

Cognitive Emotional Stimulation Program (CESP) for memory improvement in older community-dwelling adults (Programa de Estimulación Cognitiva Emocional [PECE] para la Mejora de la Memoria de Personas Mayores que Viven en la Comunidad)

Submission date 09/10/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/11/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/09/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Retired people who live independently frequently complain of memory loss and of not generally being in good humour or a happy mood when carrying out their daily activities. This state often coincides with the reduction of physical, cognitive or social activities characteristic of retirement. There are also erroneous beliefs among elderly and healthcare professionals regarding normal memory function. Expressions such as with age its normal to forget things or retirement is a time to rest, or its too difficult to learn new things as you get older often serve as self-fulfilling prophecies, and they lead the more elderly to adopt a passive attitude toward memory loss. In recent decades it has been shown that elderly people can improve their memory skills through instruction and practice with the help of stimulation programs. The benefits of Cognitive Emotional Stimulation Programs (CESPs) are immediate but tend to reduce with time. Reinforcement sessions have been proposed as a means to maintain the positive effect of intensive programs. Another way to approach memory problems is not based in intensive programs, but instead by participating in leisure activities. Several research studies have demonstrated that people who participated in a greater number of leisure activities experienced greater improvements in their performance. However, the greater frequency of social and physical activities was reflected in better social networks, but not in significant memory improvement. The aim of this study is to assess the long-term effect of a new time-extended CESP program. This proposal brings together the advantages of intensive programs (they are structured and evaluated) and the advantages of routine annually programmed leisure activities.

Who can participate?

Senior (aged 65 or over) retired community-dwelling persons living independently.

What does the study involve?

Participants were randomly allocated to either the experimental group or the control group. The control group received 32 intensive sessions three times weekly for 11 consecutive weeks in 2006, and the experimental group received 32 sessions in 32 weeks from October to May each year between 2006 and 2012, with a total of 192 sessions.

What are the possible benefits and risks of participating?

The benefits of participation in the study are stimulation of everyday memory, improved functionality of everyday life, and shared experiences with peer groups. There are no risks of participating in this study.

Where is the study run from?

Universidad de León (Spain).

When is the study starting and how long is it expected to run for?

The study ran from January 2006 to July 2012.

Who is funding the study?

City Council of Ponferrada and Universidad de León (Spain).

Who is the main contact?

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Study website

<http://envejecimientoentodaslasedades.unileon.es/primera-generacion.html>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Six-year effects of the time-extended stimulation program on everyday memory in healthy older persons: a randomized controlled trial

Acronym

Long-Term

Study objectives

Extended stimulation programs preserve everyday memory of healthy older adults in the long term.

On 14/08/2015 the overall trial end date was changed from 30/07/2012 to 31/12/2014.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical & Technical Committee of the City Council of Ponferrada (Spain)

Study design

Two-arm randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Memory improvement in older community-dwelling adults

Interventions

A two-group (experimental and control) randomized controlled procedure with a 2:1 allocation ratio was carried out, combined with stratified randomization by age, sex and MMSE scores.

The control group received 32 intensive sessions at a frequency of three times weekly for 11 consecutive weeks in 2006, and the experimental group received 32 sessions in 32 weeks from October to May each year between 2006 and 2012, with a total of 192 sessions. The program was carried out in two phases: the first analyzed the differences between the extended and intensive CESP after both groups received 32 sessions; and the second phase analyzed the effect of the 160 sessions of training received only by the experimental group.

Added 29/09/2015:

COGNITIVE EMOTIONAL STIMULATION PROGRAM

Subdomains included in the memory training program are: name, recognition, prospective memory, orientation, short term memory, attention, concentration-calculation and language-construction. The design of the memory training program sessions combines the proposal of a group memory therapy model (Wilson & Moffat, 1992) with cognitive stimulation exercises collected in Requena's memory program Memoria Mejor (2002, 2005). Wilson's therapy group deals with contents related to each module, as it is detailed below. The emotional dimension is treated with discussion groups (Wilson & Moffat, 1992). Cognitive stimulation exercises from the program Memoria Mejor stem from ordinary Pastime activities appearing in the local press and magazines.

