

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

<b>Submission date</b> 27/04/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/06/2007	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 06/11/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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).

## **Study design**

Randomised single-blind placebo-controlled cross-over study

## **Primary study design**

Interventional

## **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 Científico y Humanístico 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?
<a href="#">Protocol article</a>	Study protocol:	01/12/2007		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes