

'Getting the Balance Right' - A comparison of physiotherapy and exercise treatments for people with multiple sclerosis (MS)

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Registration date 30/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/07/2009	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A randomised controlled trial of physiotherapy and exercise interventions for ambulatory people with multiple sclerosis (MS)

Acronym

Getting the Balance Right

Study objectives

Strand A will concern individuals with multiple sclerosis (MS) who walk independently or use one stick to walk outside. The objective is to compare the immediate and long term effect of yoga, physiotherapist led exercise class, fitness instructor led exercise class to a control group who do not change their exercise habits.

Strand B will concern individuals with MS who walk with bilateral support or a rollator, they may use a wheelchair for longer distance outdoors. The objective is to compare the immediate and long term effect of one-to-one physiotherapist led intervention, group intervention led by a physiotherapist, or group yoga intervention to a control group who do not change their exercise habits.

More details can be found at: <http://www.ms-society.ie/pages/getting-the-balance-right>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Health Services Executive, Mid West Regional Hospital, approved in April 2008

Study design

Cluster-randomised single-blind multi-centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Patient information can be found at: <http://www.ms-society.ie/pages/research-programme>

Health condition(s) or problem(s) studied

Multiple sclerosis (MS)

Interventions

The physiotherapy interventions for strands A and B are standardised and based on the latest evidence for practice in order to allow reproduction of the programmes. The yoga and fitness instructor interventions are not specified, in order to represent normal practice, but are well documented to allow comparison later.

To ensure standardisation of physiotherapy interventions, training for those physiotherapists delivering the programmes will be held on three occasions, supporting documentation will be provided and follow up advice and information for deliverers will be supplied as necessary by email and telephone. The content of the interventions for both strands is described below. The attendance and participation of each study participant will be documented on a weekly basis.

The control groups in both strands will not receive any intervention for the 12 weeks and were told to continue with their normal routine. Once the control period is over participants will receive the treatment of their choice but the response to this will not be assessed as part of this trial.

Strand A:

Intervention 1: Physiotherapy led strength and aerobic training

Participants will attend an hour long circuit class once a week for 10 weeks. This will be a circuit style class consisting of "sit to stand" / squat, bridging, resisted shoulder flexion, walking / bike, resisted elbow flexion, lunges or resisted knee extension, hip extension, calf raises. All exercises will be completed at 50-80% of the participants' one-repetition-maximum and the load will be increased by 2-5% when twelve repetitions are easily achieved. The aim is for the participant to be failing on the last repetition. If the next available load is higher than 2-5% (such as going from 1 kg to 2 kg in resisted shoulder flexion) the participant can increase the repetitions so that they are still failing to achieve full range of motion on the last one. The primary aim is to achieve 'overload' of the muscle to achieve gains in strength. Participants will be educated about the overload principle and that delayed onset of muscle soreness is a normal phenomenon. After five weeks of attending the class, participants will be advised to complete a second hour of strengthening themselves at home.

A second component of the class will be advice regarding aerobic exercise. In the first class, 10 minutes will be devoted to formally explaining aerobic exercise, Uhtoff's phenomenon (whereby increasing heat in people with MS can temporarily exacerbate symptoms) and the evidence supporting aerobic activity. Each participant will be given a target heart rate. This will be calculated using the Karvonen formula which is: $\text{Target Heart Rate} = \text{Resting Heart Rate} + 65\% (\text{Maximum Heart Rate} - \text{Resting Heart Rate})$.

The participants will be advised in the initial assessment how to get their resting heart rate, by feeling their carotid pulse for 30 seconds first thing on waking. The first beat they feel will be zero. As a maximal exercise test will not be conducted, each participant's age predicted maximum heart rate will be used as the target heart rate (i.e. $220 - \text{age}$). If they are unable to detect a pulse they will aim to exercise at a Rate of Perceived Exertion level of 11-14.

Participants will be initially asked to complete two sessions of independent aerobic activity per week for 20-30 minutes. From week 5, they will be asked complete this three times a week. Participants can choose the type activity that they did (i.e. swimming / walking / running / cycling). They will take their pulse every 10 minutes to ensure they are achieving the correct intensity.

Intervention 2: Fitness instructor led group exercise

Where possible, the fitness instructors will all have attained a level 2 National Certificate in Exercise and Fitness (NCEF). They will be given a standardised pack in order to document the interventions.

Intervention 3: Yoga classes

Yoga instructors will be accredited by the Yoga Federation of Ireland. They will be given a standardised pack in order to document the interventions.

Strand B:

Intervention 1: Group physiotherapy

Participants attended a weekly hour long class for 10 weeks. The circuit style class consisted of exercises that combined strength and balance. Participants will complete six different exercises at each class. The exercises were adapted from the falls prevention literature where similar programmes have been seen to improve, balance and reduce the number of falls in an elderly population.

