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

Submission date	Recruitment status	[ ] Prospectively registered
27/04/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/06/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/11/2019	Mental and Behavioural Disorders	[ ] 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

Study information

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

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 the Institute of Psychiatry ethical committee, King's College London in April 2003 (ref: 076/03).

Primary study design
Interventional

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

Study type(s)
Quality of life

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 Specified

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

Key secondary outcome(s)
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.

Completion date
01/10/2007

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

Healthy volunteers allowed
No

Age group

Senior

Sex
Not Specified

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
15/03/2007

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
United Kingdom

England

Venezuela

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

Sponsor information

Organisation
10/66 Dementia Research Group (UK)

ROR
https://ror.org/04jmzkq74

Funder(s)

Funder type
University/education

Funder Name
Board of Scientific and Humanistic Development, Central University of Venezuela Caracas (Consejo de Desarrollo Cientifico y Humanistico Universidad Central de Venezuela Caracas) (Venezuela)

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?
Protocol article	Study protocol:	01/12/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes