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RESEARCH ARTICLE

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An intervention to reduce neuropsychiatric symptoms and caregiver burden in dementia: Preliminary results from a randomized trial of the tailored activity program–outpatient version

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Objective: To evaluate the efficacy of the tailored activity program–outpatient version (TAP-O) and to reduce neuropsychiatric symptoms (NPS) in patients with dementia and caregiver burden compared with a control group (psychoeducation intervention).

Methods: Twenty-one persons with dementia and their caregivers were recruited and randomized. The intervention group received TAP-O, designed for outpatients with dementia and their caregivers. TAP-O consisted of eight sessions in which an occupational therapist assessed the patient's abilities and interests; prescribed tailored activities; and educated caregivers about dementia, NPS, and how to implement meaningful activities in the daily routine. The control group received eight sessions of a psychoeducation intervention about dementia and NPS.

Results: Compared with controls, patients receiving TAP-O had a significant decrease in hallucination ($P = 0.04$), agitation ($P = 0.03$), anxiety ($P = 0.02$), aggression ($P = 0.01$), sleep disorder ($P = 0.02$), aberrant motor behavior ($P = 0.02$), and in caregiver burden ($P = 0.003$).

Conclusions: Findings suggest that TAP-O may be an effective nonpharmacological strategy to reduce NPS of outpatients with dementia and to minimize caregiver burden.

KEYWORDS

caregiver burden, dementia, family caregiving, neuropsychiatric behaviors, nonpharmacologic intervention, occupational therapy

1 | INTRODUCTION

Although dementia is generally characterized by progressive cognitive and functional impairment, a key clinical feature is neuropsychiatric symptoms (NPSs).[1] These symptoms are heterogeneous and may include agitation, shadowing, aggressiveness, apathy, sleep disorders, resistance to perform daily activities, delusions, hallucinations, and appetite changes.[1-3] Neuropsychiatric symptoms affect up to 90% of all persons living with dementia over the course of their illness and, if untreated, may worsen cognitive and daily functioning, accelerate long-term hospitalization, and increase health care costs.[4,5] For caregivers, the presence of NPS is related to increased

distress, depression, poor quality of life, and increased time of caregiving.[2,5,6]

Pharmacological interventions are frequently used to manage NPS, however, they can lead to adverse effects, exacerbation of behaviors, or even increase mortality rates.[7,8] For these reasons, some studies have recommended non-pharmacological approaches as the initial first-line treatment, including caregiver supportive interventions.[9-14] Nonpharmacological treatments pose fewer side effects, which render them as safer options than pharmacological interventions. Music therapy, aromatherapy, art therapy, behavioral therapy, reality orientation, tailored activities, and physical exercises have shown promising results for the management of NPS.[15]

According to Gitlin et al,[16] a promising nonpharmacological treatment is the intentional use of activities that are tailored to the interests and abilities of persons living with dementia. Evidence suggests that individuals with dementia can effectively engage in activities when these activities are adapted to meet the individual's abilities.[17,18] Gitlin et al[5,16,19,20] developed and tested the tailored activity program (TAP), a home-based intervention delivered by occupational therapists. In this program, occupational therapists identify interests, roles, and capabilities of persons with dementia and adapt the proposed activities according to their cognitive and functional conditions. These activities are prescribed to families who are instructed in how to integrate them in daily care routines. Using an activity prescription, TAP provides strategies in four specific areas: setting up the environment, simplifying the activity, enhancing participation, and simplifying communication. In a pilot study of 60 dyads (persons with dementia and their caregivers), reductions in the overall incidence of NPS and specific behaviors such as shadowing, agitation, argumentation, and repetitive questioning were reported. In a Brazilian study of the TAP home-based intervention, Novelli et al[21] demonstrated that after 4 months of implementation, individuals with dementia had a reduced frequency and intensity of behaviors; caregivers showed reduced distress and improved quality of life. There are no studies testing TAP in an outpatient setting with patients undergoing treatment for dementia; thus, this study aims to investigate the effectiveness of the TAP intervention adapted for an outpatient memory clinic (tailored activity program–outpatient version [TAP-O]) on reducing NPS and caregiver burden in patients with dementia.

