Investigating ways to manage foot drop in MS

What is the title of the study?
Comparing Functional Electrical Stimulation and Ankle Foot Orthosis in the management of foot drop in MS

Which institution is responsible for the study?
NHS Ayrshire and Arran, Glasgow University, Glasgow Caledonian University and Strathclyde University.

What's this study about?
This randomised controlled trial is investigating Functional Electrical Stimulation (FES) and Ankle Foot Orthosis (AFO) in the management of persistent foot drop in people with MS. The study aims to investigate:

- The effects of FES and AFO on walking speed and oxygen consumption
- The effects of FES and AFO on fatigue, physical activity levels, quality of life, stability and disability
- The cost-effectiveness of both therapies, and the experiences of the participants

How will this help people affected by MS?
There is currently no evidence as to whether FES or AFO is the best treatment for foot drop in people with MS. This study aims to help clinicians to choose the most suitable therapy, and ultimately help people with MS maintain their mobility and improve their quality of life.

What will participants be asked to do?
Participants will be randomly assigned to receive either AFO or FES treatment. Participants in the AFO group will be measured by a clinician and then return for a fitting. Participants in the FES group will be seen by a physiotherapist, who will set up their FES device.

Both groups will be asked to attend four assessment visits at the Douglas Grant Rehabilitation Unit (DGRU) in Irvine, Scotland – the initial set-up, then at 12, 24 and 52 weeks – along with two additional clinical visits to check the devices.

The assessment visits will consist of:

- walking assessments whilst wearing a heart rate monitor and a face mask to measure breathing. Rest periods will be provided between walking.
- questionnaires about current MS symptoms and general wellbeing.
- at the end of the appointment, participants will be asked to wear a waterproof activity monitor (on the thigh) for one week. This can be returned in a prepaid envelope.

Participants will also be asked to record the details of any falls throughout the course of the study. At the end, participants will be asked to attend a focus group to talk about their experience of using the device over the last 12 months. This session would be audio recorded.

Who can take part?
This study is recruiting people with MS who are patients at:

- NHS Ayrshire & Arran
- NHS Greater Glasgow & Clyde
- NHS Lanarkshire
- NHS Dumfries & Galloway
- NHS Lothian
- NHS Fife
- NHS Tayside.

You can take part in this study if you:

- Have been diagnosed with MS
- Are over the age of 18
- Have had persistent foot drop over the last three months due to your MS
- Are able to walk continuously for five minutes at a comfortable pace
- Have had relatively stable MS for at least three months

Unfortunately, you won't be able to take part if you:

- Currently or previously used FES or AFO for foot drop
- Have other significant medical conditions affecting your walking
- Have a significant cognitive impairment that could affect your ability to take part in the study

Who is conducting the research?
This MS Society-funded study is being led by Linda Renfrew. Other members include Dr Paul Mattison, Dr Lorna Paul, Danny Rafferty, Roy Bower and Anna Smith.

When can I take part in this study?
Recruitment for this study began in August 2014 and will continue until March 2017.

Where is this research taking place?
This study is taking place at the Douglas Grant Rehabilitation Centre in Ayrshire Central Hospital, Irvine.

Who has reviewed this study?
This study has been approved by the West of Scotland Research Ethics Committee and the Research & Development department of NHS Ayrshire & Arran.

What are the potential side effects?

There are no major risks taking part in this study. Some people may find walking continuously for five minutes strenuous. This can cause symptoms such as pain or fatigue to increase, but this will subside within 20-30 minutes. The assessment will be stopped if claustrophobia is experienced whilst wearing a face mask to measure breathing.

There is a small risk of an allergic reaction while wearing the electrodes used in FES (this can be resolved in 99.5 per cent of cases by using anti-allergenic versions). If the AFO is rubbing and causing irritation, this can be resolved be the researcher through adjustments. The activity monitor may cause minor irritation, in which case it can be removed and re-applied when the irritation has alleviated.

Who is supporting this study?
NHS Ayrshire & Arran and the MS Society are supporting this study. Co-applicants at Glasgow Caledonian University, Glasgow University and Strathclyde University are contributing expertise and equipment.

Interested?
If you would like to find out more about this study and would like to receive a participation information sheet, please contact Linda Renfrew at linda.renfrew@aapct.scot.nhs.uk.

Please note that enquiring about participation does not commit you in any way.