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Music therapy for improving health and well-being in institutionalized older adults

Submission date
29/03/2021

Recruitment status
No longer recruiting

Registration date
06/04/2021

Overall study status
Completed

Last Edited
24/08/2022

Condition category
Other

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Numerous studies have supported the beneficial effects of the use of musical interventions in healthy older people or elders with mild-to-moderate impairments, including increased equilibrium and balance and reduced fall risks, reduced pain, enhanced memory, executive and other cognitive functions, enhanced communication and social skills, enhanced social performance and reduced isolation, better behavioural and psychological functioning despite cognitive impairment, decreased depression and anxiety, and increased self-esteem. Consequently, music-based therapeutic interventions have been found to have a positive effect on overall quality of life among older people.
As previous research has obtained promising results, it can be expected that the benefits of music are not anecdotal. Nevertheless, the quality of such research is deficient in a number of studies and firm conclusions cannot be derived. Moreover, this research has focused on negative indicators of well-being and functioning (e.g., depression).
The main aim of this study is to explore the outcomes of a music-complemented intervention integrated into the therapeutic activities offered to institutionalized elderly people with no-to-mild cognitive deterioration at their residential setting. Several indicators of physical health, cognitive functioning, emotional well-being, pain, health-related quality of life and happiness will be measured.

Who can participate?
Older adults who are healthy or mildly impaired who are residents in a residential center in the central area of Spain (Community of Madrid)

What does the study involve?
Participants are randomly allocated to the intervention group or the wait-list control group. The intervention will consist of 20 group sessions and 20 individual sessions which will be carefully designed based on research findings on music therapy and music-related disciplines. They will be also based on the previous experiences and preliminary data of the research team.
The music used throughout the training sessions will be based on the musical preferences for songs, singers or styles indicated previously by the users on a music survey.
The individual sessions will last 30-45 minutes and will be held weekly. In the individual sessions, mainly passive, receptive techniques will be used (i.e., the person is receptive, letting the music

reach him/her without further action). The group sessions will be held with a frequency of two sessions per week, adapted to the center's activities schedule. Each session will last about 45-50 minutes. In these sessions, a combination of passive and, mostly, active, expressive-productive techniques will be applied (i.e., the user has a greater participatory involvement, for example, activities that entail dancing, singing, playing an instrument, making sounds and so forth). Participants are assessed at the start of the study, after the intervention and at 2-week, 1-month, 2-month, 3-month, and 6-month follow-ups.

What are the possible benefits and risks of participating?
The global population of adults aged 60 or over surpassed 900 million in 2017 (12%) and is expected to double by 2050, when it is projected to reach nearly 2.1 billion (22%), in the words of the United Nations and the World Health Organization. Thus, interventions aimed at increasing elders quality of life and overall well-being, positive and healthy ageing, and a reduction of risks for disease and disability will be increasingly needed. The abovementioned outcomes are the expected benefits of participating in the music intervention. This study will contribute to research on music therapy by demonstrating the effects of a planned music-based intervention on several health and wellbeing-related outcomes. The intervention has no expected risks for the participants.

Where is the study run from?
University of Granada (Spain)

When is the study starting and how long is it expected to run for?
March 2021 to July 2023

Who is funding the study?
Junta de Andalucía (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MUCE2021

Study information

Scientific Title
Effects on physical, emotional, cognitive, health-related quality of life and subjective well-being indicators of music therapy within comprehensive care for institutionalized older adults: a randomized controlled trial

Acronym
Musicare

Study objectives
The specific hypotheses are the following:
1. A positive impact of the music intervention on the outcomes in the intervention group (IG) compared to the stability in the (waiting list) control group (CG) is expected. Specifically, the researchers expect that, after the intervention, the participants who receive the intervention will demonstrate better functional status and autonomy, stronger handgrip, better cognitive functioning, better overall mood, lower pain, higher health-related quality of life (HRQoL) and greater happiness (i.e., hedonic and eudaimonic well-being as well as overall molar happiness) than patients in the CG.
2. The benefits derived from the music intervention are expected to be transitory and will decrease progressively after a brief time period following the discontinuation of the intervention (i.e., from post-intervention to the last follow-up), supporting that the intervention must be maintained over time for the effects to be durable.
3. The researchers expected to find that individually administered sessions will have different effects compared to group-administered sessions. Specifically, the researchers expect that active techniques (mainly in group sessions) would lead to more pronounced effects in terms of physical health, HRQoL and subjective well-being, while passive techniques (mainly in individual sessions) would translate into greater benefits in terms of cognitive functioning, pain perception and emotional well-being, thus contributing to overall benefits of music therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-center interventional 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
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Institutionalized geriatric adults

Interventions
This is a multivariate, unifactorial randomized controlled trial with an experimental design 2x7 with random recruitment and distribution into two independent, equivalent and matched groups (music-complemented care group and standard care group) and seven repeated measures (baseline, post-intervention and 2 weeks, 1 month, 2 months, 3 months and 6 months follow-ups). Prior to the randomization and allocation of the participants to the study groups, matching by age, sex, history of institutionalization and clinical status in terms of cognitive deterioration will be performed to control for the possible confounding effect of these variables.

