



include agitation, depression, apathy, repetitive questioning, aggression, sleep disorders, wandering, anxiety, delusions, or a variety of inappropriate behaviors, are consistently underdetected and undertreated. Although they are universal, they occur across disease trajectory and etiologies.<sup>5-9</sup>

Emerging conceptual frameworks for BPSD suggest that they may be the outcome of neurobiological changes, caregivers and/or environmental-related factors, unmet needs, or a combination thereof.<sup>5,7</sup> As BPSD are only weakly associated with cognitive impairment level, other processes, including the interaction of individuals with their environment, seem to be implicated.<sup>10</sup>

Given the lack of effective pharmacological treatments for BPSD, most medical associations have called for the use of nonpharmacologic therapies as first-line treatment.<sup>7</sup> However, a few nonpharmacological therapies have been tested in randomized controlled studies around the world and even fewer in Brazil.<sup>2</sup> Promising nonpharmacological approaches for the treatment of BPSD involve structured problem-solving interventions and tailored in-home care,<sup>9,11</sup> caregiver education and supportive programs,<sup>12</sup> and the intentional use of activity.<sup>11,13-17</sup> As to the latter, there is growing evidence showing that persons with dementia can effectively engage in activities graded to their abilities,<sup>18</sup> resulting in a reduction of a range of behavioral symptoms, in both the nursing home and home settings.<sup>5,16,19</sup>

The Tailored Activity Program (TAP) is an in-home activity intervention program that has been shown in the US context to effectively reduce the frequency of BPSD.<sup>16</sup> The 8-session program is delivered by occupational therapists over a 3 to 4-month period. It involves the systematic assessment of the interests and abilities of the person with dementia, the caregiver willingness and ability to use activities, and the physical environment, in which 3 activities are developed. Activities are designed to match the preserved abilities (vs. introducing new learning) and to maximize opportunities for participation and engagement.<sup>17</sup> Caregivers are provided with training on how to set up and use the tailored activities in daily care and are provided with education about dementia and behaviors (eg, behaviors are not intentional).

In the original trial, TAP was shown to be cost-effective<sup>16</sup> and resulted in decreased frequency of BPSD. It also improved QOL in persons with dementia. In addition, caregivers reported reduced objective burden (time spent in daily care), skill enhancement, mastery, and self-efficacy using activities.<sup>5,11,16,17</sup> Despite the promising results in the United States, the applicability and effects of this program have not been systematically assessed in other countries.

We recently adapted TAP for the Brazilian context. Cultural adaptations included translating all materials into Portuguese, using assessments validated with this population, even though the domains assessed were similar to those in the original program. Moreover, the *Caregiver's Guide to Dementia*,<sup>20</sup> which provides examples of strategies for addressing behavioral symptoms including how to use the activities, was modified to reflect the Brazilian context. The adaptations resulted in the TAP—Portuguese version for Brazil, TAP-BR. These procedures have been described in detail elsewhere.<sup>21</sup>

The purpose of this present study was to evaluate the effect of TAP-BR on the number, frequency, and intensity of BPSD and QOL of persons with dementia. In addition, we sought to assess the impact of the TAP-BR on caregiver distress and caregiver QOL.

We hypothesized that the participation in TAP-BR would reduce the number, frequency, and intensity of BPSD among study participants with dementia and reduce caregiver distress, as well as improve perceived QOL at 4 months and that of the person with dementia.

## MATERIALS AND METHODS

### Study Sample and Procedures

A phase II parallel 2-group randomized clinical trial was conducted with 30 dyads, 15 of whom were randomized, using randomization in blocks of 4, to receive the treatment, referred to as the experimental group (EG), and 15 of whom were randomized to a wait-list (WL) control group (CG). The EG received TAP-BR over 4 months, and the WL CG (n=15) received usual care. We used the G-Power software to calculate the power of the sample, and this sample of 15 dyads has a 90% chance of detecting strong correlations.<sup>22</sup>

Participants were recruited between 2013 and 2014, through media announcements in the city of Santos, a large seaside city in the Southeast of Brazil. Interested caregivers contacted the research team by phone and were screened for eligibility. The inclusion criteria for the person with dementia were as follows: 60 years of age or older, previous diagnosis of dementia according to National Institute on Aging-Alzheimer's Association<sup>23</sup> criteria, able to perform at least 2 basic activities of daily living (eg, bathing, grooming, and dressing), presence of  $\geq 2$  BPSD in the last 30 days, and being under stable pharmacological treatment for at least 3 months. Family caregivers had to be 18 years of age or older, provide at least 4 hours of daily care, and willing to learn to use activities during care. Dyads were excluded if the person with dementia was nonresponsive to short commands, confined to bed, terminally ill (eg, advanced cancer), had  $> 2$  hospitalizations in the last year, were involved in other intervention studies, or if the caregiver was seeking nursing home placement within the study period.

We received 42 phone calls through media announcements, and, after applying the inclusion and exclusion criteria, 30 dyads were included in the sample, and 12 were excluded.

The 30 dyads were randomized to an EG and a CG, by randomization in blocks of 4 generated by a computer, performed by a blinded research assistant.

Dyads were assessed at baseline (T0) and 4 months later (T1) by a research assistant blind to the group allocation.

With regard to the total sample, there was a 2-dyad sample loss at the start of the TAP-BR application, because of subject desistance, and 2 new dyads were included in this group; hence, the final sample was of 15 dyads in each group. There was no loss in the CG because retention strategies were applied. The dyads were contacted bimonthly and inquired about their general well-being. There was no sample loss in the postintervention evaluation.

To strengthen treatment fidelity, the occupational therapy interventionists (n = 7) received 24 hours of training. The training involved lectures and role-play sessions by a master trainer certified in the TAP program. Interventionists were closely supervised by the study coordinator and participated in biweekly meetings to review cases and troubleshoot implementation challenges.

### INTERVENTION GROUP

The TAP-BR focuses on matching activities to the cognitive and functional capabilities, previous roles, habits,

and interests of the person with dementia, as well as training family caregivers in their use as part of daily care. True to the original intervention, TAP-BR involved 8 sessions delivered by occupational therapists over 4 months in the home.

The program has been described in more detail elsewhere.<sup>5,17</sup> Briefly, it is composed of 3 treatment phases. In phase 1 (assessment), the interventionist used a set of assessments to identify preserved capabilities (cognitive, physical and social skills, work performance, and mood), previous interests, frequency, and intensity of BPSD in the person with dementia, as well as communication techniques and daily care routines of the caregiver and the characteristics of home environment. As to the latter, lighting, access, seating, and other factors were considered in the locations of the home in which the chosen activities were to be performed.

In phase 2 (implementation), interventionists applied the assessment data obtained in phase 1, worked with the caregivers and, if possible, the person with dementia, to identify and implement 3 potential activities of interest to be implemented therapeutically. Interventionists then tailored the chosen activities to match the capabilities of the person with dementia. For example, a person with dementia who is at fall risk, would be provided a seated activity; a person with moderate dementia who can recognize colors and shapes, but not sequencing, might be provided a sorting activity.

Caregivers are provided with training about how to set up the activity and environment, how to give instructions and offer cues, and how to lower their standard of performance (relax the rules). Emphasis is placed on communication and simplification techniques to ensure a supportive environment for the person with dementia and for the conduct of the activity. Each activity is demonstrated directly to the person with dementia, and contacts are spaced to provide families the opportunity to practice and use the activities independently.

In phase 3 (generalization), interventionists continue to provide caregiver training and support by working with the caregiver, to learn how to simplify the activity in preparation for future declines, and how to generalize the strategies learned (eg, communication and task simplification) to other care challenges.<sup>17</sup>

## STUDY MEASURES

Background characteristics of dyads, including age, education, sex, and dyadic relationship (spouse or non-spouse), were mapped to describe the sample in this study. In addition, the mini mental state examination<sup>24,25</sup> was applied to describe the cognitive profile of the person with dementia. All measures used in this study with people with dementia and caregivers are widely used in clinical practice and scientific research and have been validated for use in Brazil.

## PERSON WITH DEMENTIA OUTCOMES

The primary outcome measures for the person with dementia was the Neuropsychiatric Inventory (NPI),<sup>6,26</sup> considering the number, frequency, and intensity of BPSD. NPI is based on an informant interview and assesses 12 neuropsychiatric symptoms (delusions, hallucinations, dysphoria, anxiety, agitation/aggression, euphoria, disinhibition, irritability/lability, apathy, aberrant motor activity, nighttime behavior disturbances, as well as appetite and eating abnormalities) commonly observed in dementia. The NPI consists of 3 subscales for each symptom: frequency (4-point scale), intensity (3-point scale), and caregiver distress (5-point scale). The total NPI score (frequency×intensity) and the total caregiver distress

score were calculated as the sum of the scores for each symptom. The total NPI score is the sum of the subscale scores. We also considered the number of behaviors endorsed and derived a total score reflecting the count of “yes” responses.

We used the Quality of Life Scale (Quality of life–Alzheimer’s disease-self-report)<sup>27,28</sup> to evaluate perceptions about the QOL of the person with dementia through self-report. The instrument consists of 13 items (physical health, energy, mood, living situation, memory, family, marriage, friends, you as a whole, ability to do chores, ability to do things for fun, money, and life as a whole) quantified on a 4-score scale, with score 1 classified as poor, and score 4 as excellent, where the total score ranges from 13 to 52. Scores represented mean response with higher scores indicating better QOL.

## CAREGIVER OUTCOMES

For the caregiver the primary outcome measure was the NPI Distress,<sup>6,26</sup> which was developed to provide a quantitative measure of the distress experienced by caregivers, in relation to individual symptom domains assessed by the NPI. The NPI Distress is quantified on a 5-point scale, with score 0 classified as no distress, and score 5 as extreme distress.

We used the Zarit Burden Interview<sup>29,30</sup> to evaluate the burden in caregivers. The instrument has 22 items that reflect the respondent’s areas of concern such as health, social and personal life, financial situation, emotional well-being, and interpersonal relationships. Each item is scored from 0 (never) to 4 (nearly always). The scale’s total score is obtained adding all items and may vary from 0 to 88. The greater the total score, the greater the burden.

The Quality of Life Scale (proxy report and caregivers version about their QOL)<sup>27,28</sup> was applied to evaluate the caregivers’ perceptions about the QOL of the person with dementia and their own QOL.

## DATA ANALYSES

The  $\chi^2$  and the Wilcoxon rank-sum tests were used to compare the EG and WL on demographic variables and other descriptive characteristics at baseline. Repeated measures analysis of variance (ANOVA), with time (pre-intervention vs. postintervention) as a within-subject factor and group (EG vs. WL) as a between-group factor, was conducted for each outcome measure, and we considered  $P < 0.05$  as significant. When time×group interactions reached significance, the Bonferroni post hoc tests were conducted. In addition, Cohen  $d$  effect sizes were calculated to assess treatment effects for each outcome.

## RESULTS

### Study Sample

For persons with dementia, 50% were female individuals, mean age was 81.37 ( $\pm 7.57$ ), educational level was 9.97 ( $\pm 5.32$ ) years, and the cognitive level was 17.93 ( $\pm 6.43$ ). With regard to the caregivers, 93.33% were female, the mean age was 65.97 ( $\pm 10.13$ ), and the educational level was 12.10 ( $\pm 4.44$ ) years. There was no statistical difference between the groups with regard to baseline characteristics (Table 1).

### Effects of TAP-BR on Persons With Dementia and on Caregivers

At 4 months, participants in the EG compared with those in the WL had significantly improved QOL. Caregivers reported improvement in their own QOL ( $P = 0.02$ ; Cohen

**TABLE 1.** Demographic Characteristics of Sample (Persons With Dementia and Their Caregivers)

Variables	EG (n = 15)	CG (n = 15)	P
Persons with dementia			
Age (y)	79.40 (± 7.72)	83.49 (± 7.13)	0.30
Education	11.40 (± 4.93)	8.56 (± 5.48)	0.08
Sex (% of women)	46.66	53.33	0.78
MMSE	19.0 (± 5.90)	23.82 (± 6.73)	0.10
Caregivers			
Age (y)	64.33 (± 6.76)	68.16 (± 12.61)	0.23
Education	13.87 (± 2.83)	10.33 (± 5.11)	0.03
Sex (% of women)	93.33	73.33	0.57
Relationship (%)	Spouse—46.70 Daughter—40 Sister—6.06 Husband—6.70	Spouse—26.66 Daughter—26.66 Husband—26.66 Niece—20	— 0.29 — —

EG—Tailored Activity Program—Brazilian version intervention and CG—wait-list; P-values refer to Kruskal-Wallis test for age and level of scholarship, for sex P-value refers to  $\chi^2$  test and for relationship to the Fischer test. CG indicates control group; EG, experimental group; MMSE, mini mental status examination.

