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Music and Movement for Health: a feasibility trial of a music and dance programme for the health and wellbeing of community-based older adults

Submission date
17/02/2022

Recruitment status
No longer recruiting

Registration date
18/02/2022

Overall study status
Completed

Last Edited
28/10/2024

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims

Ireland has an ageing population. Many older adults in Ireland have a chronic condition, low levels of physical activity and experience loneliness and social isolation. About a third of adults over 65 years of age fall each year. The unprecedented consequences of the coronavirus (COVID-19) pandemic, lead to cocooning measures, non-essential contact and social distancing measures, all impact on physical function, mental health and social isolation. There is a lack of community-based activities for older people that are tailored, fun, support social connectedness and provide achievable physical benefits, that impact health and wellbeing. This study aims to examine the feasibility of the study design, its application to a music and movement for health programme, and its associated costs. The secondary aim is to obtain preliminary information on the effect of the music and movement for health programme on physical function, balance, physical activity, loneliness, social isolation cognition and mood in older adults.

Who can participate?

Community-dwelling older adults 65 years and older, able to walk 3 meters with or without an assistive device, with a basic level of English literacy or an identified person who can translate English to their first language, and able to hear and follow instructions.

What does the study involve?

People who are eligible will be allocated to either the intervention group or the control group. The intervention group will be invited to take part in a group-based 90-minute music and movement for health programme each week for 12 weeks and also 60 minutes of home-based music and movement (including a customised playlist) to be completed at home each week for 12 weeks. The control group will be invited to participate in an assessment at the start of the study and after 12 weeks. A group-based 90-minute music and movement for health programme each week for 6 weeks will be provided for the control group after the 12-week assessment. Participants will also complete a fall calendar for the 12-week programme duration and are invited to take part in an interview or group discussion (in person, by telephone or by video call).

What are the possible benefits and risks of participating?
Movement and/or music have been shown that they can improve health, function, and quality of life. There are no serious risks associated with this study. One potential adverse event that could occur when engaging in a physical activity such as movement to music is the risk of falling. To reduce this risk, the researchers will tailor the programme to provide support where appropriate, progress the speed and tempo in line with the ability of the participants. Those unaccustomed to exercise may experience some muscle soreness, which is normal when starting exercising. However, a gentle warm-up and cool-down will be performed at every class to allow the body to gradually adjust to exercising. There will also be frequent rest periods during the movement sessions to ensure that the participants do not get too tired. Participants will be free to sit and rest at any time during the class if they need to. The researchers will also practice the music and movement home programme to ensure the participants know what to do when taking part at home. There is the potential that confidentiality could be broken in a group setting. At the start the participants will be reminded that the discussions that take part are confidential and they will be asked not to share the content of the discussion with others.

Where is the study run from?
University of Limerick (Ireland)

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

Who is funding the study?
Health Research Board (Ireland)

Who is the main contact?
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Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
DIFA-2020-005

Study information

Scientific Title
Music and Movement for Health: a pilot pragmatic, cluster randomised controlled trial to ascertain the feasibility of a tailored community-based music dance programme and preliminary effects on health and wellbeing in older adults

Acronym
Move2Music

Study objectives
Hypotheses include:
1. This pragmatic, cluster randomised, controlled pilot trial is feasible and acceptable, and will show that a larger definitive trial will be feasible
2. The Music and Movement for Health intervention programme is safe, cost-effective and acceptable
3. The Music and Movement for Health programme shows preliminary improvement in physical function, balance, physical activity, mood, quality of life and reduces loneliness as well as social isolation compered to no intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/01/2022, University of Limerick Education and Health Sciences Research Ethics Committee (Room E1/004, Education and Health Sciences Faculty Office, University of Limerick, Limerick, Ireland; +353 (0)61234102; ehsresearchethics@ul.ie), ref: 2022_01_08_EHS

Study design
Pragmatic cluster randomized controlled feasibility pilot trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Health and wellbeing of older adults

Interventions

The music and movement for health programme is a community-based music and dance programme delivered by a dance teacher and music therapist over 12 weeks. Participants allocated to the intervention group will take part in a supervised 90-minute session each week over the course of 12 weeks and includes a warm-up, music, singing and dance, creative response, followed by a cool-down a social tea and chat where participants will be encouraged to ask questions, provide feedback, and will be facilitated by Behavioural Change Techniques (BCTs) to incorporate music and dance into daily activity (French, Olander, Chisholm, & Mc Sharry, 2014). A customised playlist will be developed in conjunction with the programme to facilitate participation in a home music and movement programme, whereby participants will be asked to perform the home programme (3 x 20 minutes) each week. Home programme completion will be monitored using a daily log. All participants will be advised to report any adverse effects and safety will be monitored during the sessions. The control group will be a true control comparison group of participants. They will not participate in an intervention but will be asked to keep a falls diary for the duration of the 12 control weeks. The control group will be offered the chance to participate in the music and movement for health programme at the end of data collection if they desire. Participants will be asked to continue with any usual concomitant care and advised not to take up any new physical activity that includes dancing and /or music, which could have a confounding effect on the outcomes of the trial.