Key points

- This is a clinical trial to evaluate the effects of activities program in reducing NPS in persons with dementia.
- TAP is a safe nonpharmacological approach that provides caregivers with specific techniques to manage NPS.
- TAP is directed at both person with dementia and the caregiver in contrast to prescriptive or didactic treatments focused on a "patient."
- TAP provides caregivers with information concerning what the person with dementia can and cannot do; in general, caregivers overestimate the abilities of persons with dementia and have a poor understanding of how dementia impacts behaviors.

2 | METHOD

2.1 | Study design

This was a randomized controlled, double-blind pilot study comparing TAP-O with a psychoeducation intervention, both involving eight sessions. All sessions were performed at an outpatient clinic located in a tertiary university hospital. This study was approved by the Institutional Review Board of the university (number 12 346), and written informed consent was received from a caregiver or relative for all patients. This trial was registered in the Brazilian Clinical Trials Registry (ReBec), number RBR-66DH44.

2.2 | Participants

Patients and their caregivers were recruited from community medical centers through media advertising in São Paulo (Brazil), between August 2015 and June 2016. The following eligibility criteria were required for patient enrollment: (1) diagnosis of dementia performed by a physician diagnosis; (2) Mini-Mental State Examination[22] score < 24; (3) caregiver present for at least 4 hours per day; (4) presence of at least three types of NPS, identified by a questionnaire at time of first contact; and (5) if taking psychotropic medications (antidepressants, benzodiazepines, antipsychotics, or anticonvulsants) or antidementia medication (memantine or cholinesterase inhibitors), on a stable dose for 60 days prior to enrollment to minimize confounding effects of medications on NPS. Exclusion criteria were

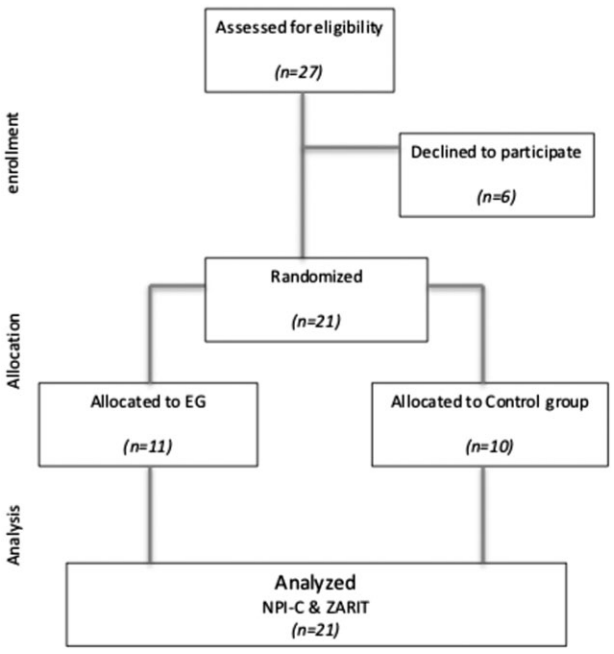

FIGURE 1 Consort diagram showing the flow of participants through each stage of the trial

diagnosis of schizophrenia, bipolar disorder, or dementia secondary to head trauma and being bed-bound (confined to bed or chair) or nonresponsive (unable to understand short commands). Figure 1 depicts the CONSORT diagram of the study.[23]

2.3 | Procedures

Patients attended eight sessions over a 3-month period (one session per week). At baseline and at the endpoint of the study period, a psychiatrist and two occupational therapists administered the outcome measures. The participants were randomly assigned to one of two groups: experimental group (EG: TAP) or control group (CG: psychoeducation). They were randomized using the randomly permuted blocks method (available at http://www.randomization.com). The person responsible for the randomization had no contact with the patients. Participants and the psychiatrist and occupational therapists administering the outcomes measures were blinded to the assigned interventions.

2.4 | Intervention

2.4.1 | Tailored activity program–outpatient version

The TAP-O was adapted from the TAP in-home version with the authorization of Laura N. Gitlin, PhD. Few modifications to the protocol were required for implementation in an outpatient setting. The intervention protocol and written materials were translated from English to Brazilian Portuguese, then back translated into English. This version was submitted for analysis by an experienced occupational therapist from the original TAP developer team. Finally, we retranslated TAP-O into Brazilian Portuguese. There were two modifications made to the original TAP: the context in which the intervention was delivered and the resource book provided to caregivers. TAP-O sessions occurred at the hospital and a Brazilian book, *You're not Alone*, provided by the Brazilian Association of Alzheimer's and used in the TAP-Brazilian in-home version[21] replaced the *36 Hour Day* (Mace & Rabins, 2012). Table 1 details these modifications. Consistent with the TAP in-home version, the TAP-O is delivered by an occupational therapist and consists of eight face-to-face contacts that average 1 hour.

TAP-O involves three phases: (1) assessment of patients to identify cognitive and functional capacities (attention, ability to follow instructions, problem solving, and ability to learn) and characterize their previous abilities, interests, and roles; in addition, caregivers receive education about dementia symptoms and how to manage NPS and learn stress reduction techniques; (2) implementation of three activity prescriptions, which provide strategies to simplify communication and adapt activities based on the patient's cognitive and functional profile that promote engagement[5,8]; caregivers are instructed in how to use the activities at home; (3) generalization of techniques (eg, cueing and other communication strategies) to daily activities, such as self-care, and methods for simplifying activities as the disease progresses. For this study, three Brazilian occupational therapists received 30 hours of training in the TAP protocol (provided by Laura N. Gitlin, PhD, and her team at Johns Hopkins University, United States).

2.5 | Control group

Participants in the control group received regular care and participated in psychoeducation group sessions, which lead by trained occupational therapists over eight sessions in the outpatient clinic. Similarly to the TAP-O group, in the first session, printed material was provided to the caregiver with information about dementia, activities, and communication. The content of subsequent sessions was based on caregiver concerns and included education and sharing of personal experiences.

2.6 | Outcome measures

2.6.1 | NPSs in person with dementia

The Brazilian version of the neuropsychiatric inventory-clinician rating scale (NPI-C)[24,25] is a comprehensive tool, which provides an accurate measurement of NPS with high concurrent validity and interrater reliability in the Brazilian setting.[25] The NPI-C consists of 14

TABLE 1 Material used by original TAP (home version) X material used by TAP (Brazilian outpatient version)

Original TAP	TAP-O Brazilian Version	Function
TAP intervention manual	TAP-O intervention manual	Information about the method and procedures for the interventionist
Documentation binder—TAP	documentation binder—TAP-O	To register each session including assessments information
Allen cognitive level assessment battery manual	Allen cognitive level assessment battery manual	Instructions about cognitive assessments included in the TAP: Allen cognitive battery
Caregiver guide using activities and other strategies to prevent, reduce and manage behavioral symptoms (authorship: Laura Gitlin E Catherine Piersol)—Livro com 8 capítulos	Caregiver guide (translation of Chapters 1, 2, 3 and 5)	Instructions about: use of activities in the routine, communication strategies, management of the behavior symptoms, home safe, and caregiver burden.
Activity prescription template	Activity prescription template	Used to prescribe activities in the TAP context. This prescription is delivered to the caregiver with instructions about activities considering the patient's environment and the material necessary to the activity
Book "36 hours a day" (Alzheimer Association).	Book *You're not alone* (Brazilian Association of Alzheimer)	Used to provide instructions about dementia and daily care of people with dementia

Abbreviations: TAP, tailored activity program; TAP-O, tailored activity program–outpatient version.

psychopathological domains: delusions, hallucinations, agitation, aggression, depression/dysphoria, anxiety, elation/euphoria, apathy/indifference, disinhibition, irritability/lability, aberrant motor behavior, sleep disorders, appetite and eating disorders, and aberrant vocalizations. The sum of severity ratings across the existent behaviors was calculated.

2.6.2 | Caregiver burden

The Brazilian version of the Zarit burden scale[26,27] comprises 22 items with a 5-point Likert scale from 0 (never) to 4 (nearly always). The items refer to caregiver-patient relationship and caregiver health condition, psychological well-being, finances, and social life. The total score across the items was calculated with higher scores indicating greater burden.[27]

2.7 | Statistical analysis

Normality of distribution for each variable was computed using the Kolmogorov-Smirnov test. Intergroup comparisons were performed through Student *t* test or Mann-Whitney (U) test, depending on normal or non-normal distribution of the variable, respectively. Results were considered significant for a $P < 0.05$. ANOVA with repeated measures was used to analyze the effect of time (*t*0 and *t*1), group (experiential and control), and the interaction between the two factors. Generalized linear model was used for each NPS as dependent variables and two categorical independent variables: time and group. The main hypothesis was considered valid if time × group interaction was statistically significant. Intergroup comparisons for predata and postdata were performed using Student *t* test for parametric data and Wilcoxon test for nonparametric data, with Bonferroni correction.

3 | RESULTS

Table 2 displays the demographic and clinical characteristics of the sample at baseline. This sample comprises 21 patients with dementia and their respective caregivers. Patients with dementia had a mean age of 78.7 years and were predominantly female (71.4%), were undereducated (61.9% with <8 years of formal education), and had moderate dementia (mean mini–mental state examination [MMSE] score of 15.3). Caregivers were predominantly composed of middle-aged, older (mean age 58.7 years), female (76.2%), and most were a relative of the patient with dementia (71.4%). There were no statistically significant differences between the intervention and control groups in patient

TABLE 2 Demographic and clinical characteristics of the control group (n = 10), TAP-O (experimental group) (n = 11), and total sample (N = 21) at baseline

Characteristics	Control Group (n = 10)	TAP-O (n = 11)	Total Sample (n = 21)	*P* Value
Persons with dementia				**0.82**
Age (years), mean (s.d.); [range]	**78.40 (6.24) [68-89]**	**79.00 (5.71) [70-91]**	**79.00 (5.71) [70-91]**	
Gender, n (%)				0.16
Male	5 (50%)	1 (1%)	6 (28.6%)	
Female	5 (50%)	10 (90%)	15 (71.4%)	
Marital status, n (%)				0.04
Married	6 (60%)	2 (18.2%)	8 (38.1%)	
Widower	3 (30%)	9 (81.8%)	12 (57.1%)	
Divorced	1 (10%)	0 (0%)	1 (4.8%)	
Schooling, n (%)				0.21
Until 8 years	8 (80%)	5 (45.5%)	13 (61.9%)	
More than 8 years	2 (20%)	6 (54.5%)	8 (38.1%)	
Type of dementia, n (%)				0.94
AD	9 (90%)	10 (91%)	19 (90.5%)	
Others	1 (10%)	1 (9%)	2 (9.5%)	
				0.03
MMSE, mean (s.d.); [range]	16.90 (3.10) [10-20]	13.82 (2.90) [10-18]	15.30 (3.30) [10-20]	
Number of NPS, (s.d.); [range]	7.90 (2.02) [6-12]	7.73 (2.45) [4-12]	7.81 (2.20) [4-12]	0.86
Caregivers				
Age, mean (s.d.)	60.7 (16.4)	56.8 915.0)	58.7 (15.4)	0.58
Gender, n (%)				
Male	1(10%)	4 (36.4%)	5 (23.8%)	0.16
Female	9 (90%)	7 (63.6%)	16 (76.2%)	
Relation to person with dementia, n (%),				0.05
Relative	9 (90%)	6 (54.5%)	15 (71.4%)	
Nonrelative	1 (10%)	5 (45.5%)	6 (28.6%)	
MMSE, mean (s.d.); [range]	27.4 (3.8)	26.2 (3.4)	26.8 (3.5)	0.32

Abbreviations: AD: Alzheimer disease; MMSE: mini mental state exam; NPS: neuropsychiatric symptoms; TAP-O, tailored activity program–outpatient version. Experimental group: group receiving tailored activity program intervention; control group: group receiving psychoeducational intervention.

TABLE 3 Severity of neuropsychiatric symptoms measured by NPI-C and caregiver burden in CG and TAP-O (experimental group) in t_0 (baseline) and t_1 post-intervention

Test	Symptoms (NPI-C Subtests)	Group	t_0 (Mean; d.p.)	t_1 (Mean; d.p.)	t_1–t_0	*P* Value*
NPI-C	Delusions	TAP-O	4.10 (4.97)	3.30 (5.30)	−0.80	0.62
		CG	1.10 (1.60)	1.60 (2.22)	0.50	0.32
	Hallucinations	TAP-O	3.55 (3.01)	2.30 (2.93)	−1.25	0.04
		CG	0.60 (0.84)	1.30 (1.57)	0.70	0.10
	Agitation	TAP-O	14.73 (6.71)	9.73 (6.10)	−5.00	0.03
		CG	7.10 (6.19)	9.00 (7.46)	1.90	0.10
	Aggression	TAP-O	5.82 (4.02)	2.55 (2.62)	−3.27	0.01
		CG	1.20 (2.25)	2.60 (3.30)	1.4	0.04
	Depression	TAP-O	9.91 (4.70)	6.18 (4.33)	−3.73	0.06
		CG	7.80 (5.70)	9.50 (5.66)	1.7	0.11
	Anxiety	TAP-O	11.55 (5.60)	7.36 (6.08)	−4.19	0.02
		CG	6.70 (7.10)	8.10 (7.92)	1.4	0.34
	Euphoria	TAP-O	2.55 (1.80)	1.82 (1.94)	0.73	0.07
		CG	0.40 (1.26)	1.30 (2.40)	0.90	0.18
	Apathy	TAP-O	20.82 (8.38)	18.18 (10.81)	−2.64	0.38
		CG	18.30 (9.70)	21.40 (9.28)	3.1	0.12
	Disinhibition	TAP-O	8.91 (5.92)	7.00 (5.70)	−1.91	0.29
		CG	3.60 (4.81)	6.10 (6.21)	2.5	0.11
	Irritability	TAP-O	11.0 (8.28)	7.10 (5.03)	−3.90	0.08
		CG	6.30 (6.71)	10.50 (9.85)	4.20	0.06
	Aberrant motor behavior	TAP-O	7.45 (7.70)	4.30 (4.10)	−3.15	0.02
		GC	6.30 (5.41)	5.90 (5.80)	−0.40	1.00
	Sleep disorder	TAP-O	9.45 (6.05)	5.36 (5.26)	−4.09	0.02
		GC	5.40 (5.91)	6.90 (7.40)	1.5	0.10
	Appetite disorder	TAP-O	4.55 (3.78)	4.64 (2.91)	0.09	0.60
		GC	2.50 (2.76)	2.80 (2.66)	0.30	0.18
	Vocalizations aberrant	TAP-O	2.10 (2.70)	1.20 (1.54)	−0.90	0.14
		GC	0.60 (1.26)	1.00 (1.63)	0.40	0.31
	Zarit scale	TAP-O	32.45 (16.76)	22.73 (12.03)	−9.72	0.003
		GC	20.40 (12.00)	21.90 (12.55)	1.50	0.10

Abbreviations: CG: control group; NPI-C, neuropsychiatric inventory-clinician rating scale; TAP-O, experimental group.

and caregiver gender, education, and age and type of dementia and NPS in the patient. There was a significant difference (P = 0.003) between groups in the MMSE score (experiential < control).

Table 3 shows that there were statistically significant differences between the two groups in the presence of agitation (P = 0.03), hallucinations (P = 0.04), anxiety (P = 0.02), aggression (P = 0.01), sleep disorder (P = 0.02), and aberrant motor behavior (P = 0.02), favoring those who received the intervention. Caregiver burden was significantly lower in the experiential group (P = 0.003) compared with the control group at 3 months.

