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RESEARCH ARTICLE

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Cognitive stimulation therapy for people with dementia in Brazil (CST-Brasil): Results from a single blind randomized controlled trial

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Abstract

Objective: The prevalence of dementia has been increasing particularly in developing countries but care provision is still limited in these regions. Psychosocial interventions are recognized as useful tools to improve cognitive and behavioral difficulties, as well as quality of life of people with dementia (PwD) and their caregivers. Cognitive stimulation therapy (CST) is an evidence-based psychosocial intervention, recommended and implemented in many countries. In Brazil, there is no validated psychosocial intervention for dementia care. The present study aims to explore feasibility and obtain preliminary data on the efficacy of CST-Brasil in a sample of 47 people with mild to moderate dementia attending an outpatient unit.

Methods: A single-blind design was used, with participants being randomly allocated to either 14 sessions of CST + treatment as usual (TAU; $n = 23$) or TAU ($n = 24$) during 7 weeks. Changes in cognition, quality of life, depressive symptoms, caregiver burden and functionality were measured.

Results: PwD receiving CST and their family caregivers expressed good acceptance of the intervention, with low attrition and high attendance. Participants receiving CST exhibited significant improvements in mood and in activities of daily living compared to TAU. There were no significant effects in cognition, quality of life and caregiver burden.

Conclusions: CST-Brasil proved to be a feasible and useful intervention to improve mood in PwD, with high acceptance between study participators. CST-Brasil is a promising psychosocial intervention for dementia and should be explored in other clinical settings to allow generalization to a wider Brazilian context.

KEYWORDS

cognitive stimulation, CST, dementia, psychosocial intervention

1 | INTRODUCTION

Dementia currently affects 50 million people worldwide, and this number is expected to have an almost threefold increase by 2050, following increases in life expectancy.[1] It is estimated that 57.7% of all people with dementia (PwD) live in low- and middle-income countries, where the increase in incidence will be more significant.[2] In Brazil, it is estimated that 1.6 million people live with dementia.[3,4]

Brazil needs to improve public awareness of dementia, the quality of care, and quality of life (QoL) for PwD and their families.[5] Government efforts up to now have been mainly directed to improve diagnosis and proper use of antidementia drugs under national guidelines provided by the Ministry of Health.[6] However, non-pharmacological interventions may also play a role in the treatment of Alzheimer's disease (AD) and other dementias.[7] These interventions encompass various methodologies, such physical activities, occupational therapy, psychological therapy and cognitive intervention.[8] The importance of non-pharmacological interventions is well supported by the literature, with studies suggesting the use of this approach to manage behavioral and psychological symptoms of dementia, as well as to improve cognition in PwD.[7,9]

Cognitive stimulation therapy (CST) is an evidence-based psychosocial intervention, recommended by UK National Institute for Health and Care Excellence (NICE) guidelines,[10] and endorsed by Alzheimer's Disease International.[11] CST aims to mentally stimulate PwD through psychological techniques (e.g., implicit learning and multisensory stimulation) during a 14-session group intervention.[12] It has been translated and validated in different cultures and languages, being used in over 29 countries. Benefits were demonstrated by evidence-based studies and meta-analysis both in cognition and QoL for PwD in the mild to moderate stages.[13] Additionally, evidence suggests that CST is a cost-effective intervention, being more cost-effective than usual care when looking at benefits in cognition and QoL.[14]

Considering the above, there is a case for urgent social and clinical need to validate interventions for PwD in developing regions. Indeed, non-pharmacological treatment options are not offered routinely in developing countries[11] and little is known about their effectiveness in these regions.[15] There is limited data regarding CST efficacy in low- and middle-income countries[16] and the current study may add valuable information for future development in this field. Moreover, to our knowledge, the present study is the first one in Latin America in a middle-income country.

