

# Functional electrical stimulation (FES)

Treating foot drop in MS

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Experts in MS

# Contents



3 **Executive summary**

6 **Introduction**

- What is foot drop?
- What is functional electrical stimulation (FES)?
- Access to FES

12 **How cost-effective is FES?**

- Is FES cost-effective?
- Can FES save money?

22 **How does FES affect quality of life?**

- What's quality of life and why is it important?
- Effects on health-related quality of life measures
- Reduced cognitive effort and fatigue

- Increased confidence and self-esteem
- Increased independence and ability to do physical activities

30 **How does FES improve walking?**

- How does FES affect walking speed?
  - Initial orthotic effects
  - Ongoing orthotic effect
  - Therapeutic effect

35 **How does FES affect quality of gait?**

- What does quality of gait mean and why is it important?
- What are the effects of FES on the quality of gait?

40 **Does FES reduce falls?**

- Falls in MS
- Fear of falling in MS
- Can FES reduce falls and fear of falling?

46 **Conclusion**

47 **References**

54 **Appendix: Methods summary**

Disclaimer: This pack draws together examples of the evidence on FES in MS related foot drop. This is not a systematic review or clinical practice guideline. See our methods summary for more information on how this pack was created.

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## 75%

of people with MS are estimated to experience walking issues due to their condition

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**“Reduced and unreliable mobility affects every facet of life. The effort to do even simple tasks leaves me physically and emotionally exhausted.”**

Iain, 55, living with relapsing remitting MS

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# Executive summary

Maintaining mobility is one of the highest priorities for people with MS. Walking issues are very common, with 75% of people with MS estimated to experience them due to their condition. And they are also among the most disabling symptoms, being the main contributor to disability within the first 10 years of being diagnosed with MS.

Foot drop is a common walking issue affecting people with MS. People with foot drop have trouble lifting their foot up and toward their shin when walking. This leads to an increased risk for falls and an increase in the mental and physical effort that is spent on walking. People with MS-related foot drop often have to rely more on others and restrict their physical and social activities out of fear of falling and injuring themselves. This can lead to social isolation and affect people's quality of life.

In 2009, the National Institute for Health and Care Excellence (NICE) approved functional electrical stimulation (FES) as a treatment for MS related foot drop. This means that NICE looked at the evidence and research available for FES at the time and found it to be effective and safe enough to be offered routinely.

FES works by applying electrical stimulation to the nerves in the legs through electrodes that are placed on the skin. The electrical impulses make muscles in the legs contract and lift the foot towards the shin.

The Purchasing and Supply Agency found FES to be cost-effective with an incremental cost-effectiveness ratio (ICER) of £19,238 per quality adjusted life year (QALY) gained. Since then several cost-effectiveness studies have confirmed these findings using different

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**“FES has improved both my ability to walk and my confidence, I no longer need a stick to balance. If I did not have the FES I would be too fearful to walk more than a few yards.”**

David, living with relapsing remitting MS

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data and methods, and have found that FES is cost-effective with ICERs between £6,137 and £15,406 per QALY.

Since 2009, the research around the effectiveness of FES in improving quality of life and walking outcomes has also grown and become more robust. Research shows that FES can significantly improve people’s quality of life. A recent meta-analysis including studies that used standardised quality of life measures found that FES significantly improves physical functioning, psychological wellbeing and increases people’s perceived competence, adaptability and self-esteem.

Qualitative studies report similar benefits and participants report reduced fatigue, reduced mental effort of walking and psychological benefits such as increased confidence and self-esteem. They also report increased independence and being more able to be physically and socially active.

Walking speed remains the main indicator for the clinical effectiveness of FES in improving walking. A 2017 meta-analysis of 19 studies found that FES increases walking speed by an average of 7% with the first immediate use, and by 11% when used on an ongoing basis.

Research also suggests that FES can improve the quality of gait, which is the quality of the movements people make when walking. Studies show that it can shift unhealthy movement patterns toward healthy ones and improve knee and ankle movements.

People with MS related foot drop also report reduced falls and trips, and quantitative research supports this finding. One study found that participants who used FES recorded 72% less falls than the comparison group. Research also suggests that FES can reduce the fear of falling and make people feel more confident and able to participate in activities.

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**“I wish it was more readily available as foot drop is so common in MS and Stroke. It would help prevent people falling and keep people independent for longer.”**

Rob, living with secondary progressive MS

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**“I believe that everyone who could benefit from an FES should be given the opportunity to try one and find out if it could help their life.”**

Patrick, 67, living with secondary progressive MS

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**1 in 5**

people with MS would like FES

**40%**

of those people are accessing it

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Even though FES has been NICE approved for over 13 years, people with MS struggle to access it. Treatment clinics that offer FES are limited and not geographically accessible to many. Funding for FES is also fragmented over the whole UK and most healthcare professionals don't know how they can refer patients to receive FES elsewhere.

Our 2019 My MS My Needs survey found that around 1 in 5 people with MS would like FES. But out of those, less than half (40%) are accessing it.

This means that thousands of people in the UK might be missing out on a treatment that could help them. Based on the available research, we are confident that FES is effective and cost-effective and could help many people with MS. FES doesn't work for everyone, but we think that everyone who could benefit should be able to try it.



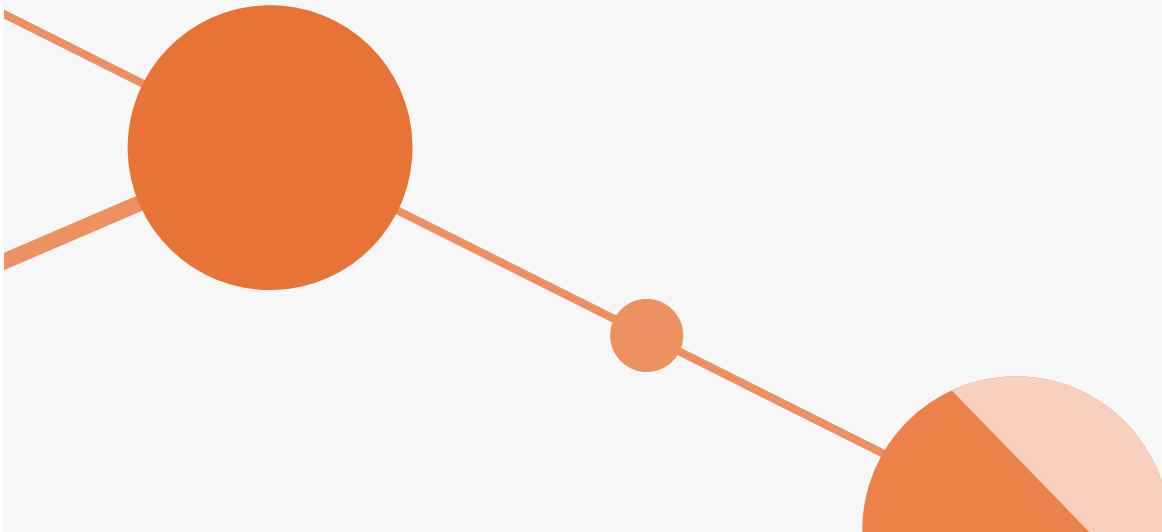
# Introduction

- 7 What is foot drop?
- 8 What is functional electrical stimulation (FES)?
- 9 Access to FES

Research suggests that around 75% of people with MS will experience walking issues as part of their MS. Walking problems are among the most disabling effects of MS and are the main contributor to disability within the first ten years of being diagnosed with MS<sup>1-3</sup>.

Walking issues have also been found to have a negative impact on people's employment status and their ability to do daily living activities, such as shopping or doing things around the house<sup>4,5</sup>. That's why maintaining mobility is one of the highest priorities for people with MS<sup>2</sup>.

One walking issue that commonly affects people with MS (or other neurological conditions) is foot drop.



# What is foot drop?

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**“My wife had to hold on to me all the time in case I tripped or stumbled; even at home I had to be extremely careful on the stairs and couldn’t do the simplest of tasks without getting exhausted.”**

Michael, 68,  
living with primary  
progressive MS

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Foot drop is also commonly called drop foot or dropped foot. People with foot drop have trouble lifting their foot properly when walking. In MS, this is often caused by muscle weakness in the leg and ankle or by a disruption in the nerve pathway between the brain and legs<sup>6,7</sup>.

Since people with foot drop can’t lift their foot properly, it can affect their ability to walk normally. Their foot can drag or catch on the ground, increasing the risk of trips or falls<sup>8</sup>. Foot drop can also make the ankle less stable, as more weight may be put on the outer edge of the foot. It also impacts walking speed and people affected by foot drop often have to expend more mental and physical energy on walking<sup>1</sup>.

As a result, people with MS-related foot drop have to rely more on others and often restrict their physical and social activities out of fear of falling and injuring themselves. This can lead to social isolation and affect people’s quality of life<sup>9</sup>.

# What is functional electrical stimulation (FES)?

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“FES has improved both my ability to walk and my confidence, I no longer need a stick to balance. If I did not have the FES I would be too fearful to walk more than a few yards.”

David, living with relapsing remitting MS

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Functional electrical stimulation (FES) is an assistive technology used for foot drop in MS and other conditions. FES devices are small devices with electrodes that are normally placed on the skin.

The FES device applies electrical stimulation to the nerves in the legs. This makes specific muscles contract so that the foot is lifted up towards the shin (ankle dorsiflexion) and the outer border of the foot is tilted upwards (eversion). The electrical stimulation is synchronised with the walking movement, so that the foot is lifted when the person is swinging their leg up when walking. This prevents the foot from dragging or catching on the ground. When weight is returned to the foot, the foot is placed in a more stable position<sup>10,11</sup>.

FES is an orthotic treatment, which means it assists walking when it's being used. But it doesn't necessarily improve the user's walking ability whenever they're not wearing the FES device. So it's used on an ongoing or occasional basis, similar to a walking stick or other assistive devices.

People with MS can use FES for as long as they benefit from it. Those who benefit from it often use FES until their walking difficulties get worse and they can't walk anymore. One study looked at the long term use of FES and included 126 participants (including 62 with stroke and 39 with MS). It found that participants used FES for a mean time of 4.9 years, but 33 people still used FES after a mean of 11.1 years<sup>12</sup>. Every person's MS is different, but some may be able to benefit from FES for a very long time.



# Access to FES

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**“I think everyone with walking difficulties due to MS should have access to an FES. It enables people to retain their independence and that is so important to their general wellbeing.”**

Rachel, 44, living with relapsing remitting MS

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In 2009, the National Institute for Health and Care Excellence (NICE) approved FES as a treatment for foot drop that is caused by a neurological condition such as MS or stroke<sup>13</sup>. This means that NICE looked at the evidence and research available for FES at the time and found it to be effective and safe enough to be offered routinely.

But many people with MS who could benefit from FES are still having trouble accessing it. Our 2019 My MS My Needs survey found that around 1 in 5 people with MS would like FES. But out of those, less than half (40%) are accessing it. And around 1 in 3 respondents didn't even know what FES is.

In many areas in the UK, FES isn't routinely funded for people with MS, and the funding is very fragmented. Treatment clinics that offer FES are limited and not geographically accessible to many. People with MS often have to travel to other regions to access FES. This isn't sustainable and also adds additional barriers for people with MS, such as having to travel, or having to pay for FES privately.

It's estimated that walking issues affect around 75% of people with MS<sup>1</sup>, with foot drop being one of the most common issues. This means that thousands of people in the UK might be missing out on a treatment that could help them.



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“I felt my mental health was suffering due to the bleak outlook and I was worried about the future and the impact my disability would have on my wife and family. I had good days and bad days which impacted on our daily life.”

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# Michael

68, living with primary progressive MS

“Drop foot on my right side and fatigue were my main issues as this limited my walking capabilities considerably. I bought a mobility scooter because things were worsening and I was very limited in what I could join in and do with the family. I was limited in helping my wife do the shopping or anything that involved walking.

My wife had to hold on to me all the time in case I tripped or stumbled; even at home I had to be extremely careful on the stairs and couldn't do the simplest of tasks without getting exhausted. I would usually take a long time in the morning to clear the brain fog and then could potter around the house but any other activity would need to be carefully planned and usually an afternoon sleep was needed to recharge. I did have a couple of falls downstairs and several trips.

My quality of life was slowly getting worse and we were searching online for any other treatments to try. We found FES by chance on an American site for stroke victims and then started to search UK sites for something similar.

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**“The second best benefit is that my brainfog/fatigue has diminished dramatically.”**

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**“My mental health has improved as I now feel the future is not as bleak.”**

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**“I feel it should be funded by the NHS once a thorough assessment and trial have proved successful (not everyone can get on with it) as in the end it will save NHS resources both from a physical and mental health point of view.”**

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We discovered that our CCG did not fund this, despite NICE guidelines recommendations. We knew we would have to go privately and the choice was Salisbury to Odstock Medical.

FES has totally changed my life. I can now join in with activities more easily such as badminton and games with the grandchildren. My wife and I are able to go back to walking albeit shorter than we used to but still I have achieved a 6 mile walk without any knee braces, sticks or toe lift.

I no longer feel the need to see a physio as I am getting exercise through walking again; my muscle wastage has evened out. We can now plan ahead for holidays with less limitation as to where we can go and we can be more spontaneous about going out generally.

FES has given me choice over what I do whereas without it I would always say “no” to anything which involved walking or exertion.

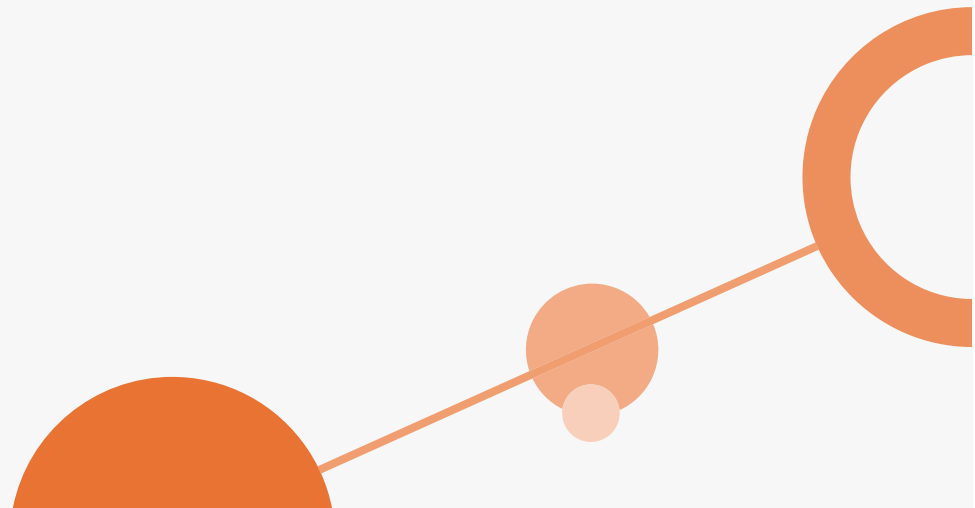
Without my FES I believe I would be reliant on my mobility scooter to do anything more than a 5 minute walk. I would be using the brace, sticks and toe lift and probably sleeping most afternoons to recharge. I wouldn’t be able to play with my grandchildren and would be much more reliant on others to assist me. Also I feel I would need more support from my GP and NHS services.”

# How cost-effective is FES?

- 13 Is FES cost-effective?
- 19 Can FES save money?
- 28 Increased independence and ability to do physical activities

Based on the cost-effectiveness research we can be confident that FES is a cost-effective treatment for foot drop that is due to MS or stroke.

Four studies have looked at how cost-effective FES is. All four found it to be cost-effective and within the £20,000 willingness-to-pay threshold used by NICE. The data and models are different for each study, so the incremental cost-effectiveness ratios (ICERs) differ. They range from £6,137 to £19,238 per quality-adjusted life-year (QALY).



## What is cost-effectiveness?

Cost-effectiveness describes whether a treatment provides good value for money. If a treatment offers increased effectiveness against an illness or symptom at a reasonable cost, it is considered cost-effective. If it offers increased effectiveness and is also cheaper than standard treatments or saves money in other ways (for example by reducing management costs), it is cost-saving.

Cost-effectiveness is normally estimated by producing the incremental cost-effectiveness ratio (ICER). This is calculated by dividing the difference in cost between the old and new treatment by the difference in effectiveness between them.

The ICER is expressed as the cost per quality-adjusted life year (QALY) gained. QALY is based on the idea that a person's health state can be summarised as a number, with 1 meaning perfect health and 0 meaning death. QALYs are calculated by multiplying the sum of a person's health state with the length of time the health state lasts. The change in a person's health state as a result of the treatment is worked out by comparing their quality of life before and after receiving the treatment.<sup>14</sup>

A cost of £20,000 to £30,000 per QALY gained through a treatment is within the cost-effectiveness threshold used by the National Institute for Health and Care Excellence (NICE).

## Is FES cost-effective?

Researchers have analysed the cost-effectiveness of FES in multiple studies and using different methods. All studies found that FES is cost-effective within the £20,000 willingness-to-pay threshold used by the National Institute for Health and Care Excellence (NICE).

The incremental cost-effectiveness ratios (ICERs) range from £6,137 to £19,238 per quality-adjusted life-year (QALY). This is likely due to differences in the design, methodology and the data used for each study.

For example, two studies looked specifically at the cost-effectiveness of FES for the treatment of foot drop in people with MS<sup>15,16</sup>, while one looked at cost-effectiveness across different conditions (including stroke and MS)<sup>12</sup> and one study looked at stroke patients only<sup>17</sup>.

