Validation of the Cognitive Stimulation Therapy (CST) Program for People with Dementia in Portugal

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Abstract

Background: Cognitive Stimulation Therapy (CST) is considered a gold-standard, evidence-based and cost-effective approach to improve cognitive function and quality of life of people with mild to moderate dementia. **Aims:** To validate CST for the Portuguese population and test its effectiveness. **Methods:** A single-blind, multi-center, randomized controlled trial recruited 112 older people with dementia. The primary outcome measure was cognition and secondary measures were quality of life, communication, autonomy, anxiety, depression, and global functioning. We also explored whether CST benefits people differently according to context, gender and level of cognitive reserve. **Results:** Fifty-five people were randomized to the intervention and 57 to the control group. In the post-test, the intervention group significantly improved relative to controls in cognition (ADAS-Cog, $p = 0.013$), communication (HCS, $p = 0.045$), behaviour (CAPE-BRS, $p = 0.017$) and in global dementia rating (CDR, $p = 0.008$). Quality of life, depression and anxiety had no significant differences. The estimated number needed to treat was four for one to benefit a cognitive improvement (ADAS-Cog). **Conclusions:** Group CST is valid for the Portuguese population with benefits for people with mild to moderate dementia.

Introduction

Recent systematic reviews of psychosocial interventions for people with dementia have concluded that Cognitive Stimulation has the highest level of evidence to improve cognitive function and quality of life (Kim et al., 2017; McDermott et al., 2019), independent of acetylcholinesterase inhibitor medication (Aguirre et al., 2013). It is usually provided in a group and more flexible than cognitive training as it does not have to match specific therapeutic modalities (Clare & Woods, 2004). Neural plasticity and capacity for cognitive-deficit compensation may underlie the efficacy of non-pharmacological interventions (Stern et al., 2000). Cognitive stimulation is recommended by Alzheimer´s Disease International [ADI] in the World Alzheimer´s Reports (2011, 2014); and by the National Institute for Health and Clinical Excellence and the Social Care Institute for Excellence [NICE-SCIE] (2006, 2011). It has remained the only non-pharmacological intervention recommended to improve cognition, independence, and well-being in the 2018 guidelines update (NICE, 2018).

More specifically, the "Making a Difference" program, also known as Cognitive Stimulation Therapy (CST), was developed at University College London over 20 years ago (Spector, Orrell, Davies, & Woods, 2001; Spector et al., 2003). It is currently one of the most popular and globally used programs to improve cognitive function and quality of life of people with mild to moderate dementia (Woods, Aguirre, Spector, & Orrell, 2012). It has also shown to be cost-effective (Knapp et al., 2006). CST is a 14 session structured program, typically twice a week and offering a variety of small group activities. Focused on communication and social interaction, it promotes discussion of various topics and shared opinions / experiences seeking generalization to real life contexts (Spector et al., 2003; Spector, Thorgrimsen, Woods, & Orrell, 2006). CST has been applied in different contexts - senior residences, nursing homes, day care centers,

hospitals and at home (Lobbia et al., 2018; Rai, Yates, & Orrell, 2018), and has been described as a positive experience for both patients and staff (McAulay & Streater, 2018; Spector, Gardner, & Orrell, 2011). It appears to have more facilitators than barriers and offers people with dementia the opportunity to fully engage in social interactions where their opinions are valued (Dickinson, Gibson, Gotts, Stobbart, & Robinson, 2017). It has been already translated and adapted to for numerous cultures and is currently available in 30 countries (www.ucl.ac.uk/international-cognitive-stimulation-therapy), with some more recent work in Nigeria (Olakehinde et al., 2019), India (Raghuraman, Lakshminarayanan, Vaitheswaran, & Rangaswamy, 2017), Brazil (Bertrand et al., 2018), China (Wong, Yek, Zhang, Lum, & Spector, 2017) and Taiwan (Tsai, Lee, Lai, Chou, & Su, 2019).

Most studies corroborate the positive impact of CST on the general cognitive functioning of people with dementia (Lobbia et al, 2018). The program also showed benefits in specific cognitive domains, such as language (Capotosto et al., 2017; Hall, Orrell, Stott, & Spector, 2013; Paddick et al. 2017; Spector et al., 2003, 2010), memory (Hall et al., 2013; Paddick et al., 2017), orientation (Hall et al., 2013) and praxis (Paddick et al., 2017). Inconsistent results were found in the reduction of depressive and anxiety symptoms, behavioural disorders and daily life functioning (Lobbia et al, 2018).

In Portugal the CST "Making a Difference" manual for the Portuguese population was culturally adapted (Alvares-Pereira, Sousa, & Silva-Nunes, 2020). The "Formative Method for Adapting Psychotherapy" (FMAP) model was followed for the cultural adaptation of the program, suggested in the Aguirre, Spector and Orrell (2014) guidelines. Some adaptations, especially around language, were required for 11 of the 14 CST sessions. The adapted program was considered acceptable and enjoyable in a small sample of 6 people with dementia (PwD) in a residential care context. The

feasibility of CST and its suitability for PwD in Portugal has been recognized and the conditions for its implementation and validation on a larger scale have been created (Alvares-Pereira, Sousa, & Silva-Nunes, 2020).

The aim of this study was to contribute to advancing clinical practice in dementia. We proposed to validate the CST program for the Portuguese population by conducting a single-blind, multicenter, randomized controlled trial and to test the effectiveness of CST on cognition (primary outcome), quality of life, communication, autonomy, anxiety, depression and global functioning (secondary outcomes) of people with mild to moderate dementia. We also intended to determine whether CST benefits participants differently depending on the context (resident versus community) and their level of cognitive reserve (low / medium or high).

Based on the CST literature, we hypothesized that:

1: CST-Portuguese will improve cognition of people with mild to moderate dementia.

2: CST-Portuguese will improve quality of life, communication, autonomy, anxiety, depression, global functioning of people with dementia.

3: The benefits of CST-Portuguese will vary depending on cognitive reserve.

Methods

Participants

Sixteen public, private and social organizations were formally contacted and eight agreed to participate (two day centers, two nursing homes, two psychogeriatric centers, one hospital, one rehabilitation center). A convenience sample was used from the participating organizations.

Using inclusion criteria from the original CST trial, people were considered suitable for full assessment and participation if they:

(a)   met the DSM-5 criteria for neurocognitive disorder (dementia) (American Psychiatric Association, 2013);

(b)   scored between 10 and 24 on the Mini- Mental State Examination (MMSE) (M. Folstein, S. Folstein, & McHugh, 1975);

(c)   had some ability to communicate and understand communication - a score of 1 or 0 in questions 12 and 13 of the Clifton Assessment Procedures for the Elderly – Behaviour Rating Scale (CAPE–BRS; Pattie, & Gilleard, 1979);

(d)   were able to see and hear well enough to participate in the group and make use of most of the material in the program, as determined by the researcher;

(e)   did not have major physical illness or disability which could affect participation;

(f)   did not have a diagnosis of learning disability.

Because there is no evidence that people with a certain subtype of dementia benefit more from CST than other (Aguirre et al, 2013), the dementia subtype was not considered.

Sample

Nine groups were conducted, each with 5-6 participants who attended the 7-week program, for a sample of 105 participants. Participants ranged in ages 59-98 with an average of 83.60 (SD = 7.64). Most were women (86.7%) widowed (59%) and 65.7% had educational level under 4 years. It was noted that 62.9% of the participants were residents (nursing home, psychogeriatric center and rehabilitation center) and 37.1% lived at home, and 23.8% attended a day center.

Caregivers

Health professionals (nurses and other staff) who had close contact with the residents and family members who provided care and had a close relationship with the person with dementia (son/daughter or spouse) answered the evaluation scales.

Ethics

The research project was approved by a Lisbon ethics committee (Approval number 1/2018) and informed consent was obtained from participants.

Design and process of randomisation

In order to guarantee the single-blind character of this study, the evaluation process and the conduction of the groups were carried out by different researchers. The randomisation process was performed centrally using a web-based system (Sealed Envelope), by an administrator external of the study, and was based on randomly mixed block sizes. An un-blinded member of the team informed participants of their allocated group. Full assessments were conducted in the week prior to, and the week following the intervention by researcher assistants blinded to group allocation.

Of the 348 people screened, 112 participants (55 intervention, 57 control) entered the study. Seven people from the control group were excluded from the analysis - 2 due to death and 5 due to the impossibility of reassessment (refusal or discharge). Thus, 105 participants completed the study, 55 in the CST group and 50 in the TAU group (Fig. 1). Using the Gpower program (Faul, Erdfelder, Lang, & Buchner, 2007), for the Ancova test this sample size enabled us to detect an effect size of 0.4 with 0.8 power.

Procedure

Before the study began, participants received and signed the consent form, containing information about the study and the voluntary, anonymous and confidential nature of their participation. The evaluation sessions took place at the centers that

approved the study and consisted of a socio-demographic questionnaire and the assessment measures.

CST sessions took place twice a week for 7 weeks, with each session lasting 45 to 60 minutes. Facilitators were previously trained to conduct CST sessions by researchers who had attended the CST training at University College London (UCL). Whilst CST groups ran, the control groups continued with usual activities ('treatment as usual'/TAU), which might have involved, for example, unstructured occupational activities such as painting, talking, playing games, watching television or participating on annual events. The institutions that collaborated were asked not to execute any new interventions or take part in any other research for the duration of the study. Of note, the CST group also continued with TAU, so this study focused on the additional impact of CST over the TAU received by all participants.

CST materials

CST is a 14-session structured program. It follows 18 'key principles', which include mental stimulation, a focus on opinions rather than facts, encouraging 'new ideas, thoughts and associations' and stimulating executive functioning and language skills. Each session has two difficulty levels - A and B - to choose according to the characteristics of the group members. Sessions themes include physical games, word association, categorizing objects and number games. For a standardized process and risk reduction of parasite variables "CST bags" were created to be used by all groups. Culturally specific materials were developed for each themed session (e.g., pictures of public figures, pen drive with sounds recorded, bowling and bingo games, dolls, recipes, origamis, maps, cards with questions, pictures of vegetables, fruits, clothes, animals for categorization objects). These materials were accompanied with detailed activities instructions for facilitators in a manual and included in bags. The diversity of materials

delivered allowed the facilitators to select in each session activities according to participants´opinions and preferences (Alvares-Pereira, Sousa, & Silva-Nunes, 2020).

