A Novel Method of Teaching English to People with Mild Cognitive Impairment Using Songs: A Randomized Controlled Trial Protocol

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Abstract.
Background: People with mild cognitive impairment (MCI) need to prevent the further decline of their cognitive functions, and one way to do so is by learning a foreign language.
Objective: This study describes the development of a protocol for a novel, non-pharmacological intervention for people with MCI that seeks to prevent or reduce cognitive decline by teaching English through songs.
Methods: The development of this protocol follows a mixed-methodology approach, consisting of three stages: 1) development of the protocol of the intervention, 2) a randomized controlled trial study with two arms over six months that includes an intervention group and a control group, and 3) the evaluation of the protocol by trainers. In the second stage, we recruited a total of 128 people with MCI from the five participating countries of this study (Greece, Spain, Croatia, Slovenia, and Italy). This educational program will assess three main outcomes after 6 months of the English Lessons with the Use of Songs for People with Mild Cognitive Impairment (E.L.So.M.C.I.) workshops.
Results: Our primary outcome will hopefully be an improvement in general cognition in the intervention group compared to the control group from baseline to 6 months follow-up. Secondary outcomes include a decrease in participants' anxiety and depression and an improvement in their quality of life. Development of English language skills is the last outcome.
Conclusion: This is the first study to develop a protocol and implement and assess this intervention in a randomized controlled trial. We expect this intervention to help people with MCI in cognitive, psychological, and social aspects.

Keywords: Anxiety, cognition, depression, learning English, mild cognitive impairment, non-pharmacological intervention, prevention, randomized controlled trial, songs for learning English

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INTRODUCTION

Alzheimer's disease (AD) and other dementias are considered the most common neurodegenerative disorders, with an estimated prevalence of 10–30% in the global population over 65 years of age [1]. Dementia is a devastating disease that affects more than 50 million people worldwide. This number is expected to double every 20 years, reaching more than 150 million in 2050 [2, 3].

Mild cognitive impairment (MCI) is the preclinical stage of dementia [4]. People with MCI develop greater cognitive dysfunctions than expected for their age, greater symptoms of depression, lower quality of life, and avoidant coping strategies, including withdrawal from social engagement [5]. However, they do not experience the functional changes characteristic of AD or other forms of dementia [6]. The main difference between MCI and dementia is how people function in daily tasks. MCI is heterogeneous in its clinical spectrum and has historically been challenging to define, identify, and monitor in clinical practice. MCI does not always lead to dementia and can remain stable over time or revert to normal cognition if reversible causes such as disrupted sleep, depression and anxiety symptoms, medications, vitamin deficiencies, etc., are treated [7]. People with MCI may be at an increased risk of conversion to dementia, in which there is further cognitive decline and marked impairment in daily life [8]. Therefore, MCI is understood as an intermediate state between normal aging and dementia [9].

As MCI may progress to dementia, the prevention of MCI is likely to be the best way to avoid the onset of dementia and any further deterioration of cognitive functioning [6]. It has been systematically displayed that participation in activities that stimulate brain function [10] can help strengthen cognition in the elderly [11, 12] and protect them from cognitive impairment due to aging or neurodegenerative disease [13]. The interventions that focus on appropriate and stimulating treatments should improve cognitive function and delay or prevent the development of dementia [14, 15].

Foreign language learning is thought to delay the onset of dementia [16, 17]. Antoniou et al. (2013) suggest that learning a foreign language could improve cognitive plasticity in older adults with cognitive decline, as this type of learning requires the use of extensive neural networks, soliciting working memory, inductive reasoning, sound discrimination, speech segmentation, task switching, rule learning,

and semantic memory [18, 19]. Moreover, they posit that learning a foreign language could have important social implications, as gaining access to a second language could facilitate communication with foreigners and increase travel opportunities [19, 20]. Furthermore, intensive foreign language learning has been proven to improve participants' attention skills compared to control groups that do not learn a non-native language [21]. New synaptic connections are facilitated, but the perseverance of results after 9 months needed continuous practice after the end of the foreign language course [21]. Additionally, in a study by Bellander et al. (2016) in which Swedish individuals were learning Italian for 10 weeks, it was observed, after a whole-brain analysis of the participants, that there were larger changes in gray matter structure of the right hippocampus in the experimental group compared to a control group that was not learning a foreign language [22]. Thus, foreign language learning could serve as a way of preventing the cognitive changes of MCI enhancing their cognitive abilities such as attention and memory.

In the last few decades, numerous music therapy techniques and interventions have been developed for preventing and improving cognitive decline [23]. A lot of studies analyzed the positive impact of music therapy on cognitive, psychological, and behavioral symptoms in people with dementia and AD [24–26]. According to these results, the positive effect is associated with neural plasticity, and more specifically, with functional and structural brain plasticity in temporal (medial and lateral) regions, prefrontal and parietal areas, and the basal ganglia [27, 28]. Additionally, many theoretical and experimental studies support the use of songs for effective teaching and learning of a second language, such as English, and suggest a mutual reinforcement between learning songs and a second language [29]. Experts in this field underline the multiple benefits derived from using songs as an educational tool, such as the acquisition of linguistic skills (vocabulary, grammar, and syntax) and paralinguistics (accents, tones). Among the results of many studies, it is highlighted that the linguistic gains obtained in the groups where in which songs had been employed are higher than in groups that used other methodologies [29–31]. In addition to the benefits on cognitive abilities, communication, and comprehension, songs in the learning process have a psychological impact, which is probably the most significant one [32].

Since English is the lingua franca nowadays, there is strong evidence that learning English is

more beneficial for people with MCI than learning another language. People who know English can communicate in this language, even at a basic level, and comprehend many words and concepts of daily life. However, because people with MCI have deficits in their cognitive abilities, it is not easy for them to learn a foreign language through a conventional teaching method. Therefore, there is an increased need to apply more creative approaches and methodologies that will help them remember more easily, such as using songs as a teaching tool in learning English. The methodologies that are used in this educational protocol are better described in the "Methods" section of the current paper.

The study is designed to build an educational intervention by developing an intervention protocol for older people with cognitive dysfunctions who may also experience anxiety and/or depressive symptoms. It can be used in clinical practice as an intervention for psychological symptoms. The main hypothesis of implementing this educational intervention is that the intervention group, which participates in the English lessons twice a week for 6 months, will perform better on global cognition tasks, such as those that test memory, attention, and perception, compared to the control group. Another goal of implementing this educational intervention is to have a positive impact on participants' psychological symptoms and quality of life. Improvements in the knowledge of English will be considered the last goal of the intervention.

