


Randomized controlled trial of a multicomponent program for informal caregivers of Alzheimer's patients

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Ensayo controlado aleatorizado de un programa multicomponente para cuidadores informales de pacientes con Alzheimer

Ensaio controlado randomizado de um programa multicomponente para cuidadores informais de pacientes com Alzheimer

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Abstract

Objective: To evaluate the effect of a multicomponent plus respite care program on care burden and social support of informal caregivers of patients with major neurocognitive disorders associated with Alzheimer's disease. **Materials and Methods:** A parallel randomized controlled trial was conducted with 58 caregivers who were randomly allocated to one of the following three comparison groups: a multicomponent plus respite care group (n=19), a respite care group (n=19), and a control group (n=20). Burden and social support were assessed using the Zarit Scale and Medical Outcomes Study at baseline with a post-intervention at 5 months and follow-up at 10 months. The assessment of effects was measured by using a mixed-effects model with unstructured covariance matrix. **Results:** Caregivers were mostly patients' children (72%), female (76%) having a mean age of 55.1 years (12) and less than secondary education (58%). A significant reduction of 13.1% (95%CI -19.3:6.9) in caregiver burden was found in the multicomponent plus respite care group, showing a sustained effect at 10 months (p<0.001). A non-significant increase of 10.8% (-1.7;23.4) in post-intervention social support was found in the multicomponent plus respite care group. However, the effects increased over time achieving an increase at 13.2% (p=0.039) at the 10-month follow-up. No significant effects on caregiver burden or social support were reported for the respite care group. **Conclusions:** The multicomponent plus respite care group demonstrated beneficial effects on care burden and social support for Alzheimer's caregivers.

Keywords: Family Caregiver, Dementia, Social Support, Overload, Multi-Component Program.

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Ensayo controlado aleatorizado de un programa multicomponente para cuidadores informales de pacientes con Alzheimer

Resumen

Objetivo: Evaluar la eficacia del programa multicomponente más respiro en la sobrecarga y el apoyo social de cuidadores informales de pacientes con Trastorno Neurocognitivo Mayor tipo Alzheimer. **Materiales y Método:** Ensayo controlado aleatorizado en paralelo en 58 cuidadores aleatorizados a uno de los tres grupos de comparación: Grupo de intervención multicomponente más respiro (n=19), grupo de sólo respiro (n=19) y grupo control (n=20), se evaluaron la sobrecarga y el apoyo social mediante las escalas de Zarit y Medical Outcomes Study, en línea de base, post intervención a 5 meses y un seguimiento a 10 meses. La evaluación del efecto se realizó mediante un modelo de efectos mixtos de covarianza no estructurada. **Resultados:** Los cuidadores fueron en su mayoría los hijos de los pacientes (72%), mujeres (76%) con una edad media de 55,1(12) años y con educación inferior a secundaria (58%). Se encontró una reducción significativa de la sobrecarga de 13,1 (IC95% -19,3;6,9) puntos en el grupo multicomponente más respiro, con un sostenimiento del efecto a 10 meses ($p<0.001$). Se encontró un incremento, aunque no significativa del apoyo social post intervención de 10,8 (-1,7; 23,4) para el grupo multicomponente y respiro, sin embargo, el efecto se incrementó en el tiempo logrando un aumento a 13,2 puntos ($p=0,039$) a los 10 meses de seguimiento. No se observó un efecto significativo en la sobrecarga ni apoyo social para el grupo que solo recibió respiro. **Conclusiones:** El programa multicomponente más respiro mostró tener un efecto benéfico en la sobrecarga y apoyo social de cuidadores de Alzheimer.

Palabras clave: Cuidador Familiar; Demencia; Apoyo Social; Sobrecarga; Programa Multicomponente.

Ensaio controlado randomizado de um programa multicomponente para cuidadores informais de pacientes com Alzheimer

Resumo

Objetivo: Avaliar a eficácia do programa multicomponente mais alívio na sobrecarga e suporte social de cuidadores informais de pacientes com Transtorno Neurocognitivo Maior do tipo Alzheimer. **Método:** Ensaio controlado randomizado em paralelo em 58 cuidadores randomizados para um dos três grupos de comparação: Grupo de intervenção multicomponente mais alívio (n=19), grupo apenas alívio (n=19) e grupo de controle (n=20), foram avaliados a sobrecarga e suporte social usando as escalas de Zarit e Medical Outcomes Study, linha de base, pós-intervenção em 5 meses e um acompanhamento de 10 meses. A avaliação do efeito foi realizada usando um modelo de efeitos mistos de covariância não estruturada. **Resultados:** Os cuidadores eram, em sua maioria, filhos dos pacientes (72%), mulheres (76%) com uma de idade de média de 55,1 (12) anos e com escolaridade inferior ao ensino médio (58%). Foi encontrada uma redução significativa na sobrecarga de 13,1 (IC95% -19,3;6,9) pontos no grupo multicomponente mais alívio, com uma sustentação de efeito em 10 meses ($p<0,001$). Foi encontrado um aumento, embora não significativo, no suporte social pós-intervenção de 10,8 (-1,7; 23,4) para o grupo multicomponente e alívio, no entanto, o efeito aumentou ao longo do tempo, alcançando um aumento para 13,2 pontos ($p=0,039$) aos 10 meses de acompanhamento. Nenhum efeito significativo na sobrecarga ou suporte social foi observado para o grupo que apenas recebeu alívio. **Conclusões:** O programa de multicomponente mais alívio mostrou ter um efeito benéfico na sobrecarga e no suporte social dos cuidadores de Alzheimer.

Palavras chave: Cuidador Familiar; Demência; Suporte Social; Sobrecarga; Programa Multicomponente.

Introduction

Alzheimer's disease is one of the most frequent illnesses among the elderly; it is a determinant of mental decline and causes behavioral and cognitive disruptions that lead to the loss of functional capacity¹, dependence, and demand for continuous care². According to the World Health Organization (WHO), as of 2020, Alzheimer's disease is the most common form of dementia and may contribute to 60-70% of cases³. In the case of Colombia, according to the data provided by the Comprehensive Information System of Social Protection (SISPRO, for its acronym in Spanish) and the National Survey of Health, Welfare, and Aging (SABE, for its acronym in Spanish) between 2009 and 2015, 36,082 people were treated with diagnoses related to dementia included in the International Classification of Diseases, Tenth Revision (ICD-10)⁴. Most of the people who cover the basic and instrumental needs of adults with Alzheimer's disease are informal caregivers, which means they have no formal training, do not receive any payment despite investing much of their time in caregiving, and are subjected to chronic stress with significant repercussions on their physical and emotional health⁵.

Assuming a caregiving role can bring multiple and negative health consequences that depend, to some extent, on the caregivers' personal attributes⁶ and the presence of caregiving burden, which is more frequent among informal caregivers⁷ than among formal caregivers.

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Likewise, the demands of the caregiving role may produce a higher level of loneliness. About half of the caregivers (43.3%) report at least a moderate level of loneliness, which could lead to low social support and thereby a two-way interpretation: low social support leading to feelings of loneliness or loneliness leading to low social support⁸⁻⁹. Loneliness has been associated with negative outcomes like increased depression and anxiety¹⁰, and it may even increase the probability of death by 30%¹¹. In this regard, the prevalence of the variables of burden and social support as factors that considerably influence caregivers and their quality of life makes sense¹²⁻¹³.

In relation to interventions, caregivers' programs have been created mainly to reduce the discomfort of caregiving¹⁴. Among these interventions, psychoeducation, psychotherapy, respite and self-care programs are effective in modifying behaviors and emotions associated with psychological distress¹⁵.

The multicomponent intervention programs for informal caregivers of people with dementia report favorable short-term effects on personal development areas, with demonstrated efficacy in reducing depressive symptoms¹⁶⁻¹⁷. These programs, in turn, allow caregivers empowerment through knowledge about their relative care¹⁸⁻¹⁹.

Multiple intervention programs like the Resources for Enhancing Alzheimer's Caregiver Health (REACH II)²⁰ are considered model programs as they seek a simultaneously positive effect on primary outcomes (e.g., caregiving demands) and secondary outcomes (e.g., financial strain) finding a favorable response in the reduction of anxiety associated with the patient's reality²¹.

Regarding the type of interventions for caregivers that include occupational therapy and communication training²²⁻²³, an improvement in communication skills of caregiver-patient dyads¹⁶ is observed, and the importance of including people with neurocognitive disorders in such programs is highlighted²⁴.

In light of the evidence, intervention programs can reduce negative effects of the caregiving role²¹⁻²⁵; however, some criticisms have been made regarding the impact and methodological quality of the interventions²⁶⁻²⁷⁻²⁸. In relation to multicomponent programs, they have an impact on different caregivers' health outcomes; however, their effectiveness depends on the components they include²¹⁻²⁹. This fact leads to reflect on the unification of criteria and components of interventions and their effect on Latin American populations.

Taking into account that researchers seek from this multicomponent perspective to link the elements within a total system where no boundaries are established between the involved disciplines, so not only is it about how the theoretical and methodological component converges but also about its uses in problem-solving. Some evidence in this regard is based on the fact that the caregiving framework and its derived variables require an approach that includes different disciplines to contribute to formulate public policies that favor caregivers. For example, Ducharme et al. found that caregivers in the experimental group were more confident in dealing with caregiving situations than those in the control group, specifically highlighting a proactive intervention approach from the onset of the care³⁰.

Therefore, the present research evaluates the effect of a multicomponent program involving a transdisciplinary intervention to reduce burden and improve social support of caregivers of Alzheimer's patients.

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Materials and Methods

Design. A three-armed randomized controlled trial with an allocation ratio of 1:1:1.

Participants. Caregivers of Alzheimer's patients meeting the following inclusion criteria (1) being a family member of the patient, (2) living together with the patient in the same residence, (3) being a caregiver for at least eight hours a day, and have been a caregiver for more than three months, and (4) not being paid. Exclusion criteria included ceasing to be an unpaid primary caregiver due to prolonged hospitalization (more than 20 days), institutionalization, or patient's death.

Study setting. The study was conducted in Bucaramanga (Colombia) and its metropolitan area, between February 2019 and February 2020. An enrollment process was carried out in day centers for non-institutionalized older adults in primary care, health centers, and an open call on social media.

Interventions

1. Multicomponent intervention. Integrated by psychoeducation, systemic communication, and physiotherapy, it had the objectives of improving body posture, movements, and

physical activity and promoting assertive communication in which communication quality and affectivity were recognized through the transdisciplinary work of 6 psychologists, 4 physiotherapists, and 4 speech therapists, who had academic competence in the subject. The intervention was validated by experts and interdisciplinary workgroups in which the content of the program was proposed: (1) presentation and introduction, (2) mental health and subjective well-being, (3) personal resources, (4) caregiving skills, (5) perception of functional social support, (6) communication relationships, (7) physical health, and (8) professional support network. The multicomponent intervention proved to be applicable and was carried out for 8 weeks, once a week with a duration of 4 hours a day, a period when the caregivers had a “respite” at the time of attending the program.

2. “Respite” relays. Respite care relays were carried out for 8 weeks, once a week, with a duration of 4 hours per day by nursing assistants from a home care provider company. The nursing assistants were previously trained in the proper management of patients and support activities of daily living. The training had an intensity of 8 hours and was given by the transdisciplinary team.
3. The groups were allocated as follows: Group A received the intervention and “respite”, group B received only respite relays, and group C (control group) received “respite” relays only at the end of the intervention as a participation retribution.

Outcomes

Primary outcome

Burden of caregiver. It was assessed using the Zarit Caregiver Burden Scale, the Martín-Carrasco et al.'s version³¹. It was designed to assess the subjective experience of overburden. It consists of 22 items answered on a 5-point Likert scale ranging from never (1 point) to almost always (5 points). The total score ranges from 22 to 110, divided into three levels: no burden (≤ 46 points), mild burden (47–56), and severe burden (≥ 57). This tool presents high reliability and face, content, and construct validity for the Colombian population³².

Secondary outcome

Social support. It was assessed using the Medical Outcomes Study (MOS) Social Support Survey³³, and it has estimated reliability for the Colombian population (Cronbach's alpha between 0.921 and 0.736)³⁴. The MOS Social Support Survey has 20 items. The first item responds to the size of the social network, and the remaining 19 refer to four dimensions of functional social support: emotional and informational support (items 3, 4, 8, 9, 13, 16, 17, 19; cut-off points: 24 points); instrumental support (items 2, 5, 12, 15; cut-off point: 12 points), positive social interaction (items 7, 11, 14, 18; cut-off point: 12 points), and affectionate support (items 6, 10, 20; cut-off point: 9 points). It has 5 Likert-type responses: Never (1), seldom (2), sometimes (3), most of the time (4), always (5); so, the higher the score, the greater perceived social support.

The results were measured in three moments during home visits: baseline, postintervention follow-up (five months after baseline measurement), and an additional follow-up (ten months after postintervention follow-up).

The results were measured in three moments during home visits: baseline, postintervention follow-up (five months after baseline measurement), and an additional follow-up (ten months after postintervention follow-up).

Sampling size. Based on a previous study in Canada that reported a mean score of the Zarit Caregiver Burden Scale of 22.4 out of 88 (SD: 16.2)³⁵ and the study by Carrasco et al. who observed a burden reduction of 8.09 in the intervention group and 2.08 in the control group³⁶, the sample size was calculated with an alpha of 0.05, a statistical power of 80%, and an effect size of 10 points with a standard deviation of 10.5 points. The sample size was 60 participants, 20 for each intervention group, taking into account a possible 5% of losses to follow-up. The sample was recruited through convenience sampling based on a census of people with the intention to participate obtained from the different enrollment centers and an open call on social media.

Random allocation

Once the 58 caregivers agreed to participate in the study, each was assigned a consecutive code. Subsequently, a person external to the intervention and follow-up measurements and without prior contact with the participants generated a table with random numbers between 1 and 3 using the RANDBETWEEN function of Microsoft Excel and allocated these random values to the list of participants' codes, ensuring that all participants had the same probability of being in any of the study groups. The groups to which the participants were allocated were (1) multicomponent intervention group plus respite care intervention for 8 weeks, (2) only respite intervention group for 8 weeks, and (3) control group without any intervention.

Blinding. Neither the participants nor the professionals who delivered the intervention were blinded; the data analyst was blinded by accessing a database in which the intervention and control groups were not identified.

Analysis of results. A database was created using the online survey tool Lime-Survey. Data were entered twice by independent typists, and subsequent verification of data mismatches in Microsoft Excel was carried out to reduce typos.

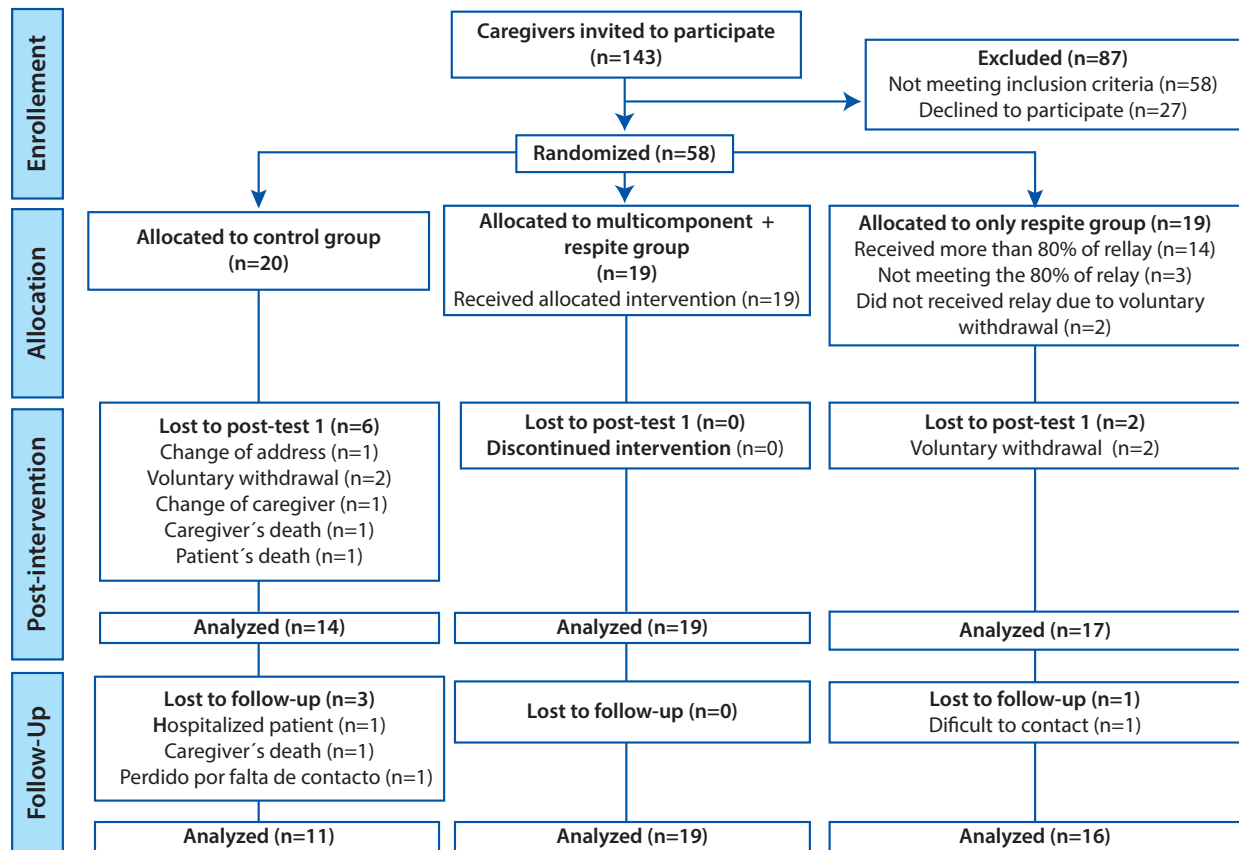
The description of the caregivers' characteristics was carried out using absolute frequencies, percentages, and measures of central tendency, such as mean and median, and variability, such as standard deviation or minimum and maximum values, after performing the Shapiro Wilk test of normality. One-way analysis of variance (ANOVA), Fisher's exact test and Kruskal Wallis test were used to verify random allocation of the three comparison groups. To measure the absolute effect size of the interventions as a mean difference, a repeated measures analysis was conducted using a mixed effects model with unstructured covariance to compare baseline, post-intervention (5 months later), and follow-up (10 months later) results, especially when measures are correlated over time. The analysis was performed using STATA-16 SE³⁷.

Ethical considerations. The Research Ethics Committee of the Universidad Pontificia Bolivariana approved this study by granting the approval CE_A_40 of April 26, 2019. All caregivers signed the informed consent. Participants allocated to the control group were compensated with the "respite" component of the intervention for 8 weeks after the study's observation period ended.

Results

A hundred forty-three caregivers were contacted, of whom 58 met the inclusion criteria, agreed to participate in the study and were randomly allocated to the three groups as follows: control group (n=19 caregivers), multicomponent intervention plus respite group (n=19 caregivers), and only respite group (n=20 caregivers) (See Figure 1, Flow diagram). Of these caregivers, 50 participated in the postintervention follow-up, and there was a loss of 13.8% from the initial sample. Four more losses were reported at the next follow-up, equivalent to an additional 8% loss. It is noteworthy that the multicomponent plus respite group did not have any loss of participants throughout the study.

Figure 1. Flow diagram of study enrollment. Bucaramanga and Metropolitan Area, Colombia, 2019-2020.



Baseline characteristics

Regarding the patients with Alzheimer's disease, the mean age was 80.5 years, mostly women (65.5%) and a median of 3.3 years since diagnosis. Based on the caregivers' perception, degrees of impairment of the patients were assessed, and it was found that 48% had highly impaired memory, and 52% had moderately impaired behavior and mood. On the other hand, the caregivers' profile reveals a majority of women (76%), daughters (72%), with an average age of 55.1 years, with an educational level of high school or less (58%), no income (36%), unemployed (56%), and not using support networks (92%). At baseline, no statistically significant differences in characteristics of patients and caregivers were found between comparison groups, indicating comparability between groups (Table 1).

Table 1. Characteristics of patients with neurocognitive disorder of the Alzheimer-type and their caregivers. Bucaramanga and its Metropolitan area, Colombia 2019-2020

Variable	Total	Control group	Multicomponent plus respite	Only respite	p Value
	n=50	n=14	n=19	n=17	
Patients' characteristics					
Age, Mean (SD)	80,5 (7,8)	82,3(9)	78 (8,6)	81,1 (6,5)	0,278†
Sex, n (%)					
Male	20 (34,5)	4 (28,6)	5 (26,3)	8 (47,1)	0,419‡
Female	38 (65,5)	10 (71,4)	14 (73,7)	9 (52,9)	
Years since diagnosis, median (min-max)	3,3 (1-10)	4(1,41-15)	3,3 (1,5-10)	3 (1 - 10)	0,555§
Caregiver's perception of memory impairment, n (%)					
Little impaired	3 (6)	1 (7,1)	2 (10,5)	0	0,619‡
Moderately impaired	23 (46)	6 (42,9)	10 (52,6)	7 (41,2)	
Greatly impaired	24 (48)	7 (50)	7 (36,9)	10 (58,8)	
Caregiver's perception of behavioral impairment, n (%)					
Little impaired	9 (18)	5 (35,7)	3 (15,8)	1 (5,9)	0,312‡
Moderately impaired	26 (52)	5 (35,7)	11 (57,9)	10 (58,8)	
Greatly impaired	15 (30)	4 (28,6)	5 (26,3)	6 (35,3)	
Caregiver's perception of mood impairment, n (%)					
Little impaired	9 (18)	3 (21,4)	4 (21,1)	2 (11,8)	0,216‡
Moderately impaired	26 (52)	10 (71,4)	8 (42,1)	8 (47,1)	
Greatly impaired	15 (30)	1 (7,14)	7 (36,9)	7 (41,8)	
Caregivers' characteristics					
Age, mean (SD)	55,1 (12)	55,9(14,2)	55,8 (10,7)	53,5 (12,2)	0,826†
Sex, n(%)					
Male	12 (24)	6 (42,9)	3 (15,8)	3 (17,7)	
Female	38 (76)	8 (57,1)	16 (84,2)	16 (83,3)	0,170‡
Socioeconomic level, n (%)					
Low (1-2)	14 (28)	4 (28,6)	5 (26,3)	5 (29,4)	
Middle (3-4)	32 (64)	8 (57,1)	14 (73,7)	10 (58,8)	
High (5-6)	4 (8)	2 (14,3)	0	2 (11,8)	0,537‡
Marital status, n (%)					
Single without children	9 (18)	3 (21,4)	1(5,3)	5 (29,4)	
Single with children	4 (8)	1 (7,1)	2 (10,5)	1 (5,9)	
Married	14 (28)	4 (28,6)	7 (36,9)	3 (17,7)	
Cohabiting	8 (16)	3 (21,4)	2 (10,5)	3 (17,7)	
Divorced	12 (24)	3 (21,4)	6 (31,6)	3 (17,7)	
Widower/widow	3 (6)	0	1 (5,3)	2 (11,8)	0,671‡
Educational attainment, n (%)					
No education	1 (2)	1 (5)	0	0	
Elementary	8 (16)	4 (28,6)	2 (10,5)	2 (11,8)	
High School	20 (40)	3 (21,4)	10 (52,6)	7 (41,2)	
Technician	7 (14)	2 (14,3)	1 (5,3)	4 (23,5)	
University	10 (20)	4 (28,6)	4 (21,1)	2 (11,8)	
Postgraduate	4 (8)	0	2 (10,5)	2 (11,8)	0,352‡
Employment situation, n (%)					
Active	13 (26)	4 (28,6)	4 (21,1)	5 (29,4)	
Retired	9 (18)	2 (14,29)	4 (21,1)	3 (17,7)	
Unemployment	28 (56)	8 (57,1)	11 (57,9)	10 (52,9)	0,976‡
Monthly income, n (%)					
No income	18 (36)	6 (42,9)	4 (21,1)	8 (47,1)	
Less than 1 minimum wage	10 (20)	4 (28,6)	5 (26,3)	1 (5,9)	
1 minimum wage or more	22 (44)	4 (28,6)	10 (52,6)	8 (47,1)	0,198‡
Kin relationship, n (%)					
Spouse	11 (22)	4 (28,6)	4 (21,1)	3 (17,7)	
Child	36 (72)	9 (64,3)	15 (78,9)	12 (70,6)	
Grandchild	2 (4)	1 (7,1)	0	1 (5,9)	
Other	1 (2)	0	0	1 (5,9)	0,790‡
Support people with problems, n (%)					
None	2 (4)	1 (7,14)	1 (5,3)	0	
Partner	5 (10)	1 (7,14)	2 (10,5)	2 (11,8)	
Children	16 (32)	6 (42,9)	4 (21,1)	6 (35,3)	
Other relatives	21 (42)	6 (42,9)	10 (52,6)	5 (29,4)	
Other	6 (12)	0	2 (10,5)	4 (23,5)	0,484§
Use of support networks, n (%)					
Yes	4 (8)	2 (14,3)	2 (10,5)	0	
No	46 (92)	12 (85,7)	17 (89,5)	17 (100)	0,366‡
Care hours, median (min - max)	24 (6-24)	24 (6-24)	24 (12-24)	24 (10-24)	0,0919§
Years as caregiver, median (min - max)	3 (0,5-10,5)	2,08 (0,5-8)	4 (0,7-10,5)	3 (0,5-10)	0,2182§
Social network size - MOS, mean (SD)	3,6 (2,1)	3,9 (1,6)	3,5 (1,9)	3,4 (2,6)	0,759†
Social support -MOS, mean (SD)	64,7 (16,6)	70,4 (19)	59 (14,6)	64,7 (14,5)	0,1015†
Burden -Zarit's scale, mean (SD)	45 (16,8)	38,6 (18,6)	52,4 (15,2)	44,4 (14,1)	0,0349†

Note: SD = Standard deviation, †One-way ANOVA, ‡ Fisher's Exact Test, § Kruskal-Wallis test. Authors' elaboration.

Regarding caregiving burden, 7(14%) caregivers reported mild burden and 15 (30%) severe burden at baseline, and 7(15.2%) caregivers reported mild burden and 7 (15.2%) severe burden at the end of the study. It is worth noting that the multicomponent intervention group reported a higher burden at baseline when compared to the other comparison groups (p=0.0349). Therefore, the effect size (d) was estimated, taking the first measurement as the point of comparison and not the comparison of measurements between groups. Although the multicomponent plus respite group had a higher initial burden, we observed a significant burden reduction of 13.1 in the post-intervention measurement (95% CI -19.3;-6.9) and maintenance of the effect after 10 months by finding a difference between the baseline and follow-up measurement of 15.4 points (95%CI-21.5;-9.2) (Table 2).

Table 2. Caregivers’ adjusted burden levels in the intervention and control groups throughout follow-ups. Bucaramanga and its Metropolitan area, Colombia 2019-2020

Zarit Burden Scale	Reference Group			Multicomponent plus respite			Respite		
	Mean (95% CI)	Difference (95% CI)	Value p	Mean (95% CI)	Difference (95% CI)	Value p	Mean (95% CI)	Difference (95% CI)	Value p
Baseline	41,5 (35,1;47,9)	---	NA	53,4(47,0;59,7)	---	NA	41,5 (34,9;48,1)	---	NA
Post-intervention	37,8 (30,5;45,0)	-3,8 (-10,7;3,2)	0,290	40,3 (33,9;46,6)	-13,1 (-19,3;-6,9)	<0,001	42,2 (35,4;49,0)	0,7 (-5,7;7,2)	0,824
Follow-up	33,8 (25,8;41,7))	-7,8 (-15,4;-0,1)	0,046	38,0 (31,7;44,4)	-15,4 (-21,5;-9,2)	<0,001	42,6 (35,6;49,6)	1,1 (-5,5;7,7)	0,740

Note: Values adjusted using a mixed-effects model with unstructured within-subject covariance. Authors’ elaboration.

Social support

The caregivers’ support network consisted of a mean of 3.9 (2.2) persons at baseline, and no differences were found between comparison groups (Table 1). The control group had a significant worsening of social support over time, decreasing 22.2 points (95%CI -34.4; -10.0) between baseline and post-intervention measurements; this deterioration was maintained in all dimensions of social support. On the other hand, the multicomponent plus respite group achieved an increase of 10.8 points in social support after the intervention and 13.2 points (p=0.039) at 10-month follow-up. This result indicates an increase in the effect over time, maintaining this trend in the dimensions of social support and tangible and instrumental support. Finally, there was a trend towards a decrease in social support in the only-respite group, although not significant (Table 3).

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Table 3. Adjusted mean score of the MOS Social Support Survey and differences between intervention and control groups throughout follow-ups.

	Reference group			Multicomponent plus respite			Respite		
	Mean (95%CI)	Difference (IC95%)	p Value	Mean (95%CI)	Difference (95%CI)	p Value	Mean (95%CI)	Difference (95%CI)	p Value
Overall score									
Baseline	71,5 (60,9;82,2)	---	NA	56,3 (45,3;67,2)	---	NA	66,2 (55,3;77,1)	---	NA
Post-intervention	49,3 (38,7;60,0)	-22,2 (-34,4 ; -10,0)	<0,001	67,1(56,1;78,1)	10,8 (-1,7 ;23,4)	0,09	63,3 (52,4;74,2)	-2,9 (-15,5 ;9,6)	0,645
Follow-up	39,9 (29,3;50,6)	-31,6 (-43,8 ; -19,4)	<0,001	69,5 (58,5;80,5)	13,2 (0,7 ;25,8)	0,039	55,6 (44,7;66,5)	-7,6 (-20,2;4,9)	0,098
Emotional support									
Baseline	30,7 (26,1;35,3)	---	NA	23,6 (18,8;28,3)	---	NA	28,5 (23,8;33,2)	---	NA
Post-intervention	21,2 (11,6;25,8)	-9,6 (-14,9;-4,2)	<0,001	28,6 (23,9;33,4)	5,1 (-0,4;10,5)	0,071	27,2 (22,5;31,9)	-1,3 (-6,8;4,2)	0,638
Follow-up	17,2 (12,6;21,8)	-13,6 (-18,9;-8,2)	<0,001	29,8 (25; 34,5)	6,2 (0,7;11,7)	0,027	23,6 (18,9;28,3)	-4,9 (-10,4;0,5)	0,077
Tangible and instrumental support									
Baseline	14,2 (11,7;16,7)	---	NA	11,3 (8,8;13,9)	---	NA	12,9 (10,4;15,4)	---	NA
Post-intervention	9,9 (7,4;12,3)	-4,4 (-7,1;-1,6)	0,002	14,1 (11,5;16,6)	2,7 (-0,1;5,6)	0,058	12,6 (10,1;15,1)	-0,3 (-3,1;2,6)	0,856
Follow-up	8,8 (6,3;11,2)	-5,5 (-8,2;-2,7)	<0,001	14,2 (11,6;16,7)	2,8 (0,0;5,7)	0,049	10,8 (8,3;13,3)	-2,1 (-4,9;0,8)	0,156
Social companionship (leisure and recreational activities)									
Baseline	14,0 (11,7;16,4)	---	NA	11,5 (9,1;13,9)	---	NA	13,1 (10,7;15,4)	---	NA
Post-intervention	9,5 (7,2;11,9)	-4,5 (-7,1;-1,9)	0,001	13,5 (11,1;15,9)	2,1 (-0,6;4,8)	0,137	12,5 (10,2;14,9)	-0,5 (-3,2;2,2)	0,703
Follow-up	7,5 (5,2;9,8)	-6,6 (-9,2;-3,9)	<0,001	13,9 (11,5;16,3)	2,4 (-0,3;5,1)	0,079	11,2 (8,8;13,6)	-1,8 (-4,5;0,9)	0,182
Affectionate support, which involves expressions of love and affection									
Baseline	12,6 (10,6;14,5)	---	NA	9,9 (7,9;11,9)	---	NA	11,7 (9,8;13,7)	---	NA
Post-intervention	8,8 (6,8;10,7)	-3,8 (-5,9;-1,7)	<0,001	10,9 (8,9;12,9)	1,0 (-1,2;3,2)	0,367	10,9 (8,9;12,9)	-0,8 (-3,0;1,3)	0,448
Follow-up	6,5 (4,6;8,4)	-6,1 (-8,2;-3,9)	<0,001	11,6 (9,7;13,6)	1,7 (-0,4;3,9)	0,117	10,0 (8,1;12,0)	-1,7 (-3,9;0,4)	0,117

Note: Values adjusted using a mixed-effects model with unstructured within-subject covariance. Authors' elaboration.

Discussion

It is pertinent to highlight the study's main findings regarding burden reduction compared to interventions that address variables from different transdisciplinary components³⁸. Negovanska et al.³⁹ analyzed the benefits caregivers perceived when participating in a program and found that group support and social support were key articulators of well-being perception. Likewise, in our study, the perception of social support increased significantly at the end of the intervention program.

However, it is worth mentioning the findings of Adler et al., who state that, although the institutional respite program reduced burden and depression, caregivers' scores were similar to the initial ones at the end of the program. This finding is comparable to the results of our study in which burden decreased, and it was maintained at follow-up, a result attributed more to sustained changes in actual performance than to caregivers' assessment variations and to the fact that such respite care may provide an environment where it is less likely to result in behavioral problems. Andrén and Elmståhl⁴¹ tested an intervention with a group of caregivers and compared it with a control group and observed an increase in satisfaction in the intervention group, relative to interventions that include respite care and take into account that caregivers' burden and declining health are frequent. Lund et al.⁴² suggest that respite care encourages caregivers to manage healthy behaviors by setting detailed and progressive goals or objectives. On the other hand, our program showed efficacy because it allowed caregivers to get formal support from respite care provided by nursing assistants in charge of caring for the patients while the caregivers were participating in the intervention; this can be verified in the results of social support and burden. It should

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be noted that the respite intervention alone did not improve the variables measured, but it did allow the caregivers to be available to participate in self-care promotion programs.

Furthermore, to evaluate the impact of the study, patients' characteristics were determined, and similarities with previous studies were found, in which affections in memory, behavior, and affect were observed.

Concerning caregivers, women are the ones who are responsible for caregiving⁴³, and there is a deterioration in their health, social, and family relationships. It should be noted that caregivers consider themselves unemployed without any income and think their work is done more out of love, dedication, and commitment. They do not use support networks, although they acknowledge their existence. In addition, the median number of hours they spent on caregiving is 24 hours per day. Studies have determined that these characteristics increase the burden⁴⁴ and promote a significant deterioration in health. Given this situation, the multicomponent intervention program was designed to improve quality of life and reduce burden. This is supported by research, which shows that programs with robust methodologies and adequate pre- and post-test assessment would guarantee positive results in caregivers receiving the intervention²⁴.

At post-intervention follow-up, burden decreased by 13.1 points ($p < 0.001$); furthermore, patients with high behavioral impairment increased burden by 14.8, supporting that Alzheimer's disease produces higher levels of burden⁴⁵.

Some authors have even proposed alternative strategies to respond more specifically to the needs of caregivers. For example, Viale et al.⁴⁶ state that identifying contextual factors and resources is necessary to promote patterns of cooperation, conflict resolution, and communication. Zarit et al.⁴⁷ even proposed an individualized intervention protocol focused on three domains: care demands, caregiver's roles and relationships, and resources.

It is important to highlight the added value of these interventions, as Chien et al cited by Milders and collaborators²⁹ mentioned, and to recognize them as medical alternatives. Strengths are also reported regarding no negative effects on caregivers' well-being²⁹.

Our intervention program was focused on three areas: psychoeducation to provide the caregivers with theoretical elements about the disease and patient care; psychosocial support focused on designing personal empowerment and self-help strategies; and group interventions in which actions were guided to be developed in the day-to-day work of caregiving. Therefore, the increase in the perception of social support and the decrease in burden coincide with the results mentioned by validated programs, with a robust methodology, that favor a population affected and largely forgotten.

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Regarding limitations of the study, adherence of the intervention groups was high at the pre-post intervention stage; however, a higher-than-expected loss to follow-up was observed in the control group. It is important that the control group receives a constant incentive to stay

in the study despite not receiving the benefits of the interventions at the time of the study. Therefore, the development of new theoretical models that address the changing needs of caregivers over time; the development of interventions that can be delivered in a flexible and individually “tailored” manner; and assessment of positive and negative aspects of caregiving to foster greater resilience are recommended.

Conclusions

From the present study’s findings, the importance for global health of improving the impact of psychosocial interventions on caregivers’ lives should be highlighted. The profile of caregivers of Alzheimer’s patients in a Latin American setting is marked by vulnerability patterns such as advanced age, low educational level, no payment or income, and no support networks.

A multicomponent intervention based on respite care availability allows informal caregivers to reduce the burden and increase social support perception, especially in the dimensions of social support and tangible and instrumental support. At the same time, there was evidence of sustainability or improvement over time.

Although this study has a small sample size, it approached, with a more rigorous methodology and in a Latin American setting, the evidence of a positive effect on caregivers’ mental health of a multicomponent intervention with a transdisciplinary approach. Besides, it is considered valuable evidence in settings where the health system only provides patient care and does not offer services for caregiver care. In particular, the evidence presented here can be taken as a starting point for creating government-supported programs or for the formulation of public policy on the informal caregiver role.

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