## Why are the findings different between cost-effectiveness studies?

Cost-effectiveness is most commonly calculated using modelling. This means that researchers create a model of the clinical situation that closely represents reality. They build models on a number of assumptions about the treatment effects, patient populations, treatment costs and so on. These assumptions are usually based on previous research and available data.

Because modelling is always uncertain and based on assumptions, different assumptions are tested. In the base case analysis, researchers run the model

with the assumptions that they think best represent reality. In sensitivity analyses, the model stays the same, but one assumption is changed for each analysis. This allows researchers to see how each assumption affects cost-effectiveness<sup>14</sup>.

Since all the models in this evidence pack are based on different sources of data, the assumptions are slightly different for each model. This explains the different findings.

You can learn more about cost-effectiveness in general and how to judge whether an analysis or model is reliable [in this article](#).

Also, two of the studies based the quality of life improvement on changes in walking speed, rather than quality of life measures<sup>12,17</sup>. Although research has shown that FES improves both walking speed and quality of life, some research suggests that the two are not closely related and occur independent of each other<sup>15,18</sup>. So it's important to keep this possible limitation in mind.

All studies found FES to be cost-effective, although the ICERs differed between studies. You can read more about the methods and assumptions used in each study below.



## NHS Purchasing and Supply Agency 2010<sup>17</sup>

In 2009, the NHS Purchasing and Supply Agency found that FES is cost-effective with an incremental cost-effectiveness ratio (ICER) of £19,238 per QALY gained over a time horizon of five years. An overall QALY gain of 0.041 was calculated.

The average costs of FES treatment were estimated to be £140 for the initial assessment, £1,500 for the first year and £450 for each subsequent year.

The cost-effectiveness model used walking speed as its main indicator and correlated it to quality of life. The average gain in walking speed as a result of FES treatment was calculated by averaging the results from four previous studies, all based on patients with stroke related foot drop.

The researchers then corresponded this information to changes in the Health Utility Index 3 (HUI3), a standardised system for measuring health status and health-related quality of life<sup>19</sup>. This gave them an estimate of changes in quality of life.

This study also estimated that quite a few people would get skin irritation due to the electrodes, but this was likely overestimated, resulting in a lower QALY gain estimate.

## Taylor et al. 2013<sup>12</sup>

A study from 2013<sup>12</sup> also found that FES is a cost-effective treatment for foot drop, with an ICER of £15,406 per QALY gained.

The researchers analysed 126 patient records retrospectively across different neurological conditions (including 62 with stroke and 39 with MS). The median time of FES use was 3.6 years (mean=4.9, standard deviation=4.1, 95% confidence interval 4.2-5.6) with 33 people still using FES after a mean of 11.1 years.

The researchers calculated costs by taking the average number of clinic appointments and estimating costs. They estimated the average treatment cost per patient to be £3,095 (2012 prices).

The average cost per patient was then divided by the mean time of FES use and divided further by the 0.041 QALY gain from the previous 2010 cost-effectiveness study<sup>17</sup>.

## Juckes et al. 2019<sup>15</sup>

Juckes et al. found FES to be cost effective with an ICER of £6,137 per QALY gained compared to standard care over five years. They found an overall average QALY gain of 0.55.

The study focused on 82 patients with MS and followed their FES treatment over six months. The researchers measured the treatment effects and changes in quality of life using the EQ-5D-5L (includes measures of mobility, self-care, usual activities, pain/discomfort and anxiety/depression), walking speed tests and the Psychosocial Impact of Assistive Devices Scale (PIADS).

A separate group of 44 people with MS using ankle-foot orthosis (AFOs) were used as a control group for quality of life. They had completed the EQ-5D-5L questionnaire in 2018.

A Medtech innovation briefing (MIB56) published by NICE<sup>20</sup> estimated the total costs for FES to be £3,320 over five years, including the device, consumables and clinic appointments. This was inflated to 2017/2018 prices by the researchers, resulting in an estimate cost of £3,393.

Costs for ankle-foot orthoses were not included, since they were deemed to be standard of care. This means that they were assumed to be received by all patients, including those using FES.

Cost-effectiveness was calculated over a five year time horizon following methodology recommended by NICE<sup>21</sup>. FES was found to be a cost-effective treatment with an ICER of £6,137 per QALY gained.

## Renfrew et al. 2019

The second 2019 study<sup>16</sup> found FES to be cost-effective with an ICER of £14,285 per QALY gained over two years. The total QALY gain over the two years was 1.36, which was 0.05 QALY higher compared to AFO.

The study recruited 85 participants with MS related foot drop who hadn't used FES or AFOs before. They were then split into a FES group (42 participants) and an AFO group (43 participants). Participants were followed over 12 months.

The researchers measured quality of life improvements using the EQ-5D-5L, which covers mobility, self-care, usual activities, pain/discomfort and anxiety/depression<sup>22</sup>. This data was then converted to a utility index to determine QALY.

Device costs were taken from purchase costs at the time of the study. NHS staff costs were based on the time spent delivering the treatment during the trial, multiplied by the Information Services Division unit cost. Over the two years, FES cost an average of around £1,447 per person.

## Can FES save money?

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“Before FES I fell frequently, and had to go to A&E on three occasions – I’ve broken both my little fingers, one so badly that it’s permanently disfigured.”

Rachel, 44, living with relapsing remitting MS

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“Without the FES I would be in a wheelchair the whole time. Could I finance an electrical wheelchair, possibly not. Would I need a carer? ”

Patrick, 67, living with secondary progressive MS

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The cost-effectiveness studies don’t take into account potential cost-savings as a result of FES.

Research shows that FES can increase independence and the ability to take part in daily living tasks<sup>18, 23-26</sup>. This could mean that people with MS related foot drop don’t have to rely on carers as much, which could result in reduced social care costs.

Research also suggests that FES can reduce falls<sup>24, 26, 27</sup>. This might mean fewer hospital admissions and other healthcare is required, thus translating into cost savings for the NHS.

But more research is needed to understand how FES affects those aspects and how it may save costs.

# Rachel

44, living with relapsing remitting MS



"I was diagnosed with RRMS in 2015, after I started experiencing difficulties walking - my left leg becoming very fatigued and heavy after about 10-15 minutes walk.

MS has impacted almost every area of my life - I have cut down my hours at work, and have to carefully manage my time to avoid becoming too fatigued. I am very reliant on my husband to do things around the house when I am too tired to. I am not able to be as active with my children as I would like to, and we are restricted as to where we can go as I can't walk far and have had to stop driving. I have to do online grocery shopping because walking around the shop is too much for me.

Before FES I fell frequently, and had to go to A&E on three occasions - I've broken both my little fingers, one so badly that it's permanently disfigured. I was becoming scared of walking outdoors.



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“If I didn’t have my FES  
I think I would be pretty  
much confined to my home.  
I try to have a 20 minute  
walk outside every day and  
I wouldn’t be able to. I’d be  
less healthy and less happy.  
It’s likely I’d have had to stop  
working as I’d be unable  
to commute.”

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My physiotherapist gave me lots of exercises and I did Pilates but this didn’t improve my walking markedly. The physiotherapist also gave me a splint but this was a bit uncomfortable, I also felt very self-conscious about wearing it as it is very obvious. I was offered an FES, I didn’t have any problems accessing this. It took a while to get used to putting it on every day but I’m now a dab hand at it. Walking with the FES means I have a lot more confidence and I have travelled a lot more because I haven’t worried so much about how to get around - though I still get tired I can do enough walking to make a day out worthwhile.

I think everyone with walking difficulties due to MS should have access to an FES. It enables people to retain their independence and that is so important to their general wellbeing.”



# How does FES affect quality of life?

- 23 What's quality of life and why is it important?
- 24 Effects on health-related quality of life measures
- 26 Reduced cognitive effort and fatigue
- 27 Increased confidence and self-esteem

Improving quality of life and independence is one of the key aims of assistive technologies such as FES. A 2019 systematic review and meta-analysis found that FES improves quality of life in people with MS. The included studies used various measures and found that FES might improve physical functioning, psychological wellbeing and increase people's perceptions of competence, adaptability and self-esteem.

Participants in qualitative studies have reported similar benefits. They range from reduced fatigue and mental effort needed for walking to psychological improvements such as increased confidence and self-esteem. FES also seems to increase users' independence – they are more able to take care of themselves, to take part in social activities and to be physically active.



# What's quality of life and why is it important?

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“There is so little available to help people with advanced MS, this seems something that could make a huge difference to someone's quality of life.”

Patrick, 67, living with secondary progressive MS

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Health-related quality of life describes the impact that a person's health status has on their quality of life. It includes physical, mental, emotional and social health and functioning.

Previous research with over 4,500 people with MS shows that people with MS have a lower quality of life than the general population. In this study, their average health state score (a measure to describe health-related quality of life) was only 59.7, compared to 86 in the general population<sup>28</sup>.

Assistive technologies such as FES are designed to improve function, help users live more independently at home and participate in their community<sup>29</sup>.

This is why it's important to think about the effectiveness of FES in terms of the overall impact it can have on people's quality of life. Even small changes in walking speed or ability could have a big impact on users' perceived benefits and their quality of life.

Previous FES research also suggests that changes in walking speed don't automatically reflect changes in quality of life. These changes can happen independent of each other, so we need to research and understand both<sup>18</sup>.

And measures such as walking speed can be affected by factors such as neuromuscular fatigue<sup>30</sup>. So it's important to also consider self-reported and qualitative measures to get the most accurate picture of the potential benefits of FES.

# Effects on health-related quality of life measures

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“FES has totally changed my life. I can now join in with activities more easily such as badminton and games with the grandchildren.”

Michael, 68,  
living with primary  
progressive MS

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In 2019, researchers did a systematic review of studies that measure the effect of FES on health-related quality of life in people with MS<sup>31</sup>. Seven out of the eight studies included found that FES had a positive effect on quality of life in people with MS.

The review included eight studies with a total of 168 participants. The studies used four different measures for health-related quality of life: MSIS-29, SF-36, COPM, PIADS, with some using more than one measure.

Three studies used the Multiple Sclerosis Impact Scale (MSIS-29), which measures the physical and psychological impact of MS<sup>34</sup>. One of those studies found significant improvements in the total score and the physical and psychological subscales<sup>32</sup>. Another found a significant improvement in the psychological subscale<sup>33</sup>, but one study

with nine participants found no significant improvements<sup>35</sup>.

Three studies used the 36-item Short Form Health Status Survey (SF-36), which measures quality of life across eight physical, emotional and social domains. Mayer et al. found significant improvements in physical functioning and role limitations physical, which describes the impact of physical health problems on the individual's work and activities of daily living<sup>25</sup>. Taylor et al.<sup>36</sup> found small, statistically nonsignificant improvements in pain, general health and fatigue. And one study with two participants noted improvements in pain, energy/fatigue and the role limitations due to physical health<sup>37</sup>.

Two studies used the Psychological Impact of Assistive Devices Scale (PIADS). It

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**“I was amazed how much difference it made, I felt as if I could run round the gym. I was fortunate that my consultant recommended FES and was also able to access NHS funding for me. ”**

David, living with relapsing remitting MS

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measures the effect of assistive devices on health-related quality of life and covers three aspects: competence, adaptability and self-esteem<sup>38</sup>. Barrett and Taylor compared FES with no FES use and found significant improvements in all three aspects after 18 weeks of FES<sup>18</sup>. The other study found statistically significant improvements in the self-esteem domain. But this study compared implanted FES to external FES. Participants in this study had already used an external FES device for 6 months, before receiving an implantable FES device for this trial<sup>36</sup>.