$d=0.57$ ) and that of the person with dementia ( $P=0.01$ ; Cohen  $d=0.56$ ); however, no differences were found for QOL ratings by persons with dementia themselves. In BPSD, participants in the EG had significantly reduced total NPI ( $P=0.00$ ; Cohen  $d=0.95$ ), number ( $P=0.00$ ; Cohen  $d=0.93$ ), frequency ( $P=0.00$ ; Cohen  $d=1.12$ ), intensity ( $P=0.00$ ; Cohen  $d=0.77$ ) of BPSD, and caregiver distress ( $P=0.00$ ; Cohen  $d=0.87$ ).

The results (Table 2) suggested moderate effect sizes for caregivers' perception of the QOL of persons with dementia and their own QOL. Effect sizes were large for the BPSD outcomes including number, frequency, intensity, and caregiver distress with BPSD. In addition, caregiver burden scores were significantly higher in WL at 4 months.

Results from the repeated measures ANOVA, with group as a between-subject factor and time as a within-subject factor, showed significant interactions for most outcomes measures (Table 3).

With regard to the person with dementia's QOL, multiple comparisons (Table 2) indicated that it remained stable for EG, whereas it significantly declined for WL. Caregivers' own QOL improved for the EG and remained stable for WL. And caregivers' perception with regard to the persons with dementia's QOL improved for EG, whereas it declined for the WL group.

As to the NPI parameters, multiple comparisons (Table 2) indicated that frequency and intensity of BPSD decreased in the EG, whereas they remained stable in the WL. Moreover, caregivers' distress declined in the EG, whereas it remained stable for the WL. There were no significant interactions between group and time for NPI number of BPSD and the Zarit score.

Table 4 presents the results of the multiple comparisons of the variables of interest comparing the EG and CG in the baseline evaluation and in the postintervention evaluation. The results point to a difference between the EG and the CG in the postintervention evaluation; as regards the results of Table 2, we could identify positive or beneficial impact of TAP-BR on individuals with dementia and their caregivers. These results also show that, in the BPSD variables, there was a significant difference between EG and CG, and the CG presented more BPSD in comparison with EG (Fig. 1).

**TABLE 2.** Results for Outcome Measures in the Experimental and Wait-list groups in Preintervention and Postintervention Assessments in Means and SDs

Variables	Mean (SD)		P	Cohen d Effect Size
	Baseline	Posttest		
PQOL				
TAP-BR	38.47 (2.53)	38.80 (4.44)	0.36	0
CG	34.87 (6.07)	32.47 (7.56)	0.01	0.35
CPQOL				
TAP-BR	32.20 (5.37)	35.00 (4.54)	0.01	0.56
CG	29.80 (5.68)	28.40 (5.97)	0.12	0.24
CQOL				
TAP-BR	38.67 (5.64)	41.47 (4.07)	0.02	0.57
CG	36.53 (3.64)	35.73 (4.08)	0.02	0.26
NPI				
TAP-BR	23.80 (12.46)	13.20 (9.57)	< 0.001	0.95
CG	37.80 (21.90)	37.27 (20.51)	0.41	0.02
No. behaviors (NPI)				
TAP-BR	6.53 (3.96)	3.67 (1.80)	< 0.001	0.93
CG	6.53 (2.83)	6.33 (2.64)	0.34	0.07
Frequency of behaviors (NPI)				
TAP-BR	15.07 (5.84)	9.00 (4.87)	< 0.001	1.12
CG	19.40 (8.39)	18.93 (7.16)	0.34	0.06
Intensity of behaviors (NPI)				
TAP-BR	8.00 (4.31)	5.07 (3.24)	< 0.001	0.77
CG	12.13 (6.65)	11.87 (6.55)	0.37	0.04
Caregiver distress (NPI)				
TAP-BR	13.63 (9.65)	6.87 (5.15)	< 0.001	0.87
CG	20.20 (15.22)	20.20 (13.77)	0.5	0.0
Zarit Burden interview				
TAP-BR	30.33 (11.44)	30.40 (15.39)	0.5	0.30
CG	32.47 (11.55)	35.33 (13.55)	0.02	0.22

Paired samples *t* test were used to compare the groups. Cohen *d* was used to compare means in the outcomes measures.

CG indicates control group; CPQOL, proxy report about patient's quality of life; CQOL, caregivers report about own quality of life; NPI, Neuropsychiatric Inventory; PQOL, patients' report about own quality of life; TAP-BR, Tailored Activity Program—Brazilian version.

**DISCUSSION**

This study evaluated the effects of the TAP-BR on BPSD, caregiver burden, and QOL of persons with dementia and that of caregivers.