The independent variable is the music intervention, with two levels: the IG receiving the intervention as described, and the CG receiving the usual center's therapeutic sessions without music. The CG acts as wait-list group. The participants in this group will receive treatment as usual whilst study measures are completed and will then be eligible to receive group music therapy once the last follow up has been completed.

The dependent variables are the scores obtained in each evaluation phase in the level of independence, prehensile strength, cognitive state, emotional well-being, perception of pain, HRQoL, hedonic well-being (i.e., hedonic balance and satisfaction with life), happiness and eudaimonic well-being, as described in the outcome measures section.

The participants will not know the hypotheses and expected outcomes of the intervention. Researchers will be distributed in those applying the measures, who will be blind to participants' allocation, and those assigning the study groups and implementing the intervention, who will not participate in measurements.

The intervention will consist of 20 group sessions and 20 individual sessions which will be carefully designed based on research findings on music therapy and music-related disciplines. They will be also based on previous experiences and preliminary data of the research team (Castillejos & Godoy-Izquierdo, 2020).

The music used throughout the training sessions will be based on the musical preferences for songs, singers or styles indicated by the users in the music survey. These preferences will be filtered according to the following musical dimensions of the melodies: tempo, consonance-dissonance, sound volume and tonal mode, in accordance with the psychophysiological phenomena expected. According to different studies, fragments with a fast tempo, consonant-type, in a major mode and powerful in acoustic and sonic intensity tend to produce feelings evaluated as pleasant, activating and dominant, compared to fragments with a slow tempo, dissonant-type, in minor mode and weak and low-volume melodies, which tend to induce feelings evaluated as unpleasant, less activating and less dominant (e.g., Vieillard & Bigand, 2014). By selecting the first type of musical fragments, the researchers will try to enhance the impact of the intervention on the users' physiological and mental states.

The individual sessions will last 30-45 minutes per participant, with minimal inter- and intra-subject variations. In the individual sessions, mainly passive, receptive techniques will be used (i. e., the person is receptive, letting the music reach him/her without further action). On occasions, just listening to music would lead to autonomous improvisation of singing, clapping or dancing. In such cases, the researchers will not suppress or correct these experiences; instead, they will let them occur and ignore them as much as possible.

For group sessions, participants in the IG will be in turn divided into two subgroups consisting of 12-13 subjects, approximately. For both subgroups, the group sessions will be held with a frequency of two sessions per week, adapted to the center's activities schedule. Each session will last approximately 45-50 minutes. In these sessions, a combination of passive and, mostly, active, expressive-productive techniques (i.e., the user has a greater participatory involvement, for example, activities that entail dancing, singing, playing an instrument, making sounds and so forth) will be applied.

Based on the aims of each of the sessions, these will be flexibly adjusted so that the pace of the work will be set by the interaction of the participant(s) and the therapist. The therapist will emphasize making the participant(s) feeling better at each moment, appraising if they are enjoying and connected with each activity and accordingly adapting the duration of the different dynamics to the experiences of the participants (Castillejos & Godoy-Izquierdo, 2020).

The control group will receive their standard care with no music intervention applicable.

This is an evidence-based intervention (e.g., Castillejos & Godoy-Izquierdo, 2020; García, 2014; Raglio et al., 2014; McPherson et al., 2019; Solé et al., 2017). The training will be conducted by a psychologist trained and qualified for designing and delivering such interventions who is a member of the research team and who will not involved in assessment phases.

Intervention Type
Behavioural

Primary outcome measure
1. Physical health measured by:
1.1. The Barthel Index (BI) to assess the elders' functional status, independence and autonomy in the activities of daily living at baseline, 2 weeks, 1 month, 2 months, 3 months and 6 months after the last session
1.2. Hand strength: a dynamometer (mod. Deyard Tech EH101 or similar) will be used to assess hand grip by the maximal static prehensile strength at baseline, during the intervention, and 2 weeks, 1 month, 2 months, 3 months and 6 months after the last session. Hand strength will be

taken as an indicator of vitality and physical health status
2. Cognitive performance measured by the Mini-Mental State Examination (MMSE), to assess the cognitive functioning and dementia status of the participants at baseline, 2 weeks, 1 month, 2 months, 3 months and 6 months after the last session
3. Mood status measured by the Positive Affect and Negative Affect Scale (PANAS) to assess participants' positive and negative mood at baseline, during the intervention, and 2 weeks, 1 month, 2 months, 3 months and 6 months after the last session.
4. Pain measured by:
4.1. The Brief Pain Inventory (BPI) to assess participants' chronic pain multidimensional experiences at baseline, 2 weeks, 1 month, 2 months, 3 months and 6 months after the last session
4.2. The Pain Visual Analog Scale (VAS) for monitoring pain intensity and changes in pain intensity over time at baseline, during the intervention, 2 weeks, 1 month, 2 months, 3 months and 6 months after the last session
5. Health-related quality of life measured by the Nottingham Health Profile (NHP) to assess quality of life in terms of energy, sleep, pain, social isolation, emotional reactions and physical mobility, and whether or not participants' state of health influences activity in seven areas of everyday life: work, looking after the home, social life, home life, sex life, interests and hobbies and holidays at baseline, 2 weeks, 1 month, 2 months, 3 months and 6 months after the last session
6. Hedonic and eudaimonic dimensions of subjective well-being measured by:
6.1. The Affective Balance Scale (ABS) to assess the affective component of hedonic well-being at baseline, 2 weeks, 1 month, 2 months, 3 months and 6 months after the last session
6.2. The Life Satisfaction Scale (LSS) to assess the cognitive component of hedonic well-being at baseline, 2 weeks, 1 month, 2 months, 3 months and 6 months after the last session
6.3. The Happiness Scale (HS) to assess global o molar subjective hedonic well-being and current sources of happiness at baseline, during the intervention, and 2 weeks, 1 month, 2 months, 3 months and 6 months after the last session
6.4. The Flourishing Scale (FS) to assess flourishing, meaning the self-judgments on having a purposeful and meaningful life, as an indicator of eudaimonic, psychological well-being at baseline, 2 weeks, 1 month, 2 months, 3 months and 6 months after the last session.
6.5. The Positivity Scale (PS) to assess personality traits for positive functioning (i.e., the tendency to view life and personal experiences with a constructive perspective) and overall well-being at baseline, 2 weeks, 1 month, 2 months, 3 months and 6 months after the last session

Secondary outcome measures
1. Satisfaction with the intervention, measured using face-valid items at postintervention and 2-week, 1-month, 2-month, 3-month and 6-month follow-ups
2. Satisfaction with the outcomes of the intervention, measured using an interview at postintervention and 2-week, 1-month, 2-month, 3-month and 6-month follow-ups
3. Changes in participants' functioning perceived or recorded by the care center staff measured using medical/clinical records at postintervention and 2-week, 1-month, 2-month, 3-month and 6-month follow-ups

Overall study start date
15/03/2021

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Resident in a care facility for the elderly
2. Aged ≥ 65 years
3. Without cognitive impairment or with mild cognitive impairment according to MMSE scores (according to normative data for the Spanish population by Lobo et al. (2002), scores of ≥ 24 and 21–23 indicate normal and mild impairment, respectively)
4. Capacity to give informed consent
5. Acceptance of being intervened with music

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
50

Key exclusion criteria
Patients will be excluded if any of the following conditions are present, in order to avoid possible confounding effects:
1. Suffering from any severe or acute illness at the time of the study that could negatively interfere with their participation
2. Suffering from moderate or severe cognitive impairment determined by MMSE scores (according to Lobo et al. (2002), those scoring 12–20 and < 12 can be classified as having moderate and severe impairment, respectively).
3. Suffering from severe hearing or motor problems or high degree of dependence
4. Having previously completed a music therapy training program within the last year
5. Having high musical expertise
6. Having been subjected to changes in pharmacological therapy in the last month
7. Spending most of the daily time outside the residential centre

Date of first enrolment
15/04/2021

Date of final enrolment
15/03/2022

Locations

Countries of recruitment
Spain

Study participating centre

Residential centre for the elderly
Madrid
Spain
28160

Sponsor information

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University of Granada

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University/education

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Funder(s)

Funder type
Government

Funder Name
Junta de Andalucía CTS267

Alternative Name(s)
Andalusian Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer-review journals

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Débora Godoy Izquierdo (deborag@ugr.es).

IPD sharing plan summary
Available on request