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Targeted ballet program for people with multiple sclerosis

Submission date
13/07/2017

Recruitment status
No longer recruiting

Registration date
21/07/2017

Overall study status
Completed

Last Edited
05/09/2023

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a condition which affects the brain and/or spinal cord and causes problems with vision, movement, sensation and balance. Walking impairment is common in MS, particularly with advancing disability. Walking and mobility are among the most valued functions of people with MS. This shows the importance of finding approaches to restore walking in MS, particularly among people with advanced disease whose walking impairment affects their quality of life and independence. Researchers have noted that rehabilitation is the only way of improving function in MS, and exercise training seems to be an effective approach that has other positive side effects and benefits. There are two major gaps in the existing evidence of exercise and walking in MS. There is no documented evidence for improving agility or smooth coordination of movements in exercise interventions for those with MS. The focus on agility and smoothness of movement is critical for improving gait and movement. Such improvements lead to more walking and social engagement, whereas lack of coordination in gait and poor balance lead to an increased risk of falling and injury. A ballet program has been designed that should improve agility, balance and whole body movement coordination in people with MS who have walking impairment. The aim of this study is to assess the feasibility, safety and effectiveness of this ballet program for people with MS who have problems with mobility and coordination. This study will estimate the effect of the ballet program on balance, agility and smoothness of movement for the design of larger studies.

Who can participate?
Patients aged 18 and over with MS

What does the study involve?
Participants are trained twice a week for one hour in the dance class for a total of 16 weeks. Changes in balance, agility and smoothness of movement are assessed before and after the 16 weeks of classes.

What are the possible benefits and risks of participating?
This study may broaden the scope of treatment and rehabilitation in people with mild to severe MS in the near future at a fraction of the cost of traditional drug treatment. The rehabilitation of motor impairments through dance may improve disease management and the personal and

social aspects of a patient's life. Beyond the common physical and psychological benefits of exercise training, there are potential additional benefits for participants including improvements in neurological (nervous system) disability and walking mobility. There are risks of injury for people engaging in an exercise program after a prolonged period of inactivity. Such risks include strains, sprains, muscle soreness, joint pain and general fatigue, but serious physical injury is unlikely given the screening, physician approval, and oversight by trained exercise specialists and researchers, and periods of rest between interventions. Risks of injury and harm are reduced by including appropriate warm-up and cool-down exercises and promoting gradual increases in exercise over time. The exercise training is performed in an environment with air conditioning and multiple fans to control the temperature. The participants are allowed to drink water as needed through the exercises periods to avoid dehydration. Participants are reminded to stop exercising and inform the staff if they experience a negative reaction such as chest pain, shortness of breath, light headedness, or nausea. Participants are fully informed of the risks of starting an exercise program. Fear of falling, slips, trips and falls are possible during the mobility measurements. This risk will be minimized by allowing for the use of assistive devices (i.e., ankle-foot orthoses and canes) and steady surfaces during testing as well as having a gait belt around the participant's waist and a research assistant within arms' reach for stabilizing the participant in the event of a slip, trip or fall.

Where is the study run from?
University of Illinois at Urbana Champaign (USA)

When is the study starting and how long is it expected to run for?
May 2015 to December 2016

Who is funding the study?
National Multiple Sclerosis Society (USA)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PP3418

Study information

Scientific Title
Targeted dance program for improved mobility in multiple sclerosis

Study objectives
The targeted ballet program will safely improve balance, functional ability, gait characteristics and mitigate ataxia in adults with multiple sclerosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office of the Vice Chancellor for Research, Office for the Protection of Research Subjects, 01/05/2015, ref: 15749

Study design
Single-center one-arm non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions

The TBP lasted one hour per session and met twice a week over the course of 16 weeks. Participants were allowed up to two absences and given opportunities to make up classes. The instructor who designed the TBP had teaching certification from the Bolshoi Academy of Ballet and training in the pathophysiology of motor disorders. Exercises focused on improving balance and general mobility, and reducing ataxia of movement. The class protocol had a core structure that started with seated ballet technique (20 min), followed by exercises using the ballet barres (15 min), and then exercises across the floor (20 min), and then followed by a cool-down period (5 min).

