# Targeted ballet program for people with multiple sclerosis

| Submission date              | <b>Recruitment status</b>                |  |  |
|------------------------------|--|--|--|
| 13/07/2017                   | No longer recruiting                     |  |  |
| Registration date 21/07/2017 | <b>Overall study status</b><br>Completed |  |  |
| Last Edited                  | <b>Condition category</b>                |  |  |
| 05/09/2023                   | 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., anklefoot 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? Prof. Citlali Lopez-Ortiz lopezort@illinois.edu

# **Contact information**

**Type(s)** Public

**Contact name** Dr Citlali Lopez-Ortiz

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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 Urbana United States of America 61801

# Sponsor information

**Organisation** University of Illinois at Urbana-Champaign

**Sponsor details** Fourth Floor, Swanlund Administration Building MC-304 601 E. John Street Champaign United States of America 61820 +1 (0)217 333 0034 ovcr@illinois.edu

**Sponsor type** University/education

Website https://research.illinois.edu

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? |
|------------------------|---------|--------------|------------|----------------|-----------------|
| <u>Results article</u> | results | 18/10/2018   |            | Yes            | No              |
| <u>Protocol file</u>   |         | 01/04/2016   | 05/09/2023 | No             | No              |