The main results show that TAP-BR had a beneficial impact, with statistical significance and moderate to large effect sizes in the BPSD outcomes, including the reduction of number, frequency, intensity, and caregiver distress with

**TABLE 3.** Results for the Repeated Measures Analysis of Variance for the Outcomes Measures

Variables	Group	Time	Interaction
PQOL	0.011	0.175	0.035
CPQOL	0.037	0.306	0.006
CQOL	0.001	0.095	0.004
NPI	0.001	0.008	0.016
Frequency of the behaviors (NPI)	0.001	0.001	0.020
Intensity of the behaviors (NPI)	0.003	0.008	0.025
No. the behaviors (NPI)	0.001	0.017	0.115
Caregiver distress (NPI)	0.010	0.014	0.002
Zarit Burden interview	0.628	0.790	0.321

CPQOL indicates proxy report about patient's quality of life; CQOL, caregivers report about own quality of life; NPI, Neuropsychiatric Inventory; PQOL, patients' report about own quality of life.

**TABLE 4.** Results of the Multiple Comparisons Between the Experimental and CG in the Outcomes Measures

Variables	Groups			Difference	P	Confidence Interval	
PQOL	TAP-BR	CG	(Baseline)	-3.53	0.085	-7.57	0.51
	TAP-BR	CG	(Posttest)	-6.46	0.002	-10.51	-2.43
CPQOL	TAP-BR	CG	(Baseline)	-1.73	0.390	-5.74	2.28
	TAP-BR	CG	(Posttest)	-6.13	0.003	-10.14	-2.12
CQOL	TAP-BR	CG	(Baseline)	-2.53	0.087	-5.45	0.38
	TAP-BR	CG	(Posttest)	-6.26	0.001	-9.18	-3.34
NPI	TAP-BR	CG	(Baseline)	14.33	0.024	1.97	26.69
	TAP-BR	CG	(Posttest)	24.53	0.001	12.17	36.89
Frequency of the behaviors (NPI)	TAP-BR	CG	(Baseline)	4.86	0.053	-0.08	9.81
	TAP-BR	CG	(Posttest)	10.86	0.001	5.92	15.81
Intensity of behaviors (NPI)	TAP-BR	CG	(Baseline)	4.33	0.031	0.41	8.25
	TAP-BR	CG	(Posttest)	7.20	0.001	3.28	11.12
Caregiver distress (NPI)	TAP-BR	CG	(Baseline)	6.02	0.141	-2.07	14.12
	TAP-BR	CG	(Posttest)	14.26	0.001	6.22	22.31
No. the behaviors	TAP-BR	CG	(Posttest)	-14.30	0.001	-18.40	-10.26

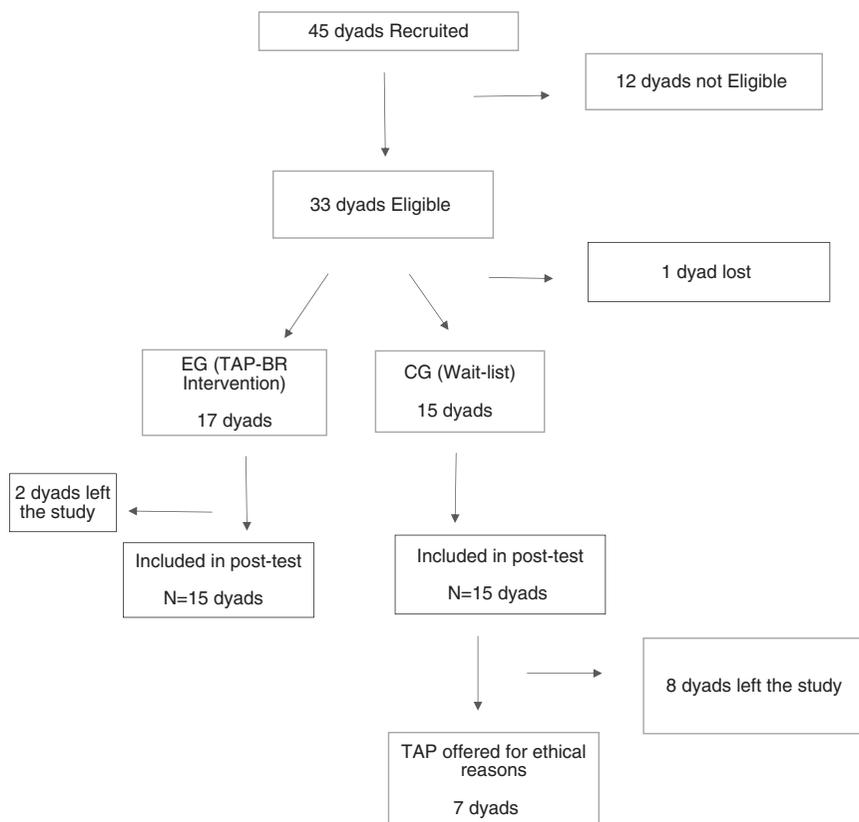
Bonferroni post hoc tests were used in these multivariate comparisons between the groups.

CG indicates control group; CPQOL, proxy report about patient’s quality of life; CQOL, caregivers report about own quality of life; NPI, Neuropsychiatric Inventory; PQOL, patients’ report about own quality of life; TAP-BR, Tailored Activity Program—Brazilian version.

BPSD, after 4 months of intervention. Another beneficial impact of TAP-BR was the improvement, as reported by caregivers, in both their own QOL and that of the person with dementia, except perceived QOL improvements by persons with dementia themselves.

Moreover, the WL group reported an increase in the number, frequency, and intensity of the BPSD and in caregivers’

distress, and a worsening of the caregivers’ perception about the QOL of the person with dementia and about their own QOL. Thus, at 4 months, we showed improvements in these outcomes for the EG group and worse scores in the WL group. These results suggest that the TAP-BR is a powerful program that may prevent new behavioral occurrences, reduce the frequency and intensity of behavioral problems, and improve QOL.



**FIGURE 1.** Consort flow chart of subject recruitment and attrition. CG indicates control group; EG, experimental group; TAP-BR, Tailored Activity Program—Brazilian version.

Comparing the results of this study with the original trial<sup>16</sup> in relation to demographic variables, we can identify similarities in the age of the persons with dementia and that of their caregivers, and the higher percentage of male individuals in the current sample. We also report similar outcomes in behavioral symptoms to the findings in the original TAP study.<sup>16</sup> In addition, this pilot trial extends the results of the original study by showing significant effects for caregiver distress related to BPSD and improved perceived QOL for caregivers and the person with dementia in other cultures (cross-validation). Moreover, the effect sizes reported in this study were higher than those in the original study.

Most importantly, this study extended the outcome measures to include the frequency and intensity of BPSD separately and caregivers' distress related to these symptoms. Such aspects had not been investigated previously and represent an original contribution.

Interestingly, the TAP-BR had a positive impact on the caregivers' distress, but did not reach reduction of care burden overall in EG. One explanation may be that the training and support provided to the caregiver in TAP-BR promote a better understanding of the disease and readiness to implement strategies, and thus may not affect perceived burden in the same way as perceived distress.

BPSD have been associated with worse disease progression in dementia, added considerable burden to caregivers, and increased care costs. Considering that the Alzheimer's Association<sup>2</sup> indicated that reducing disease burden on families stands as a critical public health priority, it is extremely important to establish the effectiveness of programs that provide structured problem-solving and tailored in-home care.

The implementation of tailored activity protocols has shown positive results in previous studies.<sup>13–15</sup> The present results lend further support to the notion that the TAP-BR can be an effective nonpharmacological treatment resource that can be deployed, as a standard procedure, in the care for persons with dementia and their family caregivers.

It should be noted that the TAP program, and consequently the TAP-BR, involves a shift in standard treatment protocols, as it assumes a dyadic approach, as both the person with dementia and the caregiver are the focus of the intervention. Caregivers are not only critical to the continued delivery of meaningful activities, but they also learn ways to manage their own distress, the capabilities of the person they care for, and that behavioral symptoms are part of dementia progression, but that they can be prevented and managed.

It is important to consider that in Brazil, there are no studies to date that have evaluated the efficacy of nonpharmacological treatments, involving occupational therapy or other health professionals. This study fills this gap and offers evidence to support nonpharmacological treatment for dementia care.

The primary study limitation is the small sample. In addition, caregivers who participated had high levels of education, which do not reflect the Brazilian demographic characteristics, and this may limit the possibility to generalize current findings to other regions of Brazil.

The method is under study and the next steps involve conducting a research with caregivers at lower educational levels and comparing TAP-BR with other interventions to identify whether improvement is attributed to the activity.

## CONCLUSIONS

The results of this randomized controlled study are very promising and provide compelling evidence that the TAP-BR is an effective strategy to support dementia caregivers in other cultures (cross-validation). The beneficial effects of the TAP program suggest that its implementation as standard dementia care in the public health system network can be considered.

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