

Efficacy of a Psychoeducative Group Program for Caregivers of Demented Persons Living at Home: A Randomized Controlled Trial

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Objectives. To test the efficacy of a psychoeducative group program for informal caregivers of persons with dementia.

Methods. The study was a multicenter randomized controlled trial. Randomization was stratified according to sex and kinship. Participants randomized to the control group were referred to the traditional support groups. Participants in the study group had fifteen 2-hr weekly sessions focusing on stress appraisal and coping. Eligible participants (primary caregivers of community-dwelling persons with dementia) were blindly assessed before the randomization and after 16 weeks on the following measures: frequency and reactions to behavioral problems (primary outcome), burden, psychological distress, anxiety, perceived social support, and personal efficacy.

Results. A total of 158 participants were randomized to the study ($n = 79$) and control ($n = 79$) groups in 12 successive waves. Results show that study participants presented a 14% decrease in their reactions to the behavioral problems of the care-receivers as opposed to a 5% decrease in the control group ($p = .04$). The frequency of behavior problems also decreased ($p = .06$), as did the cross-product frequency/reaction ($p = .02$). There was no significant effect on the secondary outcome variables.

Discussion. This is one of the first studies showing a significant effect of this type of support group program on the caregivers of participants with dementia.

ALZHEIMER'S disease and other forms of dementia constitute a major health problem, because these illnesses affect 8% of people aged 65 and older, and more than one third of people aged 85 and older (Canadian Study of Health and Aging, 1994). The expected aging of the population will be associated with a huge increase in the number of people affected by these illnesses. Close to one half of people suffering from dementia live at home, where they maintain significant spatial references and quality of life (Baumgarten, 1989; Canadian Study of Health and Aging, 1994). Without family support, many more persons with dementia would be compelled to leave their homes and enter an institution. It is estimated that withdrawal of the assistance provided by immediate family and friends would increase the need for long-term residential care by 34% (Commission d'Enquête sur la Santé et les Services Sociaux, 1987). Thus, it is important to find ways to support caregivers who wish to keep persons with dementia at home for as long as possible.

The responsibility for maintaining a person with dementia at home most often falls on the relative (generally the spouse or daughter of the person with dementia) who provides the majority of care (Garant & Bolduc, 1990), often referred to as the primary caregiver. However, this involvement is a major source of stress and has a negative impact

on the caregiver. Reviews of the effects of dementia caregiving (Ory, Yee, Tennstedt, & Schulz, 2000; Schulz, O'Brien, Bookwala, & Fleissner, 1995) demonstrate a consistent association of caregiving with depressive symptomatology, clinical depression, and anxiety. Although the evidence is more equivocal and generally weaker, many reports show physical morbidity, such as self-related health, number of illnesses, health care utilization, and cardiovascular problems. The burden is the primary reason for resorting to institutionalization (Jutras, 1988) and, compared with a low burden, a high burden nearly doubles (relative risk of 1.8) the risk of being admitted to an institution (Hébert, Dubois, Wolfson, Chambers, & Cohen, 2001). Several studies confirm that the burden felt by the caregiver is less related to the demented person's cognitive deficits and disabilities than it is to the troublesome behaviors exhibited by the person with dementia and the stress they generate in the caregiver (Boucher, 1999; Chenoweth & Spencer, 1986; Haley, Levine, Brown, Berry & Hughes, 1987; Hébert et al., 2001; Ory et al., 2000; Poulshock & Deimling, 1984; Schulz et al., 1995). This suggests that decreasing troublesome behaviors and stress could eventually reduce burden and delay institutionalization.

Among the various interventions designed to help caregivers (for reviews, see Acton & Kang, 2001; Bourgeois,

Schulz & Burgio, 1996; Kennet, Burgio, & Schulz, 2000; Knight, Lutzky, & Macofsky-Urban, 1993; Toseland & Rossister, 1989), support groups represent an interesting and inexpensive solution for reducing the burden and stress of the caregivers. These programs are widespread in health and voluntary organizations. Although many pre-experimental and quasiexperimental studies suggest that these programs would be effective in reducing the burden and prolonging the time the person with dementia can be cared for at home (Gendron et al., 1986; Glosser & Wexler, 1985; Kahan, Kemp, Staples, & Brummel-Smith, 1985), the majority of controlled experimental studies have been unable to show that they have any significant effect (Gendron, Poitras, Dastoor, & Pérodeau, 1996; Haley, Brown, & Levine, 1987; Hébert, Leclerc, Bravo, Girouard, & Lefrançois, 1994; Zarit, Anthony, & Boutsellis, 1987). This lack of efficacy could be linked to both the program content and the methodology of the evaluative studies. The group interventions evaluated to date show that the content is of low intensity (on average eight 2-hr weekly sessions) and superficially covers a very broad range of issues, mainly using information and emotion-sharing strategies (Lavoie, 1995). To be effective, this type of program should be spread over a longer period, refer to a specific theoretical framework, and have well-defined objectives that focus primarily on the management of troublesome behaviors and the reactions they create. From the methodological viewpoint, the limitations of pre- or quasiexperimental designs make interpreting this type of study hazardous, particularly when measuring the psychological effects of this type of group intervention (Biegel, Sales, & Schulz, 1991). Randomized controlled trials to date present many other limitations: small sample size and low power to detect a moderate effect; lack of responsiveness of the primary outcome variables that measure constructs that are too general, such as well-being, anxiety, or burden; lack of selection of participants who can best benefit from the intervention; and absence of implementation and process analysis (Schulz, 2001; Zarit & Leitsch, 2001).

Based on these observations, a multidisciplinary network of Quebec (Canada) researchers interested in these issues designed a more intensive, innovative program based on a cognitive approach that focuses on the management of troublesome behaviors and the stress they generate. This program is based on the transactional theory of stress and coping that was translated into a specific intervention framework by Folkman and colleagues (1991) to improve stress management skills. The objective of the present study was to verify the efficacy of the program in reducing caregivers' reactions toward troublesome behaviors and indirectly reducing their burden, psychological distress, and anxiety, and improving their perception of social support and well-being. The primary hypothesis was that the program should decrease the frequency of and reactions to behavior problems, particularly disruptive ones, and ultimately decrease the caregiver's burden and the desire to institutionalize the person with dementia. An implementation and process analysis was also performed using qualitative methodology and will be reported separately.

METHODS

The study was a multicenter randomized controlled trial using assessments of participants before and after participation in the program. Randomization was performed within each center and wave using the minimization technique (Pocock, 1993), stratified on the caregiver's relationship to the person with dementia (spouse vs. other) and gender. Participants randomized to the study group received the experimental program, and those assigned to the control group were referred to the regular support group program offered by the Alzheimer Society or health care organizations in their region. These programs are widespread in Quebec (free of charge and without a waiting list), and it would have been unethical to deprive participants in the control group of a currently available resource, even though there is no evidence that these programs are effective. These programs also fulfilled the role of a placebo, thereby avoiding the Hawthorne effect and also making it possible to show whether the study program was significantly better than existing programs.

Psychoeducative Program

The experimental program aimed to improve the caregiver's ability to cope with the numerous daily sources of stress associated with caring for a person with dementia. It was developed according to the Lazarus and Folkman (1984) transactional theory of stress and coping that was translated into a specific intervention program by Folkman and colleagues (1991). It comprised two components: cognitive appraisal and coping strategies. The participant first accurately appraises the specific stressful situation and identifies the type of stressor, based on its modifiable and non-modifiable characteristics. He/she then chooses the appropriate coping strategy according to the type of stressor: problem-solving strategies when the stressor is modifiable or emotion-focus strategies (such as reframing) when it is not. Seeking social support is also a strategy that can be used for both types of stressors. Corbeil, Quayhagen, and Quayhagen (1999) operationalized this model for individual interventions and showed that it significantly decreases the stress associated with caregiving.

We designed a group intervention based on this framework. The program included fifteen 2-hr weekly sessions. It comprised two components. The first component was *cognitive appraisal* (four meetings), whose primary objective consisted of improving the caregivers' ability to shift from a global stressor to a specific stressor. Breaking down a global situation into specific elements not only helps caregivers clarify the problem, but also increases their awareness that something can be done. The second and third objectives of this component were to develop the caregivers' ability to distinguish between the changeable and unchangeable aspects of a stressor, and their awareness of the importance of the match between the changeability of a stressor and the choice of coping strategies. These notions were discussed between the group leader (a health professional experienced in the care of persons with dementia and group facilitation) and the caregivers. The caregivers were also asked to complete a home assignment to practice their ability to select four specific stressors linked to their caregiving situation

