

My story as informal care-giver: a randomised controlled trial

Submission date 30/05/2007	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 30/05/2007	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 22/08/2007	Condition category Mental and Behavioural Disorders	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives

The new preventive intervention will lead to a significant decrease in psychological problems and perceived stress, an improvement in the quality of life of the informal care-givers as compared with a waiting list control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local ethics committee (METIGG kamer Noord) on the 23rd January 2007.

Study design

Randomised, multicentre, placebo controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Informal care-givers, prevention, depression, burnout, stress

Interventions

The Informal care-givers in Balance course consists of eight 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. At the first three sessions, the participants learn to interview their own parent according to the life review method. 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.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Depressive symptoms
2. Perceived stress
3. Quality of life

Outcomes will be measured at:

T0: one week before start of intervention

T1: after three months (directly after intervention)

T2: after six month (three months after intervention)

Key secondary outcome(s))

No secondary outcome measures

Completion date

31/12/2008

Eligibility

Key inclusion criteria

Adults above the age of eighteen who provide informal care for a parent and feel they are under stress as a result.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

1. The parent of the informal care-provider is no longer able to take part in the life review, e.g. because of having severe dementia
2. The health situation of the parent or informal caregiver requires acute assistance

Date of first enrolment

01/09/2007

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Trimbos-Instituut

Utrecht

Netherlands

3500 AS

Sponsor information

Organisation

Trimbos-Institute - Netherlands Institute of Mental Health and Addiction (The Netherlands)

ROR

<https://ror.org/02amggm23>

Funder(s)**Funder type**

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration