Prevention of psychological problems in older widowed persons by means of a visiting service: A randomized trial

Submission date	Recruitment status No longer recruiting	Prospectively registered		
12/09/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/09/2005	Completed	[X] Results		
Last Edited 07/01/2021	Condition category Mental and Behavioural Disorders	Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr S. Onrunst

Contact details

Trimbos Institute/Netherlands Institute of Mental Health and Addiction P.O.Box 725
Utrecht
Netherlands
3500 AS
+31 (0)30 2971100
sonrust@trimbos.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ZON-MW 63-224

Study information

Scientific Title

Prevention of psychological problems in older widowed persons by means of a visiting service: A randomized trial

Study objectives

Contact with fellow-sufferers, as offered by visiting services to widowed persons with little social support, would show superior effects in improving mental health, quality of life and reducing financial costs to society, compared by a control condition

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

International

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Psychological problems

Interventions

Experimental: visiting service.In the visiting service, recently widowed persons are offered to hold supportive one-to-one talks with trained fellow-sufferers. The objective is to provide social support. The volunteers make maximally 10 home visits, spread out over a one-year period. Control condition: respondents in the control condition are offered a brochure about the prevention of depression. These respondents are free to seek help elsewhere on their own initiative.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Mental health
- 2. Cost-effectiveness

Secondary outcome measures

- 1. Quality of life
- 2. Grief process
- 3. Mastery of condition
- 4. Loneliness

Overall study start date

01/11/2002

Completion date

01/05/2007

Eligibility

Key inclusion criteria

- 1. Widow/widower
- 2. Aged 55 years or older
- 3. Has lost his/her partner through death 6-12 months earlier
- 4. Feels lonely according to the 'Lonelisness Scale'
- 5. No mental disorder according to the MINI

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

350

Total final enrolment

216

Key exclusion criteria

When not met the five inclusion criteria mentioned above, people are excluded.

Date of first enrolment

01/11/2002

Date of final enrolment

01/05/2007

Locations

Countries of recruitment

Netherlands

Study participating centre Trimbos Institute/Netherlands Institute of Mental Health and Addiction Utrecht Netherlands 3500 AS

Sponsor information

Organisation

Trimbos Institute (The Netherlands)

Sponsor details

Da Costakade 45 Postbus 725 Utrecht Netherlands 3500 AS

Sponsor type

Charity

ROR

https://ror.org/02amggm23

Funder(s)

Funder type

Research organisation

Funder Name

ZON-MW, The Netherlands Organization for Health Research and Development

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?
Results article	results	12/06/2008	07/01/2021	Yes	No