PASTIME (Requena, 2002, 2005)

The Program includes training sessions (where new exercises are presented and explained) and reinforcement sessions (where home made exercises are corrected). These exercises have been ordered in sequences according to their difficulty level. The difficulty scale grades exercises from the basic learning level to the master level, which is able to cope with any arbitrary exercise appearing in the local press. Among the types of collected exercises the following are prominent: 1. Conversion from letters to numbers (4 levels of difficulty), 2. Extraction of words from other words (1 level of difficulty), 3. Word completion from missing vocals (1 level of difficulty), 4. Recognition of misplaced words (2 levels of difficulty), 5. Alphabet soups (13 levels of difficulty), 6. Peseta/euro conversion (1 level of difficulty), 7. Tagram (5 levels of difficulty), 8. Domino (8 levels of difficulty), 9. Magic stair (several misplaced words forming a new word when properly ordered) (1 level of difficulty), 10. Crosswords combined with labyrinths (1 level of difficulty), 11. Knight moves (3 levels of difficulty), 12. Operations with addresses (associating addresses with places and descriptions) (1 level of difficulty), 13. Calculation of values (deduction of fruit values) (1 level of difficulty), 14. Word puzzles (1 level of difficulty) and 15. Templates with colors and shapes. Each difficulty level is composed by 6 exercises. All exercises and their corresponding handbooks with keys and solutions are available in : <http://envejecimientoentodaslas edades.unileon.es/primerageneracion.html>

GROUP MEMORY THERAPY MODEL (WILSON & MOFFAT, 1992)

Block I - Cognitive content

Module I: 'How does the memory work'

The objectives of the CESP are explained, as well as issues regarding the different types of memory and memory in old age. This module included home exercises so that participants could accurately measure their own performance in different memory tasks.

Module II: 'Making it easier to remember'

External aids were explained, such as temporary storage (e.g., purchasing list), long term storage (e.g., address book), planning (e.g., calendar) or organizing one's space (e.g., keeping each thing

in its appropriate place).

Module III: 'Concentration'

This module deals with maintaining concentration skills, such as having brief periods of rest during reading, suppression of external distractions (e.g., working in a calm room or doing one thing at a time.) or working against one's intrusive thoughts (e.g., verbalizing the action during its performance).

Module IV: 'Practice makes perfect'

Information to be learned by the experimental subjects is presented in group settings (e.g., names of people or objects). Each group member identified information to learn and remember, such as people's names, objects or dates. One of those elements is selected to practice daily using worksheets. This exercise was spaced throughout the day using a rule of doubling the time interval in between practice sessions (e.g., the exercise commences at 10:30 am, 10:32, 10:36, 10:44 and so on: Moffat, 1992).

Module V: 'Remembering to run errands'

The group focused on exploring ways to reduce the chance of forgetting (e.g., method of Loci). It consists of creating an itinerary (almost always a sequence of rooms) that are very familiar to the subject. This itinerary is linked to tasks or issues that the experimental subject wishes to remember (e.g., to do errands or make phone calls).

Module VI: 'Remembering information'

Practicing this module entailed tasks such as recalling a newspaper article or recent news seen on television. Homework related to this is also given (e.g., fill-in-the-blank exercises on paper regarding the news).

Module VII: 'Active listening and expressing ideas'

Cards with sequences of listening abilities, as well as indications for expressing ideas, were handed over to the participants. Each group member gave a presentation about a freely chosen topic. The cards were distributed amongst the group members to maintain a minimal rate of conversation and also to remember the presentation's main issues.

Module VIII: 'Making the best use of my memory'

Exercises within this module try to stimulate mental skills that reinforce memory. They included sensory stimulation exercises (e.g., improving visual acuity using a photograph), voluntary attention (e.g., identifying a misspelled word), intellectual structuring (e.g., re-ordering a disorganized text), language (e.g., word puzzles) or calculus (e.g., sudokus).

Module IX: 'Exercising memory strategies'

Training subjects are required to exercise categorization activities, like grouping information. In order to remember a list of words the subject must organize them into different categories, which requires a degree of abstraction. In practice a disorganized list of elements is given, in a second step they must be organized into different categories and in a third, those elements must be remembered without naming the categories.

Block II: Emotional content

Module X: 'Confronting other problems'

Many of the group members have similar worries, including cognitive, emotional, family, economic and legal problems. The group was encouraged to discuss the problems or struggles that are proposed by the psychologist or a group member. If any particular group member required specific information, he or she is referred to a social worker at the senior citizens community centre.

Module XI: 'Emotion and memory'

This module concentrates on the relationship between mood and memory performance (or more precisely about the self-perception of memory performance). The relationship between confidence in one's memory and factors like depression, anxiety, good and bad days, etc. Relaxation and auto-instructional training were proposed to aid memory when lapses occur.

The contents of the 32 training sessions were organized in the following way: the first eleven training sessions corresponded with the eleven modules, each of the first nine pastimes occupied a session (from the 12th to the 20th), while the following pastimes occupied two training sessions each (from the 21st to the 32nd). Concerning the 160 refreshing sessions only received by the experimental group, they were distributed in 32 sessions during the following five years after the treatment (one weekly session from october to may). The contents of refreshment had different individual exercises, but were organized just as training sessions.

Correspondence between Subdomains of memory training program, Pastime and Modules.