The six exercises and possible progressions are described below. These are to be performed in sets of 12. When a participant is able to perform 12 repetitions of an exercise safely this can be progressed up to 3 sets of 12 repetitions. When a participant can perform 3 sets safely the exercise will be progressed so as to continuously challenge the participant. Not all participants will progress through all the exercises. The progression is dependent on the ability of the participant and their safety while performing the exercises.

1. 'Sit to Stand', progressed by altering:

1.1. Hand Positioning - Participants may initially need to use hands for support to rise from chair, then progressing to hands by side and then to hands across chest

1.2. Seat Height - Participants may initially require a higher seat height which can be lowered to increase the intensity of the exercise

1.3. Repetitions - To be performed in sets of 12 and number of sets to be increased to 3 as participant progresses

1.4. Weights - Handheld weights may be given to participants who need further progression

2. Squat, progressed by altering:

2.1. Support - Participants may initially need bilateral support, this can be decreased to unilateral and then to no support as participants' ability increases

2.2. Repetitions - To be performed in sets of 12 and number of sets to be increased to 3 as participant progresses

2.3. Weights - May be given to participants who are able to perform 3 sets of 12 squats safely with no support

3. Calf raises, progressed by altering:

3.1. Support - Participants may initially need bilateral support, this can be decreased to unilateral support and then to independent calf raises as participant progresses

3.2. Repetitions - To be performed in sets of 12, to be increased as participant progresses

3.3. Other options - If participants are able they may perform single leg calf raises or if they can perform 3 sets of 12 independent calf raises weights can be added as further progression

The following three exercises are to be completed within parallel bars.

4. Step ups, progressed by altering:

4.1. Support - Participants may begin with bilateral support, and then decrease to unilateral support, then to no support

4.2. Stepping - Initially participants may step onto step and back to starting position, then step

onto step and over, and then onto step, over and backwards to starting position

4.3. Step height - When participants are comfortable with all directions of stepping step height may be increased

5. Side stepping, progressed by altering:

5.1. Support - Participants may begin with bilateral support, and then decrease to unilateral support, then to no support

5.2. Number of steps - Initially participants may only take one step in each direction. This can be increased as participants' ability increases

If a participant is unable to take a step to the side, weight shifting from side to side in standing may be performed and progressed to stepping when the participant is able.

6. Tandem stepping/walking, progressed by altering:

6.1. Support - Participants may begin bilateral support, and then decrease to unilateral support, then to no support

6.2. Stepping - Participants may initially just place one foot in front of the other and hold this position. The number of steps can then be increased as the participant progresses.

6.3. Crossover - Participants may become competent at tandem walking. This can then be progressed to one foot crossing over in front of the other.

Intervention 2: One-on-one physiotherapy

These participants will receive individual treatment depending on the problem list and goals established by the chartered physiotherapist who was treating them. The content of the intervention will be recorded for each individual treatment session. The duration of the individual sessions will be the same as the group led physiotherapy.

Intervention 3: Yoga

Participants will attend a weekly yoga class of approximately one hour's duration. All yoga instructors will be members of the Yoga Federation of Ireland and will keep a log of the content of each yoga class.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Multiple Sclerosis Impact Scale 29, v2

All primary and secondary outcomes will be assessed at the following timepoints: Week 1, (before intervention), week 12 (after intervention/control period) and week 24 (follow-up)

Secondary outcome measures

1. Muscle strength using hand held dynamometry
2. Modified Ashworth Scale
3. Physiological Cost Index
4. Six-minute walking test
5. Berg Balance Scale
6. Modified Fatigue Impact Scale

All primary and secondary outcomes will be assessed at the following timepoints: Week 1, (before intervention), week 12 (after intervention/control period) and week 24 (follow-up)

Overall study start date

01/04/2008

Completion date

01/10/2009

Eligibility

Key inclusion criteria

1. Both males and females, aged ≥ 18
2. Diagnosis of MS confirmed by their consultant physician or neurologist
3. Resident in the republic of Ireland

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

328 (Strand A 240, Strand B 88)

Key exclusion criteria

1. Currently experiencing an exacerbation of symptoms due to relapse
2. Patients who have had steroid treatment within 3 months of the baseline measurement
3. Pregnant at time of referral
4. Under 18 years of age

Date of first enrolment

01/04/2008

Date of final enrolment

01/10/2009

Locations

Countries of recruitment

Ireland

Study participating centre
Department of Physiotherapy
Limerick
Ireland
-

Sponsor information

Organisation
University of Limerick (UK)

Sponsor details
Castletroy
Limerick
Ireland
-

Sponsor type
University/education

Website
<http://www.ul.ie>

ROR
<https://ror.org/00a0n9e72>

Funder(s)

Funder type
Charity

Funder Name
Multiple Sclerosis Society of Ireland (MS Ireland) (Ireland) - through Tesco (UK) 'Charity of the Year' funding

Funder Name
Pobal (Ireland) - Dormant Accounts Flagship Fund

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/07/2009		Yes	No