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Effects of a Psychological Intervention in a Primary Health Care Center for Caregivers of Dependent Relatives: A Randomized Trial

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Purpose: To assess, in the context of Primary Health Care (PHC), the effect of a psychological intervention in mental health among caregivers (CGs) of dependent relatives. **Design and Methods:** Randomized multicenter, controlled clinical trial. The 125 CGs included in the trial were receiving health care in PHC. Inclusion criteria: Identifying oneself as principal CG of a dependent relative with dementia or any other disability, and having performed this task for at least 6 months. CGs were randomized to an intervention group (cognitive-behavioral treatment for managing dysfunctional thoughts about caregiving and training in self-help techniques) or to a control group (care as usual). CG mental health (General Health Questionnaire [GHQ-12]), dysfunctional thoughts about caregiving, quality of life, and burden were measured. Results: The intervention group showed improvement in mental health: A mean reduction in GHQ-12 score of -3.33 points was recorded in the intervention group vs. the control group (95% CI: -5.95 to -0.70; p = .01; Cohen d = 0.55). Improvement was also recorded in dysfunctional thoughts about caregiving: (-5.84; 95% CI: -10.60 to -1.09; p = .01; Cohen d = 0.62). Among the CGs that completed the initial and final assessments, a mean of 4.77 (SD 2.68) attended a maximum of

8 sessions. Men attended more often (5.00 sessions with *SD* 2.68) than women (4.70 sessions with *SD* 2.45; p < .001). *Implications:* Psychological group intervention in the context of PHC, aimed at the CGs of dependent persons with dementia and other disabilities, has improved mental health condition in CGs.

Key Words: Intervention, Mental health, Dysfunctional thoughts

Demographic changes over recent decades have led to a marked aging of the general population. Changes in life expectancy contribute to an increase in the number of people suffering chronic diseases that may limit functional abilities, causing dependency. The elevated number of dependent people has "the potential to put major pressure on health care and other support systems" (Harwood, Sayer, & Hirschfeld, 2004, p. 256). This new sociodemographic reality has a significant influence upon the care activities of Primary Health Care (PHC) centers, responsible for taking care of chronic patients (Donath et al., 2010), and shows the need for developing strategies and infrastructures for health and social care of people with disabilities and their caregivers (CGs; Harwood et al., 2004).

The family CG is currently one of the most important resources in the care of dependent patients. Accepting the responsibility for taking care of a relative often generates physical, psychological, and economic problems that can lead to overload—thereby worsening the CG's quality of life and physical and mental health (Goldstein et al., 2004; Losada et al., 2010; Pinquart & Sorensen, 2007).

General practitioners may play an important role in improving or avoiding decline in the emotional and physical conditions of their CG patients, because they can guide them toward resources and treatments that can alleviate CG stress and burden (Joling et al., 2008; Schoenmakers, Buntinx, & DeLepeleire, 2010). Meeting the requirements of the CGs of dependent relatives is not an easy task, and there is a need for the implementation of evidence-based psychosocial treatments that can improve the quality of care received by CGs (Vasse et al., 2011). Most interventions have been carried out with CGs of patients with dementia. In the review published by Lopez and Crespo (2007), 81.5% of the programs were found to have targeted CGs of people with dementia. Cognitive behavior therapy (CBT) interventions, such as that developed by Márquez-Gonzalez, Losada, Izal, Perez-Rojo, and Montorio (2007), are among the interventions that have received strongest support for reducing CGs distress (Gallagher-Thompson & Coon, 2007; Pinquart & Sorensen, 2006). In general, CBT interventions are aimed at assisting CGs by training them to help in a more flexible or adaptive way. Promoting realistic ways of facing caregiving demands, and helping them to better adapt to daily caregiving demands by increasing self-care (e.g., increased leisure and rest time), are ways in which CBT interventions influence CG distress. Although these types of intervention have been effective in research settings, before recommending their generalized use it is very important to demonstrate their efficacy when applied in the usual patient care settings (Mittelman, 2008; Pillemer et al., 2003). Studies in which research findings are transferred to everyday practice are few in number, though promising results have been reported (Burgio et al., 2009; Gitlin, Jacobs, & Earland, 2010a; Teri, McCurry, Logsdon, & Gibbons, 2005; Teri et al., 2012; Wethington et al., 2007).

The aim of this study was to assess, in a PHC context, the effect of a CBT intervention that was developed for improving the mental health of CGs of patients with dementia (Márquez-Gonzalez et al., 2007).

Methods

Design

This is a multicenter, randomized, controlled clinical trial.

Participants

All primary CGs and patients registered with the Home Care service at two PHC centers in Salamanca (Spain) were contacted to take part in this intervention study. Inclusion criteria were the following: identification as the primary CG, defined as the person accepting the primary responsibilities related to the care of the dependent person; being a relative of the care recipient; having provided care for more than 6 months; and both CG and care recipient living in the same home. CGs were excluded if they were not the primary CG, if the care recipient died, if they could not be contacted (change of address, wrong telephone number, etc.), or if they declined to participate (Figure 1). Most of the participants were women (74.4%), with a mean age of 62.35 years and, at the time of the study, had been caring for an average of 9 years. Table 1 shows baseline demographic and clinical characteristics of the sample.

Sample Size

The sample comes from a previous study exploring the basal conditions of the CGs of dependent patients from two health care zones. The 153 CGs receiving care were included. This study offered participation to those who met the eligibility criteria. With the 141 initially included participants, a common standard deviation of 6 points for the General Health Questionnaire (GHQ-12), and accepting an alpha risk of 0.05 and a beta risk of 0.20, the sample suffices to detect a difference in overall GHQ-12 score of 3 points (Perez-Penaranda et al., 2009).

Randomization

Through consecutive sampling, 141 CGs were included. After the baseline interviews, the CGs were randomized to the intervention or to the control group in a proportion of 2:1, using Epidat version 3.0.

Intervention

CGs in the intervention group were assigned to groups each containing 8–12 CGs. The intervention took place in accordance with the manual developed by Losada, Montorio, Izal, and Márquez-Gonzalez

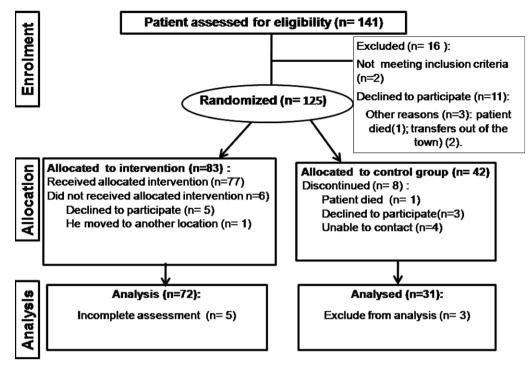


Figure 1. Flow of caregivers through the trial.

Table 1. Comparison of Control and Intervention Groups at Baseline: CGs and Care Recipients

	Control group, $n = 42$	Intervention group, $n = 83$	Total, $n = 125$	p value
CGs				
Age (mean, SD)	64.95 ± 11.78	61.07 ± 11.91	62.35 ± 11.96	.10a
Gender, <i>n</i> (%)				.74 ^b
Women	32 (76.20)	61 (73.50)	93 (74.40)	
Men	10 (23.80)	22 (26.50)	32 (25.60)	
Kinship, <i>n</i> (%)				.63 ^b
Husband/wife	14 (33.30)	21 (25.30)	35 (28.00)	
Children	16 (38.10)	43 (51.80)	59 (47.20)	
Parents	8 (19.00)	14 (16.90)	22 (17.60)	
Other relatives	4 (9.50)	5 (6.00)	9 (7.20)	
Educational level, <i>n</i> (%)				$.07^{\rm b}$
Illiterate	2 (4.8)	11 (13.3)	13 (10.4)	
Primary-secondary	24 (57.1)	31 (37.3)	55 (44.0)	
Higher	16 (38.1)	41 (49.4)	57 (45.6)	
Number of months providing care (mean, SD)	116.34 ± 145.00	105.91 ± 115.89	109.45 ± 126.00	.66ª
Care recipients				
Age (mean, SD)	77.22 ± 20.35	72.79 ± 18.83	74.13 ± 19.30	.32a
Gender, <i>n</i> (%)				.02 ^b
Women	20 (47.60)	55 (66.30)	75 (60.00)	
Men	22 (52.40)	26 (31.30)	48 (38.40)	
Illness N (%)				.16 ^b
Dementia	7 (16.70)	28 (33.70)	35 (28.00)	
Mental health	5 (11.90)	9 (10.80)	14 (11.20)	
Musculoskeletal	7 (16.70)	14 (16.90)	21 (16.80)	
Heart disease	6 (14.30)	10 (12.00)	16 (12.80)	
Others	16 (38.00)	21 (25.20)	37 (29.60)	

CGs, caregivers.

^aAssessed using *t* test.

^bAssessed using chi-squared test.

Table 2. Content of the Intervention (Márquez-Gonzalez et al., 2007)

Session 1. In this first session, the content of the intervention was explained, an evaluation was made of initial knowledge of the content, and the stress model was presented.

Session 2. Emphasis was placed on enhancing CG awareness of the importance of self-care.

Session 3. This session explained the differences in the concepts of situation, thought, and emotion, and focused on knowledge of automatic thoughts and on the importance of analyzing the latter.

Session 4. Having understood the concept of thought in the previous session, this session addressed errors of thought.

Session 5. This session focused on important aspects that affect mood state: valuing free time, carrying out pleasant activities, and learning to adjust thought to reality.

Session 6. This session helped CGs to know more about the feeling "you should" (guilt): where it comes from, how it is formed, and strategies to identify it.

Session 7. This session included an analysis of CG rights and looked at the difficulties found for applying them.

Session 8. Finally, once the CGs were aware of their rights, this session addressed the subject of learning how to ask for help.

CGs, caregivers.

(2006) (content shown in Table 2). The intervention consisted of eight 90-min sessions carried out over 8 consecutive weeks at the health care centers. The groups were directed by a psychologist other than the principal investigator of the study, with help of cotherapists (a physician and a nurse from the PHC center). No special aid or incentive was provided for attending the sessions. Prior to the intervention, four group sessions with the participation of CGs not included in this study were video-recorded, for use in the training sessions. Between sessions, CGs were asked to complete "homework" aimed at generalizing the trained skills to their everyday context (Losada et al., 2006; Márquez-Gonzalez et al., 2007). Homework was reviewed by the therapists at the beginning of each session.

Usual Care

Participants in Both Groups Had Unrestricted Access to Usual Health Care.—The control group received only usual care. In Spain, the support offered to dependent patients is coordinated by public institutions (Health and Social Services centers) and regulated by a specific Law (Boletín Oficial del Estado, 2006). The quantity and type of support provided by the institutions depend on the level of functional status of the care recipient and are managed by their relatives. In addition, since

2003 the PHC centers offer specific care for CGs. and most of the initiatives in this context have been related to basic care education: feeding, prevention of falls, etc. General practitioners (GPs), in collaboration with PHC nurses, offer most of the consulting office care in public centers and in the homes of dependent people. In addition, they coordinate the care required from other specialists (neurologists, psychiatrists, etc.) or social services (social support, institutionalization, etc.). Support for the CG is infrequent, especially when the CG's own GP is different from the one attending the dependent person. Care from psychologists is only offered at support centers and Mental Health Units, and must be previously requested by the psychiatrist; as a result, such care is only suggested in severe cases; for a description of the Spanish health strategy for dementia, see also Mateos, Franco, and Sanchez (2010).

Measures

The sociodemographic variables and characteristics of care at baseline were age and gender of the CGs and care recipients, kinship with the care recipient, number of months providing care, and the cause of dependency. All participants were assessed through face-to-face interviews by a psychologist not participating in the intervention between 2 and 6 weeks pre-intervention and 1 and 3 weeks postintervention.

Primary Endpoint

The primary endpoint was mental health as self-perceived by the CG and scored using the 12-item version of the GHQ-12. This is a self-administered screening questionnaire designed for use in consulting settings and aimed at detecting individuals with a diagnosable psychiatric disorder (Goldberg & Hillier, 1979). A small number of studies have had a longitudinal component (Pevalin, 2000). The GHQ has also been used to evaluate the effectiveness of group therapy based on cognitive-behavioral principles (Lincoln et al., 2011). In its original version, it had 60 items (GHQ-60), which were subsequently reduced to 30, 28, and 12 items (GHQ-12; Goldberg & Williams, 1988). The GHQ-12 is the most widely used screening instrument for common mental disorders, in addition to being a more general measure of psychiatric well-being. The results of validation of the GHQ-12 performed in 15 countries throughout the world have been good, and involving various types of populations, including elderly people. Although it has sometimes been considered unidimensional, several studies have revealed

Table 3. Comparison of Control CGs (n = 42) and Intervention (n = 83) Group: Baseline and Postintervention

	Baseline Mea	ın [SD] score	Postintervention Mean [SD] score		Mean difference		
	Control group $(n = 42)$	Intervention group $(n = 83)$	Control group $(n = 31)$	Intervention group $(n = 72)$	Between groups	p value	Cohen d
GHQ-12	13.29 (6.90)	14.03 (6.27)	14.03 (6.85)	12.22 (6.22)	-3.33 (-5.95 to -0.70)	.01	0.55
Cognition and physiological	2.95 (1.30)	2.88 (1.29)	2.83 (1.26)	2.36 (1.30)	-0.64 (-1.25 to -0.02)	.04	0.45
General welfare	6.97 (3.26)	7.44 (3.10)	7.41 (3.49)	6.51 (3.08)	-1.68 (-3.05 to -3.11)	.01	0.53
Confronting challenges	2.12 (1.39)	2.36 (1.39)	2.32 (1.27)	2.05 (1.24)	-0.63 (-1.28 to 0.0)	.05	0.43
Self-assessed individual	1.24 (1.52)	1.34 (1.37)	1.45 (1.52)	1.29 (1.44)	-0.36 (-0.88 to 0.15)	.16	0.30
Dysfunctional thoughts about caregiving	30.67 (11.44)	31.40 (14.88)	31.96 (13.48)	25.71 (13.16)	-5.84 (-10.60 to -1.09)	.01	0.62
Quality of life (Ruiz and Baca's Questionnaire)	76.31 (25.07)	70.68 (23.70)	78.96 (20.50)	76.47 (24.50)	5.10 (-1.45 to 11.67)	.12	0.39
Short Zarit Interview	10.79 (7.28)	12.65 (6.40)	10.34 (6.78)	12.50 (6.12)	0.50 (-1.99 to 3.00)	.68	0.12

the existence of different factors (Muñoz, Vazquez, Rodriguez, Pastrana, & Varo, 1979; Sanchez-Lopez & Dresch, 2008). The customary types of scores used are a bimodal scale (0-0-1-1) and a 4-point Likert-type scale (0-1-2-3). In this study, we used the latter type of scoring method, because it produces a more acceptable distribution of scores for parametric analysis (with less skewness and kurtosis). The scores were used to generate a total score ranging from 0 to 36. The positive items were corrected from 0 (always) to 3 (never), and the negative items from 3 (always) to 0 (never). Higher scores are indicative of poorer mental health. The scale had good internal consistency in this study (Cronbach's alpha = 0.83).

Secondary Endpoints

The dysfunctional thoughts about caregiving questionnaire (Losada et al., 2006) was used for assessing CG thoughts that may act as barriers or obstacles to an adaptive coping style with regard to caregiving. This is a 16-item measure developed in accordance with cognitive-behavioral principles. Responses are scored on a Likert-type scale ranging from 0 ("totally disagree") to 4 ("totally agree"). In its development study, this scale showed a 3-month test-retest reliability of 0.60 and a correlation of 0.59 with a brief version of the Dysfunctional Attitudes Scale developed by Andrews, Lewinsohn, Hops, and Roberts (1993).

Quality of life was assessed with Ruiz and Baca's Questionnaire (1993), comprising 39 items, each with a Likert-type 5-point score (0–4). Assessment is

made based on response options relating to specific situations and ranging from "not at all", indicating that the situation does not occur, to "a lot"—in affirmation of the opposite. This study yielded an internal consistency index (Cronbach's alpha) of 0.94.

Burden was measured through the Short Zarit Burden Interview (Gort et al., 2005). This scale has shown a sensitivity of 100%, a specificity of 90.5%, a positive predictive value of 95.45%, and a negative predictive value of 100% in defining CG burden in primary care. The short and screening versions of the Burden Interview produced results comparable to those of the full version (Gort et al., 2005).

Data Analysis

Statistical normality was checked using the Kolmogorov-Smirnov test. Quantitative variables were expressed as the mean and standard deviation, whereas qualitative variables were expressed on the basis of their frequency distribution. The comparisons between intervention and control groups at baseline were based on the chi-squared test, and on the Student's t-test for analyzing qualitative and quantitative variables with two categories. The effectiveness of the intervention was evaluated by comparing the differences experienced by the two groups before and after the intervention, based on the following expression: Effectiveness: ([Final mean - Baseline mean in the intervention group]) - ([Final mean - Baseline mean in the control group)], and using multivariate analysis of variance (MANOVA; Table 3). Analysis of the changes

Table 4. Clinical Significance of Main Outcomes at Postintervention

	Control group $(n = 42)$			Intervention group $(n = 83)$			Difference in Net	
	Improved	Worsened	Net	Improved	Worsened	Net	Improvement (95% CI)	
	n (%)	n (%)	Improvement	n (%)	n (%)	Improvement		
GHQ-12	5 (16.7)	7 (23.3)	-2 (-6.66)	25 (36.8)	8 (11.8)	17 (25.00)	31.66 (14.34–35.66)	
Cognition and physiological	7 (23.30)	9 (30.00)	-2 (-6.66)	35 (51.50)	11 (16.20)	24 (35.29)	41.95 (23.75–46.83)	
General welfare	3 (10.00)	8 (26.70)	-5 (-16.66)	26 (38.20)	13 (19.10)	13 (19.11)	35.77 (8.62–29.60)	
Confronting challenges	8 (26.70)	12 (40.00)	-4 (-13.33)	30 (44.10)	17 (25.00)	13 (19.11)	32.44 (8.82–29.40)	
Dysfunctional thoughts about caregiving	8 (28.60)	6 (21.4)	2 (7.20)	26 (42.60)	5 (8.20)	21 (34.40)	19 (20.25–48.55)	

Note: GHQ-12, General Health Questionnaire.

in the primary endpoint between the intervention group and the control group was carried out on an intent-to-treat (ITT) basis (Lautenschlager et al., 2008). Following the ITT principles, the participants were included regardless of the level of exposure to treatment (Gitlin, Winter, Dennis, Hodgson, & Hauck, 2010). Cohen d was calculated to measure the effect size (Cohen, 1988). In order to evaluate clinical significance for outcomes, we used the criterion of a 0.50 SD improvement from baseline to follow-up (Gitlin et al., 2010b). Two logistic regression models were used to analyze the probability of improvement in mental health and dysfunctional thoughts in the intervention group. As dependent variables, the first model used improvement or no improvement in mental health, whereas the second model used improvement or no improvement in dysfunctional thoughts (0 = no improvement)and 1 = improvement). In turn, as independent variables (enter method) the first model used group (1 = intervention and 0 = control), gender (men = 1) and women = 0), CG age, and basal GHQ-12 score, whereas the second model used basal dysfunctional thoughts.

The statistical analyses were carried out using the SPSS statistical package, 17.0 version (SPSS, Inc., Chicago, IL), with a significance level of p < .05.

Results

Participant Flow and Recruitment

PHC physicians and nurses supplied the research team with data on 141 CGs between July 2008 and November 2009. Of these, 125 (88.65%) were finally included in the study (Figure 1). Table 1 shows

baseline demographic and clinical characteristics for each group. No statistically significant differences were observed between the two groups in terms of the sociodemographic variables, except for care recipient gender (p < .05), with men being more prevalent in the control group and women in the intervention group.

Outcomes and Estimation

Statistically significant improvements observed in the CGs of the intervention group (baseline to postintervention; Table 3), compared with those of the control group, in terms of mental health (total score and in three of the four dimensions) and dysfunctional thoughts about caregiving. In relation to global self-perceived mental health, a mean reduction in the GHQ-12 test score of -3.33 points was obtained in the intervention group vs. the control group (95% CI: -5.95 to -0.70). Improvement was also recorded dysfunctional thoughts about caregiving: (-5.84; 95% CI: -10.60 to -1.09). The results of the MANOVA revealed significant differences in GHQ-12 (F = 4.69; p = .01; Cohen d = 0.55) and in two of its dimensions: cognition and physiological (F = 5.56; p = .04; Cohen d = 0.45) and general welfare (F = 4.07; p = .01; Cohen d = 0.53). Significant differences were also found for dysfunctional thoughts about caregiving (F = 5.05; p = .01; Cohen d = 0.62). No significant differences were observed in self-assessed individual quality of life and burden.

Table 4 shows the proportion of participants showing clinically significant changes (SD > 0.50) in relation to the measures that had revealed statistically significant changes after the intervention.

Table 5. Logistic Regression Analysis

	В	Significance	OR	(95% CI)
Model 1				
IntervControl	1.78	0.02	5.91	(1.25-27.89)
(1)				
Gender (1)	1.61	0.04	4.98	(1.06-23.33)
Age CG	0.04	0.11	0.96	(0.91-1.01)
GHQ-12	0.23	< 0.001	1.25	(1.12-1.41)
Constant	-4.25	0.03	0.01	
Model 2				
IntervControl	1.46	0.05	4.31	(0.99-18.74)
(1)				
Gender (1)	1.82	0.02	6.18	(1.35-28.25)
Age CG	-0.04	0.20	0.96	(0.90-102)
Dysfunctional	0.12	< 0.001	1.13	(1.06-1.20)
thoughts				
Constant	-4.63	0.02	0.01	

Notes: CGs, caregivers. Dependent variable: Improvement dysfunctional thoughts (0 = no improvement; 1 = improvement).

Independent variables: IntervControl (1 = intervention; 0 = control). gender: 0 women, 1 men; age CG; basal dysfunctional thoughts. OR: odds ratio.

We only analyzed those CGs who completed the initial and final evaluations of each questionnaire. The net improvement in the intervention group vs. the controls showed significant differences (p < .05) in all four measures.

In the logistic regression analysis of significant improvement, mental health yielded an OR of 5.91 (95% CI: 1.25-27.89; p = .02) for the intervention group vs. the control group, whereas dysfunctional thoughts yielded an OR of 4.31 (95% CI: 0.99–18.74; p = .05; Table 5).

Attrition

In the intervention group, the dropout rate was 13.09%, and no differences were observed in the sociodemographic and clinical characteristics between those who completed the study and those who did not. However, the dropout rate in the control group was 26.19%, with a greater proportion of women (p = .06) and of CGs caring for people without a diagnosis of dementia (p = .012; Figure 1).

Among CGs who completed the initial and final assessments, the mean number of sessions attended was 4.77 (SD 2.68; out of a maximum of eight sessions). Men attended more often (5.00; SD 2.68) than women (4.70; SD 2.45; p < .001). Twelve CGs attended one to two sessions (21.81%), 15

attended three to five sessions (27.27%), and 28 attended more than five sessions (50.91%). No relationship was found between the number of sessions attended by CGs and the changes recorded in mental health and dysfunctional thoughts.

Discussion

The obtained results suggest that the implementation of a psychological intervention in PHC improves the mental health of CGs of dependent persons. This intervention was initially carried out in a research setting with CGs of patients with dementia (Losada et al., 2006; Márquez-Gonzalez et al., 2007). It therefore appears to be effective not only in CGs of relatives with dementia but also in CGs of relatives with problems of dependency due to several chronic disorders. An improvement in mental health in the intervention group of CGs was observed, with a moderate effect size. The observed effect size of the variable dysfunctional thoughts about caregiving was also moderate. Even though the effect size obtained is moderate, this result is similar to or better than that reported in other studies carried out with CG samples (Mittelman, 2008), and is better than that found in pharmacological research, in which the effect size obtained is small (Lingler, Martire, & Schulz, 2005). Given that the situation of CGs is chronically stressful, the fact that emotional discomfort does not increase, and that it even decreases significantly, can be regarded as an important achievement (Gaugler, Mittelman, Hepburn, & Newcomer, 2010).

Our results coincide with those of Losada and colleagues (2006) and Márquez-Gonzalez and colleagues (2007) insofar as we found a significant improvement in mental health and a significant reduction in dysfunctional thoughts in the CGs of the intervention group. These results are in support of the idea that the modification of dysfunctional thoughts is one of the mechanisms of action through which cognitive-behavioral interventions contribute to reducing discomfort in CGs (Losada, Márquez-Gonzalez, & Romero-Moreno, 2011; Rodriguez-Sanchez et al., 2011). However, no significant changes were recorded in either quality of life or burden, indicating that the intervention does not have significant effects on global variables of discomfort related to dimensions additional to mental and physical health.

The results from this study suggest that the probability of having better mental health and

dysfunctional thoughts is higher for men. These results are similar to those found by Pinquart and Sorensen (2006), who found lower improvements in subjective well-being in intervention studies with higher percentage of female CGs, even though greater improvements in depression and burden were also reported in the Pinquart and Sorensen (2006) study for studies with higher percentage of female CGs.

Regarding the intensity of the intervention, and according to the meta-analysis published by Brodaty, Green, and Koschera (2003), the "dosage" of our intervention can be classified as moderate (3–5 sessions of mean CG attendance). The failure to find significant differences between those who attended all the intervention sessions and those who did not may be explained by the fact that, even though some sessions were not attended, for those attended sessions participants were requested to do the homework (e.g., involvement in pleasant activities) for all the week days. This between sessions therapeutic work may explain the obtained effects in CGs who did not attend all the sessions (Lopez & Crespo, 2007).

Transferring Cognitive-Behavioral Interventions to the PHC Center Context

In the research context of non-pharmacological treatment, it is difficult to find translational studies (Burgio et al., 2009; Gitlin et al., 2010b; Teri et al., 2005, 2012; Wethington et al., 2007). These studies contribute to determining whether treatments found to be effective in the research setting are equally effective in real-life practice, and as in our specific case, in the PHC context (Mittelman, 2008; Pillemer et al., 2003). The role of general practitioners as motivators for change in informal CGs is highly significant, because the mediation of support services through the GP can lead to a significant increase in the utilization of interventions (Chene et al., 2005; Donath et al., 2010). It is important to investigate the efficacy of GP counseling of CGs of dependent relatives with a view to overcoming current barriers to the use of support services (Donath et al., 2010; Joling et al., 2010; Nutting et al., 2008; Schoenmakers, Buntinx, & DeLepeleire, 2009). To our knowledge, no positive results in terms of improving CGs mental health in the primary care setting such as those as in our study have been reported (Mateos et al., 2010; Vasse et al., 2011; Wethington et al., 2007).

Rejection and dropout rates in interventions with CGs are generally very high, with figures of up to 74% (Newcomer, Yordi, DuNah, Fox, & Wilkinson, 1999). In our case, however, only 13.09% of the CGs in the intervention group dropped out of the study. This is a very positive figure considering that no incentives of any kind were offered, and that no special aid was arranged to facilitate attendance. It may be that greater accessibility to PHC for CGs contributes to reducing dropout rates compared with those reported for interventions in other settings. However, because Spanish PHC centers offer no psychological resources (unless they are specifically contracted for research purposes as in this case), there is a need to set up a specific care system that would allow psychological interventions targeted to CGs.

Limitations

The main limitation of our study refers to the need to assess whether the effects persist over time. or whether booster sessions are needed to maintain the obtained results. Another limitation of this study is the dropout rate. In the control group, the dropout rate was too high (26.19%), and above the usually observed rates (Sorensen, Pinguart, & Duberstein, 2002). However, in the intervention group, the dropout rate was far lower than expected (13.09%), suggesting that the intervention was well accepted. Another important limitation is that we found no improvements in quality of life or burden. As a result, this intervention cannot be recommended as an isolated measure to improve the global or general situation of CGs. In addition, we have not controlled the effect which receiving social contact through the participation in the intervention may have had upon the obtained results. The inclusion of a social contact control group could help to increase our knowledge about the potential of the described intervention for reducing CG distress.

Implications

Although in 2006 a Spanish legislation was approved for the Promotion of Personal Autonomy and the Support of Dependent Persons (Boletín Oficial del Estado, 2006), acknowledging the importance of caring for the CG and establishing different procedures for providing resources, almost all the support provided by the governmental agencies has been of an economic nature, and "care for the family

(regular CG) or psychosocial interventions are usually excluded from health care services in most of Spain" (Mateos et al., 2010, p. 882). The results of this study show that a group psychological intervention aimed at the CGs of dependent persons with dementia and other diseases in PHC centers can improve CG mental health conditions. In addition, such programs may make it possible for patients in normal practice to benefit from therapies that have demonstrated their effectiveness in research less closely related to routine practice. Considering the efficacy and feasibility of interventions such as the collaborative care model developed by Unutzer and colleagues (2002) for treating late life depression in primary care settings, including procedures for allowing collaboration among psychologists, geriatricians, nurses, physicians, and other health care professionals in PHC centers, particularly significant benefits could be obtained in CGs well-being by developing these interventions in early stages of the caregiving role (Ducharme et al., 2011).

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References

- Andrews, J. A., Lewinsohn, P. M., Hops, H., & Roberts, R. E. (1993).Psychometric properties of scales for the measurement of psychosocial variables associated with depression in adolescence. *Psychological Reports*, 73, 1019–1046.
- Boletín Oficial del Estado. (2006). Ley 39/2006 de Promoción de la Autonomía Personal y Atención a las personas en situación de dependencia. BOE, 299, 44142–44156. Retrieved from http://boe.es/boe/dias/2006/12/15/pdfs/A44142-44156.pdf
- Brodaty, H., Green, A., & Koschera, A. (2003). Meta-analysis of psychosocial interventions for caregivers of people with dementia. *Journal of the American Geriatrics Society*, 51, 657–664. doi:10.1034/j.1600-0579.2003.00210.x
- Burgio, L. D., Collins, I. B., Schmid, B., Wharton, T., McCallum, D., & Decoster, J. (2009). Translating the REACH caregiver intervention for use by area agency on aging personnel: The REACH OUT program. The Gerontologist, 49, 103–116. doi:10.1093/geront/gnp012
- Chene, R., Garcia, L., Goldstrom, M., Pino, M., Roach, D. P., Thunderchief,
 W., & Waitzkin, H. (2005). Mental health research in primary care:
 Mandates from a community advisory board. *Annals of Family Medicine*, 3, 70–72. doi:10.1370/afm.260
- Cohen, J. (1988). Statistical power analysis for the behavioural sciences. Hillsdale, NJ: Lawrence Erlbaum.
- Donath, C., Grassel, E., Grossfeld-Schmitz, M., Menn, P., Lauterberg, J., Wunder, S., Holle, R. (2010). Effects of general practitioner training and family support services on the care of home-dwelling dementia patients--results of a controlled cluster-randomized study. BMC Health Services Research, 10, 314. doi:10.1186/1472-6963-10-314
- Ducharme, F. C., Levesque, L. L., Lachance, L. M., Kergoat, M. J., Legault, A. J., Beaudet, L. M., & Zarit, S. H. (2011). "Learning to become a family caregiver" efficacy of an intervention program for caregivers following diagnosis of dementia in a relative. *The Gerontologist*, 51, 484–494. doi:10.1093/geront/gnr014
- Gallagher-Thompson, D., & Coon, D. W. (2007). Evidence-based psychological treatments for distress in family caregivers of older adults. *Psychology & Aging*, 22, 37–51. doi:10.1037/0882-7974.22.1.37