Assessment measures

A sociodemographic questionnaire included gender, age, birthplace, marital status, household, educational level, profession, residence, and application context (ambulatory, day center, nursing home, psychogeriatric or rehabilitation center). We also administered the standardized assessment measures used in the Spector et al. (2003) study to evaluate cognition, global functioning, quality of life, behavior, communication, depression and anxiety. A cognitive reserve scale was added as it was a specific outcome studied in this research.

Cognition

The Alzheimer's Disease Assessment Scale - Cognitive subscale (ADAS-Cog, Rosen, Mohs, & Davis, 1984) Portuguese version (Guerreiro, Fonseca, Barreto, & Garcia, 2008) is a brief neuropsychological battery designed to characterize cognitive performance and composed of 11 subscales: word recall, naming objects and fingers, commands, constructional praxis, ideational praxis, orientation, word recognition, recall of test instructions, spoken language ability, word-finding difficulty and comprehension of spoken language. A higher score corresponds to a greater degree of cognitive decline.

Global functioning

The Clinical Dementia Rating (CDR, Hughes, Berg, Danziger, Coben, & Martin, 1982) adapted by Morris (1993) in the Portuguese version (Montaño, & Ramos, 2005) provides a global rating of dementia with 95% of sensitivity and 94% of specificity (Juva et al., 1995). This measure is divided into six domains: memory, orientation, judgment or problem solving, community activities, home and hobbies, and personal care. Global information is collected in two separate questionnaires, one for the

patient and another for the informant who is asked to compare the person's current performance against their previous performance. The final CDR classification corresponds to the degree of severity of dementia. Memory is considered primary and the others domains are secondary.

Quality of life

Quality of Life - Alzheimer's Disease (QoL-AD, Logsdon, Gibbons, McCurry & Teri, 2002) is a 13 item scale including physical health, energy, mood and living situation. It is applied to the patient in the form of an interview following a pre-defined script and to their primary caregiver in the form of a questionnaire. It is rated on a Likert scale (1-4) and has adequate test-retest reliability in the Portuguese version (Bárrios et al., 2013).

Behaviour

The Behaviour Rating Subscale (BRS) of the Clifton Assessment Procedures for the Elderly (CAPE, Pattie & Gilleard, 1975) has 18 items and four domains: Physical disability, apathy, communication and social disorders. It should be completed by caregivers (professional or family carers). Higher scores indicate greater disability. The authors found adequate psychometric properties with a Cronbach's alpha = 0.77).

Communication

The Holden Communication Scale (HCS, Holden, & Woods, 1995) assesses communication and social behaviour in the context of dementia. This scale has 12 items and three domains and is completed by the caregiver using a Likert scale (0-4). Higher scores correspond to greater decline in communication. It has high internal consistency (Cronbach's alpha = 0.94) and test-retest reliability (r = 0.71) (Strøm, Engedal, Benth, & Grov, 2016).

Depression

The Cornell Scale for Depression in Dementia (CSDD, Alexopoulos, Meyers, Young, Abrams, & Shamolan, 1988; Vieira, Lopes, & Vieira, 2007) evaluates signs and symptoms of depression in people with dementia. It has 19 items in five domains and the information is obtained through an interview with the caregiver. The total score ranges from 0 to 40 points. High scores suggest major depressive symptoms.

Anxiety

Rating Anxiety in Dementia (RAID, Shankar, Walker, Frost, & Orrell, 1999) is an 18 items Likert scale (0-3) with four domains. This scale should be completed by the caregiver based on the semiology manifested within two weeks prior to the evaluation. At its cutoff point for presence of clinically significant anxious symptomatology (score ≥11) it has 90% sensitivity and 78.5% specificity according to DSM IV-R Anxiety criteria.

Cognitive reserve

The Cognitive Reserve Questionnaire (CRQ, Rami et al., 2011) evaluates cognitive reserve (RC) in eight items. The total score ranges from 0 to 24 points. In this questionnaire information can be obtained directly from the subject or if the person is unable to do so, a caregiver may be consulted. Higher scores correspond to higher cognitive reserve levels. Portuguese validation scale (Sobral, Pestana, & Paúl, 2014) showed adequate reliability and internal consistency and cutoff points for medium / high (≥7 points) and low (≤6 points) CR levels.

Data analysis

Statistical analysis was performed using 25.0 version of the Statistical Package for Social Sciences (SPSS) software. In order to characterize the sample regarding the outcomes (baseline and post-test) we used descriptive statistics. The uniformity of the groups regarding the demographic and psychometric characteristics was verified.

Additionally, we calculated the difference-variables for each domain under study from the difference (M2-M1) between the post-test (M2) and the pre-test (M1). Using ANCOVA (covariating educational level / cognitive reserve) we determined if the differences between groups were significant in the domains and subdomains assessed. We also analyzed the numbers needed to treat (NNT) to find out how many people need to be treated with CST in order for one person to benefit.

Independent variables considered in the study were gender, age, educational level, context and group (CST and TAU), and the dependent variables were cognition, global functioning (dementia severity), quality of life, depression, anxiety, autonomy / behaviour, communication, in pre and post-test, as well as their difference-variables, calculated for the seven domains mentioned above. Missing values were dropped out. The number of cases was less than 5% of the sample.

Results

One hundred and five participants completed the study, 55 in the CST group and 50 in the TAU group. The groups were quite homogeneous at baseline in the sociodemographic variables considered (gender, age, marital status and context) showing no significant differences (Table 1). However, the educational level variable was on the threshold of significance (p = .106) consequently we chose to control it in subsequent parametric analyzes (ANCOVA), ensuring that it did not interfere with the outcomes. The groups had no significant differences on the outcomes at baseline.

