

‘Falls prevention for people with multiple sclerosis: A pilot trial’

Participant Information Leaflet

What is the purpose of this study?

Many people with Multiple Sclerosis experience falls. We have developed a falls prevention programme for people with Multiple Sclerosis and we need to assess how suitable and effective the programme is.

What will I have to do if I choose to participate?

Should you be interested in taking part or have any questions about the study you can contact the researchers via the contact details provided on the next page. The researcher will then ask you a number of questions to see if you are eligible to take part in the study. You will be asked to return a consent form to the researchers. You will then attend an assessment with a researcher to assess your strength, balance, walking and feelings about falls. We will then give you falls diaries to complete for two months. This is like a calendar where you will write down if you had a fall or if you had to seek medical attention due to a fall. You will then attend the same assessment with the same researcher to reassess your strength, balance, walking and feelings about falls before the class starts.

You will then attend a class delivered by a chartered physiotherapist twice a week for 90 minutes for 12 weeks. The classes will consist of 45 minutes of exercises aimed at improving your strength, balance and walking and 45 minutes of education about falls, which will include group discussions and problem solving. You will be given an exercise programme to perform at home. After the 12 weeks, you will again have your strength, balance, walking and feelings about falls assessed and complete another two months of falls diaries to see if the intervention has been successful. After completing the two months of falls diaries you will attend one last assessment with the researcher to assess your strength, balance, walking and feelings about falls. We are doing all of these assessments to firstly see what happens when you don't have classes so we can compare it to when you finish the classes. Secondly we want to see if the effect of treatment lasts after the classes are finished.

Who is being asked to participate in this study?

People with multiple sclerosis who are over the age of 18 years, have experienced a fall in the last three months, and who are able to walk for 10 metres with or without a walking aid (one stick or one crutch).

Are there any benefits in taking part in this study?

You will be taking part in a 12 weeks of classes aimed at reducing your falls, improving your balance, strength, walking and confidence about falls. You will also be providing valuable data to inform the development of falls prevention interventions for people with Multiple Sclerosis.

Are there any risks in taking part in this study?

As the exercises are trying to improve your balance they need to challenge your balance sufficiently so there is a small risk that you may fall, however the exercises used are similar to those used by physiotherapists in the community so the risk is no greater than routine physiotherapy. Furthermore, the classes will be delivered by a chartered physiotherapist with the support provided adapted to your ability.

What happens if I do not wish to take part in this study?

Your choice to participate in this study is entirely voluntary. If you do not wish to take part or if you wish to withdraw from the study at any point you may do so without reason or penalty

Will my details be kept confidential?

Your identity will remain completely confidential. A study number will identify you and your name will not be published or disclosed to anyone.

What happens to the information?

You will remain anonymous throughout this study. When we present the results, they will be averages and so you will not be able to be identified. We will let the MS Society know what the average results were, and will present them to physiotherapists and at other conferences. We hope to write research papers about the results also and may combine them with results from other studies to answer other questions in future.

Who is organising this research?

This study is being carried out by the MS Research Team at the University of Limerick, led by Prof. Susan Coote.

What do I do now?

If you would be interested in taking part in this study or have any further questions about the study you can contact the researchers by the information below.

Should you have any further questions or queries about this study please do not hesitate to contact:

Principal Investigator

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This research study has received Ethics approval from the Education and Health Sciences Research Ethics Committee (EHS_2017_09_03). If you have any concerns about this study and wish to contact someone independent you may contact:

Chairman Education and Health Sciences Research Ethics Committee

EHS Faculty Office

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