Names: Pastime 1-5, 9-11,14 and Module IV

Recognition: Pastime 1-15 and Module VIII

Prospective memory: Pastime 1-15 and Modules IV, V, IX

Orientation: Pastime 5,7,8,10-12 and Module V, IX

Short term memory: Pastime 1-15 and Module VI, IX

Attention: Pastime 1-15 and Module II, IX

Concentration and calculation: Pastime 6,8,12,13 and Module III

Language and construction: Pastime 1-5,7-9,1,14,15 and Module VI,VII

Therapeutic training

One of the programme's aims was to train 8 qualified psychologists (M.A. or Ph.D.) in CESP administration and intervention, according to the following parameters:

1. Basic Training

This was done prior to the beginning of the research study and it lasted 25 hours. The Basic Training was delivered as an intensive course, both theoretical and practical, to address the following topics:

1.1. Memory: Memory operations, phases and types of memory; Memory disturbances; Strategies.

1.2. CESP training: Training model; Session implementation and distribution of content per session; Specific exercises; Incorporation of the memory training program into daily life activities; Role-playing with voluntary older adults; Audiovisual tools.

1.3. Group management.

2. Monitored sessions

This was accomplished through continuous activities co-ordinated throughout the study involving the regular contact of the research group with each CESP therapist. These frequent encounters allowed information to be disseminated about the CESP and related topics. This helped to improve and maintain the therapists' skills, as well as to make the practice of the different CESP therapists more uniform. The therapists were blind to which groups formed part of the experimental and control group.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Three assessments were performed: at baseline; after 32 training sessions (follow-up 1); and a final evaluation of both groups in year 6 (follow-up 2). In the case of the control group, follow-up 1 took place after 32 sessions at the 11th week. In the case of the experimental group, follow-up 1 occurred after 32 sessions in 32 weeks.

A number of instruments were used to evaluate the psychological effects of the CESP.

1. The Mini-Mental Cognitive Examination (MEC-35) test, the Spanish adaptation (Lobo et al., 1979, 1987) of the Mini-Mental State Examination (MMSE, 35 items: Folstein et al., 1975), was used to measure cognitive impairment, which explores orientation, memory, attention, language, calculation and some constructive praxias. The MMSE is widely used to quantify intellectual deterioration and its progression over time, and is particularly useful in evaluating the elderly. It can be used repeatedly and thus can document an individual's response to training or treatment. The MMSE has an 84.6% sensitivity and an 82% specificity (Saz & Lobo, 1993).
2. Memory was evaluated through a standardized measure of both objective (Rivermead Behavioural Memory Test, RBMT) and subjective memory (Memory Failures Everyday, MFE). The RBMT is a battery designed to tap the participant's memory in everyday tasks. There is evidence that favours the use of the RBMT in older adults (Wilson, Cockburn, Baddeley, & Hiorns, 1985) and for neuropsychological assessment of memory impairment (Cockburn, 1996). The RBMT assesses different types of memory such as associative memory, prospective memory, visual memory, verbal memory, topographic memory, control, and recognition strategies, producing a global score from 0 to 12 points. A Spanish version of the RBMT has been used and validated with the Wechsler Memory Scale (Sánchez & García, 1992; Alonso & Prieto, 2004).
3. The Memory Failures Everyday (MFE) test (Sunderland, Harris, & Gleave, 1984) has 28 items relating to daily life situations and activities. They are originally scored in a nine-point Likert scale (from it has not happened once in the last three months to it happens more than once daily), which has been transformed into a three-point scale (never or rarely, sometimes, often), which was chosen for our study for its simplicity of use. These items reflect common daily situations, e. g., forgetting a message, not remembering where an object has been placed, etc. The MFE allows frequent errors to be measured, helping in the clinical diagnosis of cognitive problems and providing useful information regarding evaluation. The psychometric properties of this test within the Spanish population are a reliability of 0.89 and a validity of 0.48.
4. The Geriatric Depression Scale (GDS: Yesavage, 1983) is a well-known scale used to measure mood in older adults. The GDS consists of 30 items answered dichotomously. It has also been adapted to and validated for the Spanish geriatric population. The normality cut-off point in the Spanish population is 17/18, with a sensitivity and specificity of around 95 % (Ramos, 1993).

Secondary outcome measures

A final evaluation of both groups in year 6 (follow-up 2). follow-up 2 took place after the last 6th year, after the experimental group receives 162 refresher sessions in 162 weeks

Overall study start date

12/01/2006

Completion date

31/12/2014

Eligibility

Key inclusion criteria

1. Aged 65 years or over
2. Senior retired community-dwelling persons living independently

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

1756

Key exclusion criteria

1. Self-reported diagnoses of Alzheimers disease
2. Severe sensory impairment (sight and/or hearing)
3. Moderate dependence (need help to perform daily life activities more than twice a day)
4. Unavailability during the study period

Date of first enrolment

12/01/2006

Date of final enrolment

30/07/2012

Locations

Countries of recruitment

Spain

Study participating centre

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Government

Funder(s)

Funder type

Government

Funder Name

City Council of Ponferrada and Universidad de León (Spain), research contract O181

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration