

# Efficacy of a multicomponent support programme for caregivers of disabled persons: a randomised controlled study

<b>Submission date</b> 04/05/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/06/2019	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Olli-Pekka Ryyänen

**Contact details**  
University of Kuopio  
Department of Public Health/General Practice  
Mäkikatu 7  
Kuopio  
Finland  
70100  
+358 (0)405 14 17 41  
ollipekka.ryynanen@uku.fi

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## Study information

### Scientific Title

Efficacy of a multicomponent support programme for caregivers of disabled persons: a randomised controlled study

### Acronym

CAREGIVER

### Study objectives

A tailored support programme for caregivers of the disabled persons is effective in helping them to continue their caregiving.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the Ethical Committee of Kymenlaakso Central Hospital, Kotka on the 17th December 2001 (addition 17th February 2003).

### Study design

A randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Quality of life

### Participant information sheet

### Health condition(s) or problem(s) studied

Caregiving of a disabled person

### Interventions

Tailored two weeks training period in a rehabilitation centre, with tailored physical exercise, lessons about caregivers role to give psychological support and increase caregivers' knowledge and checking for medical treatments.

The control group received usual care.

The follow-up time was two years for mortality and continuation of caregiving, one year for quality of life and Zung's depression scale.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

1. Mortality of the care receiver
2. Continuity of caregiving
3. Placement of the care receiver into an institutional care

Primary outcomes were measured at two years.

**Secondary outcome measures**

1. Health related quality of life of the caregiver (15D Measure of Health-Related Quality of Life)
2. Depressive symptoms of the caregiver (Zung's depression scale)

Secondary outcomes were measured at one year.

**Overall study start date**

26/02/2003

**Completion date**

31/12/2006

**Eligibility****Key inclusion criteria**

1. 135 caregiver - care receiver dyads randomly divided into an intervention group (n = 66) and a control group (n = 69)
2. Caregiver of a disabled adult person living in Kuusankoski and Kouvola region (south-east Finland)
3. Caregiving continued at least six months
4. Ability to leave the care receiver to temporary institutional care
5. Ability to live in spa-hotel conditions during the intervention

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

135

**Total final enrolment**

135

**Key exclusion criteria**

1. Serious mental or physical disease of the caregiver
2. Caregiving only occasional
3. Not able to leave the care receiver
4. Not able to live in a spa-hotel during the intervention

**Date of first enrolment**

26/02/2003

**Date of final enrolment**

31/12/2006

**Locations****Countries of recruitment**

Finland

**Study participating centre****University of Kuopio**

Kuopio

Finland

70100

**Sponsor information****Organisation**

The Social Insurance Institution of Finland (KELA) (Finland)

**Sponsor details**

c/o Dr Paavo Rissanen

PO Box 450

Helsinki

Finland

00101

-

paavo.rissanen@kela.fi

**Sponsor type**

Government

**Website**

<http://www.kela.fi/in/internet/english.nsf>

**ROR**

<https://ror.org/057yw0190>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

The Social Insurance Institution of Finland (KELA) (Finland)

## **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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2013	11/06/2019	Yes	No