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

Submission date Recruitment status Prospectively registered 04/05/2007 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 19/09/2007 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category Other 11/06/2019

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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# Additional identifiers

**Protocol serial number** cg171201

# 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

#### Study type(s)

Quality of life

## 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(s)

- 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.

#### Key secondary outcome(s))

- 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.

## 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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)

#### **ROR**

https://ror.org/057yw0190

# Funder(s)

# Funder type

Government

#### **Funder Name**

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

# **Results and Publications**

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?
Results article	results	01/07/2013	11/06/2019	Yes	No