

Learning to preserve: foreign language training as a cognitive *vaccine* to prevent old-age disorders?

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55779

Source

ToetsingOnline

Brief title

FlexLang

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym

cognitive complaints, Cognitive decline, mood complaints.

Health condition

Cognitieve achteruitgang door veroudering

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bilingualism, cognitive decline, cognitive flexibility, depression

Outcome measures

Primary outcome

The main study parameters concern i) cognitive flexibility; ii) brain activity in the theta band during switch tasks, and iii) changes in oxy- and deoxyhemoglobin concentration during switch tasks. Baseline characteristics and changes herein following foreign language training will be analysed.

Secondary outcome

Secondary study parameters include clinical measures, measures of vulnerability for depression, quality of life and language proficiency. These measurements provide additional information to interpret and understand the effects induced by the language intervention vis-à-vis other forms of intervention and to understand the changes in neurocognitive functioning.

Study description

Background summary

As the world population is growing older, the proportion of seniors increases and more individuals will have to face the challenges that accompany old age. One of the most documented challenges that accompanies ageing is cognitive decline. Although subtle losses in cognitive function are part of normal cognitive ageing, individuals differ greatly in their susceptibility to age-related cognitive decline. Some individuals seem able to compensate for these changes better than others; they show cognitive reserve. It is suggested

that individuals with a higher cognitive reserve can tolerate more pathology and can therefore shift the onset of manifestations of cognitive decline. Other challenges that accompany ageing can cause emotional suffering, including depression. Old age depression is associated with decreased physical, cognitive and social functioning, which in turn contributes to a decreased quality of life. Among the most prevalent cognitive deficits in depression are deficits in executive functioning, especially cognitive flexibility. Deficits in cognitive flexibility affect the disposition to adaptively regulate emotional states, which contribute to the persistence of the depressive disorder but is also a vulnerability factor. Therefore, increasing cognitive flexibility might trickle down to benefit the course of depression. One experience that has repeatedly been related to enhanced cognitive flexibility is bilingualism: lifelong bilingualism is inherently associated with cognitive advantages and the attenuation of cognitive decline. Bilingualism could therefore serve as a tool to combat old-age cognitive decline and mood disorders.

Study objective

The main objective of this study is to determine whether a bilingual experience in old age affects cognitive flexibility and its neural underpinnings, which could in turn explain health advantages. Secondly, this study aims to evaluate the effect of a bilingual experience on health outcomes (vulnerability for depression, cognition and quality of life). We do so by introducing a bilingual experience later in life, operationalized as a foreign language course for seniors. If a bilingual experience indeed has protective effects, foreign language learning could serve as an important tool towards healthy ageing and, as such, have an important clinical application.

Study design

This study is an open-label randomized controlled trial with pre- and post-intervention measurements in individuals with subjective, but not objective, cognitive decline. Participants are pseudorandomly assigned to the language intervention or to one of the two control groups; a music intervention or a social (art) intervention. These control conditions are chosen to assess the unique role of foreign language training versus other cognitive training programs or social engagement aspects. All interventions last three months, with the possibility to extend the training period to six months, which allows studying *dose-response* relationships. During the study - and following an initial screening - there are four measurements. All participants will be measured at baseline (T0) and three months after the start of the training (T1). For those who choose to end the training after three months, this examination will serve as the post-intervention examination. Participants who have chosen to extend the training period to six months will complete the post-intervention examination (T2), at six months after the start of the intervention. All participants have a follow-up examination (T3) six

months after the end of their intervention (either 9 or 12 months after the start of the training, dependent on the length of the chosen intervention: 3 or 6 months, respectively). All measurements consist of questionnaires and neuropsychological assessment and all measurements, except for the follow-up examination (T3), include EEG/fNIRS measures to measure brain activity. Learning progress will be measured at post-intervention (T1 and T2) and at follow-up (T3) using IELTS. Research assistants that are blind to the training condition will perform all clinical assessments.

Intervention

All intervention methods have a duration of two times three months. The three months option will increase a priori motivation and lower the threshold to participate. After the first three months, participants are free to extend the training period to six months or not.

In the language intervention group, participants will be taught a foreign language, English. Participants will practise English at home for 45 minutes per day, five days a week, using materials provided in an online learning environment, provided by a certified online training institute. Besides that, they will engage in real-life classes of 90 minutes per class every other week in groups of approximately 15 to at most 20 participants.

Participants assigned to the music intervention will receive musical training in which they will learn to play an instrument, learn to read music and practise rhythm using methods provided in the same online learning environment. Similar to the language intervention, participants are expected to practise at home for 45 minutes per day, five days a week and to engage in real-life classes of 90 minutes each, every other week.

In the social (art) intervention, participants will attend 90-minute social meetings every fortnight in which they will participate in different art workshops.

In all interventions groups, participants will be asked to log their out-of-class exposure using a diary during the time they participate in the intervention.

Study burden and risks

Following an initial screening, included participants are invited for the baseline examination. All interventions, the language and both controls, start hereafter. A post-intervention examination is planned three months after the start of the interventions. For those who choose to continue the training for six months, the post-intervention examination is repeated at six months after start. Finally, participants are invited for a follow-up examination 6 months

after the end of the intervention.

The initial screening consists of an interview to assess current and past psychopathology (30 minutes) and questionnaires (70 minutes) to assess whether potential participants are eligible to participate. Two weeks before all examinations, questionnaires will be sent to the home address of the participant to reduce the burden of the examinations. Filling in these questionnaires takes 50 to 60 minutes. The baseline and post-intervention examinations all consist of questionnaires (approximately 25 minutes), neuropsychological tests (40 minutes), and measures of brain activity using simultaneous non-invasive fNIRS/EEG methods during a switching task and during a resting state measurement (30 minutes). The baseline and post-intervention examinations therefore take approximately 3 hours. In the follow-up examination six months after the end of the intervention, the questionnaires and neuropsychological testing session will be repeated in addition to a short interview to assess psychopathology (total session duration of 2.5 hours). No brain activity measures will be performed in this follow-up examination.

The language and music intervention have a similar intensity. In both interventions, participants are asked to practise at home 5 days a week, 45 minutes a day. In addition, every fortnight participants will attend real-life classes for 90 minutes each. For the social (art) intervention, participants only attend real-life classes every other week for 90 minutes during which they will practice several kinds of art.

Concerning the fNIRS/EEG measures, participants will be exposed to near-infrared light, which has no known influence on health. No disadvantages are expected with regard to any of the measures or with regard to any of the interventions. However, participants might benefit from the interventions in that it may increase their proficiency in English, music or art skills and it may increase social exposure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Elderly (65 years and older)

Inclusion criteria

- 1) between 65 years and 80 years of age;
- 2) native Dutch speakers;
- 3) functionally monolingual. That is, they should not use any language other than Dutch in their daily lives (they use the Dutch language 80% of the time);
- 4) not multilingual, although they may have learned additional (foreign) languages in their lives;
- 5) proficiency in the English language is below B1 level;
- 6) a current experience of self-perceived or informant-perceived persistent decline in cognitive capacity in comparison to his/her previously normal cognitive status which is unrelated to an acute event (as measured with the Subjective Cognitive Decline Questionnaire; score > 5)
- 7) normal age-, sex-, and education-adjusted performance (≥ 23) on the Montreal Cognitive Assessment (MoCA);
- 8) participants should display normal intelligence ($IQ > 85$) as assessed with the Dutch Adult Reading Test (DART);
- 9) they should be able to read
- 10) they should have access to a computer or tablet with internet connection and have basic skills using it as both interventions take place using an online format.

Exclusion criteria

- 1) a diagnosis of MCI, prodromal AD or dementia according to DMS-V criteria;
- 2) having extensive experience playing a musical instrument for the last 20 years;

- 3) a psychiatric or neurologic disease (apart from AD), medical disorder, medication, or substance use;
- 4) any current DSM-V disorders according to the SCID-I interview or a past diagnosis in the last 10 years;
- 5) any current or past alcohol or drug dependency or abuse;
- 6) daily use of benzodiazepines;
- 7) neurological problem (including epilepsy, dementia, neuromuscular disorders);
- 8) hearing or visual impairments other than correctable to normal by hearing devices or glasses.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	30-11-2018
Enrollment:	113
Type:	Actual

Ethics review

Approved WMO	
Date:	23-08-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	21-06-2019

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-07-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-10-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL65233.042.18
Other	NTR: NL7137

Study results

Date completed:	01-04-2022
Actual enrolment:	113