4 | DISCUSSION

To the best of our knowledge, this is the first clinical trial comparing the outpatient version of the TAP-O with a psychoeducational intervention to reduce NPS in persons with dementia and lesson caregiver burden. This preliminary study replicates in part previous studies testing the TAP in-home version[5,18,20,28] and nonpharmacological interventions in reducing hallucinations,[29] agitation,[30-32] anxiety,[30] and motor disturbance.[33] Brodaty and Burns[34] report there are NPS that are more responsive to nonpharmacological interventions when compared with hallucinations and delusions. It seems that NPSs such as apathy, agitation, depression, sleeping disorders, and irritability are more susceptible to nonpharmacological interventions.[8,19] Our findings show the tailored activities had a similar impact on hallucinations and other NPS.

Conceptual models suggest the presence of NPS is a consequence of heightened vulnerabilities to physical and social environments due to neurodegenerative processes.[5,20] The tailored activities may minimize these vulnerabilities and help persons with dementia remain physically active and meaningfully engaged, providing a better quality of life.[5,20,35]

There are a number of limitations to this study. First, the sample size was small; however, it is important to highlight that this is an ongoing study and final results with a larger sample will be analyzed. Second, the procedure for confirming the patient had dementia was based on medical reports and the MMSE score; a complete medical and functional assessment was not performed. However, Creavin et al[36] report the MMSE is often used to establish the presence of dementia, along with medical documentation and caregiver report. It is worth mentioning that the inclusion of patients with MMSE scores below 24 and with at least three NPS supports the sample profile.

A third limitation relates to the possible influence of psychotropic drugs. All patients randomized in the study were taking at least one psychotropic medication. During the study, no alterations in patient prescriptions or doses were noted; therefore, we assumed that the use of psychotropic medications did not influence our results.

The difference between experimental and control groups is a fourth limitation that must be considered. Although the patients were randomly assigned to one group, the experiential group had significantly lower scores on the MMSE (Table 2), and higher NPI-C scores at baseline compared with the control group (Table 3). These preliminary results suggest that the TAP-O intervention may have a positive impact on NPS even in persons with severe dementia. The premise of the TAP-O, as the TAP-home version, is to engage the person in activities independently of the severity of cognitive impairment.[20] The TAP-O intervention is tailored to the cognitive level, and

all activities are prescribed according to preserved capabilities and lifelong roles/interests of persons with dementia.[5,20]

Finally, we observed a worsening in NPS in the control group after 3 months. According to some longitudinal studies, this pattern is expected.[37-39] However, this finding may be related to improved caregiver understanding of NPS. Depending on cultural background, caregivers may not understand the symptoms of dementia. According to Stella et al,[25] apathy and depression may be considered "normal" characteristics of aging by society. Additionally, caregivers may assume NPS are "purposeful," reflecting negative intentions towards the caregivers.[5] Thus, it is possible that caregivers understand why and how NPS manifest after psychoeducational intervention. It is interesting to note that in spite of patients presenting worse NPI scores after intervention, the level of caregiver burden was maintained in the control group. It may be that patients in this group were not actually worse, but their caregivers were able to recognize the NPS more accurately than in the baseline assessment.

5 | CONCLUSIONS

We presented the preliminary results of an ongoing randomized, double-blind, clinical trial, testing the outpatient version of an occupational therapy intervention (TAP intervention) for patients with dementia and their caregivers to reduce NPS and caregiver burden. The results are encouraging and point towards several potential benefits of this nonpharmacological intervention. This study contributes to the growing body of evidence reinforcing the effectiveness and benefits of occupational therapy in the multidisciplinary management of vulnerable persons with dementia and their caregivers. The TAP-O seems to be an effective nonpharmacological intervention to reduce the presence of NPS in persons with dementia and decrease burden for caregivers. We acknowledge that this preliminary set of data must be confirmed by the analysis of the final sample of this study and by the replication of the present intervention in larger samples in future trials.

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CONFLICT OF INTEREST

None declared.

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