In sum, this study has the following primary objectives: 1) to evaluate the structure and content of the educational intervention by participants and trainers; 2) to identify a standard intervention protocol suitable for people with MCI, which will define a clinic-based pathway for future enrollment in such an intervention. The secondary objectives are: 3) to evaluate the effectiveness and efficacy of the educational intervention for mild cognitive dysfunctions in people with MCI using neuropsychological assessment; 4) to evaluate the reduction of mild-to-moderate anxiety and depression symptoms in participants in the intervention; 5) to measure the possible improvement of the quality of life of people with MCI; and 6) to assess the enhancement of knowledge of the English language.

METHODS

Design

The protocol for this study uses songs as tools for a better understanding of the concepts and rules of the English language and easier memorization for people with MCI. This intervention also borrows elements from Communicative Language Teaching [33], Natural Approach [34], (De)suggestopedia [35], and Neurolinguistic Programming (NLP) [36], which can support the learning process and improve cognitive cultivation. The design of this intervention has been based on the author AC's (English Teacher and Linguist) previous experience teaching English to adults in Lifelong Learning Centers in Greece. These people were usually pensioners, above 60 years old, who wanted to learn English. But most of them had some cognitive disabilities, and conventional lessons could not apply very easily to this group. Thus, there was a need to adapt the theory from Theoretical and Applied Linguistics. For that reason, a new approach was tested by combining elements from the four prementioned methodologies in language learning. We used more teaching aids than usual and followed the learning pace of the learners. Author AC tested various methods from Applied Linguistics and selected the four most effective of them. Moreover, after several trials, it turned out that the frequent use of songs in the educational process was the most effective teaching aid for this target group. These specific educational methodologies help people focus on natural acquisition rather than on typical learning of the target language.

Furthermore, the teaching methodology of the intervention has been used in a pilot study with seven participants, all people with MCI, in Greece. The pilot study lasted from December 2017 to July 2019 at the Greek Association of Alzheimer's Disease and Related Disorders (GAADRD). At the end of the program, the people with MCI shared positive feedback on the structure, the contents of lessons, and their experience in the English language by answering a self-reported questionnaire. Neuropsychological assessments were used and proved the efficacy of this methodology on cognitive and psychological symptoms (Christakidou et al, unpublished data).

Additionally, this innovative intervention was successfully submitted and granted by the Erasmus+KA2 - Cooperation for Innovation and the Exchange of Good Practices - KA204 - Strategic Partnerships for Adult Education (project number: 2020-1-EL01-KA204-078922). The English Lessons with the Use of Songs for People with Mild Cognitive Impairment (E.L.So.M.C.I.) project is coordinated by the Greek Association of Alzheimer's Disease and Related Disorders (Greece) and is supported by the partners Asociación Familiares Enfermos Alzheimer
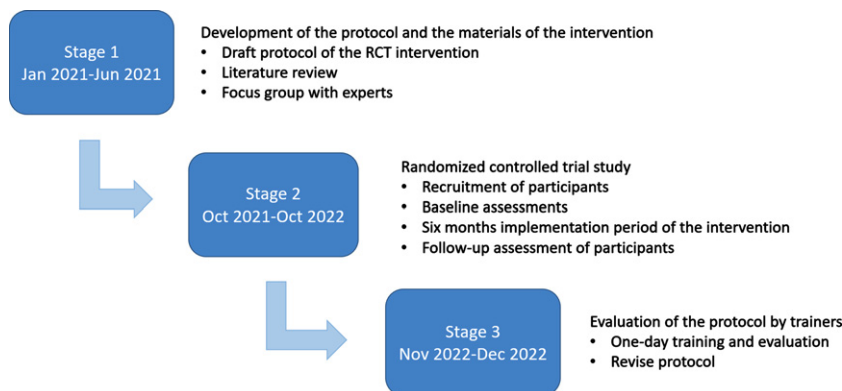
Fig. 1. Timeline and stages for developing the E.L.So.M.C.I. intervention protocol.

Valencia (Spain), Spomincica Alzheimer Slovenija (Slovenia), Anziani e non solo (Italy), and Klinika za psihijatriju Vrapce (Croatia). All partners are active in the field of cognitive disorders and dementia and come from Mediterranean countries with similar temperaments and cultures. The first language of these countries is not English, and for that reason, English was taught in the course.

In this effort to extend the initial protocol of the Greek intervention to a European approach, we re-designed and re-developed the existing protocol of the prototype method. The timeline of the study on developing the E.L.So.M.C.I. intervention protocol is described in Fig. 1.

The development of the E.L.So.M.C.I. intervention protocol follows a mixed-methodology approach consisting of three stages. First, the project team focused on developing the protocol and the material of the intervention through a literature review, a focus group with 10 experts in this field, and the existing draft protocol (Stage 1). The protocol and the material for Stage 1 have already been prepared. Second, a randomized controlled trial (RCT) study is held to implement the intervention in five different countries (Greece, Italy, Spain, Croatia, and Slovenia) and to detect the impact on the cognitive and psychological dimensions of participants. The trial will be conducted and reported according to Consolidated Standards of Reporting Trials (CONSORT) guidelines [37] (Stage 2). The main steps of the methodology of the E.L.So.M.C.I. intervention protocol are presented in detail in this paper. Lastly, an evaluation process on the protocol of the intervention will be carried out by 30 professionals who work with people with MCI. This will be accomplished by implementing a 1-day training program on the

intervention in groups of 6 experts in each country. These groups will run through all the materials and the structure of the intervention protocol, and they will provide an evaluation to finalize the intervention (Stage 3).

Stage 1: Development of the E.L.So.M.C.I. protocol and the materials of the intervention

The method was based on the initial protocol from the pilot study (2017–2019). By following this method, learners can make connections and references between theory and certain lyrics of the songs with much less effort than in conventional ways of teaching and learning English [38–40]. The current approach also includes activities resembling real-life situations and enhances an experiential learning approach. For that reason, role play and drills are included, as well as dialogues that are useful in everyday life, such as phrases we use when we meet people.

Additionally, in Stage 1, an extensive systematic review of the literature has been performed regarding interventions using songs and teaching foreign languages to people with cognitive disabilities (Christakidou et al., unpublished data). Combining these results with the protocol implemented in the pilot study in 2017–2019, and following the methodology of innovative methods and approaches in Foreign Language Teaching, GAADRD created a revised draft protocol that specializes in the needs of people with MCI. This first step was completed by an online focus group of ten experts (health care professionals in the field of cognitive impairments and language teachers) from five countries. All of the professionals shared schematic approaches, introduced the specific needs of people with MCI, and agreed on

a complex specification for the intervention and the materials [41].

In the preparation phase of the material, four animated videos were created by a graphic designer to better understand the words and expressions included in the lyrics of the songs. A specialized animation designer illustrated and visualized the lyrics of several songs with images and created videos to be taught in class. This combination of lyrics with images and the created animated videos can facilitate the learning process and MCI people's perception through the senses of sight and hearing [39, 40, 42].

In addition, in the preparation phase, the trainers had to gather teaching material to help them teach English using songs and other teaching aids, such as images, videos, and games. Each song is associated with a specific aspect of the English language, such as a grammatical rule, pronunciation of specific phonemes, syntax, or a structure that is difficult to understand by just learning a rule since it does not exist or is not encountered frequently in the participants' mother tongue. The protocol can be adapted in other countries and national contexts. For instance, the pronunciation of English words is transcribed so that the participants can read it and write it down in a way they can understand, according to their prior knowledge of their native linguistic system. If the native languages of the participants are Greek, Italian, Spanish, Slovenian, or Croatian, they can use the materials produced by the E.L.So.M.C.I. project [41].

Stage 2: Randomized controlled trial study

Study sites

People with MCI were approached to participate in the study by a lead investigator or an appointed research assistant from the daycare centers of the associations of the five countries that participate in the E.L.So.M.C.I. project, with recruitment beginning on 1 September 2021 and continuing to 30 December 2021.

It is important to underline that these countries have been selected to participate in the intervention because the participants' first language is not English, therefore English can be used as a tool for their cognitive training. They are also Mediterranean countries with similar temperaments and cultures that use music and songs daily.

Participants: inclusion and exclusion criteria

The diagnosis of people with MCI was done using neurological examination, neuropsychological and neuropsychiatric assessment, medical/social history, neuroimaging, and blood tests. The inclusion criterion was the diagnosis of MCI according to Petersen criteria [43], following a neuropsychological assessment and a neurological examination. There were no age criteria, as people with MCI can be of a wide range of ages. The exclusion criteria were: (a) the existence of severe behavioral or neuropsychiatric symptoms, such as aggressiveness, irritability, or apathy, as that could affect the validity of the diagnosis; (b) other neurological disorders; (c) uncontrolled hypertension or terminal illness; (d) severe mental illness; (e) severe anxiety and/or depression symptoms; (f) sensory deficits, such as uncontrolled visual and hearing problems; (g) participation in other interventions. We did not exclude people with mild symptoms of depression or anxiety because this intervention aims to impact the mental health of the participants as a secondary outcome. All participants have been given a participant information sheet and have been required to complete informed consent before collecting any measurements.

Randomization

Participants were randomly allocated into two groups: an intervention group and a control group. Matching and randomization were applied to assign cases to groups. Matching procedures reduce baseline differences between intervention and control groups, and randomization can prevent bias in assigning participants to groups [44]. Groups of two recruited cases were matched as closely as possible for age, gender, education, cognitive abilities, and level of anxiety and depression (stratified randomization). In our study, the web-based RRApp randomization system was used. Before the inclusion of participants, an information technology technician performed randomization using an algorithm. All of the independent evaluators are blind to group assignment, and the participants are not informed of primary outcome measures or the study hypothesis.

Intervention and control groups
Intervention group All participants were screened for eligibility by a clinical psychologist who works with people with MCI and then assigned to one of the two groups. After the first screening with the neuropsychological assessment, a professional (health care professional or English code with experience with people with cognitive deficits) who has received the standardized formal training in the intervention starts implementing the protocol. The RCT
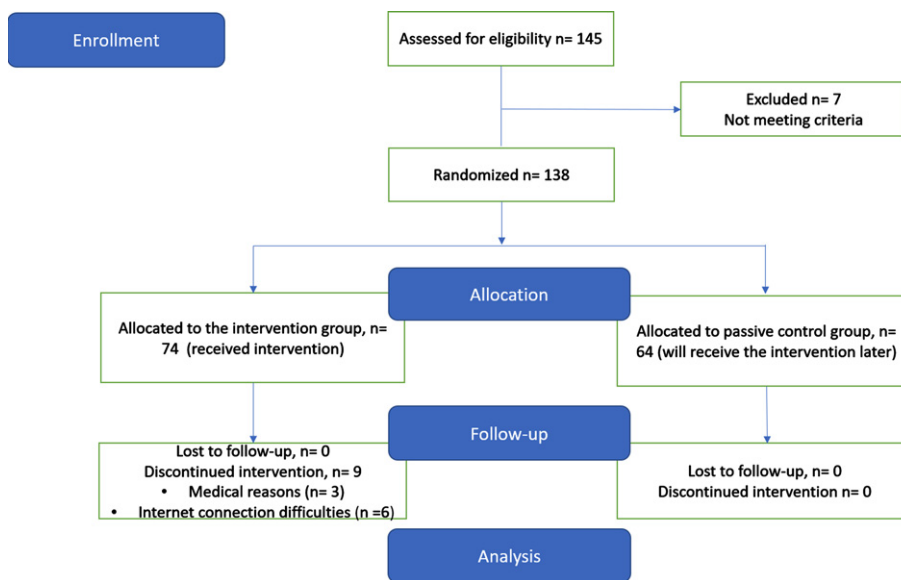
Fig. 2. Flow of the participants.

study lasts for 6 months in total. Each session lasts approximately 60 min, and participants have lessons on-site or online twice a week. The choice of this specific intensity of lessons was based on the preferences of participants of the pilot study that took place between 2017–2019. The participants' duties and schedules then did not give them space to have lessons more often. Their health problems did not allow them to have lessons of two or more hours per day. Our intention was not to push these people too much and increase their stress levels but to help them learn in a relaxed manner. Furthermore, the content of the lesson included songs that the participants could listen to as many times as they liked after each lesson was over. This repetition offered them exposure to the target language beyond the two hours of weekly lessons. The effectiveness of this duration for non-pharmacological interventions has been well demonstrated through research findings and the experience of implementing non-pharmacological interventions in the GAADRD day care centers during the last ten years [45, 46]. The intervention, as outlined below, has been designed for people with different levels of knowledge of the English language. Each group consists of four to seven participants. In the current study, there are two groups in each country, divided into different levels of English knowledge. The first includes people with very limited or no prior knowledge of English,

and the second includes people who already know English (intermediate level). The groups use similar material, but the second group goes quicker. A detailed breakdown of the intervention structure and content can be seen in the following sections.

Control group This cohort is a non-intervention control group for the study, recruited as a waiting list cohort and will receive the intervention later. In brief, the potential participants were informed that they may be assigned to one intervention. All participants in the control group completed all of the evaluation measures at each time point. Thus, participants in both groups received neuropsychological assessments before the intervention and after the end of the intervention. Figure 2 describes the participants' flow chart.

Assessments and follow-up interviews
The effectiveness of the intervention is examined by neuropsychological assessments performed at baseline and when the program ends. The participants of each group will be examined and followed up at the same time within one week after the completion of the intervention period.

The neuropsychological assessment includes a comprehensive battery of psychometric tests: 1) Mini-Mental State Examination (MMSE) for the

assessment of general cognitive function [47]; 2) Functional Cognitive Assessment Scale for general functional performance (FUCAS) [48]; 3) Functional Rating Scale for Symptoms of Dementia (FRSSD) for ADL (evaluates caregivers' opinion about the daily function of people with cognitive disorders) [49]; 4) Geriatric Depression Scale (GDS) to evaluates people's depression symptoms [50]; 5) State-Trait Anxiety Inventory (STAI) for anxiety symptoms [51]; and 6) Neuropsychiatric Inventory (NPI) to exclude people with psychopathological symptoms [52]. It is important to highlight that this study uses these scales because they are used as a battery for measuring cognitive abilities, executive function, and psychological symptoms in the Greek Association of Alzheimer's Disease and Related Disorders. Most of them have been validated and applied in the other four countries participating in the current European program. If any of them is not used in their clinical practice, they can include another similar one that measures the same cognitive functions and psychological symptoms. In this study, at least the MMSE has to be used in all five countries for the results to be comparable[1]. In the 6-month follow-up assessment, in addition to the previous scales, the Quality-of-Life Scale (QOLS) will also be used to evaluate potential changes in the daily life of participants [53].

To assess the intervention and get feedback, we have created two semi-structured questionnaires: one for learners and one for trainers. Multiple aspects of the intervention will be evaluated, and an assessment analysis will be followed to monitor overall satisfaction and improve the structure and content of the intervention. The questionnaires include key questions regarding the impact, the expectations, and the future tasks to be done according to the needs of participants. They are divided into three parts. The participants' questionnaire includes items that assess the intervention (understanding of the content of the units and the tests, the examples that were used and the duration of the lessons), their participation (understanding of benefits and the positive impacts in different domains) and an evaluation of the trainer (communication skills, teaching with an understandable way, offering extra help, etc.). The trainers'

questionnaire includes an evaluation of the intervention (course content, activities proposed, translations, educational materials, and duration), the impact of the intervention (the innovative approach, benefits on cognitive abilities), and the impact on them due to their participation (learning new approaches, cultivate new skills, etc.).

English learning is appraised as a tertiary outcome and measured by using tests of the English language. These tests were mainly focused on the meaning of words and phrases that were included in the lyrics of the songs. All tests can be found in the test book that accompanies the methodological guide that has been produced by the authors [41].

Analysis

Sample size calculations A priori power analysis was obtained using G*Power3.1 [54] to determine parameters, a medium effect size ($d = 0.50$), and an alpha of 0.05. Results showed that a total sample of 128 participants with two equal-sized groups of $n = 64$ was required to achieve a power of 0.80.

Statistical methods

In the current study, the statistical analysis will be performed with the IBM SPSS Statistics for Windows, Version 25.0. Age, gender, and education will be analyzed at baseline using univariate analysis (ANOVA) and Fisher's exact test when necessary.

A detailed statistical analysis plan will be developed in collaboration with an academic statistician before the start of the data analysis. The key elements of this statistical analysis are described below. Differences in continuous demographic variables at baseline between the intervention and control group will be presented as mean ± SD and tested using independent *t*-tests for normally distributed data. Non-normally distributed variables will be presented as median and range and analyzed by non-parametric tests. For categorical variables, proportions will be presented, and differences will be analyzed by the chi-square test. Effectiveness regarding primary and secondary outcomes will be analyzed by mixed-effect regression analyses with two levels (intervention and control group) with data at baseline or follow-up (after 6 months of the intervention) as outcomes. Missing data will be explored to see if they are missing at random, and various sensitivity analyses will be performed after making different assumptions about the missing data. Exploratory subgroup analyses will be carried out to examine intervention interactions

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[1]An extensive description of all the scales that are used in other countries is not included in this publication. This paper focuses only on the description of the intervention protocol (structure and content) and how this protocol has been built. The authors will provide more details about all the assessment measures that have been used in other countries in a second paper in which the final results of all countries will be presented.

with gender, age, and cognitive and psychological symptoms.

Description of the steps and the contents of the intervention

The protocol, including the content of the lessons, the learning method and the tools needed, can be found in the form of a methodological guide [41] that constitutes the main part of the first intellectual output of the E.L.So.M.C.I. project. It is for the trainers and includes all the lesson plans and the steps they should use to implement the intervention protocol participating in the current European program and other materials such as flashcards, board games, or PowerPoint presentations. Furthermore, the protocol includes a learner's work pack with materials that will be given to the learners and a test book which includes all of the tests that will be given to the learners after completing each unit.

The procedure of the implementation of the intervention

The order of the steps of each session of the intervention is the following:

1. Discuss some elements of theory and give some examples.
2. Teach the song containing an example of the theory.
3. Teach the song in one lesson or two, depending on its length (the same process can apply to a whole song or half of it in the first lesson and the other half of it in the next lesson).
4. The participants write and read the translation of each line and of the separate words in the song.
5. Explain how the theory is realized in the song.
6. Transcribe the pronunciation of the lyrics (International Phonetic Alphabet would be ideal for the transcription of pronunciation). Since most trainers are not linguists and not usually familiar with it, they can invent a way to use the native alphabet to make pronunciation comprehensible. For example, in Greek, low case "σ" can be used for "s" and capital "Σ" for "sh". Each trainer can use a system to teach pronunciation with the help of their native alphabet[2].
7. Watch the video, listen to the song, and associate the images with the lyrics.
8. Listen to the song, watch the video, and sing along.
9. When people with MCI go home, they can listen to the song and see the animated video as many times as they like, either on YouTube or in the material memory stick that trainers will give them.
10. Through repetition, participants can learn the song, understand its meaning, understand the theory, and improve their pronunciation.
11. In the next lesson, participants watch the video again and sing along.
12. Continue with some other lesson activities, such as role-play, drills, and games.
13. In the next lesson, test participants on the vocabulary and the selected patterns of the song.

The tests are used after the teaching of each unit or each song. Each test is divided into two parts. In the first part, the trainees must translate the song verse by verse. This way, they remember the song like a story with a beginning, a middle and an end. After being examined in the first part, the teacher takes the first part of the test and gives them the second part. In the second part of the test, a list of words or phrases from the song is given in random order, and the participants are asked to write their translations in their native language. This way, the learners remember words and phrases separately. The fact that these words and phrases are in random order makes the second part of the test more difficult than the first one.

The test is aimed mainly at understanding the meaning of the lyrics and not so much at grammar, syntax, or spelling, but this does not mean that in the delivery of the lesson, we focus only on the meaning. In the lesson, we also explain grammar and syntax parameters for expressions found in the song. Usually, we want to associate a song with a grammar rule and learn the rule through an example that is found in the lyrics of the song. We explain this rule in many ways, but the most effective way to remember it is by this association between the rule and a specific sentence from the song's lyrics. Certainly, we check if the participants understand this rule through exercises or questions that we ask them to answer in class or at home. The main reasons why we chose these specific meaning-based tests are because we want to help learners memorize some positive messages contained in the lyrics of the songs, which can improve their mood, and because it is easier and less discouraging

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[2](Transcription of pronunciation is ready for native speakers of the five countries that participate in the E.L.So.M.C.I. project).

for them to memorize only the meaning and not, for instance, the correct spelling of each word.

In addition to these tests, it would be useful to evaluate the participants' feedback for each song by giving them a questionnaire. The questionnaire could include questions like the following:

1) Did you like the song you learned?
2) What did you like most about the song?
3) Did the song help you understand this grammatical phenomenon/the use of this tense/ this aspect of pronunciation/ the use of this syntactical structure?
4) What emotions does the song express?
5) What is your favorite phrase from the lyrics of the song?

This was done in one song as a sample (i.e., "The Wonder of You"). It could be used for other songs too. It was not intended to be part of the protocol from the beginning. It was decided to be used in one song to see if such a metalinguistic process helps the participants feel a song better. However, since this process was not part of the protocol, it was not applied to other songs. The response of the learners was very positive. However, such an extra activity of answering a questionnaire may delay the development of the lessons. For that reason, it is optional. Or, it is better to take place as homework rather than during the lesson.

Contents of the methodology of the intervention

The protocol consists of ten units, and each unit includes several lessons, including a song. Basic knowledge begins with the alphabet and the English phonemes. It reaches grammar, which includes some basic tenses like present progressive and present simple, as well as more complicated structures, like metaphorical phrases or idioms that are in the lyrics of the songs.

Each song of each unit has been associated with certain rules of grammar, syntax, and pronunciation or with a specific theme for discussion. This way, people with MCI will not have to remember specific rules, but they will learn the rules through the examples that will be found in the lyrics of the songs. Moreover, in the attempt to understand the new language, learners will use their first language too. In this way, they will remember the corresponding vocabulary from their mother tongue, or they will reactivate concepts of their cognitive system that have started to fade and help them emerge again. In a study by Bubbico et al., it was shown that foreign language learning helps elder adults in "global cognition levels, short-

and long-term memory, attention, language access and executive functions. [. . .] These findings can be added to the current neurobiological breakthroughs of reshaping brain networks with a short language learning practice in healthy elderly subjects. Therefore, learning a foreign language may represent a potentially helpful cognitive intervention for promoting healthy aging". Thus, the focus of these interventions is not only on learning a foreign language but also on reorganizing concepts of the participants' native language [55].

This combined method helps students learn phrases to greet, introduce themselves and others, use phrases to talk about themselves and their interests, phrases to communicate on the phone, numbers, colors, kinship terms, vocabulary related to emotions, useful vocabulary about their present environment, useful vocabulary about traveling and buying things, how to make polite requests, how to talk about the weather, how to talk about the past, and how to pronounce letters and words.

Table 1 showcases the contents of each unit and what elements of the English language it presents, as well as the songs chosen as tools for the learning process.

The songs selected are mainly from the 50 s and 60 s, when the study participants might have been teenagers or young adults. Many of these songs were on radio broadcasts and may be familiar to the study participants, evoking autobiographical memory. Some participants may even know the socioemotional background of the songs. Bands like The Beatles are world icons, and their music must have reached these Mediterranean shores. In the following part, we describe the main criteria for choosing these songs.

Unit 1. Song: "You are my sunshine"

"You Are My Sunshine" by Elizabeth Mitchell has been chosen to help students of these Mediterranean countries understand the difference between sounds 's' and 'sh'. The repetition of the word "sunshine" by a native speaker of English in this song highlights the difference between the two sounds and makes it more comprehensible for Greek learners.

It is a song written in 4/4 with a slow speed and in a very characteristic major key used to convey positive emotions. The main objective is achieved since the word "sunshine" appears with half-notes, giving time to the listener to perceive the difference in pronunciation between "s" and "sh".

Table 1
Content of the lessons and elements of each unit of the intervention

UNITS	LESSONS
UNIT 1	Lesson 1.1. English alphabet
	Lesson 1.2. Consonant digraphs
	Lesson 1.3: "You Are My Sunshine"
	Lesson 1.4: Test: "You Are My Sunshine" (Vocabulary, certain expressions of the lyrics of the song, "s" and "sh" are being tested)
UNIT 2	Lesson 2.1: Hello!
	Lesson 2.2: How to introduce myself and how to introduce others
	Lesson 2.3: Table of useful phrases
	Lesson 2.4: Test on Unit 2 (Useful phrases of communication are being tested: How to introduce myself; How to introduce others; How to greet; How to say goodbye; Small talk)
UNIT 3	Lesson 3.1: Numbers 1–12
	Lesson 3.2. Song "Rock Around the Clock"
	Lesson 3.3: Test (Vocabulary, certain expressions of the lyrics of the song, and numbers 1–12 are being tested)
	Lesson 3.4: How to tell the time in English
	Lesson 3.5: Numbers 13–19, 20–99 and 100–999
UNIT 4	A) Colors
	B) Singular - Plural
	Lesson 4.1: Colors
	Lesson 4.2: Song: "What a Wonderful World"
	Lesson 4.3: Test on colors and on the lyrics of the song "What a Wonderful World. (Vocabulary, certain expressions of the lyrics of the song and colors are being tested)
	Lesson 4.4: Nouns: Plural
	Lesson 4.5: Test on Plural (The plural form of various nouns is being tested)
UNIT 5: Present Progressive	Lesson 5.1: Introduction to Present Progressive
	Lesson 5.2: Song: "I'm Singing in the Rain"
	Lesson 5.3: Test on the song "I'm Singing in the Rain" (Verbs in Present Progressive, vocabulary and certain expressions of the lyrics of the song are being tested)
	Lesson 5.4: More verbs in Present Progressive
	Lesson 5.5: Test on Present Progressive (Various verbs are being tested in the Present Progressive)
UNIT 6: Present Simple	Lesson 6.1: Introduction to Present Simple
	Lesson 6.2: Song: "An English Man in New York"
	Lesson 6.3: Test on the song "An English Man in New York" (Verbs in Simple Present, vocabulary, and certain expressions of the lyrics of the song are being tested)
	Lesson 6.4: Routines
	Lesson 6.5: Simple Present: Subordinate Clauses – Main Clauses – song "The Wonder of You"
	Lesson 6.6: Test on the song "The Wonder of You" (Main clauses and subordinate clauses in Simple Present, vocabulary, and certain expressions of the lyrics of the song are being tested)
UNIT 7: Exceptions to the rules of Present Progressive	Lesson 7.1: Song: "Here Comes the Sun"
	Lesson 7.2: Test on the song "Here Comes the Sun" (The structure "Here + Verb in Simple Present", inversion, vocabulary, and certain expressions of the lyrics of the song are being tested)
	Lesson 7.3: State Verbs. Song: "Fly Me to the Moon"
	Lesson 7.4: Test on the song "Fly Me to the Moon" (Vocabulary, certain expressions of the lyrics of the song, and specific state verbs are being tested)
	Lesson 7.5: Exception of exception: verb "feel". E.g., song "I'm Feeling Good".
	Lesson 7.6: Test on the song "I'm Feeling Good" (The verb "feel", vocabulary, and certain expressions of the lyrics of the song are being tested
UNIT 8: Travelling	Lesson 8.1: Travelling
	Lesson 8.2: Song: "Somewhere Over the Rainbow"
	Lesson 8.3: Test on the song "Somewhere Over the Rainbow" (Vocabulary and certain expressions of the lyrics of the song are being tested)
UNIT 9	Lesson 9.1: Imperative
	Lesson 9.2: Imperative: Song: "Stand by Me"
	Lesson 9.3: Test on the song "Stand by Me" (Imperative, vocabulary and certain expressions of the lyrics of the song are being tested)
UNIT 10: Simple Past	Lesson 10.1: Introduction to Simple Past
	Lesson 10.2: Song: "The Little Drummer Boy"
	Lesson 10.3: Test on the song "The Little Drummer Boy" (Verbs in simple past, vocabulary, and certain expressions of the lyrics of the song are being tested)

