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10/66 Dementia Research Group randomised controlled trial: helping carers to care - Russia

Submission date	Recruitment status
20/04/2007	No longer recruiting
Registration date	**Overall study status**
11/06/2007	Completed
Last Edited	**Condition category**
10/01/2020	Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.alz.co.uk/1066

Contact information

Type(s)
Scientific

Contact name
Prof Martin Prince

Contact details
Health Services and Population Research Department
Section of Epidemiology, P060
Institute of Psychiatry
De Crespigny Park
Denmark Hill
London
United Kingdom
SE5 8AF
+44 (0)20 7848 0137
m.prince@iop.kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
10/66 Dementia Research Group randomised controlled trial: helping carers to care - Russia

Acronym
10/66 Dementia Caregiver Intervention

Study objectives
The primary hypothesis is that an intervention focusing upon education and training of caregivers (10/66 intervention) will be associated with a reduction in caregiver psychological strain (the 20-item Self-Reporting Questionnaire [SRQ-20] score). We further hypothesise that the intervention will be associated with an improvement in the quality of life of both caregivers and people with dementia, and in the distress experienced by caregivers arising from behavioural and psychological symptoms in the person with dementia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study has been approved by:
1. The Institute of Psychiatry Ethical Committee, King's College London in April 2003 (ref: 076/03)
2. The Ethical committee of the Mental Health Research Centre of the Russian Academy of Medical Sciences in October 2003

Study design
Randomised single-blind placebo-controlled cross-over study

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
Dementia syndrome

Interventions
60 caregivers of people with dementia in each centre were randomised to receive the intervention immediately (n = 30) or six months later (n = 30). The 10/66 intervention targets the main carer, but includes members of the immediate and extended family. The aim is to provide basic education about dementia and specific training on managing problem behaviours. The three simple, manualised modules are delivered over five, weekly, half hour sessions.

1. Module one: assessment (one session):
1.1. Cognitive/functional impairment
1.2. Carer's knowledge and understanding of dementia
1.3. Care arrangements:
1.3.1. Who are the family members?
1.3.2. Who lives with the person with dementia?
1.3.3. How do they assist the main carer?
1.3.4. Which behavioural problems present most difficulties?
1.3.5. How burdened do they feel?

2. Module two: basic education (two sessions):
2.1. General introduction to the illness
2.2. What to expect in the future
2.3. What causes/does not cause dementia?
2.4. Locally available care and treatment

3. Module three: training on problem behaviours (two sessions): up to eight problem behaviours identified in the assessment are addressed:
3.1. Personal hygiene
3.2. Dressing incontinence
3.3. Repeated questioning
3.4. Clinging
3.5. Aggression
3.6. Wandering
3.7. Apathy

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Caregiver psychological distress (SRQ-20) which is assessed at baseline and after six months.

Secondary outcome measures
1. Caregiver:
1.1. Zarit Burden Interview
1.2. Quality of Life, measured with the World Health Organisation Quality of Life Assessment (WHO-QoL BREF)
2. Person with dementia:
2.1. Behavioural and Psychological symptoms (Neuropsychiatric Inventory Questionnaire [NPI-Q])
2.2. Quality of life, measured using the Dementia Quality Of Life instrument (DEMQOL)

All secondary outcomes will be measured at baseline and six months.

Overall study start date
05/04/2004

Completion date
30/12/2005

Eligibility

Key inclusion criteria
1. Aged 65 years and over
2. Meet Diagnostic and Statistical Manual of mental disorders fourth edition (DSM-IV) criteria for dementia syndrome

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
60 participants (30 in each arm)

Total final enrolment
60

Key exclusion criteria
1. Serious intercurrent illness (e.g. terminal illness) in the person with dementia, where the intervention might seem pointless to the family
2. A complete absence of family caregivers

Date of first enrolment
05/04/2004

Date of final enrolment
30/12/2005

Locations

Countries of recruitment
England

Russian Federation

United Kingdom

Study participating centre
Health Services and Population Research Department
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
10/66 Dementia Research Group (UK)

Sponsor details
c/o Prof Martin Prince
Health Services and Population Research Department
Section of Epidemiology, P060
Institute of Psychiatry
De Crespigny Park
Denmark Hill
London
United Kingdom
SE5 8AF
+44 (0)20 7848 0137
m.prince@iop.kcl.ac.uk

Sponsor type
Research organisation

Website
http://www.iop.kcl.ac.uk/iopweb/departments/home/default.aspx?locator=403

ROR
https://ror.org/04jmzkq74

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization (WHO) (Switzerland)

Alternative Name(s)

, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Switzerland

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?
Protocol article	Study protocol:	20/07/2007		Yes	No
Results article	results	01/04/2009	10/01/2020	Yes	No