

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

<b>Submission date</b> 30/05/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/05/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 22/08/2007	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Quality of life

## Participant information sheet

## 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 measure**

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)

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/09/2007

**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

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

200

**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)

## Sponsor details

P.O. Box 725

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## Sponsor type

Research organisation

## Website

<http://www.trimbos.nl/default37.html>

## 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

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration