differences in the effects according to the types of disease

the care recipients have, the amount of time spent on informal care, and the sex of the care recipients and their children?

Study design

We carry out a randomized controlled trial with two parallel groups, the experimental condition (the Informal care-givers in Balance course) and a waiting list control group. It is a pragmatic, non-blinded multi-site trial. The measurements are taken immediately prior to the intervention (t0, the baseline measurement), immediately after the intervention (t1, two months after the baseline), and five months after the baseline measurement (t2, three months after the intervention).

Intervention

The Informal care-givers in Balance course consists of seven two-hour sessions and is designed for adult children who provide structural care for a parent in need of care and are under high perceived stress as a result. Regardless of the illness of their parent, informal care-givers can attend the course except if their parent has severe dementia. At the first three sessions, the participants learn to interview their own parent according to the life review method. The life review method has people tell their own life story, evaluate their life and actively attribute meaning and purpose to their life (Butler 1963, Bohlmeijer et al. 2003, Haight 2004). Life review is an effective method for the prevention of psychological problems (Bohlmeijer et al. 2003, Bohlmeijer et al. 2005). The Trimbos Institute has developed a self-help method for life review in which adult children interview their own parents (Bohlmeijer and Cuijpers 2005). Starting at the fourth session of the course, the perspective shifts to the informal care-givers* own life. The informal care-givers focus on the meaning and effects, especially undesirable ones, of the informal care on their lives and on the balance they would like to establish in their lives in accordance with the life review method. The possibilities are addressed for introducing a better balance. This is how the course is designed to influence whatever factors can be influenced and are relevant to the emergence of psychological problems among informal care-givers.

Study burden and risks

We do not expect risks for the participants, considering that

- the participants volunteer for participation,
- the intervention is a course and not therapy
- the participants do not have severe problems

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

informal care givers
minimum age: 25 years
moderate stress

Exclusion criteria

In case of a crisis-situation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Will not start
Start date (anticipated):	01-01-2007
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO	
Date:	16-01-2007
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

CCMO

ID

NL13764.097.06