and to identify the changeable and unchangeable aspects, as well as their emotional reactions. The second component was *coping strategies* (11 meetings), whose main objective consisted of improving three well-known coping strategies (problem-solving, reframing, and seeking social support) and of establishing a fit between the changeability of stressors and the choice of coping strategy. Problem-solving (problem-focused coping) is used to alter the changeable aspects of a stressor. It is most useful when the situation concerns the person with dementia's dysfunctional behaviors, with many of these behaviors amenable to change. Over the course of four meetings, the caregivers had the opportunity to learn to use well-documented steps to clarify a target problem that was changeable and to find an appropriate solution to the problem. The problem-solving strategies integrated elements of behavioral techniques (Zarit & Zarit, 1998) in precisely defining the stressful situation, thereby making it possible to modify its frequency and intensity. The second coping strategy consisted of reframing the meaning of a stressor (emotion-focused coping). The objective was to find an alternative way of thinking about a situation so that it was easier to manage the painful emotion generated by the unchangeable aspects of a stressor. The content of reframing was based on the cognitive approach, according to which thoughts are often what generate emotions (Beck, Rush, Shaw, & Emery, 1979; Burns, 1980). Over the course of three meetings, caregivers learned to (1) recognize their misunderstanding or misinterpretation of the relative with dementia's dysfunctional behavior and reframe the meaning of such behaviors as a consequence of dementia, (2) identify some common forms of dysfunctional thoughts and replace them with more rational thoughts, (3) think about the gratifying aspects of the caregiving role, and (4) focus on the present reality. Caregivers were also encouraged to use ways to stimulate helpful thoughts, like finding time for pleasurable activities and learning to step back from a stressful situation. The third coping strategy consisted of seeking social support. Four meetings centered on this strategy, which can be helpful to focus on either a problem or emotions. Social support is viewed as a factor that has a protective effect on well-being (Gottlieb & Selby, 1989; Stewart, 1993), but caregivers appear reluctant to seek support (Collins, King, Given, & Given, 1994; Paquet, 1996). In our program, caregivers were first invited to examine their reluctance to seek support and to identify the types of support needed and the persons in their informal network and community resources likely to provide the support. Possible disagreements or conflicts in the exchange of support were discussed. Next, the caregivers examined how to mobilize this support (i.e., how to present a specific request to the selected individual or resource), and lastly how to maintain this assistance.

The theoretical framework and the program are described in more detail elsewhere (Lévesque et al., 2002). Manuals for the leader and the participants should be available shortly on request. A pilot study on a group of eight caregivers of persons with dementia that started in October 1997 enabled us to complete and fine-tune the program before offering it to a larger number of caregivers in this experimental framework. In the pilot study, the participants were

tested with the same instruments as those used in this study. After the study, we also refined some of the home assignments completed by the caregivers between the meetings.

Participants

Participants were recruited through Alzheimer societies and home care organizations in five regions of the province of Quebec (Canada). The inclusion criteria were (1) being the primary caregiver of a person with dementia for at least the previous 6 months, irrespective of whether the caregiver lived with the person or not; (2) presenting a moderate or severe burden [score on the Zarit Burden Scale higher than 9 out of 88 (representing moderate burden according to the reference values proposed by Hébert, Bravo, & Prévile, 2000)]; (3) not participating in another support group or psychotherapy during the application of the protocol (previous participation in a support group or psychotherapy was permitted); and (4) caring for a person with dementia presenting at least one behavior problem per week. In a given area, when at least 12 participants were recruited, they were assessed and then randomized to either the control or study group. The sample size needed to detect a moderate effect of the program [standardized difference of 0.5, according to Cohen's criteria (Cohen, 1977)] with 80% power and 5% alpha error was estimated to be 64 participants per group (Machin & Campbell, 1987). To take into consideration a withdrawal rate of 20%, the target sample size was 160 participants (10–13 waves of 12–16 participants). Participants signed an informed consent form, and the study was approved by the Ethics Committee of the Sherbrooke Geriatric University Institute.

Measures

Participants were interviewed at baseline and after 16 weeks (at the end of the experimental program) by trained interviewers blinded to the group assignment of the participants. At baseline, information was collected on demographic characteristics, self-perceived health, care recipient's disease, and caregiving issues. For the outcome measures, the instruments were selected on the basis of relevancy, validity, and reliability; their utilization in previous studies on caregiver support groups; and the availability of an existing French version developed with a rigorous process. For each instrument, reliability coefficients of the original version and the translated version (published previously and in the present study) can be found in Table 1.

The primary outcome measure was the Revised Memory and Behavior Problem Checklist developed by Teri and colleagues (1992), which measures the frequency of behavioral and memory problems, and the reactions that these problems generate in the informal caregiver. The 24 items describe behaviors and participants score their frequency during the preceding week (on a scale from "0 = never" to "4 = every day"), and the extent to which this problem disturbed or upset them (on a scale from "0 = not at all" to "4 = extremely"). In the Hébert and colleagues (1994) randomized controlled trial, the intensity of behavioral reactions, as measured by this scale, proved to be the most responsive variable. Three scores can be obtained from this instrument: the mean frequency score (out of 4), the mean reaction score

Table 1. Internal Consistency Coefficients (Cronbach's Alpha) of the Outcome Measures

Instrument	Original Version	French Translation	Present Study (N = 158)
Revised Memory and Behavior Problem Checklist (Teri et al., 1992)			
Frequency	0.84	0.93 ^a	0.81
Reaction	0.90	0.94 ^a	0.88
Cross-product	—	0.91 ^a	0.87
	(Teri et al., 1992)	(Hébert et al., 1993)	
Zarit Burden Interview (Zarit et al., 1985)	0.91	0.85	0.90
	(Gallagher et al., 1985)	(Hébert et al., 1993)	
Spielberger State-Trait Anxiety Inventory (State) (Spielberger, 1983, 1988)	0.96 (Men)	0.92 (Ivers, Gauthier, & Bouchard, 1996)	0.94
	0.89 (Women)		
	(Spielberger, 1983)		
Bradburn Revised Affective Scale (Bradburn, 1969)	0.66 (Reitzes, Mutran, & Pope, 1991)	—	0.72
Inventory of Socially Supportive Behavior (Krause & Markides, 1990)			
Informational support	0.81	0.83	0.73
Tangible support	0.67	0.83	0.68
Emotional support	0.83	0.84	0.88
Integrative support	0.83	0.88	0.84
	(Krause & Markides, 1990)	(Lauzon & Voyer, 1998)	
Ilfeld Psychiatric Symptoms Index (Ilfeld, 1976)			
29 items form	0.91	0.92	—
14 items form	—	0.89	0.90
	(Ilfeld, 1976)	(Préville et al., 1992)	

^aAlpha for the 53 items form.

for those with a frequency different from 0 (out of 4), and the mean cross-product frequency/reaction score (out of 16). This cross-product score has been the score most correlated with burden in previous studies (Zarit, Todd, & Zarit, 1986).

Many secondary variables were also measured. Desire to institutionalize was assessed with a 4-point ordinal scale (not having thought seriously of placing my relative; having thought seriously; having discussed placement with someone or visited an institution; having applied for placement). This scale was used in the Canadian Study of Health and Aging and was a good predictor of short-term institutionalization (Hébert et al., 2001). In the analysis, it was transformed into a dichotomized variable by grouping under low desire those who answered they never thought seriously of placing their relative and under significant desire those who had thought seriously, had done something about it, or (for post-test) had institutionalized their relative. The Zarit Burden Interview (Hébert, Bravo, & Girouard, 1993; Zarit, Orr, & Zarit, 1985) is a 22-item scale measuring the subjective load experienced by the caregiver by asking him/her how frequently (from "0 = never" to "4 = almost always") they feel various emotions in their relationship with the care-receiver for a total score out of 88. Reference values have been generated based on a representative sample of caregivers of community-dwelling people with dementia (Hébert et al., 2000). Scores between 8 and 17 represent moderate burden, scores between 18 and 32 represent high burden, and scores over 32 represent severe burden. Anxiety was measured by the Spielberger State-Trait Anxiety Inventory (Gauthier & Bouchard, 1993; Spielberger, 1983, 1988), which consists of 20 statements

for which the participants indicate the intensity of their feelings on a 4-point scale varying from "1 = not at all" to "4 = considerable." The total score ranges from 20 to 80. The Bradburn Revised Affect Scale (Bradburn, 1969) comprises five positive statements and five negative statements about feelings experienced during the preceding week. We used the scoring system developed in several surveys (Health and Welfare Canada and Statistics Canada, 1981; Seniors Secretariat, 1993; Stephens & Craig, 1990) with a three-level response based on how often a feeling occurs ("1 = often," "2 = sometimes," "3 = never"). The score of positive affects is subtracted from the score of negative affects, and 10 is added for a total score ranging from 0 to 20, in which the higher the score, the more positive the overall affect. The Inventory of Socially Supportive Behaviors (Krause & Markides, 1990) is a 40-item scale assessing four dimensions of support: informational (7 items), tangible (9), emotional (11) and integrative (13). Each item is answered on a 4-point scale (from "1 = never" to "4 = very often"), and four scores are obtained by summing the scores on the items associated with each dimension. Personal efficacy was measured by a method suggested by Bandura (1977), in which the caregivers indicate on a scale from 0 to 100 the degree of confidence they have in their ability to assume their role. The higher the score, the better the perceived efficacy. Psychological distress was measured by the short, 14-item Ilfeld Psychiatric Symptoms Index (Ilfeld, 1976) developed by Préville, Boyer, Potvin, Perrault, and Légaré (1992). Participants had to rate the 14 symptoms (related to depression, anxiety, cognitive disturbance, anger) on a 4-point scale from "1 = never" to "4 = very often." The total score ranges from 14 to 56.

Analysis

Study and control groups were first compared at baseline using *t* and chi-square tests for continuous and categorical outcome measures. The efficacy analysis compares the post-test scores of the study and control groups using an analysis of covariance, with the pretest score being added as a covariate. A test of parallelism was performed in each instance to ensure that the correlation between baseline and post-test was the same for both groups. These analyses included, first, all of the randomized participants according to their assignment, regardless of their participation in the program (intent-to-treat analysis). Secondary analyses were also performed comparing the study participants who attended at least nine sessions to the control group (as-treated analysis). Factors associated with improvement in the study group were analyzed using bivariate and multivariate analyses with disruptive behaviors (cross-product score) as the dependent variable.

RESULTS

Overall, 158 participants were randomized in 12 waves and 6 centers. Of these, 14 participants were excluded because the program did not take place because all but one participant dropped out for various reasons. Of the remaining 144 participants, 72 were included in the study group and 72 in the control group. Between the two assessments, one person with dementia died in the control group and 24 were institutionalized (11 in the study group and 13 in the control group), whereas one participant in the study group was no longer the primary caregiver. Because these participants were no longer undergoing the same caregiving experience at post-test, they were excluded from all of the analyses except those regarding the desire to institutionalize because changes in the outcome variables would be the result of the change in the caregiving situation rather than participation in a program. This results in the analysis of 118 participants: 60 in the study group and 58 in the control group. Figure 1 summarizes the flow of the participants through the study.

The majority of the participants were women (80%), married (84%), living with the person with dementia (86%), and their mean age was 60 years old. They were mainly husband or wife (61%) of the person with dementia, and one third had previously attended support groups. Most of the participants experienced a severe burden, with 72% having scores over

Table 2. Comparison of Participants at Baseline on the Demographic Characteristics and Study Variables (*N* = 118)

Variable	Study Group (<i>n</i> = 60)	Control Group (<i>n</i> = 58)	<i>p</i> Value
% Women	80.0%	81.0%	.89
Age: mean (<i>SD</i>)	59.78 (11.86)	59.77 (13.93)	1.00
% Married	81.7%	86.0%	.53
Schooling: mean years (<i>SD</i>)	11.77 (3.80)	12.19 (4.38)	.59
% Poor self-perceived health	13.8%	16.7%	.67
% Husband/wife of the person with dementia	61.7%	60.3%	.88
Caregiving time: mean years (<i>SD</i>)	2.90 (2.23)	2.74 (2.00)	.69
% Living with their relative	85.0%	86.2%	.85
% Paid work	21.7%	36.2%	.08
% Previous attendance at support groups	33.3%	33.3%	1.00
Age of the care-receiver: mean (<i>SD</i>)	73.60 (7.80)	74.67 (7.07)	.44
% Alzheimer	81.4%	76.8%	.55
% Taking antedementia drugs	63.3%	50.0%	.15
Zarit Burden Interview: Mean score out of 88 (<i>SD</i>)	42.47 (14.63)	41.44 (15.16)	.71
RMBPC frequency: Mean score out of 4 (<i>SD</i>)	1.64 (0.51)	1.55 (0.63)	.37
RMBPC reaction: Mean score out of 4 (<i>SD</i>)	2.01 (0.75)	2.18 (0.69)	.20
RMBPC cross-product: Mean score out of 16 (<i>SD</i>)	3.48 (1.75)	3.56 (2.36)	.84
State-Trait Anxiety Inventory: Mean score out of 80 (<i>SD</i>)	41.01 (12.96)	45.46 (14.82)	.09
Psychiatric Symptoms Index: Mean score out of 56 (<i>SD</i>)	26.17 (6.94)	26.45 (8.12)	.84
Inventory of Socially Supportive Behavior			
Supportive: Mean score out of 28 (<i>SD</i>)	10.77 (3.41)	11.24 (3.55)	.46
Tangible: Mean score out of 36 (<i>SD</i>)	12.87 (3.89)	12.22 (3.10)	.32
Emotional: Mean score out of 44 (<i>SD</i>)	23.83 (6.81)	23.37 (7.61)	.73
Integrative: Mean score out of 52 (<i>SD</i>)	23.68 (5.49)	23.74 (6.02)	.96
Personal Efficacy Scale: Mean capacity score out of 100 (<i>SD</i>)	77.67 (16.68)	69.83 (19.42)	.02
% Significant desire to institutionalize	51.7%	31.0%	.02
Bradburn Affective Scale: Mean score out of 20 (<i>SD</i>)	10.90 (3.06)	10.66 (3.80)	.70

Note: RMBPC = Revised Memory and Behavior Problem Checklist.

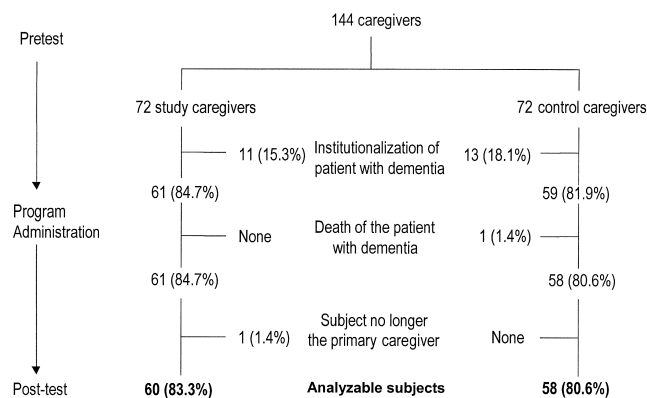


Figure 1. Flow of the participants through the study.

32 (out of 88) on the Zarit Burden Interview. There were no significant differences at pretest between the participants in the two groups (Table 2) on all demographic and outcome variables, except for the desire to institutionalize, which was significantly higher in the study group (52% vs. 31%; *p* = .02), and personal efficacy, which was significantly higher in the study group (*p* = .02).

The program was implemented as planned in all 11 remaining groups. Of the 72 participants in the study group, 8 (11%) did not attend any sessions, 9 (13%) attended from one to eight sessions, 5 (7%) attended between nine and 11 sessions, and 50 (69%) participants attended at least 12 sessions out of 15. Reasons for not attending related to juggling schedules and health problems. For the 72 participants in

Table 3. Comparison of Participants at Post-Test on the Outcome Variables ("Intent-to-Treat Analysis")

Variables	Study Group (<i>n</i> = 60)		Control Group (<i>n</i> = 56)		<i>p</i> Value ^a
	Post-Test	Difference Post-Pre ^b	Post-Test	Difference Post-Pre	
RMBPC frequency:	1.57	-0.07	1.63	0.12	.06
Mean score out of 4 (<i>SD</i>)	(0.56)	(0.41)	(0.66)	(0.51)	
RMBPC reaction:	1.77	-0.28	2.07	-0.10	.04
Mean score out of 4 (<i>SD</i>)	(0.74)	(0.55)	(0.72)	(0.60)	
RMBPC cross-product:	2.87	-0.61	3.53	0.13	.02
Mean score out of 16 (<i>SD</i>)	(1.74)	(1.53)	(2.13)	(1.86)	
RMBPC disruptive behaviors frequency:	0.94	-0.06	1.05	0.15	.08
Mean score out of 4 (<i>SD</i>)	(0.69)	(0.56)	(0.83)	(0.61)	
RMBPC disruptive behaviors reaction:	2.16	-0.41	2.53	-0.03	<.01
Mean score out of 4 (<i>SD</i>)	(0.84)	(0.87)	(0.91)	(0.83)	
RMBPC disruptive behaviors cross-product:	2.22	-0.51	2.68	0.20	.03
Mean score out of 16 (<i>SD</i>)	(1.88)	(1.68)	(2.38)	(1.64)	
Zarit Burden Interview:	40.07	-2.40	41.25	0.09	.39
Mean score out of 88 (<i>SD</i>)	(14.84)	(14.96)	(16.55)	(11.99)	
State-Trait Anxiety Inventory:	39.75	-1.27	43.17	-1.64	.39
Mean score out of 80 (<i>SD</i>)	(13.24)	(16.47)	(14.02)	(14.49)	
Psychiatric Symptoms Index:	25.01	-1.16	26.89	0.65	.13
Mean score out of 56 (<i>SD</i>)	(6.92)	(7.98)	(8.16)	(6.03)	
Inventory of Socially Supportive Behavior					
Supportive:	10.27	-0.50	10.21	-0.62	.86
Mean score out of 28 (<i>SD</i>)	(3.19)	(3.03)	(2.75)	(3.15)	
Tangible:	12.20	-0.67	11.94	0.06	.30
Mean score out of 36 (<i>SD</i>)	(3.55)	(4.01)	(2.89)	(3.18)	
Emotional	22.88	-0.96	22.61	0.04	.64
Mean score out of 44 (<i>SD</i>)	(6.17)	(5.21)	(5.72)	(6.02)	
Integrative:	23.91	0.22	23.43	-0.82	.28
Mean score out of 52 (<i>SD</i>)	(6.78)	(4.53)	(6.01)	(4.74)	
Personal Efficacy Scale:	74.58	-3.08	71.02	0.06	.74
Mean capacity score out of 100 (<i>SD</i>)	(17.64)	(20.71)	(20.64)	(21.73)	
Bradburn Affective Scale:	10.98	0.08	10.50	-0.19	.49
Mean score out of 20 (<i>SD</i>)	(3.55)	(3.39)	(3.15)	(3.02)	

Note: RMBPC = Revised Memory and Behavior Problem Checklist.

^aAnalysis of covariance with pretest score as covariate.

^bNegative sign represents an improvement.

the control group referred to Alzheimer Society meetings, 18 (25%) did not attend any meetings and 11 (15%) attended less than half the meetings.

Table 3 shows the comparison of participants at post-test for all outcome variables. On the primary outcome variable, whereas the frequency of behavior and memory problems increased in the control group by 8%, it decreased in the study group by 4%; this difference was nearly statistically significant ($p = .06$). The reaction score decreased in both groups, but more so in the study group (16% vs. 5%), and this difference reached statistical significance ($p = .04$). The difference between the two groups on the cross-product frequency/reaction was also statistically significant ($p = .02$). This improvement in reaction was even greater for disruptive behaviors (study = 19%; control = 1%; $p = .006$) than depressive and memory behaviors.