Randomisation:
People will be recruited from six geographical regions (clusters) in three counties. The clusters will be randomised to either the intervention or control using a 1:1 allocation ratio, using block randomisation. Hence, one intervention group and one control group in each county. In line with a pragmatic approach the study will have two phases for recruitment and two implementation blocks as the intervention. Participants in the same cluster will receive the same intervention, thus approximating clinical practice and the generalisability of the findings.

Concealed allocation:
The trial statistician will be responsible for generating the random allocation sequence using a computer software programme. A member of the research team will be responsible for informing participants of their allocation and maintaining an undisclosed record of each cluster's allocation in line with recommendations (Eldridge et al., 2016). Personnel directly involved in recruitment, assessment and analysis of the quantitative data will be blind to cluster allocation. Concealed allocation procedure will be followed, detailed and monitored. Only the relevant people will have access to the allocation data.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rates assessed by reporting the number of participants recruited per cluster per month
2. Retention assessed as the proportion of individuals who after enrolment completed the baseline and follow-up assessments. The researchers will calculate the minimum outcome assessment target, which is set at a retention rate of at least 80% of recruited participants with valid baseline and 12-week primary outcome data
3. Attendance at supervised sessions recorded as the percentage of participants that attend the supervised sessions. The minimum average attendance target will be set as 65%
4. Participation in the home music and dance programme recorded by self-report diary collected

each week during the 12-week intervention
5. Safety assessed through self-report of direct or unrelated adverse events (e.g., falls or pain during the programme period). A weekly falls log will be completed

Key secondary outcome(s))
Assessed at baseline and at follow-up after the 12-week intervention in the intervention group and at baseline and at follow-up after the 12-week control period in the control group:

Physical performance measures:
1. Functional mobility and balance assessed using the Timed Up and Go Test (TUG)
2. Dual task performance assessed using TUG-Cognitive (Dual Task Ability)
3. Lower leg strength and endurance assessed using the 30-second chair stand test (30CST)
4. Static balance assessed using the single leg stance test
5. Lower extremity functioning, including gait speed and balance assessed using the Short Physical Performance Battery (SPPB)

Self-report physical activity:
1. Low, basic and high-intensity physical activities assessed using the incidental and planned exercise questionnaire (IPEQ)

Loneliness and Social Isolation:
1. Loneliness measured using a modified version of the University of California-Los Angeles (UCLA) Loneliness Scale
2. Social isolation measured using the Berkman-Syme Social Network Index (SNI)

Cognition:
1. Visual search, scanning, speed of processing, mental flexibility, and executive functions measured using the Trail Making Test (TMT)

Quality of life, wellbeing and mood:
1. Health-related quality of life measured using EQ-5D-5L
2. Attachment, security, role, enjoyment and independence measured using the ICEpop CAPability measure for Older people (ICECAP-O)
3. Mood measured using the 5-item Geriatric Depression Scale (GDS-5)

Completion date
31/05/2023

Eligibility

Key inclusion criteria
1. Community-dwelling older adults 65 years of age and older
2. Ability to walk 3 metres with or without an assistive device
3. Have a basic level of English literacy or an identified person who can translate English to their first language
4. Ability to hear and follow instructions

Participant type(s)
Healthy volunteer

Healthy volunteers allowed

No

Age group
Senior

Sex
All

Total final enrolment
100

Key exclusion criteria
1. Participants will be excluded if they subjectively report health problems that contraindicate their participation in exercise or do not satisfy the requirements of the Physical Activity Readiness Questionnaire (PARQ)
2. Participants will also be excluded if they have had an acute stroke or have an unstable neurological, cardiac or respiratory condition (or are on oxygen therapy)

Date of first enrolment
21/02/2022

Date of final enrolment
21/09/2022

Locations

Countries of recruitment
Ireland

Study participating centre
University of Limerick
Castletroy
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Sponsor information

Organisation
University of Limerick

ROR
https://ror.org/00a0n9e72

Funder(s)

Funder type
Government

Funder Name
Health Research Board, Definitive Interventions and Feasibility Awards (DIFA)

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the sensitivity of the data and confidentiality. During the trial paper data will be stored securely in the office of the principal investigator at the University of Limerick (UL). Electronic data will be stored on password-protected computers or laptops supplied by UL and the cloud storage governed by UL. Only members of the research team will have access to the data. The data will be destroyed after 7 years in line with UL's Records Management and Retention Policy, hard copy paper files will be shredded confidentially.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2024	18/06/2024	Yes	No
Results article		12/10/2024	28/10/2024	Yes	No
Protocol article		26/05/2022	20/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes