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Protocolo de um ensaio aleatório controlado de estimulação cognitiva em adultos mais velhos com declínio cognitivo em contexto domiciliário

Protocol of a randomised controlled trial of home-based cognitive stimulation in cognitively impaired older adults

ABSTRACT

Objective: Cognitive stimulation (CS) is a non-pharmacological therapy with good support for its ability to limit the progression of cognitive decline in elderly people with neurocognitive disorders (NCD) by stimulating cognitive function. **Method:** We detail the structure and content of an intervention protocol in the older adults with NCD, based on individualized home-based CS. **Results:** The individualized intervention protocol based on CS is outlined and comprised of a repeatable 8-session basis scheme, with a weekly frequency and lasting approximately 45 minutes per session, administered by trained therapists. **Conclusions:** The one-on-one CS program can serve as a guide for future dissemination, with content that is easy to understand and implement, with relevant implications for clinical practice and NCD research. **Clinical implications:** There is evidence that this protocol has been successful in improving cognition and quality of life in NCD samples in Portugal; thus future dissemination of this protocol across other cognitive samples would have direct benefits to patients and offer additional treatment options for clinicians.

HEADINGS: Aged; Dementia; Program Development; Cognitive Dysfunction; Memory.

RESUMO

Objetivo: A estimulação cognitiva (EC) é uma das terapias não-farmacológicas com boas evidências pela sua capacidade de limitar a progressão do declínio cognitivo em pessoas idosas com perturbação neurocognitiva (PNC), através da estimulação da funcionalidade cognitiva. **Metodologia:** Detalhamos a estrutura e o conteúdo de um protocolo de intervenção em adultos mais velhos com PNC, baseado na EC individual em contexto domiciliário. **Resultados:** O protocolo de intervenção individual baseado na EC é delineado e composto por um esquema base repetível de 8 sessões, com frequência semanal e com duração aproximada de 45 minutos por sessão, administrados por terapeutas treinados. **Conclusões:** O programa de EC individual pode servir de guia para futura disseminação, com conteúdos de fácil compreensão e implementação, com implicações relevantes para a prática clínica e investigação da PNC. **Implicações clínicas:** Existem evidências que este protocolo tem sido bem-sucedido na melhoria da cognição e da qualidade de vida em amostras com PNC em Portugal; assim, a disseminação futura deste protocolo noutras amostras cognitivas poderá ter benefícios diretos para os pacientes e oferecer opções de tratamento adicionais para os terapeutas.

DESCRITORES: Idoso; Demência; Desenvolvimento de Programas; Disfunção Cognitiva; Memória.

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Este artigo foi submetido no SGP (Sistema de Gestão de Publicações) da RBTC em 12 de Janeiro de 2021. cod. 174.

Artigo aceito em 01 de Setembro de 2021.

DOI: 10.5935/1808-5687.20210009

INTRODUCTION

One of the consequences of ageing and the main cause of disability in older adults is neurocognitive disorders (NCD), with a prevalence of between 3% and 25%, is considered by the World Health Organization ([WHO], 2012) as a public health problem. NCD are estimated to affect 50 million people worldwide, with an expected increase to 150 million by 2050 (Patterson, 2018). The initial and less severe clinical condition is mild NCD, defined by evidence of moderate cognitive impairment compared to a previous level of individual performance in one or more cognitive domains, but without interference with the ability to perform the activities of daily life; in comparison NCD requires cognitive impairment in addition to functional impairment (American Psychiatric Association [APA], 2013).

According to Livingston et al. (2017) there are risk factors that can aggravate the development of NCD (e.g., low education, depression, low social support network). To mitigate the progression of cognitive impairment in people with NCD, non-pharmacological intervention can be used, as it promotes cognitive reserve and is generally thought to slow cognitive and functional expression of NCD (Tardif e Simard, 2011).

Cognitive stimulation (CS) is one of the recommended therapies by the National Institute for Health and Clinical Excellence (NICE) for NCD cases (NICE, 2007), promoting involvement in activities aimed at improving cognitive and social functions (Clare et al., 2003), and can be administered in a group or one-on-one format. This therapy is indicated to stimulate cognitive function (e.g. attention, calculations, executive functions, language, memory) in different severity and types of dementia. Regardless of the effect of medication, there is good evidence that CS improves cognitive functions, social interaction and quality of life (Aguirre et al., 2013; McDermott et al., 2019; Woods et al., 2012).

CS, when combined with other therapies such as reality-oriented therapy (ROT), demonstrates significant improvements in cognitive domains in patients diagnosed with NCD (Hsiao-Yean et al., 2018).

Most research on non-pharmacological therapies lacks the description of intervention protocols in detail (Orrell et al., 2017). Therefore, the ROT and CS protocol presented herein was developed, which describes our one-on-one protocol in Portuguese older adults with NCD.