- Gaugler, J. E., Mittelman, M. S., Hepburn, K., & Newcomer, R. (2010). Clinically significant changes in burden and depression among dementia caregivers following nursing home admission. *BMC Medicine*, 8, 85. doi:10.1186/1741-7015-8-85
- Gitlin, L. N., Jacobs, M., & Earland, T. V. (2010a). Translation of a dementia caregiver intervention for delivery in homecare as a reimbursable Medicare service: Outcomes and lessons learned. *The Gerontologist*, 50, 847–854. doi:10.1093/geront/gnq057
- Gitlin, L. N., Winter, L., Dennis, M. P., Hodgson, N., & Hauck, W. W. (2010b). A biobehavioral home-based intervention and the well-being of patients with dementia and their caregivers: The COPE randomized trial. *JAMA*, 304, 983–991. doi:10.1001/jama.2010.1253
- Goldberg, D. P., & Hillier, V. F. (1979). A scaled version of the General Health Questionnaire. *Psychological Medicine*, 9, 139–145. Retrieved from http://journals.cambridge.org
- Goldberg, D., & Williams, P. (1988). A users guide to the General Health Questionnaire. Slough: NFER-Nelson.
- Goldstein, N. E., Concato, J., Fried, T. R., Kasl, S. V., Johnson-Hurzeler, R., & Bradley, E. H. (2004). Factors associated with caregiver burden among caregivers of terminally ill patients with cancer. *Journal of Palliative Care*, 20, 38–43.
- Gort, A. M., March, J., Gomez, X., de Miguel, M., Mazarico, S., & Balleste, J. (2005). Short Zarit scale in palliative care. Medicina Clínica, 124, 651–653. Retrieved from http://www.elsevier.es/es/revistas/medicina-clinica-2
- Harwood, R. H., Sayer, A. A., & Hirschfeld, M. (2004). Current and future worldwide prevalence of dependency, its relationship to total population, and dependency ratios. *Buletin of the World Health Organization*, 82, 251–258.
- Joling, K. J., van Hout, H. P., Schellevis, F. G., van der Horst, H. E., Scheltens, P., Knol, D. L., & van Marwijk, H. W. (2010). Incidence of depression and anxiety in the spouses of patients with dementia: A naturalistic cohort study of recorded morbidity with a 6-year follow-up. American Journal of Geriatric Psychiatry, 18, 146–153. doi:10.1097/ JGP.0b013e3181bf9f0f
- Joling, K. J., van Hout, H. P., Scheltens, P., Vernooij-Dassen, M., van den Berg, B., Bosmans, J., van Marwijk, H. W. (2008). (Cost)-effectiveness of family meetings on indicated prevention of anxiety and depressive symptoms and disorders of primary family caregivers of patients with dementia: Design of a randomized controlled trial. BMC Geriatrics, 8, 2. doi:10.1186/1471-2318-8-2
- Lautenschlager, N. T., Cox, K. L., Flicker, L., Foster, J. K., van Bockxmeer, F. M., Xiao, J., Almeida, O. P. (2008). Effect of physical activity on cognitive function in older adults at risk for Alzheimer disease: A randomized trial. *JAMA*, 300, 1027–1037. doi:10.1001/jama.300.9.1027
- Lincoln, N. B., Yuill, F., Holmes, J., Drummond, A. E., Constantinescu, C. S., Armstrong, S., & Phillips, C. (2011). Evaluation of an adjustment group for people with multiple sclerosis and low mood: A randomized controlled trial. *Multiple Sclerosis*, 17, 1250–1257. doi:10.1177/1352458511408753
- Lingler, J. H., Martire, L. M., & Schulz, R. (2005). Caregiver-specific outcomes in antidementia clinical drug trials: A systematic review and meta-analysis. *Journal of the American Geriatrics Society*, 53, 983–990. doi:10.1111/j.1532-5415.2005.53313.x
- Lopez, J., & Crespo, M. (2007). Interventions for caregivers of older and dependent adults: A review. *Psicothema*, 19, 72–80. Retrieved from http://www.psicothema.com/pdf/3330.pdf
- Losada, A., Montorio, I., Izal, M., & Márquez-Gonzalez, M. (2006). Estudio e intervención sobre el malestar psicológico de los cuidadores de personas con demencia. El papel de los pensamientos disfuncionales [Study and intervention on dementia caregiving distress. The role of dysfunctional thoughts]. Madrid, Spain: IMSERSO. Retrieved from http://docentes.cs.urjc.es/~alosada/estudiomalestarpscuidadores.pdf
- Losada, A., Márquez-Gonzalez, M., & Romero-Moreno, R. (2011). Mechanisms of action of a psychological intervention for dementia caregivers: Effects of behavioral activation and modification of dysfunctional thoughts. *International Journal of Geriatric Psychiatry*, 26, 1119–1127. doi:10.1002/gps.2648
- Losada, A., Perez-Penaranda, A., Rodriguez-Sanchez, E., Gomez-Marcos, M. A., Ballesteros-Rios, C., Ramos-Carrera, I. R., Garcia-Ortiz, L. (2010). Leisure and distress in caregivers for elderly patients. *Archives of Gerontology and Geriatrics*, 50, 347–350. doi:10.1016/j.archger.2009.06.001
- Márquez-Gonzalez, M., Losada, A., Izal, M., Perez-Rojo, G., & Montorio, I. (2007). Modification of dysfunctional thoughts about caregiving in dementia family caregivers: Description and outcomes of an intervention programme. *Aging & Mental Health*, 11, 616–625. doi:10.1080/13607860701368455

- Mateos, R., Franco, M., & Sanchez, M. (2010). Care for dementia in Spain: The need for a nationwide strategy. *International Journal of Geriatric Psychiatry*, 25, 881–884. doi:10.1002/gps.2591
- Mittelman, M. S. (2008). Psychosocial intervention research: Challenges, strategies and measurement issues. *Aging & Mental Health*, 12, 1–4. doi:10.1080/13607860801896470
- Muñoz, P., Vazquez, J. L., Rodriguez, F., Pastrana, E., & Varo, J. (1979).
 Adaptación española del General Health Questionnarie (G.H.Q.) de
 D.P. Goldberg [Spanish adaptation of the General Health Questionnaire
 (G.H.Q.) of D. P. Goldberg (a method for identifying psychiatric cases in the community)]. Archivos de Neurobiología, 42, 139–158.
- Newcomer, R., Yordi, C., DuNah, R., Fox, P., & Wilkinson, A. (1999).
 Effects of the Medicare Alzheimer's Disease Demonstration on caregiver burden and depression. *Health Services Research*, 34, 669–689.
- Nutting, P. A., Gallagher, K., Riley, K., White, S., Dickinson, W. P., Korsen, N., & Dietrich, A. (2008). Care management for depression in primary care practice: Findings from the RESPECT-Depression trial. *Annals of Family Medicine*, 6, 30–37. doi:10.1370/afm.742
- Perez-Penaranda, A., Garcia Ortiz, L., Rodriguez Sanchez, E., Losada Baltar, A., Porras Santos, N., & Gomez Marcos, M. A. (2009). La función familiar y la salud mental del cuidador de familiares con dependencia [Family function and the mental health of the caregiver of dependent relatives]. Atención Primaria, 41, 621–628. doi:10.1016/j.aprim.2009.03.005
- Pevalin, D. J. (2000). Multiple applications of the GHQ-12 in a general population sample: An investigation of long-term retest effects. Social Psychiatry and Psychiatric Epidemiology, 35, 508–512. Retrieved from http://www.springerlink.com/content/ktx2e4b7xkeh3850/fulltext.pdf
- Pillemer, K., Suitor, J. J., Henderson, C. R., Jr., Meador, R., Schultz, L., Robison, J., & Hegeman, C. (2003). A cooperative communication intervention for nursing home staff and family members of residents. *The Gerontologist*, 43, 96–106. doi:10.1093/geront/43.suppl_2.96
- Pinquart, M., & Sorensen, S. (2006). Helping caregivers of persons with dementia: Which interventions work and how large are their effects?. *International Psychogeriatrics*, 18, 577–595. doi:10.1017/s1041610206003462
- Pinquart, M., & Sorensen, S. (2007). Correlates of physical health of informal caregivers: A meta-analysis. *Journals of Gerontology:* Psychological Sciences, 62, 126–137.
- Rodriguez-Sanchez, E., Perez-Penaranda, A., Losada-Baltar, A., Perez-Arechaederra, D., Gomez-Marcos, M. A., Patino-Alonso, M. C., & Garcia-Ortiz, L. (2011). Relationships between quality of life and family function in caregiver. BMC Family Practice, 12, 19. doi:10.1186/1471-2296-12-19

- Ruiz, M. A., & Baca, E. (1993). Design and validation of the Quality of Life Questionnaire: A generic health-related perceived quality of life instrument. European Journal of Psychological Assessment, 9, 19–32.
- Sanchez-Lopez, M. P., & Dresch, V. (2008). The 12-Item General Health Questionnaire (GHQ-12): Reliability, external validity and factor structure in the Spanish population. *Psicothema*, 20, 839–843. Retrieved from http://www.psicothema.com/pdf/3564.pdf
- Schoenmakers, B., Buntinx, F., & Delepeleire, J. (2009). What is the role of the general practitioner towards the family caregiver of a community-dwelling demented relative? A systematic literature review. Scandinavian Journal of Primary Health Care, 27, 31–40. doi:10.1080/02813430802588907
- Schoenmakers, B., Buntinx, F., & DeLepeleire, J. (2010). Supporting the dementia family caregiver: The effect of home care intervention on general well-being. *Aging & Mental Health*, 14, 44–56. doi:10.1080/13607860902845533
- Sorensen, S., Pinquart, M., & Duberstein, P. (2002). How effective are interventions with caregivers? An updated meta-analysis. *The Gerontologist*, 42, 356–372. doi:10.1093/geront/42.3.356
- Teri, L., McCurry, S. M., Logsdon, R., & Gibbons, L. E. (2005). Training community consultants to help family members improve dementia care: A randomized controlled trial. *The Gerontologist*, 45, 802–811. doi:10.1093/geront/45.6.802
- Teri, L., McKenzie, G., Logsdon, R. G., McCurry, S. M., Bollin, S., Mead, J., & Menne, H. (2012). Translation of two evidence-based programs for training families to improve care of persons with dementia. *The Gerontologist*, 52, 452–459. doi:10.1093/geront/gnr132
- Unutzer, J., Katon, W., Callahan, C. M., Williams, J. W., Jr., Hunkeler, E., Harpole, L., Langston, C. (2002). Collaborative care management of late-life depression in the primary care setting: A randomized controlled trial. *JAMA*, 288, 2836–2845.
- Vasse, E., Vernooij-Dassen, M., Cantegreil, I., Franco, M., Dorenlot, P., Woods, B., & Moniz-Cook, E. (2011). Guidelines for psychosocial interventions in dementia care: A European survey and comparison. *International Journal of Geriatric Psychiatry*. doi:10.1002/ gps 2687
- Wethington, E., Breckman, R., Meador, R., Reid, M. C., Sabir, M., Lachs, M., & Pillemer, K. A. (2007). The CITRA pilot studies program: Mentoring translational research. *The Gerontologist*, 47, 845–850. doi:10.1093/geront/47.6.845