The impacts of core stability exercise (Pilates) on posture, pain, function and quality of life in wheelchair users with Multiple Sclerosis

Submission date 30/03/2012	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date	Overall study status	Statistical analysis plan
08/05/2012	Completed	[X] Results[] Individual participant data
Last Edited 30/08/2016	Condition category Nervous System Diseases	

Plain English summary of protocol

Background and study aims

About 19% of people with Multiple Sclerosis (MS) need to use wheelchairs at some point. A good sitting position in a wheelchair is important as this allows the person to breathe deeply, use their arms efficiently and could decrease fatigue and back and neck pain. Studies of exercise in people with MS have found benefits in strength and stamina but rarely include wheelchair users. Pilates is increasingly popular with people who have MS and has added value because the exercises are possible when seated in a wheelchair. Pilates focuses on improving core stability, which should improve sitting stability and posture while sitting in a wheelchair. Theoretically, a better sitting posture should improve breathing, arm function and comfort, and could decrease back, neck or shoulder pain. However, there is no published evidence of its effects for people with MS. This project aims to investigate the impacts of a 12-week structured programme of core (trunk) stability exercises (Pilates) on sitting stability, breathing, pain, function, fatigue and quality of life for people with MS. A second aim is to explore group and individual experiences of this programme and its impacts using so-called focus groups in which these experiences will be discussed. The results of this study will provide information about whether Pilates is appropriate for further research, development and funding.

Who can participate?

People with MS, aged 18 or over, living in the Edinburgh area, who use a wheelchair but are able to transfer with minimal assistance (e.g. with the help of one person and using a sliding board), cognitive ability to follow an instructor's advice, and clinical stability for six weeks.

What does the study involve?

Participants will be randomly divided into two groups. One group will be invited to the Pilates classes: two sessions per week for the first 6 weeks and one session for the following 6 weeks. Each session will last about an hour. We will also ask people in this group to do a daily programme of 15 minutes of Pilates exercises at home and keep a record of this. The other group will continue with their usual care. This group will not attend any Pilates classes during this study, but for those interested we can help finding an appropriate class after the study is finished. The total duration of the study is around six months - 12 weeks of Pilates classes for

those in the Pilates group, followed by three months of no classes for either group. At the end of this time, a final set of measurements will be taken.

What are the possible benefits and risks of participating?

We cannot promise this study will help you but the information we get from this study will provide useful information about a possible strategy for improving quality of life when people with MS use a wheelchair. Pilates is a safe way of exercising, and the Pilates Instructor will be able to monitor you closely during the exercises. It is possible that you will feel more fatigued after the classes and/or after the measurement sessions. If you agree to take part we will invite you to attend for measurements of your posture, sitting stability and breathing capacity on four occasions within a six-month period. You can always, at any moment withdraw from the Pilates classes or tests.

Where is the study run from? Queen Margaret University in Edinburgh and supported by NHS Lothian and NHS Lanarkshire

When is the study starting and how long is it expected to run for? The study started in Spring 2010 and we intend to complete the study in early 2013.

Who is funding the study? MS Society UK

Who is the main contact? Dr Marietta van der Linden mvanderlinden@qmu.ac.uk

Contact information

Type(s) Scientific

Contact name Dr Marietta van der Linden

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Study information

Scientific Title

The impacts of core stability exercise (Pilates) on posture, pain, function and quality of life in wheelchair users with Multiple Sclerosis: a randomised controlled feasibility study

Study objectives

This project aims to investigate the impacts of a 12-week structured programme of core (trunk) stability exercises (Pilates) on sitting stability, breathing, pain, function, fatigue and quality of life. The programme will involve two one hourly classes per week for the first 6 weeks, followed by one hourly class per week for the following 6 weeks. A second aim is to explore group and individual experiences of this programme and its impacts using so-called focus groups in which these experiences will be discussed. The aims of Pilates focus on improving core stability, which should improve sitting stability and posture while sitting in a wheelchair. Theoretically, a better sitting posture should improve breathing, arm function, comfort and could decrease back, neck or shoulder pain. It is possible that these changes would improve quality of life for people who have multiple sclerosis (MS) and use wheelchairs.

Ethics approval required

Old ethics approval format

Ethics approval(s) South East of Scotland Research Ethics Committee, 09/12/2009, ref: 09/S1101/62

Study design Randomised controlled study

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 the contact details below to request a patient information

Health condition(s) or problem(s) studied

Neurological diseases, Multiple Sclerosis

Interventions

Participants were allocated to either the Pilates group (PG) or the control group (CG).

Participants in the PG were asked to attend a one-hour Pilates class twice a week for six weeks (block 1), followed by a weekly one-hour Pilates classes for the following six weeks (block 2). All classes were conducted at two day care centres and were led by an experienced Pilates instructor. A personal care assistant was present at all Pilates classes to assist with personal needs. PG participants were also encouraged to do a 15 minute daily home programme of Pilates exercises. The control group continued with their usual care.

Follow Up Length: 3 months

Intervention Type

Behavioural

Primary outcome measure

Sitting stability when leaning sideways assessed pre intervention, and 6 weeks, 12 weeks after start of the intervention and 3 month follow-up

Secondary outcome measures

- 1. Back pain
- 2. Neck pain
- 3. Pain in arms and shoulders
- 4. Sitting posture
- 5. Breathing capacity
- 6. Multiple Sclerosis Impact Score 29
- 7. Canadian Occupational Performance Measure

Overall study start date

14/01/2010

Completion date

15/09/2010

Eligibility

Key inclusion criteria

- 1. Residence in the Edinburgh area
- 2. MS diagnosis
- 3. Aged 18 or over

4. Wheelchair user but able to transfer with minimal assistance (e.g. with the help of one person and using a sliding board)

5. Cognitive ability to follow an instructor's advice

6. Clinical stability for six weeks

Participant type(s) Patient

Age group

Adult

Lower age limit

18 Years

Sex Both

Target number of participants Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria

- 1. Change in medication in the previous six weeks
- 2. Experience of a relapse during the past six weeks (defined by Sjarnadottir et ai, 2007)
- 3. Inability to safely participate in a Pilates class

Date of first enrolment 14/01/2010

Date of final enrolment 15/09/2010

Locations

Countries of recruitment Scotland

United Kingdom

Study participating centre Queen Margaret University Musselburgh United Kingdom EH21 6UU

Sponsor information

Organisation Queen Margaret University (UK)

Sponsor details Centre for Integrated Health Research Queen Margaret University Drive Musselburgh Scotland United Kingdom EH21 6UU **Sponsor type** University/education

Website http://www.qmu.ac.uk/

ROR https://ror.org/002g3cb31

Funder(s)

Funder type Charity

Funder Name Multiple Sclerosis Society (ref: 920/09)

Alternative Name(s) Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society UK, Multiple Sclerosis Society UK, MS Society

Funding Body Type Private sector organisation

Funding Body Subtype Associations and societies (private and public)

Location United Kingdom

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

Available on request

Study outputs

Output type

Results article

results 01/07/2014

Yes

No