METHOD

Based on the present protocol, an experimental design of repeated (pre, intra and post- intervention), randomized (through DatInf @ RandList software) and controlled measures in older adults with NCD in a home setting (Clinicaltrials.gov ID: NCT04417751) is conducted to evaluate the effect of the CS intervention program, in a one-on-one, long-term format.

Specifically, to this protocol tested the effectiveness of CS in cognition, mood, quality of life and functional status. The intervention group ($n = 30$) had 47 weekly, one-on-one CS sessions and 3 evaluation sessions. The control group ($n = 29$) received the usual care, which is essentially based on social interaction activities and personal skills training and stimulation activities.

The intervention protocol has been developed progressively in five phases. The first phase consisted on a review of the scientific literature on CS with older adults with NCD, in particular, regarding to the format, periodicity and duration of the sessions. We also collected socio-demographic characteristics of the participants and effects of CS on the overall cognitive state, mood state, quality of life and functional state. Based on the theoretical reviews, the Making a Difference program from Spector et al. (2006) was selected for adaptation.

Next, materials were adapted for older adults with NCD and adjusted to the Portuguese culture (e.g. commemorative dates, traditions, locations, celebrities, foods) and administered to participants throughout Portugal. Further, existing materials were selected, associated with CS and ROT principles, along with other complementary activities, aimed to stimulate attention, memory, language, calculation and executive functions.

Next, the structure and content of the sessions were defined using previously selected and developed materials. Participants had diagnoses of NCD using DSM-5 criteria by a doctoral-level provider, MMSE scores = 10-26, and aged 65+. Exclusion criteria include participants with sensory or perceptual deficits or acute mental health issues. Six older adults with NCD voluntary participated, uncompensated, in the pilot phase; this informed the final phase, a revision of the complementary materials and a new adaptation of existing material.

This study was conducted in accordance with the latest revision of the Helsinki Declaration and was approved by the Ethics Committee of the Health Sciences Research Unit: Nursing (UICISA: E) of the Nursing School of Coimbra (ESEnfC).

RESULTS

Table 1 outlines the full protocol. As our protocol addressed multiple cognitive domains in each weekly session, we focused our outcomes on global cognitive functioning and multiple domains, as specified in Justo-Henriques (2021). In summary, eight 45-minute weekly sessions were administered by a trained clinical psychologist. Individualized CS is described previously (Justo-Henriques, 2021; Justo-Henriques et al., 2019). One-on-one sessions should be conducted uninterrupted in a private, quiet and comfortable location.

Initially, the therapist greets and guides participants towards insight and reviews the objectives of the session. Next, time orientation training consistent with ROT is carried out using material that includes temporal and spatial elements (e.g. day of the week, month, day of the month, year, season and time of year, state of time and clock; Justo-Henriques, 2021).

Table 1. Intervention details by week.

Session	Contents and activities of the intervention	Material	Stimulated cognitive domain
1	Activity(ies)	N/A	N/A
2 [10, 18, 27, 35, 43]	Activity(ies): Request the participant to: identify the different colours present in the domino images on the board, as well as the domino pieces corresponding to those illustrated on the same board, placing them in their respective places; name, from the colours presented on the board, examples of fruits, legumes, flowers, etc.; perform mathematical operations (e.g, calculate the value of the sum of the yellow and green circles, giving each colour of the circle a score (e.g. each yellow circle has a value of three units and a green circle has a value of two units); remove the pieces containing the circles with the colours mentioned by the therapist.	A: composed of a board and coloured cards (domino piece format) on paper support.	Attention, memory, language, praxis, calculus and executive functions.
3 [11, 19, 28, 36, 44]	Activity(ies): Request the participant to: identify, from the reproduction of musical themes related to the authors/interpreter that appear on the roulette, the title of the theme, associating it to the card with the representative image of the same and place it next to the image of the author/interpreter on the respective roulette.	B: composed of roulette with image of singers associated with the present and the past and cards with representative images of the musical themes interpreted, on paper. Allusive sounds to the activity.	Attention, memory, language, praxis and gnosis.
4 [12, 20, 29, 37, 45]	Activity(ies): Request the participant to: describe the content of the images presented; place the cards with the images and/or syllables in the correct place of the "tree" in order to form the representative words in each image or invoked through the clues given by the therapist.	C: composed of a cardboard frame with a structure based on the concept of a family tree from a letter of the alphabet, with several branches to place cards with images or syllables.	Attention, memory, language, praxis and executive functions.
5 [13, 21, 30, 38, 46]	Activity(ies): Request the participant to: associate and collect from the table the cards with the allusive images to different musical themes, as they are being reproduced; name words/phrases associated to the theme reproduced, the title of the theme and the name of the respective author/interpreter (in case the participant cannot name them, the therapist should provide "hints/tracks" in order to continue the activity); organize and separate the cards with the allusive images to musical themes according to the respective author/interpreter.	D: composed of cards with the images allusive to different Portuguese musical themes. Audios corresponding to the themes portrayed.	Attention, memory, language, praxis, gnosis.
6 [14, 22, 31, 39, 47]	Activity(ies): Request the participant to: unscrew the covers from the tray to form the word that is the answer to each card's question; then place the covers in the initial position (i.e. in ascending order of alphabet). Repeat the exercise until you have completed the words alluding to the cards presented by the therapist.	E: composed of a wooden board with plastic lids, each with a letter of the alphabet; cards with questions according to various degrees of difficulty.	Attention, memory, language, praxis, executive functions.
7 [15, 23, 32, 40, 48]	Activity(ies): Request the participant to: associate the cards with generic images of some of the emblematic television programs in the history of Portuguese television to date; identify the audios representative of the generics of each program and associate them with the image of the card that represents it; name the presenters and the television channel associated with the different programs; report personal interest and knowledge about the programs covered in the activity.	F: composed of a poster with symbolic images of television programs and cards with associated images, on paper. Audio allusive to the activity.	Attention, memory, language, praxis, gnosis.