Unit 3. Song: "Rock around the clock"

"Rock Around the Clock" by Bill Haley has been chosen because of its dancing rhythm and because it is so famous that most of the learners have heard it before. We relate this song to numbers and time since it repeats numbers 1 – 12 many times, and it also repeats the expression "o'clock" which is helpful to learn how to tell time. When we teach the song to the learners, we must teach it at a slower speed, go line by line, and be very patient because many repetitions may be needed. Also, this song is considered as the first rock and roll style. It is a very rhythmic song composed in a major key, and it uses the sequence of chords I, IV, and V. It is catchy, which helps to memorize the numbers and encourages listeners to move their bodies to the rhythm of the music.

Unit 4. Song: "What a wonderful world"

"What a Wonderful World" by Louis Armstrong is a gem, and it offers many positive emotions and mental images to the learners and helps them obtain an optimistic view of life. It invites them to see every aspect of their life as wonderful and gives them hope for the future. Furthermore, it contains a vocabulary of more than 80 words that refer to images like green trees, red roses, blue skies, the colors of the rainbow, as well as notions like friendship and love that are so important for people's wellbeing. In language learning, we focus on colors as well as on plural. Additionally, among the tasks that are included in the sessions is drawing inspired by certain words and phrases from the song. This is a creative task, and learners participate in it with excitement. Moreover, there can be a reference to verbs of senses like "see" and "hear" and their syntactical construction with other verbs that are in bare infinitive form. Also, this song offers a great variety of mental images that can be presented as real images either in the form of flashcards, PowerPoint presentations, or videos, all of which are important language teaching aids. Furthermore, participation of learners in activities like drawing helps them express themselves, cultivates their imagination, boosts their creativity, and thus enhances the connections that accompany the learning process [56–58]. This song has slow and relaxing rhythm. It is in the key of F major with a complex harmony but simple melody. Being composed in 4/4, it conveys hope and optimism. The repetition of the motifs in the musical phrases helps give a feeling of security and relaxation.

Unit 5. Song: "Singing in the Rain"

"Singing in the Rain" by Gene Kelly has been selected to help learners understand present progressive. In these Mediterranean languages, present progressive is not used as frequently as it is in English. The song "I'm Singing in the Rain" offers them the opportunity to learn how to use present progressive in English. Since there are many verbs in present progressive in the lyrics of the song, we explain the meaning of each one of them (i.e., "I'm singing, "I'm dancing", "I'm laughing", etc.), and we highlight the fact that they refer to "now". It is also a song in 4/4 in D major key, which denotes joy and liveliness. The beat and rhythm are marked giving the feeling of stability and security.

Unit 6. Song: "Englishman in New York"

"Englishman in New York" by Sting has been selected to assist learners in understanding the use of present simple since the lyrics contain many verbs in this tense. For instance, it says: "I don't drink coffee, I take tea, my dear". The song describes some routines of an Englishman using present simple. Hence, we must explain to the learners that we use this tense mainly when we want to talk about our routines. Also, this song is in 4/4 time with a moderate tempo in the key of B minor. It begins with an instrumental intro that is accompanied by an ostinato bass that appears throughout the song, with brief variations. This ostinato and the repetition of the musical rhythmic elements gives us a sense of balance, security, and ease.

Unit 6. Song: "The Wonder of You"

Since the current English language course focuses mainly on present tenses, it is important to see more cases concerning these tenses. As far as present simple is concerned, "The Wonder of You" by Elvis Presley can be used to help teach some adverbs of frequency (e.g., "always") and how they are used in this tense. Furthermore, we can refer to main and subordinate clauses that can be used to express routines or behaviors that are repeated over and over, in which we use present simple. For example, "When no one else can understand me/When everything I do is wrong/you give me hope and consolation/you give me strength to carry on". This song composed in G major, in ternary bar 12/8. It begins with an instrumental and vocal introduction, and the ternary rhythm gives us a feeling of lightness.

Unit 7. Song: "Here Comes the Sun"

With the help of this song by the Beatles, we can see some exceptions to the rules of present progressive and present simple. We can explain that when adverbs like "here" and "there" are found in the beginning of a phrase, we use present simple instead of present progressive, even though we are describing something that is happening now. Furthermore, this song is in 4/4 binary rhythm, tempo allegro. The harmony is constant, and the dynamics gradually change. It begins with a guitar intro, though the voice is the main instrument of the song, which has a strophic form. This song conveys joy.

Unit 7. Song: "Fly Me to the Moon"

Another exception to the rules of present progressive can be discussed through the lyrics of the song "Fly Me to the Moon" by Doris Day. This song contains some state verbs, like "love", "worship", and "adore", which appear in present simple. Also, it is a theme based on a circle of fifths (D – G – C – F – B♭ – E – A – D – G – C – F) structured as a progression of the VI – II – V – I model in the keys of F major (major) and D minor (relative minor). Tempo 4/4 with a speed of 60 BPM denotes tranquility and simplicity. It is an accompanied and repetitive melody.

Unit 7. Song: "I'm Feeling Good"

"I'm Feeling Good" by Nina Simone is used as an exception to the exceptions since the verb "feel" is a state verb, but it is used in ordinary discourse either as "I feel" or "I'm feeling". We see that in the lyrics it takes both forms. Furthermore, this song is valuable because it expresses the notion of freedom with the use of many similes, metaphors, and mental images. The lyrics are full of beautiful images and there are many verbs/nouns that express movement as well as senses. It starts with Simone's voice singing the chorus with no accompaniment. After the first four bars, the instruments grandly burst into action, with a powerful brass section, lively piano, and drums. The song is in 6/4–time signature at 80 BPM and is in E minor with a verse-chorus structure. The climax of Nina's solo ends in a high note which she sustains over 4 bars.

Unit 8. Song: "Somewhere Over the Rainbow"

"Somewhere Over the Rainbow" was written for the musical "The Wizard of Oz" and sung by Judy Garland in 1939. It is a very emotional song that talks about hope. The mental images of the lyrics in this song are many, beginning from the rainbow and the bluebirds to reaching a star "where troubles melt like lemon drops" and is far away from clouds. The message of the song is significant. We must have hope for a better future in a better place. It is also a song composed in 4/4 with a calm tempo. It is in a major key and the melody has interval jumps of octave. The timbre of Garland's voice is soft and sweet with a lot of vibratos. In addition, the string and wind instruments have soft tones that complement her voice to give the version a dreamy feeling.

Unit 9. Song: "Stand by Me"

"Stand by Me" by Ben E. King can be used to help learners understand the use of the imperative in English. It also contains very positive notions, like friendship and love, as well as aspects of the counterfactual (hypothetical clauses). These phrases contain mental images, like a sky that falls, mountains that crumble, and its meaning is that whatever negative events may happen, you cannot be afraid if your beloved is by you. It is a song composed in a major key, 4/4 and with a repetitive and characteristic succession of chords (I-VI-IV-V). The tempo is regular and slow giving a feeling of tranquility and relaxation.

Unit 10. Song: "The Little Drummer Boy"

"The Little Drummer Boy" by the Harry Simeone Chorale can be taught around Christmas time. It is a song that narrates a fictional story of a poor boy who visited Jesus Christ when He was born, and since he did not have any other gift to offer, he played the drum for Him. The main tense that is used in this narration is simple past. Thus, we can explain how this tense is used in English and how it is formed in various verbs that are found in the song. It is a popular Christmas carol composed in a major key with the chord sequence I-IV-V. It has slow tempo and calm and regular rhythm. The melody is simple with repetitions. It starts with a drum beat that repeats throughout the song.

In the Methodological Guide of the E.L.So.M.C.I. project, there is a detailed lesson plan, for each lesson which guides the trainer on how to implement the intervention. Table 2 presents one example of a unit (Unit 4) and its steps.

Online lessons due to situations like COVID-19 pandemic

The current situation of the COVID-19 pandemic has caused some changes in the initial design and implementation of this intervention. Since the

Table 2
Example of a lesson plan

UNIT 4: a) COLORS and b) SINGULAR → PLURAL
LESSON 4.1: COLORS The aim of this lesson is to teach colors in English. The colors are red, green, blue, yellow, orange, purple, pink, brown, grey, black, white. Write the names of the colors on the board, their translation in your language and the transcription of their pronunciation. e.g., red = kókk*ι*vo   (ρ)εNT Ask the learners to copy them into their notebooks. Show the learners some flashcards with the names of the colors on them and ask them to repeat each color after you. Then give each one of them a flashcard and ask them: "What color is it?" They must answer raising the flashcard and saying the name of the color. After that, ask them to exchange flashcards and then say STOP! When they stop, ask each one of them what color is it? They must answer the same way. Then say: "My favorite color is . . . . What's your favorite color?" Explain what this means and then encourage them to ask one another "What's your favorite color?" When they answer they must point at the flashcard with their favorite color.
LESSON 4.2: SONG: "WHAT A WONDERFUL WORLD" Show the learners the video with the images and the lyrics of the song. After that, explain what each line and each word means. Also give them the transcription of pronunciation, especially if they do not have prior knowledge of English. Then ask them to repeat after you and sing each line together. Repeat the process. Watch the video again. Ask them to look at the lyrics and draw some images out of them. You can also choose and propose some phrases, such as "trees of green", "red roses", "bloom", "the colors of the rainbow", "the bright blessed day", "the dark sacred night", "friends shaking hands", "babies cry" etc. They must write these phrases under/above the corresponding images. They can make the drawings in class or as a homework. Next time, they will be tested on colors and on the lyrics of the song.
LESSON 4.3: TEST Test on colors and on the lyrics of the song "What a Wonderful World".
LESSON 4.4: NOUNS: PLURAL Explain how the plural is formed in English. Give some examples. Ball → balls Pencil → pencils Orange → oranges Watch → watches Box → boxes Volcano → volcanoes Leaf → leaves Baby → babies Boy → boys But Person → people Mouse → mice Goose → geese Tooth → teeth Foot → feet Deer → deer Fish → fish Listen to the song "What a Wonderful World" again and ask learners to underline the words that are in plural in the lyrics. Then write them down. Next time students will be tested on plural number.
LESSON 4.5: TEST ON PLURAL

participants belong to a group of people that is vulnerable to this virus, online lessons should be offered instead of lessons in a classroom. This shift should also change the material used. Thus, there is a need to familiarize learners with online platforms, share material on these platforms or via email, and use PowerPoint presentations instead of flashcards when needed. Furthermore, it is not easy to sing along with the whole class when the lessons are held online, since singing along may create noise and confusion. Hence,

it is better to sing the first part of the song with each learner separately, while the other learners keep their microphone muted, and then to continue with the next part of the song and follow the same process until the end of the song. Otherwise, the class can sing along, but it is better to keep the microphones of the learners muted. Only the voice of the trainer should be heard, and the trainer should check on the online videos that the learners are singing, even if their microphone is muted.

Stage 3: Evaluation of the protocol by trainers

The professionals and trainers will be asked to evaluate the protocol because one of the goals is to enhance the effectiveness of this protocol and get a multidisciplinary approach.

An assessment of the intervention will be done by thirty professionals and trainers who work with people with MCI and people with cognitive disabilities. This will be accomplished by a 1–day training program on the intervention to one group of 6 experts in each country. The training will be conducted by the experts who have taken part in the E.L.So.M.C.I. project. It will include a presentation of the E.L.So.M.C.I. project, as well as a detailed description of the methodology of the protocol, the materials that have been created, and the results of the interventions. Then, the professionals/trainers will run through all the materials of the intervention by using a Massive Open Online Course (MOOC) platform that will be designed as part of E.L.So.M.C.I. project and will include a training program on the intervention for trainers. A specific questionnaire will be used for collecting feedback that will be designed by Slovenian partners, who are responsible for the evaluation actions of the project and will be included in the MOOC. It is expected that after Stage 3, some modifications to the protocol will be necessary to include missing materials and any other proposed changes from the trainers.

Based on the Stage 2 results, the protocol will be modified, and the results of Stage 3 will specifically assist in re-designing the intervention.

Ethics

This study is approved by the Scientific and Ethics Committee of GAADRD and follows the principles outlined in the Helsinki Declaration. Participants were initially invited to take part in this study, and those who consented met with a trained facilitator who supported their engagement throughout the study. All participants who take part in the intervention need to read and sign an information consent form. The form explains the purpose of the study and that withdrawal is possible at any time. It gives the contact details of the researcher, and participants give permission for the staff to use their basic demographic information, such as age, gender, and education, as well as their total scores of neuropsychological tests for research reasons only.

All data from this study are confidential, and only the research team has access to them. Completed neuropsychological assessments and other evaluations are marked with case numbers and held in secure filing systems. Codified numerical data from the assessments are stored on secured systems and in SPSS files. Records are identified by case number only, and thus participants' names are not stored in these electronic systems. A master-list linking case numbers with participants' names and contact details is held in a password-protected computer file.

Articles, publications in journals, presentations and other publications arising from this study will contain aggregated data, so individual cases may not be identified. The produced data of this study will be included in a subsequent results publication and will be uploaded alongside the manuscript as supplementary material, in line with the research ethics approval.

DISCUSSION

The results of this study will determine whether E.L.So.M.C.I. intervention reduces cognitive impairment and self-reported anxiety and depression while also increasing knowledge in English language and improving the quality of life of people with MCI. Furthermore, the findings will provide evidence to inform guidelines for future interventions for people with cognitive dysfunctions, healthcare professionals, and language trainers, both nationally and internationally.

As MCI occurs along a continuum from normal cognition to dementia [4, 9], prevention strategies must be designed and implemented before the progression to dementia [14, 59, 60]. In recent years, due to the increasing number of people suffering from dementia, brain exercise interventions and delaying cognitive decline in people with MCI have gained considerable attention [59]. Recent longitudinal findings suggest that structured cognitive interventions can target brain function by increasing cognitive reserve and thus delay the progression of MCI [15, 59, 61–63]. E.L.So.M.C.I. protocol and the current RCT study are in line with the cumulated evidence regarding the delay of the consequences of dementia and prevention strategies through cognitive stimulation in people with MCI.

Further research within the field suggests that learning a foreign language can delay the progression of MCI people as learning language structures, such as vocabulary, useful phrases, grammar, syntax, and pronunciation, requires the utilization of extensive cognitive functions like memory, attention,

perception, etc. [16, 17, 18, 20, 64–66]. In addition, various forms of intervention have been suggested to delay cognitive decline for people with MCI by using songs and music as the main tools of stimulation [25, 26, 67]. There are also numerous studies on the use of songs for teaching and learning a second language in various populations [29, 30, 31, 68, 69]. However, none of those studies have tested or implemented an intervention focusing on learning a foreign language using songs by people with MCI, nor have they developed a structure intervention protocol.

Collaboration with Alzheimer's Associations in other countries has provided more insights into the application of the methodology to target groups from other countries and will pave the way for the international use of this approach in the future. Different countries will need to adapt the protocol of the intervention to their different cultural contexts, so we can result in one universal and inclusive protocol at the end of this project.

It is crucial to underline that during the current COVID-19 crisis, in which many countries have initiated isolation and lockdown procedures, it is likely that protective factors are compromised, particularly in people with MCI at risk of developing dementia. This may cause a cascade of events leading to cognitive impairment and mental health and behavioral symptoms [70–72]. It is well established that prevention is the most useful action against cognitive deterioration [45]. Social support, social interactions, and cognitive stimulation are important measures for reducing cognitive decline and psychological symptoms [73]. Thus, based on the pilot study and on the ongoing E.L.So.M.C.I. workshops, we suggest the use of this method to people with MCI, since it can have a positive influence on their cognitive abilities, mental health, and social life.

The strengths of this study are its preventative nature and randomized trial design, which means that the results are more likely to be generalizable to other people with cognitive disabilities. This protocol has been developed in such a way that it can be used by any professional working with this population. The goal is to communicate with them the key lessons learned in the development of the intervention and to provide them with skills and information to make the best use of the materials. Another advantage is that this study will examine multiple important outcomes while also considering factors, such as reducing anxiety and depression symptoms, when learning a foreign language in a pleasant way. Furthermore, we are somewhat uniquely placed inter-

nationally to assess the impact of such interventions on people with MCI. The systemic approach of an intervention two times per week and using a control group without exposure to any form of intervention is not routinely available. Finally, this project has been designed in such a way to follow a unique combination of three different stages, collecting data from professionals (Stage 1) and people with MCI (Stage 2) of five different countries and finalizing the best protocol which can be used internationally (Stage 3).

Limitations

A logistical issue for this study is that the cognitive impairment of MCI people causes difficulties in learning new knowledge, which may lead to a potential participant dropout. As such, our power calculations are based on study completers, rather than on enrollment quota. The study is being conducted in care settings of five Mediterranean countries, although a point of consideration is that people from other cultures differ in various aspects. In the second phase, after the participation in the intervention, participants will be evaluated using a neuropsychological assessment in order to test the impact of the intervention. However, it is not certain that the effects will last for a long time, meaning that there will be a need to repeat a follow-up assessment at a later stage. This study will not examine the long-term impact of the intervention. The authors encourage future trainers to evaluate the intervention including more follow-ups. Also, in this project trainers from different countries used different tests for the neuropsychological assessment which will limit the validity of the study results. The generalization of the study's results should be interpreted in the light of these limitations.

Conclusion

Learning the English language could improve the cognitive abilities, psychological symptoms, and well-being of people with MCI and thus avoid the deterioration of their deficits that may lead to dementia. Using songs to teach this cohort the language has not been studied enough yet. The creation of this educational protocol and the implementation of this RCT study are adjusted to the needs of people with MCI and the perspectives of professionals. If it is found to be effective, group-based interventions for people with cognitive impairments could provide a routinely available intervention that could opti-

mize participants' well-being, with the possibility of reducing cognitive decline and psychological symptoms. The protocol of this study will also enable a future evaluation of other treatment modalities.

CONFLICT OF INTEREST

The authors have no conflict of interest to report.

DATA AVAILABILITY

Data sharing is not applicable to this article as no datasets were generated until the submission of this manuscript.

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