Subsequent analyzes was conducted according to the difference in mean values (Dif Means) between post-test and pre-test in the dependent variables.

In order to study if the intervention with the CST Program had different outcomes depending on context we created two groups: the group of residents (nursing home, psychogeriatric center and rehabilitation center) and the group of community

(outpatient hospital or attending day center but living at home). Table 2 highlights a major effect of intervention on cognition (Dif_ADAS_COG, F = 9.444; p = .003), degree of severity of dementia (Dif_CDR, F = 5.870; p = .017) and behaviour / functionality (Dif_CAPE, F = 5.870; p = .017), with no interaction effect with context. This suggested that benefits of CST could be generalized to the sample and were obtained regardless PwD were residents or not.

The following analyzes were performed controlling the variable "education" in both groups, since CST tended to be more educated than TAU, presenting a score in the threshold of significance in this variable (table 1). For the comparative analysis between the pretest and the posttest in the intervention group and the TAU group, we performed an ANCOVA (covariate education) and found significant differences in cognition (F = 6.391, p = .013), communication (Holden, F = 4.105, p = .045), behaviour / functionality (CAPE, F = 5.888, p = .017) and degree of severity of dementia / disability (F = 7.266, p = .008) showing a significant improvement in these areas with CST. Quality of life (QoL-AD), depression (Cornell), and anxiety (RAID) did not show significant differences following CST (Table 3). The positive effects of CST in the mentioned areas were also verified with cognitive reserve as covariate.

Because we were specifically interested in analyzing if the level of cognitive reserve impacted upon CST, we proceeded the analysis considering a medium / high cognitive reserve level (≥7 points) and a low cognitive reserve level (≤6 points) as suggested by Sobral, Pestana and Paúl (2014). We found no significant differences in outcome measures at the end of the intervention, indicating that CST could have benefits for all PwD regardless of their level of cognitive reserve.

As there was an improvement in cognition, we analyzed the ADAS-COG subscales to find the dimensions where the improvement was most significant. We

compared the ADAS-COG subscales in the two groups (Table 4) and found a significant difference in word recall (F = 5.569, p = .020) and constructional praxis (F = 4.831, p = .030). The intervention group presented a negative mean value of the difference between pre-test and post-test which meant a better outcome at the end of the intervention.

Seeking to know the effects of CST on behaviour / autonomy of PwD through the dimensions assessed by the CAPE-BRS scale (table 5), we found significant differences between the groups in the physical disability dimension (F = 4.441, p = .038). In the post-test, participants in the CST Program had better autonomy scores (bathing, mobility, urinary incontinence, orientation, dressing and combing, and going out) than those in the control group. Communication presented scores on the threshold of significance (F = 3.605, p = .060), pointing to a tendency of improvement with CST in comprehension and spoken language ability.

To test the effects of CST on global functioning, such as memory, orientation, judgment and problem solving, community activities, home and hobbies and personal care dimensions (Clinical Dementia Rating, CDR), we calculated the frequency of subjects in pre and post-test and in both groups, with each degree of disability [None (CDR = 0), Suspect (CDR = 0.5), Mild (CDR = 1), Moderate (CDR = 2), Severe (CDR = 3)]. We found that 15% of participants globally improved following CST (total CDR), while only 4% improved with TAU in all dimensions, more participants improved in the intervention group. In CST group, there was a more marked improvement in areas directly worked in sessions, such as orientation (32.8%), critical judgment (27.3%), home occupation / hobbies (21.9%) and memory (20 %), the latter being especially relevant as it is a primary category of this measure.

To calculate the number needed to treat (NNT) with the CST Program to ensure a favourable outcome we used the difference in scores obtained in ADAS-COG in the pre-test and post-test. When we considered no deterioration as an improvement and any deterioration as adverse, 69% of the intervention group improved compared with 46% of the control group. This corresponded to four people needing to be treated for one to benefit (95% CI 3-24). Finally, we observed that the risk of having a negative outcome was lower in the intervention group (Relative Risk = 0.57) and that there is 43% risk reduction (RR reduction) to deteriorate more with CST.

Discussion

The efficacy of the Portuguese version of CST was examined with reference to traditional measures of cognition, behaviour and daily function, psychological functioning (mood) and quality of life. A unique feature of the study was to consider the cognitive reserve of the individuals with dementia, a finding that could have universal implications.

CST program showed significant improvements in cognition (ADAS-Cog, p = 0.013), communication (HCS, p = 0.045), functionality (CAPE-BRS, p = 0.017) and severity of dementia / disabilities (CDR, p = 0.008). Quality of life, depression and anxiety did not differ significantly.

Cognition. Improvements in global cognitive functioning were consistent with most previous studies (Lobbia et al, 2018). ADAS-Cog scores (primary outcome measure) also showed benefits in specific cognitive domains, namely word recall and constructional praxis. Other studies found improvements in orientation (Hall et al., 2013), praxis (Paddick et al., 2017), word recognition (Paddick et al., 2017) and short-term verbal and visual memory (Hall et al., 2013). As Spector et al. (2003) pointed out, except for orientation, worked out directly in all sessions, there was no obvious reason

for the direct effect of practical activity on groups on the scores of other ADAS-Cog tasks, such as word recall or word recognition. This suggests the generalizing effects of cognitive benefits. Considering previous studies we can infer that CST as a psychosocial intervention promotes improvement or at least maintenance of cognitive function.

Quality of life. Quality of life is recognized as an important dimension to be studied in PwD, but the results from different studies are inconsistent. Unlike previous studies (Aguirre et al., 2013; Capotosto et al., 2017; Coen et al., 2011; Spector et al., 2003) we found no improvement in quality of life (QoL -AD), self-perceived or assessed by caregivers, refuting our initial hypothesis. The results were in line with other studies (Cove et al., 2014; Paddick et al., 2017; Stewart et al., 2017; Wong et al., 2017; Yamanaka et al., 2013) that found no benefit in this area. Cultural aspects may have concealed the effect of the intervention on the perception of quality of life. Portuguese people are generally pessimistic when evaluating their quality of life. In Portugal, PwD have important unmet needs of 'company', 'psychological distress' and 'daily activities' (Gonçalves-Pereira et al., 2019). A 7-week program was probably not sufficient to change PwD or caregivers' perceptions about life dimensions measured with QoL-AD scale such as "living situation", "family", "marriage", "friends", "self", "money" and "life as a whole".

Psychological functioning (anxiety and depression). CST was not effective in reducing depression and anxiety, corroborating previous studies (Coen et al., 2011; Paddick et al., 2017; Spector et al., 2003) and confirming the study hypothesis. The scales used (Cornell and RAID) have a hetero-evaluation format and ratings may preferentially reflect what carers feel and think rather than PwD do. On this propose, Spector, Woods and Orrell (2008) suggested that in an institutional context, the scores

obtained on the scales are as informative for PwD as for their caregivers. On the other hand, this negative CST outcome may suggest that the social interaction and encouragement provided by CST may not be sufficient to effectively sustain and enhance participants´ mood and other specific interventions options (pharmacological or non-pharmacological) have to be considered preferably to treat depression and anxiety in PwD.

Behavioural functioning: Some authors (Zanetti et al., 1995) argued that behavioural measures are not sensitive enough to detect the functional impact of cognitive stimulation. In previous studies, the assessment of behaviour and everyday life functioning has been conducted with a range of measures, making it difficult to compare results. None of the reviewed studies by Lobbia et al. (2018) that included measures of everyday life functioning found improvement (Aguirre et al., 2013; Capotosto et al., 2017; Coen et al., 2011; Spector et al., 2001, 2003). In the present study, reproducing the Spector et al. (2003) study, we used CAPE-BRS and found a significant improvement in everyday life functioning in the post-test, refuting the study hypothesis. As it was a positive outcome, although contrary to the literature data, we proceeded to a detailed analysis of the different dimensions of the scale and found significant differences between groups in the physical disability dimension. People with dementia in the CST group showed better autonomy scores in the post-test than those in the TAU group (items: bathing, mobility, urinary incontinence, orientation, dressing / combing and going out). Since CAPE-BRS is not a direct measure of observed behaviour or a self-reported scale, we cannot exclude any caregiver / family subjectivity that may not translate a real improvement in performance.

Communication. Systematic reviews have shown benefits of cognitive stimulation in communication and social interaction of people with mild to moderate

dementia (Aguirre, et al., 2013; Woods et al., 2012). Spector et al. (2001) in a first study found no improvements in communication although in a later study (Spector et al., 2003) found a tendency for significance in this domain. Spoken language ability and comprehension of spoken language (communication components) were also assessed in the language domain of ADAS-Cog, with benefits reported in spoken language (Capotosto et al., 2017; Paddick et al., 2017; Spector et al., 2010) and comprehension (Hall et al., 2013; Spector et al., 2010). In the present study we also found benefits in communication (Holden) confirming the study hypothesis.

Global functioning / Severity of dementia. Previous studies used global functioning /severity of dementia (CDR) only at baseline for initial group´s characterization. In the present study we considered the different degrees of severity / disability in dementia (suspected, mild, moderate, severe) in the CDR dimensions such as memory, orientation, judgment and problem solving, community activities, home and hobbies, and personal care in pre-test and post-test. We found that in all dimensions there were more PwD who improved in the CST group. Fifteen per cent of PwD globally improved with the intervention (total CDR), while only 4% improved with treatment as usual (control group). There was a noticeable improvement in orientation, critical judgment, home occupation / hobbies and memory, the latter being especially relevant as it is a primary category of CDR. These results reinforce the favorable outcomes of CST in cognition assessed by ADAS-Cog.

Context. In the present study, improvements in the CST group were consistently better than in TAU regardless the context (residents or community). Spector et al. (2003) found significant differences in the contexts of intervention in cognition, behaviour, mood and communication. The group living in the community had benefits in behaviour and institutional residents had benefits in quality of life (Aguirre et al.,

2013). The differences found were not attributed to CST itself but were interpreted as being influenced by the quality of the center's pre-existing social involvement, the different degrees of severity of dementia in the same group, and the characteristics of the scale informants (expectations and relationship with the PwD). Currently, in Portugal there are few institutions specialized in dementia care. Day centers, home care and nursing homes provide similar services and activities, generally focused on the basic personal care. In the present study CST showed that it is a valid non-pharmacological intervention for residents or PwD living in the community. This is an important finding as it can be made available with benefits to most individuals with mild to moderate dementia.

Cognitive reserve (CR). Identifying who benefits most with CST is challenging and it can be crucial for its effectiveness. Aguirre et al. (2013) pointed that older age and being female were associated with increased cognitive benefits from CST. On the other hand, people with different levels of cognitive reserve have shown to benefit differently with cognitive training and cognitive stimulation. In previous studies, cognitive training benefited more subjects with low cognitive reserve rather than high cognitive reserve (Mondini et al., 2016). Olazarán et al. (2004) also found more benefits of cognitive stimulation in PwD with low educational level (CR proxy). These findings were attributed to the fact that PwD with high cognitive reserve probably have more neuropathology as they show the same clinical symptoms to people with low cognitive reserve and are less able to learn new generalizable strategies to improve their cognitive performance.

So far, to the knowledge of the authors, no study has been conducted with CST and cognitive reserve of PwD. In the present study, considering a medium / high cognitive reserve level (≥7 points) and a low cognitive reserve level (≤6 points), CST

benefited people with mild to moderate dementia regardless their cognitive reserve level. Nonetheless, results should be considered with caution as they may be due to the assessment measure used. Although the Cognitive Reserve Questionnaire (CRQ, Rami et al., 2011) used in the present study has shown good psychometrics´ qualities a more detailed questionnaire such as the Cognitive Reserve Index (CRI, Nucci et al., 2012) built to retrospectively access experiences and activities throughout life, could be useful to elucidate more who benefits most with CST.

Number Needed to Treat (NNT). The NNT is a measure to depict the effectiveness of a healthcare intervention by estimating the number of people who need to be treated in order to one to benefit. The lower the NNT, the more effective the intervention (Biswas, 2017). In Paddick et al. (2017) study, the NNT was two for a four-point improvement in ADAS-Cog. In Spector et al. (2003), the NNT was 6 to 8 people needed to be treated for one to benefit (depending on the analysis performed). In our study, we found that four people needed to be treated for one to benefit, which was a favourable result.

Limitations

The fewer men with dementia in the groups, as usually happens in similar studies with this age range, makes cautious the generalization of outcomes to population. No follow-up was conducted, so any longer-term benefits were not explored.

When the control group performed the treatment as usual it was not consistent across sites. TAU subjects have been actively involved in other activities in some places and not in others whilst CST ran.

Staff's perceptions about therapy groups could have introduced a bias in the scales rating. We took precautions to avoid this by ensuring that the person who

conducted the groups was not involved in the evaluation process. However, it is likely that other team members were aware of which people were in the groups and this may have influenced their ratings.

Future directions

Cognitive stimulation is recommended for people with mild to moderate dementia irrespective of drug treatments received. We consider it important to develop further studies on CST efficacy related or not with anti-dementia medication, specifically whether the cumulative effects enhance the effectiveness and maintenance of outcomes.

It seems also relevant to study the influence of cognitive reserve or some socio-behavioural variables of PwD on response to CST to better understand which variables are associated with the most favorable outcomes and which people are most likely to benefit.

No significant impact of CST was found on everyday life functioning of people with mild to moderate dementia. We believe that the diversity of autonomy scales used in previous studies did contribute to this effect. In the present study, positive outcomes were found in this domain, so we propose the preferential use of CAPE-BRS scale and a more detailed analysis of dependency levels in the future.

It is not entirely clear whether the benefits observed with CST derive mainly or in part from social interaction or its cognitive component. We think it would be interesting to reinforce the study of non-cognitive dimensions, developing the skills of communication and socialization.

Finally, direct effects of CST on reducing anxiety and depressive symptoms have not been consensual. It could be interesting to compare the ratings given by informants (hetero-evaluation) with those of PwD (self-reported scales).

Conclusion

This research has shown that CST-Portuguese is valid and effective in improving cognition, communication, autonomy and severity of dementia. Although, it did not find significant effects in quality of life, depression and anxiety, CST can be an important tool for those working with PwD in Portugal in different contexts.

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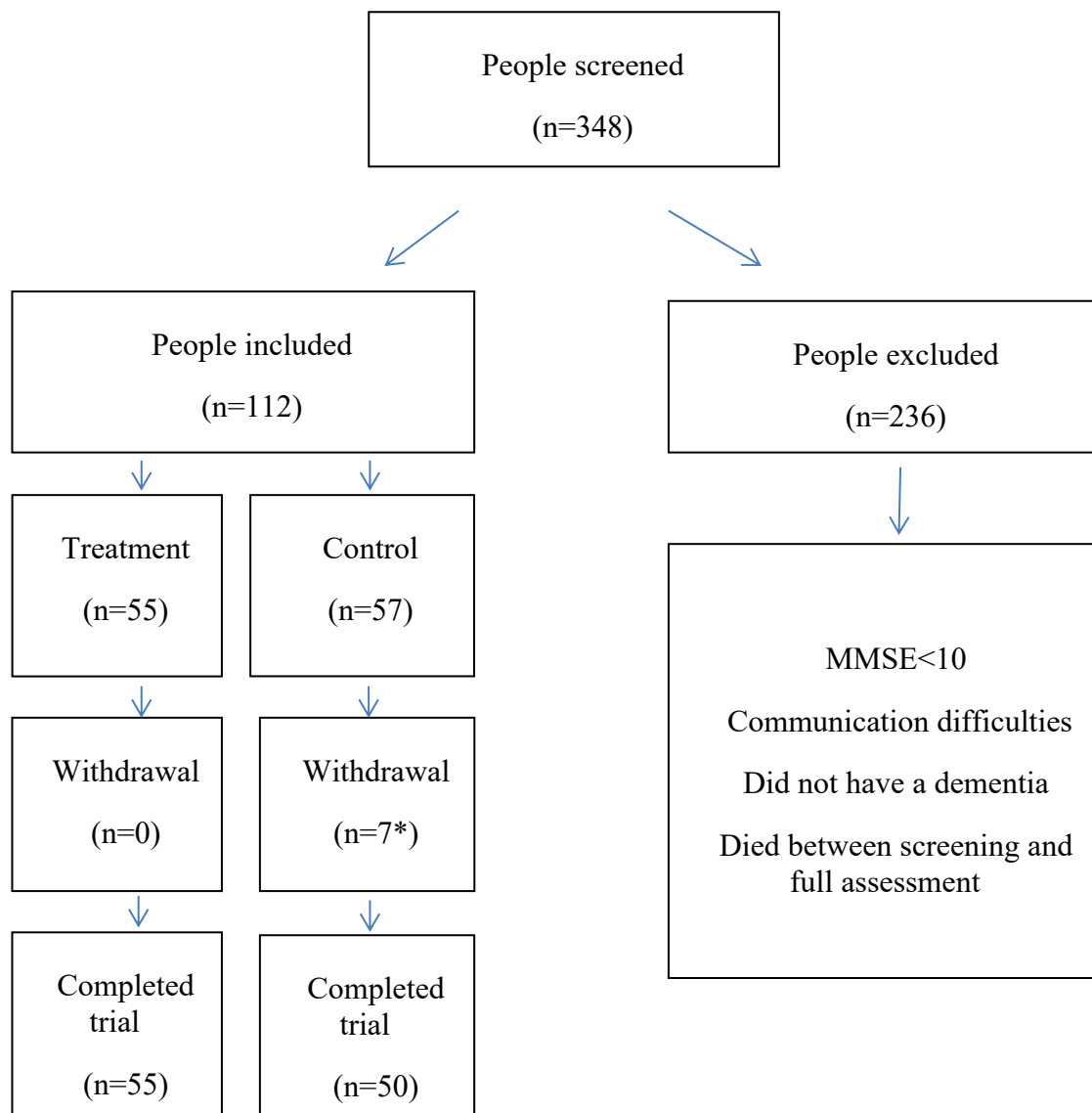
Fig. 1. Study design and randomization process

Figure 1. Study design and randomization process

MMSE, Mini-Mental State Examination; Treatment: CST intervention; Control:

Treatment as usual (TAU); *2 deaths and 5 refused or discharged

Table 1. Differences between groups in demographic variables

	Control Group (n=50) % (n)	Intervention Group (n=55) % (n)	Inferential statistics
GENDER			
Female	86.0% (43)	87.3% (48)	X^2 = .037; p=1.00
Male	14.0% (7)	12.7% (7)	
AGE			
59-68 years	2.0% (1)	5.5% (3)	
69-78 years	26.0% (13)	20.0% (11)	Fisher test=1.411;
79-88 years	44.0% (22)	49.1% (27)	p=.750
89-98 years	28.0% (14)	25.5% (14)	
	$\bar{X}$= 84.26	$\bar{X}$= 83.00	
	SD = 8.602	SD = 6.672	t=1.002; p = 0.319
	Min =59 Max =97	Min =67 Max =97	
MARITAL ST			
Single	10.0% (5)	14.5% (8)	
Married	22.0% (11)	21.8% (12)	
Divorced	6.0% (3)	7.3% (4)	Fisher test=0.719;
Widowed	62.0% (31)	56.4% (31)	p=.887
EDUC. LEVEL			
Illiterate	12.0% (6)	9.1% (5)	
≤4 years	64.0% (32)	47.3% (26)	
5 ao 9 years	18.0% (9)	18.2% (10)	
10 - 12 years	2.0% (1)	10.9% (6)	Fisher test=7.503;
Higher education	4.0% (2)	14.5% (8)	p=.106
CONTEXT			
Ambulatory	16.0% (8)	10.9% (6)	
Day center	24.0% (12)	23.6% (13)	
Nursing home	22.0% (11)	21.8% (12)	
Psychog. center	28.0% (14)	32.7% (18)	X^2 = .724; p=.952
Rehab. center	10.0% (5)	10.9% (6)	

Table 2. Change from baseline in measures of efficacy in resident and community

context

Scale	Group	Context	Dif Means (SD)	ANOVA TWO WAY Between group difference
ADAS-COG	Control	Community	1.050 (1.162)	
		Resident	2.000 (1.000)	Group: F=9.444; p=.003** Context: F =2.051; p = .155
	Intervention	Community	-2.789 (1.192)	Group * Context: F = .290; p = .591
		Resident	-.694 (.866)	
CAPE	Control	Community	-.350 (.861)	
		Resident	1.296 (.741)	Group: F=5.870; p=.017* Context: F=.797; p=.374
	Intervention	Community	-1.316 (.883)	Group * Context: F=1.433; p=.234
		Resident	-1.556 (.642)	
CDR	Control	Community	.050 (.076)	
		Resident	.093 (.066)	Group: F=7.109; p=.009** Context: F =.027; p = .871
	Intervention	Community	-.105 (.078)	Group * Context: F = .199; p = .657
		Resident	-.125 (.057)	

ADAS-Cog, Alzheimer's Disease Assessment Scale- Cognition; ANOVA, analysis of variance; CAPE-BRS, Clifton Assessment Procedures for the Elderly- Behaviour Rating Scale; CDR, Clinical Dementia Rating; *p≤0.05; **p≤0.01

Table 3. Change from baseline in measures of efficacy (covariate education)

	Change from baseline Treatment	Control	Group difference Means (SD)	95%CI	ANCOVA Between group difference
ADAS-COG	-1.418 (5.112)	+1.440 (5.199)	-2.627 (1.039)	-4.687 to -.566	F=6.391, p=.013*
QoL-AD	-.036 (3.717)	-.510 (4.481)	.754 (.830)	-.893 to 2.402	F=.825, p=.366
Holden	-2.745 (6.292)	.320 (9.673)	-3.308 (1.633)	-6.546 to -.070	F=4.105, p=.045*
CAPE	-1,473 (3.426)	.360 (4.575)	-1.967 (.811)	-3.575 to -.359	F=5.888, p=.017*
RAID	-3.073 (8.255)	-1.900 (5.870)	-1.551 (1.453)	-4.434 to 1.331	F=1.140, p=.288
Cornell	-1.909 (4.377)	-1.200 (5.253)	-.990 (.968)	-2.909 to .930	F=1.046, p=.309
CDR	-.118 (.346)	.080 (.355)	-.191 (.071)	-.332 to -.051	F=7.266, p=.008**

ADAS-Cog, Alzheimer's Disease Assessment Scale- Cognition; ANCOVA, analysis of covariance; CAPE-BRS, Clifton Assessment Procedures for the Elderly- Behaviour Rating Scale; CDR, Clinical Dementia Rating; Cornell, Cornell Scale for Depression in Dementia; Holden, Holden Communication Scale, QoL-AD, Quality of Life - Alzheimer's Disease; RAID, Rating Anxiety in Dementia
*p≤0.05; **p≤0.01

Table 4. Change from baseline in cognitive dimensions

	Change from baseline Treatment	Control	Group difference Means (SD)	95%CI	ANCOVA Between group difference
ADAS-COG word recall	-.491 (1.215)	+.120 (1.189)	-.573 (.243)	-1.056 to -.091	F=5.569, p=.020*
ADAS-COG naming objects	.018 (.303)	.080 (.601)	-.100 (.094)	-.296 to .086	F=1.142, p=.288
ADAS-COG commands	.145 (.756)	.180 (.941)	.084 (.165)	-.243 to .411	F=.259, p=.612
ADAS-COG constructional	-2.291 (.916)	.080 (.829)	-.389 (.177)	-.741 to -.038	F=4.831, p=.030*
ADAS-COG ideational praxis	-.127 (.840)	.040 (1.228)	-.235 (.209)	-.650 to .180	F=1.258, p=.265
ADAS-COG Orientation	-2.545 (1.680)	.260 (1.367)	-.508 (.312)	-1.126 to .110	F=2.658, p=.106
ADAS-COG Word recog.	.018 (2.642)	.180 (2.939)	-.076 (.563)	-1.193 to 1.041	F=.018, p=.893
ADAS-COG recall test inst	-.382 (1.581)	.140 (1.702)	-.518 (.332)	-1.176 to .141	F=2.433, p=.122
ADAS-COG spoken lang.	.036 (.922)	.220 (.887)	-.138 (.182)	-.500 to .224	F=.575, p=.450
ADAS-COG Word finding	-.036 (1.036)	.020 (.869)	-.085 (.194)	-.470 to .300	F=.192, p=.662
ADAS-COG Comp. spoken	-.054 (.989)	.120 (.824)	-.087 (.182)	-.448 to .273	F=.231, p=.632

ADAS-Cog, Alzheimer's Disease Assessment Scale- Cognition; SubScales: Word recall, naming objects and fingers, commands, constructional praxis, ideational praxis, orientation, word recognition, recall of test instructions, spoken language ability, word-finding difficulty and comprehension of spoken language; ANCOVA, analysis of covariance; *p≤0.05

Table 5. Change from baseline in behavioural / functional dimensions

	Change from baseline Treatment (n=55)	Control (n=50)	Group difference Means (SD)	95%CI	ANCOVA Between group difference
CAPE Physical disability	-.550 (1.874)	.280 (2.458)	-.923 (.438)	-1.791 to -.054	F=4.441, p=.038*
CAPE Apathy	-.360 (1.508)	-.120 (2.135)	-.427 (.363)	-1.148 to .293	F=1.383, p=.242
CAPE Communication	-.220 (.786)	.140 (.926)	-.328 (.173)	-.671 to .015	F=3.605, p=.060
CAPE Social disturbance	-.400 (1241)	-.300 (1.216)	.076 (.249)	-.569 to .418	F=.093, p=.761

ANCOVA, analysis of covariance; CAPE-BRS, Clifton Assessment Procedures for the Elderly- Behaviour Rating Scale; CAPE Physical disability (items 1,2,3,5,6,7); CAPE Apathy (items 4,8,9,10,11); CAPE Communication (items 12, 13); CAPE Social disturbance (items 14,15,16,17,18); *p≤0.05