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Session	Contents and activities of the intervention	Material	Stimulated cognitive domain
8 [16,24, 33,41, 49]	Activity(ies): Request the participant to: associate the different cards with images of activities of daily life, placing them in sequential order of their realization throughout the day and next to the usual time represented on the poster with clock; Distribute the most typical activities of the morning and the afternoon, as well as the most allusive activities on weekdays and weekends; describe the contexts in which these activities take place; name the most representative activities of certain situations; plan the routines for a certain period indicated by the therapist the morning and the afternoon, as well as the most allusive activities on weekdays and weekends; describe the contexts in which these activities take place; name the most representative activities of certain situations; plan the routines for a certain period indicated by the therapist..	G: Composed by a poster in circular format, with an analog clock in the center and at the ends with spaces to place the cards with the daily activities. Cards with images representative of several of the daily activities. the cards with the daily activities. Cards with images representative of several of the daily activities.	Attention, memory, language, praxis, executive functions.
9 [17, 26, 34, 42]	Activity(ies): Request the participant to: name the images of the basic products (e.g. bread, milk, rice, meat) on the poster; draw up a shopping list, selecting the cards with the images of the products desired and calculate the total amount to be paid; give the therapist the cards for the purchase, according to the representative value of a sum of money, calculate the total value of the supposed purchase; calculate the value of the respective change.	H: composed of a poster with images of products and their indicative prices, individual cards with images of the products), cards representing amounts of money. All paper-based materials.	Attention, memory, language, praxis, calculus and executive functions.
25	Activity(ies): Intra-evaluation	N/a	N/a
50	Activity(ies): Post-evaluation	N/a	N/a

Note: N/A: not applicable.

The main activity (approximately 25 minutes) trains the cognitive domains (e.g. attention, memory, language, executive functions, calculations, gnosis, praxis) according to the theme defined for the respective session (see Table 1). The last five minutes of each session includes brief relaxation, debriefing, and processing (e.g., difficulties, interests, and benefits, as well as preferences for the following session; Justo-Henriques, 2021). Finally, the participant is reminded of the next scheduled session. At the end of the session, the therapist records the behavior (e.g. cooperative/interested; non-cooperative; passive) and engagement (e.g. participated; did not participate) of the participant.

DISCUSSION

The current detailed intervention protocol serves as a technical guide for clinicians who may seek to employ this protocol and reduces reliability concerns in future implementation of the protocol. We feel that our CS materials based on the cognitive functionality of older adults in a comfortable, quiet, and distraction-free setting facilitates the training of cognitive domains in the most realistic, efficient, and ecologically-friendly setting.

Psychosocial interventions, in a one-on-one format, are associated with better results, compared to group interventions, as they resort to personalised activities, which assist in closer contact between the participant and the therapist, increasing access to the intervention (Justo-Henriques et al., 2019). A one-on-one intervention enhances the collaboration of the participant in the session and allows the exercises to be oriented according to the participant's needs, preferences and references (Justo-Henriques, 2021).

A limitation of this study is the limited understanding of the effectiveness of the CS protocol given its novelty. Thus, we propose this intervention continue to be applied in multiple patient samples to allow for a better understanding of its effects on cognition, mood, quality of life and functional status in home-based elderly NCD patients.

The current individualized home-based intervention program was developed based on principles of ROT and CS therapy for older adults with NCD. However, more evidence of the long-term effects of psychosocial interventions is needed (McDermott et al., 2019). The current model may be disseminated and provide a starting point for new scientific programs and studies (e.g. specification of types and severity of dementia).

CLINICAL IMPLICATIONS

The current CS protocol has been successful in improving cognition and quality of life in NCD samples in Portugal (Justo-Henriques et al., 2020). Thus, future dissemination of this protocol across other cognitive samples would have direct benefits to patients, including those with varying degrees of cognitive impairment. Further, this protocol provides crucial and necessary additional treatment options for clinicians who are considering alternative treatments for their patients.

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