Helping carers to care: the 10/66 Dementia Research Group’s randomized control trial of a caregiver intervention in Peru

Ajudando os cuidadores a cuidar: uma prova clínica randomizada da intervenção para o cuidador desenvolvida pelo grupo 10/66 no Peru

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Abstract
Objective: There is a need, in the absence of formal services, to design interventions aimed at improving the lives of people with dementia and their families. This study tested the effectiveness of the 10/66 caregiver intervention among people with dementia and their caregivers in Lima, Peru.

Method: Design/participants: a randomized controlled trial was performed involving 58 caregivers of people with dementia that received the intervention in the beginning of the trial (n = 29) or six months later (n = 29). The intervention consisted of three modules: 1) assessment (one session); 2) basic education about dementia (two sessions); and 3) training regarding specific problem behaviors (two sessions).

Main outcome measures: Caregivers and patients with dementia were assessed at baseline and after six months. For caregivers, the measures included strain (Zarit Burden Interview), psychological distress (SRQ-20), and quality of life (WHOQOL-BREF). Dementia patients completed scales assessing behavioral and psychological symptoms (NPI-Q) and quality of life (DEMQOL).

Results: Caregivers in the intervention group reported significantly decreased strain measures six months after the intervention compared to controls. No group differences were found in respect to the caregivers’ psychological distress and to quality of life in both caregivers and patients.

Conclusion: The 10/66 intervention seems to be as effective as similar interventions used in more developed countries.

Descriptors: Caregivers; Dementia; Intervention studies; Behavioral symptoms; Quality of life

Resumo
Objetivo: Demência é um problema crescente nos países em desenvolvimento. Existe uma necessidade urgente, devido à falta de serviços formais, de desenvolver intervenções que visem melhorar a vida das pessoas portadoras de demência e de suas famílias. Este estudo testa a efetividade do programa de intervenção para pessoas com demência e seus cuidadores desenvolvido pelo grupo 10/66, em Lima, Peru.

Método: Desenho/participantes: ensaio clínico randomizado. Cincuenta y oito cuidadores de personas con demencia fueron randomizados para recibir la intervención inmediatamente (n = 29) o seis meses después de su inclusión en el estudio. La intervención está compuesta por tres módulos: 1) evaluación (una sesión); 2) educación básica sobre demencia (dos sesiones), y 3) entrenamiento para tratar comportamientos específicos (dos sesiones). Principales medidas de desenlace: los cuidadores y las personas con demencia fueron evaluados al inicio del estudio y después de seis meses. En relación a los cuidadores, los desechos fueron: sobrecarga (Zarit Burden Interview), estrés psicológico (SRQ-20); y calidad de vida (WHOQOL-BREF). En relación a las personas con demencia, los desechos fueron síntomas comportamentales y psicológicos (NPI-Q); y calidad de vida (DEMQOL).

Resultados: Los cuidadores que recibieron la intervención reportaron disminución estadísticamente significativa en las medidas de sobrecarga cuando fueron evaluados después de seis meses, en comparación a los cuidadores al grupo-controle. No hubo diferencias observadas entre los grupos en relación a la estrés psicológico de los cuidadores y calidad de vida de los pacientes y cuidadores.

Conclusión: Esta intervención parece ser tan, si no más, efectiva que intervenciones similares aplicadas en países desarrollados.

Descritores: Cuidadores; Demência; Estudos de intervenção; Sintomas comportamentais; Qualidade de vida

Introduction
Pilot studies performed by the 10/66 Dementia Research Group (10/66 DRG) in 24 centers in south and south east Asia, Africa, and Latin America revealed that the levels of psychological strain and morbidity among caregivers of people with dementia are at least as high as those seen in the developed world.1 Many caregivers have to cut back on work to take on care responsibilities, at the

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same that they are faced with additional health-related expenses.¹ Evidence from these studies also show that behavioral and psychological symptoms of dementia are common and strongly and independently associated with caregivers’ strain.² The lack of general awareness regarding the bases of these symptoms often results in stigma to people with dementia and caregivers alike.² Population-based surveys in Cuba³ and the Dominican Republic,⁴ found that dementia was strongly associated with dependence. In Cuba, dementia made a larger contribution than depression or physical illness to caregivers giving up work to care, and also to caregivers’ psychological morbidity.³ In the Dominican Republic, among those needing care, dementia patients stood out as being more disabled, requiring more care, and being more likely to have paid caregivers.⁴ Caregivers of people with dementia experienced more strain than those who provided care to patients with other health conditions. Behavioral and psychological symptoms were important mediators of the effects of dementia upon all of these caregiver outcomes.³⁴

There is robust evidence from studies in high-income countries in support of the effectiveness of caregiver interventions. A recent meta-analysis identified 30 controlled studies, 21 of which were randomized trials, involving a total of 2,040 caregivers. The participants were predominantly female spouses of persons with dementia aged 55 and older.³ The meta-analysis identified modest but statistically significant benefits of those interventions for caregiver knowledge and psychological morbidity, but no effect upon caregiver strain, with a mean effect size of 0.3 for all caregiver outcomes. Four out of seven studies that used time until nursing home placement as an outcome suggested that caregiver interventions were associated with delayed placement. In an analysis of heterogeneity, the only intervention-related feature that emerged as statistically significant was the involvement of the patient as well as the caregiver in a structured program. A subsequent and more extensive meta-analysis included 127 controlled caregiver intervention studies. Although the meta-analysis did not describe the number of randomized trials involved, non-randomized studies were associated with larger effect sizes.³ Psychoeducational interventions, cognitive behavioral therapy for the caregiver, and counseling coupled with case management were all associated with modest effect sizes upon caregiver strain, psychological morbidity, and subjective well-being.⁴

In high-income countries, specialized healthcare services are available to provide support to caregivers of people with dementia. In low- and middle-income countries such services are almost inexistent, and informal care is even more salient. At the outset of our intervention program, we were only able to identify one published caregiver intervention trial from a low- or middle-income country. Senanorang et al.⁷ from Bangkok found an improvement in the psychological and behavioral symptoms of patients with dementia after offering their caregivers a brief counseling intervention. We hypothesized that an intervention focusing upon education and training of caregivers might have an even greater impact in a setting where community awareness about dementia is low and no formal care exists. The 10/66 Dementia Research Group brief caregiver intervention ‘Helping Carers to Care’ was developed pragmatically to be delivered at home using non-specialist local resources. The first two trials of this intervention indicated beneficial effects upon psychological morbidity and distress in India,⁸ and upon caregiver’s strain in Moscow.⁹ In this paper, we report upon the first of our trials nestled within the cross-sectional baseline phase of our population-based surveys, in Lima, Peru.

Method
1. Design
A randomized, single-blind, parallel-group controlled trial of the effect of a caregiver education and training intervention for caregivers and people with dementia (trial registration number ISRCTN66355402).

2. Recruitment
Between January 2005 and September 2006, we surveyed 1,378 people aged 65 and over in two urban catchment areas in Lima, Peru (Lima Cercado and San Miguel), of whom 130 were found to have dementia.¹⁰ Between January and February 2007, these families were approached again and invited to take part in the intervention. Recruitment was supplemented with people with dementia and their families who had sought for help at a local memory clinic, the Instituto de la Memoria y Desordenes Relacionados. The only exclusion criteria were the presence of terminal or other serious current physical illnesses in dementia patients, the lack of a caregiver, or the presence of more than one person with dementia in the same household. Inclusion criteria required people with dementia to be aged 65 years and over and to meet the 10/66 Dementia¹¹ or the DSM-IV criteria for dementia.¹² Consent was obtained from the person with dementia, whenever possible, and from their main caregiver, defined as the family member or close friend who was more involved in providing and/or organizing the care for the person with dementia. Other family, unrelated, and paid caregivers were encouraged to participate in the intervention, but only the main caregiver completed the baseline and outcome assessments.

3. Randomization
Participants were randomized to receive the intervention immediately (intervention group) or alternatively after six months (waiting list control group). To ensure independence, randomization was carried out in London, United Kingdom, with the codes transmitted immediately back to the center in Peru by e-mail. We used stratified permuted block randomization, with blocks of 4 within 2 strata of baseline Zarit Burden Interview scores (see measures below) in order to ensure, to the best possible extent, equal numbers and an even distribution of caregiver strain between the two allocations. All participants received medical care as usual in the local memory clinic, where the staff was blind in regard to the randomization status.

4. Measures
Dementia diagnosis was confirmed in the previous 10/66 Dementia Research Group survey, or, in the case of those recruited
via the memory clinic, by MG, an experienced local old age psychiatrist applying the same criteria. The outcome assessments were administered to the main caregiver and the person with dementia at recruitment and six months later. Baseline assessments were completed immediately prior to randomization, and all efforts were made to ensure that the interviewer for the six month follow-up assessment was blind to the randomization status.

5. Caregiver outcomes

1) Caregiver strain

   a) Caregiver role strain - The Zarit Burden Interview (ZBI)\textsuperscript{13-16} has 22 items that measure the caregiver’s appraisal of the impact of this role on his/her life. Each item is scored on a five-point scale (0-4) and then summed up to give a total score ranging between 0 (no strain) and 88 (maximum possible strain).

   b) Caregiver psychological morbidity - The Self Reporting Questionnaire 20 (SRQ 20)\textsuperscript{17,18} comprises 20 items covering symptoms of depression, anxiety, and somatized distress. The response to each item is either ‘yes’ or ‘no’, giving a total score range of 0 to 20. It has been widely used, particularly in low- and middle-income countries, where it has generally been shown to have robust measurement properties with good validity and reliability.\textsuperscript{19}

   c) Caregiver distress arising from behavioral and psychological symptoms of dementia (BPSD) - The brief form of the Neuropsychiatric Inventory (NPI-Q)\textsuperscript{20,21} consists of questions covering 12 common BPSD: delusions, hallucinations, agitation or aggression, depression or dysphoria, anxiety, elation or euphoria, apathy or indifference, disinhibition, irritability or lability, motor disturbance, nighttime behaviors, and appetite and eating. Where the behavior or symptom is present, it is rated by the caregiver on a six-point scale (0-5) according to the distress caused. The total NPI-Q distress scores is the sum of the 12 individual domain scores, with a maximum possible score of 60. The NPI-Q has been shown to have adequate test-retest and inter-rater reliability, as well as good concurrent validity.\textsuperscript{20,21}

2) Caregiver Quality of Life (QoL)

   The 17 item WHOQOL-BREF\textsuperscript{22} comprises 26 items assessing QoL in four domains; physical, psychological, social relations, and environmental. Each item has a five-point response option. Scores are transformed to generate scores for each domain ranging from 0 (worst possible QoL) to 100 (best QoL). An international field trial demonstrated that the WHOQOL-BREF is a cross-culturally valid assessment of generic quality of life with good discriminant and content validity, internal consistency, and test-retest reliability.\textsuperscript{22,23}

6. Care recipient outcomes

1) Severity of BPSD

   Severity of BPSD was also assessed using the NPI-Q\textsuperscript{20} (see above for details). For each of the 12 symptoms, the caregiver rated overall severity as not present or present to a mild, moderate or severe degree, providing a four-point severity scale (0-4). The total NPI-Q severity score is the sum of the 12 individual domain scores, providing a maximum possible score of 48.

2) Quality of life of the person with dementia

   The DEMQOL\textsuperscript{24-26} is a self-rated measure of dementia-specific health-related quality of life, comprising 29 items, each one with a four-point response option. Total scores range from 0 (worst possible QoL) to 116 (best possible QoL). It has acceptable psychometric properties for people with mild to moderate dementia.\textsuperscript{25,26}

7. The intervention

   The 10/66 Caregiver Intervention ‘Helping Carers to Care’ was originally developed in India, with input from the wider 10/66 group including experts from developed countries. It was specifically designed for diverse low- and middle-income countries with settings characterized by limited health and social care resources where services are not designed to meet the needs of people with dementia. The intervention had to be capable of being delivered in the home setting using the resources available – in most low- and middle-income countries this means non-specialist community health workers. The content and level of the intervention was tailored to this, as well as to the cultural contexts. In Peru, it proved impossible to recruit primary care health workers as interventionists, due to difficulties in incorporating this extra work into the daily activities of the primary care health workers. Accordingly, the intervention was delivered by junior psychologists and social workers. The 10/66 intervention targets the main caregiver, but it also includes members of the immediate and extended family. The aim is to provide basic education about dementia and specific training on managing problem behaviors. The three simple, manualised modules are delivered over five weekly sessions with 30 minutes each.

   Module 1 - Assessment (one session):
   a) Cognitive and functional impairments;
   b) Caregiver’s knowledge and understanding of dementia; and
   c) Care arrangements (Who are the family members? Who lives with the person with dementia? How do they assist the main caregiver? Which behavioral problems present most difficulties? How burdened do they feel?).

   Module 2 - Basic education (two sessions):
   a) General introduction to the illness;
   b) What to expect in the future; and
   c) What causes and what does not cause dementia; and
   d) Locally available care and treatment.

   Module 3 - Training on problem behaviors (two sessions):
   Up to eight problem behaviors identified in the assessment are addressed (personal hygiene, dressing, incontinence, repeated questioning, clinging, aggression, wandering, and apathy). A structured, manualised two-day training program is delivered to those that administer the intervention. The training aims to provide generic counseling skills, assessment skills to identify the problems experienced by the patient’s family and the available resources for care, sufficient knowledge to educate the family about dementia and general caregiving strategies, and family counseling skills to maximize cohesiveness and support. Trainees

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view a training video and develop the necessary skills through a combination of vignette-based discussion, role play and live supervised interviews with group feedback. More details on the intervention, manuals, and other training materials can be found in the 10/66 DRG website (http://www.alz.co.uk/1066/).

8. Statistical analysis
Primary endpoint analyses were carried out on the basis of intention to treat, limited to those for whom a six-month outcome assessment was available. The baseline characteristics of the two randomized groups and completers within the two groups were compared. Baseline imbalances were adjusted for using generalized linear modeling. We report change scores with standard deviations, separately for those randomized to intervention and control groups. Effect sizes, with 95% confidence intervals, are presented as mean differences and standardized mean differences (SMD) for each outcome, as proposed by Cohen. SMD were calculated as the mean difference in the change score divided by the pooled
not be contacted (16 were travelling and 20 were not at home). A minimum of four attempts to contact each participant was made. The sixty-six patients contacted were eligible and were invited to participate. Nineteen of them refused to participate (13 caregivers said they were working and did not have time to participate, 4 were paid caregivers and the family did not think they needed to be trained, and 2 thought they were well and did not need the intervention). Hence, 47 participants were recruited from the survey and completed the baseline assessments. Another 11 participants were recruited from clients of the local memory clinic. They all fulfilled the inclusion criteria, accepted to participate, and completed the baseline measures. Fifty-eight participants and their main caregivers were randomized (Figure 1), 29 to the intervention and 29 to the waiting-list control group. Two participants from the intervention group died after randomization and did not complete the intervention. All baseline characteristics were evenly distributed between the intervention and control groups (Table 1).

### 9. Ethics

The trial was approved by the ethical committees of the Bethlem Maudsley/IoP in the United Kingdom and the Instituto de la Memoria, in Peru.

### Results

#### 1. Sample characteristics

One hundred and thirty-one potentially eligible people with dementia were identified from the 10/66 DRG population-based survey data. Fourteen had died, fifteen had moved and 36 could not be contacted (16 were travelling and 20 were not at home). A minimum of four attempts to contact each participant was made. The sixty-six patients contacted were eligible and were invited to participate. Nineteen of them refused to participate (13 caregivers said they were working and did not have time to participate, 4 were paid caregivers and the family did not think they needed to be trained, and 2 thought they were well and did not need the intervention). Hence, 47 participants were recruited from the survey and completed the baseline assessments. Another 11 participants were recruited from clients of the local memory clinic. They all fulfilled the inclusion criteria, accepted to participate, and completed the baseline measures. Fifty-eight participants and their main caregivers were randomized (Figure 1), 29 to the intervention and 29 to the waiting-list control group. Two participants from the intervention group died after randomization and did not complete the intervention. All baseline characteristics were evenly distributed between the intervention and control groups (Table 1).