All secondary outcomes did not show any statistically significant differences between the groups except the desire to institutionalize. Including those who were admitted to an institution during the study, the desire to institutionalize increased slightly in the study group from 56% to 61%, but the increase was greater in the control group going from

39% to 59% ($p = .003$), although this difference between the two groups did not reach statistical significance ($p = .10$) (Figure 2).

Table 4 shows the as-treated analysis, including only the participants who attended at least nine sessions in the study group. The effect of the program on the frequency, reaction, and cross-product scores on the total Revised Memory and Behavior Problem Checklist scale is more marked, and all these scores are now statistically significant. The same is true for the disruptive behavior section of this scale. Most of the secondary variables improved, but again none reached the statistically significant level.

In the study group, the factors associated with a greater improvement in the cross-product score of disruptive behaviors were: higher frequency of disruptive behaviors ($p < .001$) and behavior problems in general ($p = .003$) at baseline, and not living with the relative ($p = .01$).

DISCUSSION

This is one of the few randomized controlled studies to show a significant effect of a support group program on reactions to behavior problems. One of our previous studies

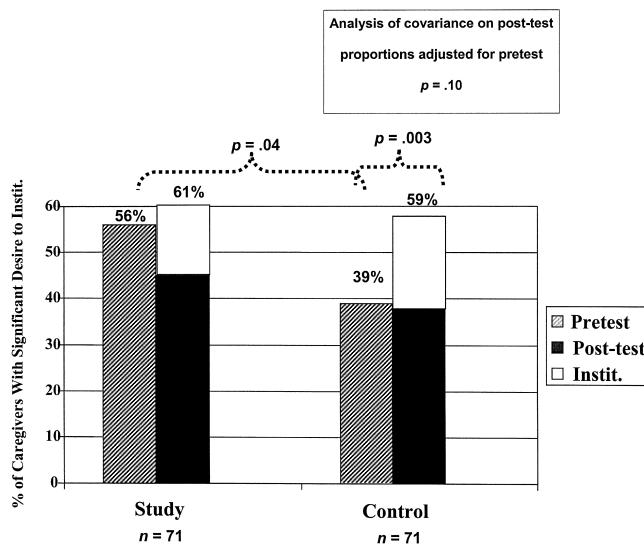


Figure 2. Changes in the desire to institutionalize (Inst.) in both groups between pretest and post-test (including those who were admitted to an institution).

(Hébert et al., 1994) showed a significant effect on knowledge only. More recently, Ostwald, Hepburn, Caron, Burns, and Mantell (1999) showed, with a randomized waiting list controlled study, that seven 2-hr weekly training sessions decreased reactions to disruptive behaviors and burden. Other group programs assessed through randomized controlled trials did not show any effect on various psychological outcome measures (Gendron et al., 1996; Haley, Brown, et al., 1987; Hébert et al., 1994; Zarit et al., 1987). The approach suggested by Mittelman and collaborators (Mittelman, Ferris, Shulman, Steinberg & Levin, 1996; Mittelman et al., 1993, 1995) was also effective in a randomized controlled trial, but included a mix of formal individual (with the caregivers, the family, and the patient) and informal support group interventions. Our program focused more intensively on behavior problems, the most important factor associated with burden and institutionalization. Because it comprises only group sessions, it is easier to implement and less costly.

The program decreased the frequency of and reactions to behaviors, particularly disruptive ones. Although the effect on reactions was expected, a decrease in frequency may

Table 4. Comparison of Participants (Nine Sessions or More) at Post-Test on the Outcome Variables ("As-Treated Analysis")

Variables	Participants 9+ (n = 46)		Control Group (n = 58)		p Value ^a
	Post-Test	Difference Post-Pre ^b	Post-Test	Difference Post-Pre	
RMBPC frequency:	1.52	-0.12	1.63	0.12	.02
Mean score out of 4 (SD)	(0.55)	(0.38)	(0.66)	(0.51)	
RMBPC reaction:	1.79	-0.31	2.07	-0.10	.04
Mean score out of 4 (SD)	(0.72)	(0.57)	(0.72)	(0.60)	
RMBPC cross-product:	2.81	-0.70	3.53	0.13	.01
Mean score out of 16 (SD)	(1.74)	(1.48)	(2.13)	(1.86)	
RMBPC disruptive behaviors frequency:	0.90	-0.11	1.05	0.15	<.05
Mean score out of 4 (SD)	(0.70)	(0.58)	(0.83)	(0.61)	
RMBPC disruptive behaviors reaction:	2.18	-0.41	2.53	-0.03	<.01
Mean score out of 4 (SD)	(0.79)	(0.89)	(0.91)	(0.83)	
RMBPC disruptive behaviors cross-product:	2.12	-0.63	2.68	0.20	.02
Mean score out of 16 (SD)	(1.89)	(1.75)	(2.38)	(1.64)	
Zarit Burden Interview:	40.29	-3.17	41.25	0.09	.31
Mean score out of 88 (SD)	(13.05)	(14.20)	(16.55)	(11.99)	
State-Trait Anxiety Inventory:	39.67	-2.91	43.17	-1.64	.30
Mean score out of 80 (SD)	(13.11)	(15.66)	(14.02)	(14.49)	
Psychiatric Symptoms Index:	24.56	-1.57	26.89	0.65	.06
Mean score out of 56 (SD)	(6.76)	(7.03)	(8.16)	(6.03)	
Inventory of Socially Supportive Behavior					
Supportive:	10.20	-0.22	10.21	-0.62	.69
Mean score out of 28 (SD)	(3.06)	(2.48)	(2.75)	(3.15)	
Tangible:	12.02	-0.54	11.94	0.06	.73
Mean score out of 36 (SD)	(3.10)	(3.63)	(2.89)	(3.18)	
Emotional	22.25	-0.66	22.61	0.04	.57
Mean score out of 44 (SD)	(6.14)	(5.03)	(5.72)	(6.02)	
Integrative:	23.79	0.29	23.43	-0.82	.28
Mean score out of 52 (SD)	(6.76)	(4.25)	(6.01)	(4.74)	
Personal Efficacy Scale:	73.70	-4.24	71.02	0.06	.90
Mean capacity score out of 100 (SD)	(17.81)	(22.56)	(20.64)	(21.73)	
Bradburn Affective Scale:	10.67	0.11	10.50	-0.19	.66
Mean score out of 20 (SD)	(3.23)	(3.05)	(3.15)	(3.02)	

Note: RMBPC = Revised Memory and Behavior Problem Checklist.

^aAnalysis of covariance with pretest score as covariate.

^bNegative sign represents an improvement.

seem surprising at first glance. However, this is logical because an improvement in the coping abilities of caregivers may have an important effect on the occurrence of disruptive behaviors. Moreover, Bookwala and Schulz (1998) have shown that the perception of the frequency of behavior problems and the stress associated with them could be increased by some caregivers' personality attributes (e.g., neuroticism, mastery). It is possible that the intervention brought the perceptions of these individuals closer to reality. This is consistent with the finding relating the largest effect of the program to the highest frequency of behavior problems at baseline.

Frequency of and reaction to behavior problems were chosen as the primary outcomes because they were the most directly targeted by the program. The program specifically targeted disruptive behaviors, and its biggest impact on the frequency of and reaction to these behaviors is thus not surprising. A measure of the "goodness of fit" of the coping strategies toward the specific stressors would have been even more appropriate, but a measurement instrument of this construct with good psychometric properties is not available as an outcome measure.

However, there was no indirect effect on more general variables like burden, stress, psychological distress, affect, and social support. This could be related to an effect of the program on the measure, because participants participating in the program may become more aware of the burden and psychological distress related to the caregiving experience. These variables may also be less responsive on a short-term basis to such interventions. This result is also consistent with the recommendations of Schulz (2001) and Zarit and Leitsch (2001), who suggested that outcome measures should focus more on immediate goals with proximal outcomes than on distal effect and global measures.

The desire to institutionalize seems to be stabilized by such interventions, and this could be a good indicator of the long-term effect of such programs. Institutionalization of the persons with dementia in this study will be monitored to verify this hypothesis.

This study presents many strengths: it was a randomized controlled trial on participants presenting significant burden. The pretest assessment was carried out before randomization, and many precautions were taken to ensure blinding of the interviewers at post-test. The interviewers reported that the participants told them which group they belonged to in only 12 out of 144 cases. For the remaining participants, we asked the interviewer to guess the assignment group, and they were unable to do so in 85 out of 132 cases (64.4%). The ones who did guess were correct in only 26 of the 47 cases, and this spread could have been obtained by chance ($p = .08$).

Referrals of control participants to another program prevented a Hawthorne effect and also undue deterioration of participants referred to a waiting list. The targeted sample size was nearly reached so the study had sufficient power to detect a moderate effect. However, a significant number of participants assigned to the study group (17; 24%) did not attend at least six sessions, decreasing the potential effect of the program. This is confirmed by the as-treated analysis, including only the study participants attending most of the

sessions. The impact of the program was then more important than the intent-to-treat analysis.

Some limitations should also be acknowledged. These include the exclusion of one wave of the study group, because one group failed to form. Also, the exclusion of participants whose relative was institutionalized was necessary for most of the outcome variables because admission to an institution represents the end of the former caregiving experience. Many authors (Bowman, Mukherjee, & Fortinsky, 1998; McCallion, Toseland, & Freeman, 1999) have reported psychological consequences of institutional admission on the relatives, particularly in the first few months after the admission. It would have been inappropriate to include these participants in the analysis and to attribute these effects to the program being tested.

The results of this study support recommending this new program to Alzheimer societies and health organizations instead of the traditional programs they are currently running.

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