To facilitate CST implementation in other cultures, adaptation guidelines have been developed[17] with an approach involving stakeholders in the cultural adaptation process. A previous report by our group has described steps used for translating CST materials, also examining implementation issues and cultural adaptation.[18] The results indicate that CST is appropriate for the Brazilian population, with some minor amendment needed to address cultural issues (e.g., faces of famous Brazilian people or typical Brazilian foods). Following Aguirre and colleagues' guidelines,[17] the current study explores the efficacy of the Brazilian version of CST (CST-Brasil) for people with mild to moderate dementia using a single-blind randomized controlled clinical trial design.

Key points

- Cognitive stimulation therapy (CST)-Brasil has been well accepted by people with dementia (PwD) and their family caregivers
- CST-Brasil has improved functional capacity and level of depression of PwD
- There is limited data regarding CST efficacy in low- and middle-income countries
- Cognitive stimulation therapy is an applicable therapy in PwD in the Brazilian context

2 | METHODOLOGY

2.1 | Participants

An initial sample of 52 outpatient participants currently attending the center for Alzheimer's disease of the Federal University of Rio de Janeiro (CDA-UFRJ) was recruited based on inclusion and exclusion criteria similar to previous CST studies.[12] Inclusion criteria were: clinical diagnosis of dementia according to DSM-IV criteria[19]; Mini-Mental State Examination (MMSE) scores between 10 and 24 (mild to moderate dementia).[20] Exclusion criteria were: presence of any communication, sensorial or physical disability that could affect their participation in CST. There was no a priori sample size calculation, with the current study providing effect sizes for a future definitive randomized controlled trial (RCT).

After participants and caregivers provided informed consent, individuals were consecutively allocated into groups (treatment as usual [TAU] or CST + TAU [CST]) using a random list generated by a computer program and after stratification for dementia severity (Clinical Dementia Rating[21] scores). The nature of the intervention prevented blinding participants to the group to which they were allocated. Nevertheless, outcome assessment and data analysis were conducted by researchers (Elodie Bertrand and Daniel C. Mograbi, respectively) blind to the intervention and without direct contact with the outpatient clinic.

2.2 | Treatment conditions

2.2.1 | Cognitive stimulation therapy

The CST program has been described elsewhere,[12] with the intervention in the current study being implemented according to the translated and adapted procedures described by Bertrand and colleagues.[18] For the treatment group, the program was conducted by

three researchers (Valeska Marinho, Iris Bomilcar and Renata Naylor), in groups with between five and eight participants. The intervention was conducted over 7 weeks, twice a week, completing a total of 14 sessions. All sessions began with the group song, followed by a warm up exercise and a main activity based on that week's theme (e.g., foods, childhood, numbers, and orientation). Sessions were tailored to the groups' abilities and to be as inclusive as possible and activities. To facilitate attendance and reduce transportation costs and barriers, the two weekly sessions were run on the same day, separated by a short break. Each session took roughly 45 min.

2.2.2 | Treatment as usual

TAU comprised regular visits every 2/3 months to a geriatric psychiatrist and cholinesterase inhibitors prescription (AChEI). All patients received AChEI and no changes in prescription were allowed for both groups during the study.

As part of the TAU, participants of the both CST and TAU groups continue to engage in activities offered at the recruitment site (CDA-UFRJ). This could include occupational therapy, physical activities and psychotherapy therapy.

2.3 | Instruments

Participants were assessed at baseline (a week before) and follow-up (a week after) the intervention. Primary and secondary endpoints were evaluated by a researcher blind to the intervention (Elodie Bertrand), without direct contact with the outpatient clinic. For all instruments, validated Brazilian versions were used. The assessment took place on dates and rooms independent from those were the intervention occurred.

2.3.1 | Primary outcome

Consistent with the UK trials, the primary outcome was cognition, assessed by the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-Cog).[22] The ADAS-Cog uses 11 tasks to evaluate cognitive domains such as memory, language, praxis and command understanding, with higher scores indicating lower performance. It is often used in clinical trials as a primary instrument to monitor response to treatment, allowing the direct comparison of CST-related improvement with other interventions.

2.3.2 | Secondary outcomes

Depression

Given the prevalence of mood disorder in PwD, and its potential impact on prognosis, the Cornell Scale for depression in dementia (CSDD)[23] was used to measure depressive symptomatology. This is a 19-item interview evaluating current mood based on observed symptoms and signs occurring the week before interview, corroborated by an informant. Higher scores indicate higher depressive symptomatology.

Activities of daily living

Considering the importance of measuring whether improvements from cognitive stimulation programs are transferred to everyday life, an outcome measuring activities of daily living (ADL) was included. The ADCS-ADL scale was used to measure the competence of PwD in basic and instrumental ADLs. The scale has 24 items, with informants selecting the most appropriate option regarding the person's level of ability.[24] Higher scores indicate more preserved ADL.

Quality of life

Consistent with the UK trials, quality of live was included as a secondary outcome. It was measured with the QoL in Alzheimer's Disease Scale (QoL-AD).[25] The QoL-AD is a 13-item questionnaire covering areas such as physical health, energy, social relationships, and enjoyment of life, with higher scores suggesting better QoL in PwD. Both the self- and informant-report versions were used.

Caregiver burden

Given the impact of burden on the caregiving relationship, an outcome measuring that was included. The Zarit Burden Interview[26] is a 22-item instrument assessing caregiver burden. Items encompass aspects such as physical health, social and personal life, financial situation, emotional well-being and interpersonal relationships. Higher scores indicate increased burden.

2.4 | Statistical analysis

Sociodemographic and clinical (CDR) characteristics were compared between groups with independent samples *t*-tests or chi-square tests according to the variable characteristics (continuous or binary respectively). To explore differences between groups in the primary and secondary outcomes 2 × 2 mixed-design ANOVAs, with group as a between-subjects factor (CST or TAU) and time as a within-subjects factor (pre- and post-intervention), were calculated. For this main analysis, participants who did not have informants, dropped out of the study or did not complete at least half of the CST program (seven sessions) were excluded. In addition to the main analysis, an intention-to-treat analysis, including participants excluded based on low adherence and missing data, was conducted for all outcomes, following the established guidelines for that.[27]

To explore the potential impact of educational level and dementia severity, complementary analyses were conducted, with different models including each of these variables as a between-subjects factor. For educational level, the median (8 years of formal education) was used to split the sample into two. For these analysis, focus was given to effect sizes, considering the reduced statistical power after splitting the sample, and to interactions including these factors.

For all analyses, α was set at 0.05. SPSS v.24 (International Business Machines Corporation [IBM], 2016) was used for all analyses.

2.5 | Ethics

The study was approved by a local research ethics committee (CAAE: 57019616.5.0000.5263) and all patients and caregivers provided written informed consent to participate.

3 | RESULTS

For the main analysis, one participant from the CST group was excluded for having attended only two of the 14 sessions, with another participant dropping out of the study. Two participants from the control group were excluded due to the absence of an informant and one participant dropped out of the study. The final sample consisted of 47 participants (CST $n = 23$; TAU $n = 24$).

3.1 | Feasibility issues: Acceptance, attendance and attrition

Acceptance of the intervention was very high, with most participants approached during recruitment being willing to take part in the study. There was very low attrition ($n = 3$; 6%) and mean attendance was high (12.8 sessions; SD: 1.6), with values ranging from 8 to 14 sessions (median = 14, with most of the sample attending all sessions). No formal measures of fidelity were taken, but adaptation of CST to the Brazilian context[18] followed established guidelines,[17] with only minor changes of content being made. Delivery was carried out by facilitators trained by the International CST Center in London. A total of four CST groups were run (average number of six participants per group) and, apart from tailoring of activities to dementia severity level, there were no differences in activities between them.

3.2 | Sample characteristics

Sociodemographic and clinical characteristics of the sample can be seen in Table 1. There were no significant differences between the CST and TAU groups for age (t [45] = 0.59, $p = 0.558$), years of education (t [45] = 1.03, $p = 0.310$), sex (χ^2 [1] = 1.18, $p = 0.278$) or CDR (χ^2 [1] = 0.02, $p = 0.882$), suggesting that the stratified randomization procedure was effective.

3.3 | Primary and secondary outcomes

3.3.1 | Cognition

There was a significant main effect of time (F [1, 45] = 8.57, $p = 0.005$, ηp2 = 0.16), with a decrease in cognitive ability (higher ADAS-Cog scores) post-intervention. There was no significant group main effect (F [1, 45] = 2.23, $p = 0.143$, ηp2 = 0.05) or interaction (F [1, 45] < 0.01, $p = 0.985$, ηp2 < 0.01). Results can be seen in Figure 1.

TABLE 1 Sociodemographic and clinical characteristics by group

Variable	CST ($n = 23$) Mean (SD)/Range	TAU ($n = 24$) Mean (SD)/Range
Age	78.3 (8.4)/65–91	77.3 (8.4)/60–91
Years of education	9.8 (6.3)/3–18	8.0 (5.3)/2–18
Sex (# women/men)	16/7	13/11
CDR (# mild/moderate)	11/12	12/12

Abbreviations: CDR, sociodemographic and clinical; CST, cognitive stimulation therapy; TAU, treatment as usual.

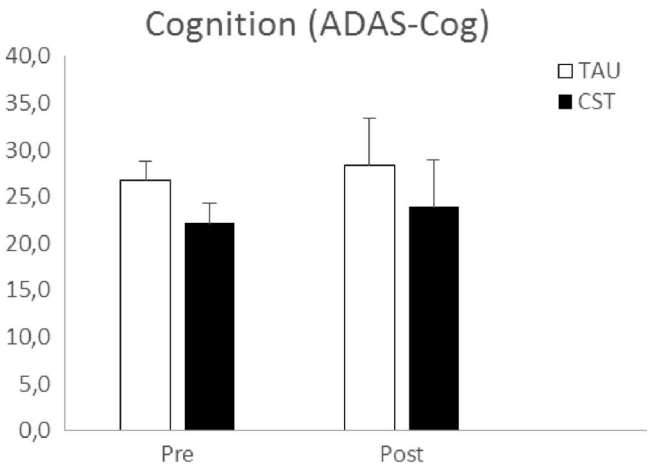

FIGURE 1 ADAS-Cog scores (means and standard errors) pre- and post-intervention. Higher scores indicate more impaired cognition. ADAS-Cog, Alzheimer's Disease Assessment Scale-cognitive subscale; CST, cognitive stimulation therapy; TAU, treatment as usual

3.3.2 | Depression

There was a significant time × group interaction (F [1, 45] = 14.99, $p < 0.001$, ηp2 = 0.25). Pairwise comparisons indicated that the CST group showed lower CSDD scores after the intervention ($p = 0.003$), while the TAU group had an increase in depressive symptoms ($p = 0.022$). There were no significant main effects of time (F [1, 45] = 0.29, $p = 0.592$, ηp2 < 0.01) or group (F [1, 45] = 0.15, $p = 0.699$, ηp2 < 0.01). Results can be seen in Figure 2.

3.3.3 | Activities of daily living

There was a significant time × group interaction (F [1, 45] = 4.50, $p = 0.039$, ηp2 = 0.09). Pairwise comparisons indicated a trend for an increase in ADL in the CST group ($p = 0.096$), but not in the

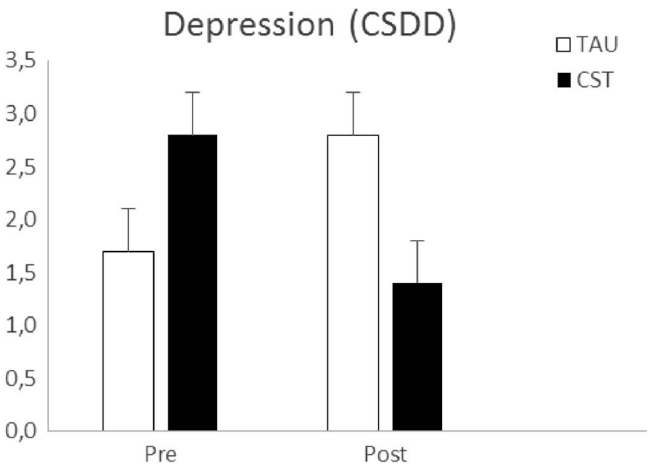

FIGURE 2 CSDD scor (means and standard errors) pre- and post-intervention. Higher scores indicate more severe depressive symptomatology. CSDD, Cornell Scale for Depression in Dementia; CST, cognitive stimulation therapy; TAU, treatment as usual

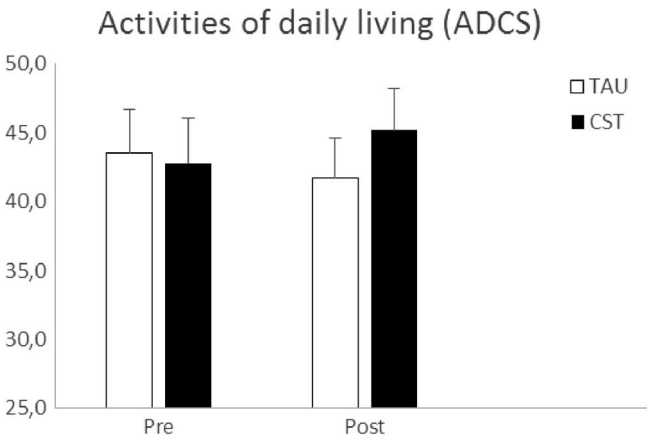

FIGURE 3 ADCS scores (means and standard errors) pre- and postintervention. Higher scores indicate better functional abilities. ADCS, Activities of Daily Living Inventory; CST, cognitive stimulation therapy; TAU, treatment as usual

TAU group ($p = 0.200$). There were no significant main effects of time (F [1, 45] = 0.09, $p = 0.762$, ηp2 < 0.01) or group (F [1, 45] = 0.11, $p = 0.742$, ηp2 < 0.01). Results can be seen in Figure 3.

3.3.4 | Quality of life

There were no significant main effects or interactions for PwD QoL, for both self-' (time: F [1, 45] = 3.19, $p = 0.081$, ηp2 = 0.07; group: F [1, 45] = 3.43, $p = 0.071$, ηp2 = 0.07; time × group: F [1, 45] = 1.15, $p = 0.289$, ηp2 = 0.02) and informant-report (time: F [1, 45] = 0.14, $p = 0.709$, ηp2 < 0.01; group: F [1, 45] = 0.32, $p = 0.573$, ηp2 = 0.01; time × group: F [1, 45] = 0.39, $p = 0.533$, ηp2 = 0.01).

3.3.5 | Caregiver burden

There were no significant main effects (time: F [1, 42] = 0.40, $p = 0.532$, ηp2 = 0.01; group: F [1, 42] = 0.83, $p = 0.368$, ηp2 = 0.02) or interaction (F [1, 42] = 0.83, $p = 0.368$, ηp2 = 0.02) for caregiver burden.

3.4 | Intention-to-treat

The intention-to-treat analysis, including all outcomes for the full sample despite limited attendance, dropouts and missing data, indicated results similar to the main analysis. The only exception was the interaction between time × group for ADL, which became a non-significant trend ($p = 0.057$), but with similar effect size (ηp2 = 0.08).

3.5 | Dementia severity

In the analyses including CDR, interactions with this factor yielded small effect sizes. The only exception was a trend for a group × CDR interaction (ηp2 = 0.08) for self-reported QoL, suggesting higher QoL in moderate dementia in the control group, but no differences in the intervention group. As expected, significant main effects of CDR were observed, with more severe patients exhibiting more cognitive impairments (ηp2 = 0.11) and lower functional capacity (ηp2 = 0.32).

3.6 | Educational level

For caregiver burden, a trend for a time × educational level interaction (ηp2 = 0.08) suggested decreased burden over time in less educated, but not in better educated participants. For ADL, a trend for a group × educational level interaction (ηp2 = 0.06) suggested higher scores in more educated participants in the control group, but no differences in the intervention group.

Trends for main effects of educational level were found for depression (higher scores with lower educational level; ηp2 = 0.07) and informant-report of quality of life (higher scores with higher educational level; ηp2 = 0.08). For all other variables, small effect sizes were found.

4 | DISCUSSION

Results from this feasibility study indicated that CST was very well accepted by participants, with high recruitment rates and low attrition. Those who received CST presented an improvement in mood, as measured by the CSDD, with a significant interaction also suggesting

increases in ADL. There were no significant effects of the intervention for cognition, QoL or caregiver burden.

Contrary to what has been found in previous CST studies, we could neither observe cognitive stabilization nor benefits in QoL in our group.[12,28,29] Previous reports found significant improvements on the MMSE, ADAS-Cog and QoL-AD, with a number needed to treat of six for the intervention group.[12] One explanation refers to the small sample size used in the current study, which may limit generalizability of the lack of findings or lead to reduced statistical power. Nevertheless, not only was the sample quite typical of PwD in the region, but effect sizes for interactions in cognition and QoL were very small, which suggests that even with much larger samples significant results would not be found, limiting this explanation.

Another potential reason for lack of cognitive improvement refers to educational level heterogeneity in the current sample, ranging from 2 to 18 years. Previous studies indicating cognitive improvement after CST had participants with either high[30] or low educational achievement,[31] and it is possible that educationally diverse groups prevented appropriate tailoring of the difficulty of sessions to allow for cognitive improvement effects. Nevertheless, it must be noted that complementary analysis with educational level did not indicate an influence of this factor on cognitive improvement. Given these findings, it is possible that cultural adaptation of privileged certain elements of CST, linked to mood but not cognitive improvement. It is worth noting that complementary analysis with dementia severity did not indicate potential interactions (e.g., differential improvement in mild or moderate PwD), with just an expected reduced cognitive ability in moderate dementia.

The lack of significant QoL effects may be linked to diminished cognitive amelioration in the current sample, considering that CST's impact on QoL may be mediated by improvements in cognition.[32] Mechanisms linking cognitive improvement and QoL may be that perceived improvement in cognitive functions may generate a more positive self-evaluation. Previous findings of QoL improvement after CST were obtained from self-reported data, and in the current study both self- and informant-report measures were used, with a similar pattern of findings, so it is unlikely that measurement type was a potential explanation for lack of significant changes. Zarit scores at baseline did not suggest high caregiver burden in our sample reducing the impact of this measure in QoL discrepancies. Other baseline factors such as female gender, low QoL at baseline, improved cognitive function and reduced depression predicted improvement in QoL in previous reports.[32]

Significant benefits were found in mood as measured by the CSDD. Depressive symptoms are a common psychological issue in dementia with a complex multifactorial etiology, including genetic, psychosocial, medical comorbidities and brain changes.[33] Due to its heterogeneous nature, evidence reporting benefits in mood from clinical trials using antidepressants is inconsistent and positive results are mainly obtained by psychosocial interventions.[33] Our results, consistent with previous CST trials which also report benefits in mood,[28,34] are in line with evidence from reminiscence therapy,[35] music therapy,[36] and physical activity[37] which may improve depression in PwD. All of these are components of CST. The benefits in mood found in the current sample did not translate into improvements in QoL, but, particularly for self-reported QoL, this is in agreement with a previous study conducted in the same setting,[38] suggesting that other variables may have greater impact on QoL.

We found a medium effect size for improvements in functional ability as measured by the ADCDS-ADL. Although highlighting the positive impact on cognitive functioning, previous CST trials did not observe a benefit in the ADL.[34,39] Improvement in ADL despite no cognitive benefits is a novel finding, given the relationship between cognition and functionality in dementia,[40] and it may reflect the impact of other variables, such as mood, in improving capacity (e.g., better mood leading to more engagement in activities). Functional impairment is a key issue in dementia affecting both patient' and caregiver's QoL, so enhancing mobility and independency is an important outcome in clinical trials. To date many different approaches have shown efficacy in delaying functional decline in dementia, including pharmacological interventions, such as the use of cholinesterase inhibitors and memantine, and also non-pharmacological interventions such as exercise.[41] However, it is important to note that the non-pharmacological interventions that were effective, according to recent reviews, involved frequent participation (in some cases, up to five times a week)[42] and duration typically over 7 weeks, with a slowing of functional decline rather than improvements in performance,[41] so CST may provide a more cost-effective intervention for ADL.

We could not find benefits to caregiver burden following the intervention. Interestingly, however, in the complementary analysis with educational level, a trend for decreases in burden was seen in less educated patients, regardless of treatment type, which may suggest the impact of engaging in treatment in providing more information about the condition. Psychosocial and psychoeducational approaches have been related to reduced caregiver distress, but standardized educational approaches are still lacking and also methodological issues preclude more definite conclusions regarding the best approach for burden reduction.[43] Psychoeducation groups can be considered efficient interventions to reduce caregiver burden,[44] and individual CST has also shown evidence of improvement in terms of the caregiving relationship and improvement in caregivers' QoL and depressive symptoms for those who completed more sessions.[45] This suggests that caregiver involvement in non-pharmacological treatments is potentially important to reduce burden, which may be incorporated in further use of CST-Brasil.

4.1 | Limitations

First, this was a small scale study, which limits generalizability of findings. Brazil is a huge country with economic and cultural disparities that should be taken into account when translating results from this study into clinical practice. Clinical trials in different cultural backgrounds and clinical scenarios should be done to allow generalization in Brazil. In addition, the small sample size also reduces

statistical power to detect significant effects. Nevertheless, regarding this point, where significant differences were not found, effect sizes were typically small. In any case, a fully powered trial is needed. Finally, inclusion criteria allowed study participation according to clinical dementia diagnosis and categorized by stages (CDR stages), but it is possible that different dementia etiologies could impact results in cognitive evaluations.

The current study has important clinical and research implications. From a clinical perspective, psychosocial interventions have been increasingly recognized as important tools for the management of dementia,[10] but in Brazil such approaches were not incorporated into government guidelines due to a lack of validated interventions.[6] The study bridges that gap indicating good acceptance and preliminary positive effects for PwD. The present study highlights the appropriateness of the cultural adaptation made to the original program and reported by our group previously.[18] The intervention can be now extended to different parts of the country, including minor changes for local adaptation, specifically in regard to the activities material (e.g., typical regional food). It also can be implemented in a wide range of settings, for example in nursing home or primary care service, adjusting for the characteristics of each structure (e.g., two weekly sessions on the same day or on separated days). Now that a CST-Brasil manual is available, a fully-powered clinical trial can be conducted.

5 | CONCLUSIONS

CST-Brasil was proven to be a valid intervention with high acceptance between study participators. It was also associated to mood improvements and benefits in functionality. To our knowledge, this is the first study using a structured and replicable psychosocial intervention in Brazil, indicating an evidence-based alternative to pharmacological treatment. CST-Brasil is a promising intervention for dementia and needs to be replicated in other clinical settings, including primary care, private and third-sector (e.g., caregiver associations) settings.

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CONFLICT OF INTEREST

We have no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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