| Table 1 - Baseline characteristics of those who were randomized and those who completed the follow-up |
|-------------------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| PERSON WITH DEMENTIA                            | Randomized      | Completed outcome assessments |
| Age (SD)                                        | Intervention (n = 29) | Waiting list (n = 29) | Intervention (n = 27) | Waiting list (n = 29) |
| Female (%)                                      | 79.3            | 69.0            | 81.5            | 69.0            |
| Educational level (completed secondary or more) = (%)  | 55.5          | 37.0 - 2MV      | 55.5          | 37.0 - 2MV      |
| Needing care (%)                                | 34.5            | 37.9            | 33.1            | 37.9            |
| Much of the time                                | 34.5            | 24.1            | 33.3            | 24.1            |
| Some of the time                                | 31.0            | 37.9            | 33.3            | 37.9            |
| Dementia severity                               |                 |                 |                 |                 |
| Mild                                            | 14 (48.3)       | 17 (58.6)       | 14 (51.9)       | 17 (58.6)       |
| Moderate                                        | 12 (41.4)       | 10 (34.5)       | 11 (40.7)       | 10 (34.5)       |
| Severe                                          | 3 (10.3)        | 2 (6.9)         | 2 (7.4)         | 2 (6.9)         |
| NPI-Q – severity score (SD)                     | 4.2 (4.8)       | 5.0 (5.3)       | 3.7 (4.6)       | 5.0 (5.3)       |
| Quality of life (DEMQOL) (SD)                   | 100.3 (82.2) - 18 MV | 91.2 (15.2) - 17 MV | 100.3 (82.2) - 18 MV | 91.2 (15.2) - 17 MV |

| CAREGIVER                                         |                 |                 |                 |                 |
| Age (SD)                                          | 53.3 (15.9)     | 47.6 (15.0)     | 53.4 (16.2)     | 47.2 (15.0)     |
| Female (%)                                        | 24 (85.7)       | 26 (89.7)       | 23 (85.2)       | 26 (89.7)       |
| Relationship to the person with dementia (%)      |                 |                 |                 |                 |
| Children                                         | 12 (41.4)       | 13 (44.9)       | 11 (40.7)       | 13 (44.9)       |
| Spouse                                           | 3 (10.3)        | 4 (13.8)        | 3 (11.1)        | 4 (13.8)        |
| Other relatives                                  | 4 (13.8)        | 5 (17.2)        | 3 (11.1)        | 5 (17.2)        |
| Others                                           | 10 (34.5)       | 7 (24.1)        | 10 (37.0)       | 7 (24.1)        |
| SRQ (SD)                                         | 4.7 (4.8)       | 6.5 (5.1)       | 4.9 (4.9)       | 6.5 (5.1)       |
| ZARIT (SD)                                       | 19.4 (13.9)     | 21.2 (9.5)      | 17.6 (11.8)     | 21.2 (9.5)      |
| NPI-Q – carer distress score (SD)                | 4.9 (6.2)       | 6.7 (7.9)       | 4.4 (6.1)       | 6.7 (7.9)       |
| QOL (SD)                                         |                 |                 |                 |                 |
| Domain 1                                         | 69.7 (14.3)     | 70.2 (14.6)     | 69.8 (14.7)     | 70.2 (14.6)     |
| Domain 2                                         | 62.8 (15.5)     | 58.0 (15.3)     | 62.8 (16.1)     | 58.0 (15.3)     |
| Domain 3                                         | 69.5 (14.5)     | 66.7 (21.0)     | 70.1 (14.8)     | 66.7 (21.0)     |
| Domain 4                                         | 64.4 (14.4)     | 58.4 (16.0)     | 66.0 (13.3)     | 58.4 (16.0)     |
| Overall                                          | 14.3 (2.5)      | 13.0 (2.8)      | 14.3 (2.5)      | 13.0 (2.8)      |

standard deviation for the change score. With a target of 30 families randomized to the control and intervention arms, the trial was powered to detect moderate to large effect sizes (0.6 to 0.8 or greater for change scores on continuously distributed outcomes) associated with the intervention, at 80% power and 95% confidence.
1. Dementia patients were predominantly female. DEMQOL assessments could not be completed by 18 participants of those with dementia in the intervention group at baseline and by 17 participants from the control group. At follow-up, the respective figures were 18/29 and 17/27. All living participants completed the outcome assessments.

2. Main outcomes

Table 2 summarizes the change scores from baseline for the main outcomes and compares them in the two arms of the trial, in terms of mean differences and SMD. Caregiver role strain, as measured by the Zarit Burden Interview, decreased in the intervention group, while increasing slightly in the control group. This was a statistically significant benefit for the intervention group. The SMD (effect size) exceeded one both before and after adjusting for baseline covariates of age, gender, and need for care. The self-reported physical quality of life of caregivers declined in both arms of the trial, but to a lesser extent among those randomized to the intervention group; this difference achieved borderline statistical significance after adjustment for covariates, with an SMD of +0.36 (95% CI, -0.19 to 0.92) before and +0.49 (95% CI, 0.0 to 0.99) after adjustment. There were substantial reductions from baseline to follow-up in caregiver psychological morbidity and distress related to BPSD, but with no net difference between those randomized to intervention or control. Changes in NPI-Q BPSD severity were similarly modest in both arms. The quality of life of people with dementia was assessed in only around one-third of participants. It improved among those in the intervention group and declined among controls, but this difference was not statistically significant either before (SMD +0.19; 95% CI, -0.88 to 1.25) or after (SMD +0.32; 95% CI, -0.84 to 1.48) adjusting for covariates.

Discussion

A recent review of existing evidence on the effectiveness of caregiver interventions concluded that future trials should be conducted with more rigor in regard to randomization procedures, blind outcome assessments, follow-up for at least six months, and well-validated and reliable outcome criteria measuring outcomes proximally (burden) and distally (depression, quality of life). We have followed these recommendations. One innovative element of the 10/66 trials is the inclusion of a dementia-specific measure of health-related quality of life, DEMQOL.

The 10/66 caregiver intervention in Peru was associated with a statistically significant reduction in caregiver role strain. Although this was a small randomized controlled trial, we were able to identify large and statistically significant effects on a key outcome. The sample size of this trial could only detect large effects relevant to settings where very little priority is given to the needs of people with dementia. Yet, the large effect size of 1.02 for caregiver strain is in excess of those typically seen linked to caregiver interventions of this kind in high-income countries.

The effect sizes for the other outcomes were all in the direction of benefit from the intervention, and the absence of significance...
and smaller effect sizes could be the result of the lack of statistical power, leading to type 2 error with respect to these outcomes. Also, the low levels of neuropsychiatric symptoms in the intervention group (NPI-Q severity mean of 4.2 and SD of 4.8, NPI-Q distress mean = 4.9 and SD of 6.2) limited the capacity of the intervention to demonstrate improvement on this measurement ('floor effect'). Given that all of the 10/66 caregiver RCTs use the same intervention design and outcomes, we shall soon be in a position to perform meta-analyses to obtain more precise estimates of the effect of the intervention on the full range of outcomes. It is noteworthy that, in contrast to a recent meta-analysis,⁵ and in accordance to our two previous trials in Russia and India,⁶,²⁸ caregiver strain seemed more subject to the effects of the 10/66 intervention than caregiver psychological morbidity. Overall, there is support to our hypothesis that even brief, simple interventions focusing on caregiver education and training may be highly beneficial in settings where awareness is low and support from formal services is limited.

The 10/66 caregiver intervention was not delivered by health care workers in Lima, and it remains to be seen whether similar results could be achieved in case the intervention is to be delivered within the actual health system context of primary care in Peru. Hopefully, the results of this and other trials, together with more epidemiological research into the populational burden of dementia, may serve to shift the under-prioritization of continued care for the elderly in low- and middle-income countries.

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Authorship: Dr Guerra, Dr Ferri, and Professor Prince performed the analysis and interpretation of data and drafted the manuscript. Dr Guerra and Ms Fonseca participated in the acquisition of data. Dr Guerra and Professor Prince were responsible for fund raising. All authors participated in the study conception and design, reviewed the manuscript for important intellectual content, and approved the final version.

Disclosures

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* Modest
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Note: IMEDER = Instituto de la Memoria, Depresion y Enfermedades de Riesgo; ADI = Alzheimer Disease International.
For more information, see instructions for authors.

References