The neuroscience of dance laboratory was used as the setting for the TBP. The laboratory was equipped with professional-grade ballet floors, barres, sound systems, piano, and piano accompanists. Mirrors, known to enhance limb position sense, provided real-time visual feedback. Ballet barres and trained assistants provided physical support and safety to participants while increasing the accessibility and adaptability of rehabilitative exercises. When deemed necessary for the safety of participants, gait belts were also used.

Intervention Type
Behavioural

Primary outcome measure
Clinical outcome measures obtained before and after the 4-month intervention period:
1. Balance, measured using the Balance Evaluation Systems Test (BESTest). This test consists of evaluations on six factors that may impair balance in patients with MS: biomechanics, stability limits, postural responses, anticipatory postural adjustments, sensory orientation, and dynamic balance during gait.
2. Smoothness of movement, measured using the International Cooperative Ataxia Rating Scale (ICARS)
3. Agility, measured using the Timed-Up-&-Go test (TUG) included in the BESTest

Quantitative measures obtained before and after the 4-month intervention period:
1. Balance, quantified using the decay of the center of pressure (COP) trajectories when stepping onto a force platform (AccuSway AMTI, MA) forward, backward, and sideways as fast as possible and attempting to hold still while looking straight ahead. The participants' height, weight, and limb length measures will be obtained for the calculation of the force plate platform.
2. Agility, quantified from the velocity in the COP trajectories
3. Smoothness of movement, obtained for walking by computing a standard smoothness index on velocity data of body landmarks such as wrists, elbows, shoulders, hips, knees, toes, ankles, and top of head in a 5 meter walk using a motion capture system (Qualisys, Sweden). This motion capture system requires the placement of markers that reflect light secured to body landmarks with standard self-adhesive wrapping tape.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/05/2015

Completion date
15/12/2016

Eligibility

Key inclusion criteria
1. Confirmation of MS diagnosis
2. Presence of ataxia determined by the International Cooperative Ataxia Rating Scale (ICARS) recommended by the NIH and the Ataxia Neuropharmacology Committee of the World Federation of Neurology with a score greater or equal to 7
3. Expanded Disability Status Scale (EDSS) scores of 2.5-6.5 based on an examination by a Neurostatus certified examiner for indicating walking impairment
4. Relapse free in the past 30 days
5. Approval for exercise training
6. Aged 40 to 65 (corrected 13/12/2017: Aged 18 and over)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
14

Key exclusion criteria
1. Presence of severe cognitive impairment based on an oral Symbol Digit Modalities Test (SDMT) score of less than 23, or the Montreal Cognitive Assessment (MoCA) Test less than 22
2. Change in use of disease modifying therapy in the past 6 months
3. Recent initiation of Ampyra or other medications that influence walking and mobility within the last 30 days
4. Presence of orthopedic conditions

Date of first enrolment
01/05/2015

Date of final enrolment
15/09/2016

Locations

Countries of recruitment
United States of America

Study participating centre
University of Illinois at Urbana-Champaign
906 S Goodwin Avenue

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Sponsor information

Organisation
University of Illinois at Urbana-Champaign

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Sponsor type
University/education

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ROR
https://ror.org/047426m28

Funder(s)

Funder type
Charity

Funder Name
National Multiple Sclerosis Society

Alternative Name(s)
National MS Society, The National Multiple Sclerosis Society, The National MS Society, National Multiple Sclerosis Society, Inc., Sociedad Nacional de Esclerosis, Sociedad Nacional de Esclerosis Múltiple, NMSS

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United States of America

Results and Publications

Publication and dissemination plan
The trialists intend to publish the results in a high-impact journal by March 2018.

Intention to publish date
01/03/2018

Individual participant data (IPD) sharing plan
The unidentified datasets generated during and/or analysed during the current study will be stored in a publically available repository at the University of Illinois at Urbana-Champaign. The website link is: https://doi.org/10.13012/B2IDB-6858418_V1. There are no known legal or ethical restrictions at this time.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/10/2018		Yes	No
Protocol file		01/04/2016	05/09/2023	No	No