One study used the Canadian Occupational Performance Measure (COPM), which uses a semi-structured interview method. Participants identify and then rate important

activities within self-care, leisure and productivity from 1 to 10 based on their performance of and satisfaction with these activities<sup>39</sup>. Participants noted significant improvements in the perceived performance and satisfaction of activities such as walking, balance, climbing stairs and managing steps and curbs after 18 weeks of FES<sup>26</sup>.

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“The second best benefit [of FES] is that my brainfog/fatigue has diminished dramatically. I would usually take a long time in the morning to clear the brain fog and then could potter around the house but any other activity would need to be carefully planned and usually an afternoon sleep was needed to recharge.”

Michael, 68,  
living with primary  
progressive MS

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## Reduced cognitive effort and fatigue

Several qualitative studies with people with MS have found that FES reduces fatigue associated with the mental effort of walking<sup>23,24</sup>. This is also supported by studies showing that FES reduces the physical effort of walking<sup>33, 40-42</sup>.

When MS affects cognitive functions such as sensory-motor function or attention, this can mean that people with MS have to concentrate more when carrying out tasks<sup>43</sup>.

Activities that combine cognitive and motor tasks at the same time (such as walking while having a conversation) are especially affected. This can affect people's mobility and their ability to take part in everyday activities<sup>44</sup>.

It can also lead to higher levels of cognitive and physical fatigue and a deterioration in the performance of tasks. In the case of walking while talking, for example, this means that people might also be at an increased risk of falling<sup>43-45</sup>.

A qualitative study from 2020 suggests that FES can reduce the conscious concentration people with MS related foot drop have to spend on walking. As one study participant put it: “the device was doing the thinking for me.”<sup>23</sup>.

This effect can reduce fatigue and have big impacts on people's quality of life. And it can enable people with foot drop to take part in social and daily activities with greater ease and comfort<sup>23</sup>.

Participants in a 2014 study also attributed 41% of falls with feeling somewhat more or much more fatigued than usual<sup>46</sup>. So by reducing fatigue, FES might also reduce the risk of falls.

While the previous research suggests that FES could reduce the cognitive burden of walking on people with MS, more research is needed to understand the mechanisms involved in this<sup>23</sup>.



# Increased confidence and self-esteem

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“The FES has made a huge difference to both me, my life and ability to achieve a level of independence. I’m only able to walk in the house with a walker but I can pretend that my MS is not quite as severe as it really is. It makes me feel so much better mentally.”

Patrick, 67, living with secondary progressive MS

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Research has shown that FES can also have positive impact on users’ psychological wellbeing and outlook. Renfrew et al.<sup>23</sup> found that participants frequently reported feeling more confident as a result of FES. They described that the FES device had restored a sense of personal autonomy and that they felt more in control than before.

Participants also described that using FES increased their self-esteem and improved their self-image, which had been negatively affected by their walking difficulties.

MS can affect how people see themselves. Someone who previously thought of themselves as active, capable and independent might struggle with negative self-image as they adjust to changes in their MS<sup>47,48</sup>. Previous research also shows that people with MS often experience low self-esteem and can withdraw from activities and social life because of this<sup>49</sup>.

The findings by Renfrew et al.<sup>23</sup> suggest that FES can have a positive effect on people with MS and how they see themselves. It may support them in the process of adjusting to their MS and re-evaluating their identity.

# Increased independence and ability to do physical activities

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“Without my FES I believe I would be reliant on my mobility scooter to do anything more than a 5 minute walk. I wouldn’t be able to play with my grandchildren and would be much more reliant on others to assist me.”

Michael, 68,  
living with primary  
progressive MS

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Previous research suggests that improved independence is the main benefit that people with MS report gaining from assistive mobility devices<sup>50</sup>.

Qualitative research on FES shows that FES can enable people with MS to engage in a range of everyday activities such as shopping, gardening, accessing public transport and more, which would have been a struggle before<sup>23</sup>. Thus increasing people’s independence and their ability to do participate in life.

Research also shows that FES can increase people’s ability to be physically active<sup>23, 24</sup>.

Physical activity can help to maintain function and health in people with MS<sup>51, 52</sup>. Regular exercise promotes cardiovascular health and is known to be neuroprotective,

meaning it protects the nervous system from decay in people with MS<sup>53</sup>.

But a study suggests that up to 80% of people with MS do not take part in any meaningful physical activity, including leisure and daily living activities<sup>54</sup>. This is partly because of physical limitations or psychological barriers<sup>55</sup>.

People with MS have reported increased participation in activities as a result of FES use. As well as feeling more confident in their walking and needing less effort or energy to walk than before<sup>23,24</sup>. These findings suggest that FES has the potential to increase people’s independence and their ability to be physically active. But more research is needed to fully understand the wider potential benefits on health, physical function, and quality of life.



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“[I] had read about research studies with FES and decided to give one a try. The difference it made was I could walk again. I was struggling a lot.”

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## Iain

55, living with relapsing remitting MS

“Pre MS I snow and water skied, rode motorbikes and completed several Belfast to Dublin maracycles. All gone now. Lost a lot. Had to medically retire from senior management position in Aug 2008. Reduced and unreliable mobility affects every facet of life. The effort to do even simple tasks leaves me physically and emotionally exhausted.

[Before FES,] life was limited. I felt I couldn’t reliably get about. Tried splints and still successfully use a range of devices. Soft toe lift ankle devices through to rigid AFO (ankle foot orthoses) and everything in between.

FES can be a great thing for us however I firmly believe it is not for everyone. You can’t just strap it on and go. It doesn’t work like that. Saying that, when it all is set it does give a training effect because you are actually using your own muscles instead of splinting which actually weakens the muscles. I continue to use my wide range of walking devices and some suit certain situations better than others. It’s a steep learning curve!”

# How does FES improve walking?

31 How does FES affect walking speed?

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32 Initial orthotic effects

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32 Ongoing orthotic effect

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33 Therapeutic effect

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Most studies on walking speed have found that FES increases walking speed in MS-related foot drop immediately at first use, and on an ongoing basis. An extensive meta-analysis from 2017 including 19 studies found that FES increases walking speed. The meta-analysis combined data from the included studies and found that FES increased walking speed by an average of 7% with the first immediate use, and by 11% when used on an ongoing basis. But FES doesn't usually

produce a therapeutic effect, meaning an increase in unassisted walking speed, in people with MS.

Research also shows that FES can improve the quality of gait, which is the quality of the movements people make when walking. Studies show that it can shift unhealthy movement patterns toward healthy ones and improve knee flexion, foot clearance and ankle dorsiflexion.

People with MS related foot drop also report reduced falls and trips, and quantitative research supports this finding. One trial found that participants who used FES recorded 72% fewer falls than the comparison group. People with MS also report feeling more confident and able to participate in life.

Although most of the studies looking at falls and quality of gait are small, these findings are promising. But more research is needed to fully understand how FES affects these areas.

# How does FES affect walking speed?

Most research has found that FES increases walking speed in MS-related foot drop immediately at first use, and on an ongoing orthotic basis.

Walking speed is the most commonly used measure in FES research. It's easy to measure and is closely related to walking efficiency and gait quality<sup>56</sup>. Researchers measure walking speed using short or long-distance timed tests. Short distance tests (for example over 10 metres) are most common in FES research.

Many FES studies on walking speed have small sample sizes. So it makes sense to look at systematic reviews and meta-analyses. These studies draw together the findings of relevant studies in an organised way and analyse the available data to get a better overall understanding.

In 2017, Miller et al. did a systematic review and meta-analysis of studies looking at the effects of FES on walking speed in MS-related foot drop. The review was extensive and included 19 studies involving 490 people with MS. Most of the included studies had small sample sizes, ranging from 2<sup>37</sup> to 39<sup>36</sup>, with one study having a notably larger sample size of 153<sup>57</sup>. 17 of the 19 studies included in the review measured walking speed over short distances, with the majority using the 10 metre walk test<sup>12, 18, 25, 35-37, 40, 42, 57-60</sup>.

Another systematic review from 2017 reviewed the available research on FES and foot drop in people with MS<sup>61</sup>. It included 12 studies involving 446 people with MS and excluded any studies with mixed populations (for example those looking at people with stroke as well as people with MS) and any studies with fewer than 10 participants. The researchers did not perform a meta-analysis.

## What are orthotic effects?

An orthotic effect is the difference in walking performance between using the FES device and walking without it. An initial or immediate orthotic effect is the change that FES makes with the first use. An ongoing orthotic effect is the difference in walking performance when walking with FES after a period of regular use compared to the baseline walking performance without FES<sup>10, 40, 56</sup>.

## Initial orthotic effects

Miller et al. found that the majority of studies reported a significant increase in walking speed following the initial use of FES for MS-related foot drop<sup>10</sup>. On average, FES increased walking speeds by 5% to 18.3% in those studies<sup>12, 32, 33, 40, 57, 58, 62</sup>. However, some of the studies reported no immediate change in walking speed<sup>18, 25, 42, 63</sup> and two small studies (2 and 5 participants, respectively) reported mixed results<sup>37, 59</sup>.

For the meta-analysis, the researchers combined the data of all these studies to find out the initial orthotic effect. The analysis revealed a statistically significant initial orthotic effect with an average increase in walking speed of 7.1%, or 0.05 meters per second (m/s)<sup>10</sup>. An improvement of 0.05 m/s or more is considered clinically meaningful<sup>64</sup>.

Similar to Miller et al., Springer and Khamis found that in the majority of studies, FES significantly increased walking speed in people with MS-related foot drop<sup>61</sup>.

## Ongoing orthotic effect

In their review, Miller et al. (2017) found that out of thirteen studies that looked at ongoing orthotic effects of FES on MS-related foot drop, eleven<sup>12, 18, 33, 35-37, 40, 42, 57, 59, 60</sup> reported a statistically significant positive ongoing orthotic effect. This effect was reported from 4 weeks<sup>59, 65</sup> up to a mean of 10.8 years<sup>12</sup> after the initial application.

The meta-analysis combined the results of all eligible studies that used short walking tests. It revealed a statistically significant long-term orthotic effect with an average increase in walking speed of 0.08 m/s (11.3%)<sup>10</sup>. This improvement is clinically meaningful (>0.05 m/s) and just below a clinically substantial (0.1 m/s) change in walking speed<sup>64</sup>.

A 2018 study looked at the effects of FES on walking speed in people with MS related foot drop after 5 years. It found that those whose unassisted walking speed had decreased were still able to gain a significant orthotic effect after 5 years of using FES. This even included some people who were unable to walk without FES<sup>66</sup>.



## What are therapeutic effects?

The therapeutic or training effect describes the impact of regular use of FES on walking performance without the device. For example, if after a year of using FES regularly a person's walking performance when not wearing the device is better than their initial performance before starting FES treatment, there's a therapeutic or training effect<sup>10, 56</sup>.

## Therapeutic effect

Even though therapeutic effects have been shown in people with foot drop related to other neurological conditions (such as stroke, Parkinson's disease or spinal cord injury), MS limits the capacity for neuro-plastic change. This means that nerves are not as able to grow new connections and reorganise. This may limit the therapeutic effect FES can have in people with MS<sup>10</sup>. But more research is needed to really understand this.

Miller et al. (2017) looked at eleven studies that investigated therapeutic effects<sup>12, 18, 33, 35-37, 40, 42, 57, 60, 63</sup> using short walking tests. The studies measured the therapeutic effect at varying time points, ranging from 6 weeks<sup>42</sup> to a mean of 10.8 years<sup>12</sup> since starting FES.

Out of those eleven studies, one reported a statistically significant therapeutic effect at 12 weeks<sup>60</sup>. However, the majority of studies found no significant effect. They reported either small non-significant improvements in walking speed or no improvements<sup>18, 33, 42, 57, 63, 65</sup>.

The meta-analysis included six studies with a total of 244 people with MS. It found no evidence that FES had a therapeutic effect in people with MS.

Five studies used longer walking tests and reported mixed results, with some showing positive therapeutic effects<sup>60, 65</sup> and others showing no therapeutic effects<sup>36, 37, 42</sup>.

The meta-analysis of studies with longer walking tests included three eligible studies, involving a total of 61 people with MS. Although the analysis showed an increase in walking speed of 10.3%, this finding was not statistically significant.

Although the meta-analysis found no significant therapeutic effect on average, some people with MS do experience a therapeutic effect. Street et al.<sup>57</sup> found therapeutic effects in one third of participants. So whether people with MS experience a therapeutic effect may depend on individual factors and how their MS affects their body.

# David

## Living with relapsing remitting MS

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“FES has improved both my ability to walk and my confidence, I no longer need a stick to balance. If I did not have the FES I would be too fearful to walk more than a few yards. My ability to walk would deteriorate and I would become immobile”

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“I feel fortunate that my FES is funded by the NHS. It makes such a difference to me. I feel that all MS sufferers should have the same access.”

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“Mobility issues have prevented my wife and I enjoying life together and have eroded my independence. They have severely curtailed my ability to socialise and participate in events.

Before FES I would frequently stumble and sometimes fall. Even with a stick I was fearful of falling. The front of my left shoe wore out after approx. 6 months. I tried a Boxia device [an ankle foot orthosis] but it rubbed my leg and was painful to use. The physiotherapist suggested FES and I was able to try it at Chichester rehab centre.

I was amazed how much difference it made, I felt as if I could run round the gym. I was fortunate that my consultant recommended FES and was also able to access NHS funding for me. The service from UCLH is excellent, however, travelling to London is difficult and tiring for me as well as being expensive, especially as I need my wife to accompany me.

The physio at UCLH has recommended that I try a dual channel FES, which will stimulate my leg too. I am so grateful for this opportunity.”

# How does FES affect quality of gait?

36 What does quality of gait mean and why is it important?

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37 What are the effects of FES on the quality of gait?

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Quality of gait describes the quality of the movements people make when walking. Some research suggests that FES can improve the quality of gait in MS-related foot drop. Studies have found that it may shift unhealthy gait patterns towards healthy ones, improve ankle dorsiflexion, foot clearance and knee flexion. But most of the studies on gait quality have small sample sizes. More large, high quality trials are needed to really understand how FES affects quality of gait in MS-related foot drop.



# What does quality of gait mean and why is it important?

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Rob describes the impact of FES on his life as “a miracle to have the machine”. The FES helps to stop his ankle from seizing up. Walking was much easier and less strenuous so he could walk further and rarely fell.

Rob, living with secondary progressive MS

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Most studies use walking speed to measure the effect of FES, but there’s also growing evidence that FES has positive effects on kinematic aspects of walking<sup>58, 59, 62</sup>.

This means that it improves the movements that people’s feet and legs make during walking. This is important because the way we move when walking can affect how safely and stable we walk and how much stress we’re putting on our joints.

Research shows that compared to healthy participants, people with MS related walking issues have a worse gait pattern and posture, and that this is not related to their walking speed<sup>62</sup>. So it’s important to understand how FES might affect the quality of walking movements beyond just walking speed.

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Rob told us that before using FES he was falling once a week at least. He walked with real effort as he had to lean over to the right to enable him to swing his left leg round enabling the dropped foot to clear the surface he was walking on. He tried foot up splints but these didn't work.

Rob, living with secondary progressive MS

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## What are the effects of FES on the quality of gait?

FES works by activating ankle dorsiflexion during walking, which means that it activates the muscles responsible for lifting the foot up towards the shin. It also activates eversion, which means that the outer border of the foot is twisted upwards, reducing the risk of turning the ankle when weight is being put on the foot again<sup>11</sup>.

Increased ankle dorsiflexion when using FES is well-documented in research<sup>35, 58, 59, 62</sup>. This is also connected to greater foot clearance, which means that the foot is less likely to catch or drag on the ground.

In addition to ankle dorsiflexion, research also points to other improvements. Some studies have found that FES increases knee flexion, meaning the knee bends further during walking, resulting in a healthier walking pattern<sup>58, 59, 62</sup>.

One study also analysed how much the walking pattern of 22 people with MS differed from a healthy control group, and how FES affects this. They calculated participants' gait profile score (derived from kinematics of the ankle, knee, hip and pelvis). They found that people with MS showed differences in most gait characteristics compared to the healthy controls when walking unassisted. But their measurements moved towards normal values immediately when using FES<sup>62</sup>.

In one study, participants also recorded reduced joint pain as a result of using FES. This effect was continuous from 6 months to 5 years after initial FES use<sup>66</sup>. This could suggest that FES might help to decrease harmful compensatory walking patterns that lead to joint pain. But more research is needed, in particular since joint pain is not measured in most FES studies.



# Patrick

67, living with secondary progressive MS

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“My experience with an FES is very good. Without one I would be a wheelchair user and this brings a whole host of physiological and psychological problems that I just about manage to avoid.”

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“MS has had a major impact upon my life. I took medical retirement in 2012, I used to work as a freelance computer consultant. My EDSS score is about 6.5. I have significant visible and invisible symptoms. I walk very slowly, have significant balance problems, cannot stand on my feet for more than a couple of minutes. My maximum walking speed is 1 Km/hour and I cannot run. Everything takes a long time. MS has had a major effect upon my left leg and my right leg is not perfect.

The FES has made a huge difference to both me, my life and ability to achieve a level of independence. I’m only able to walk in the house with a walker but I can pretend that my MS is not quite as severe as it really is. It makes me feel so much better mentally. I try to walk for between 15 to 30 minutes in the house every day. That is less than 1000 steps but a lot better than no steps. I’m quite sure the exercise has improved my quality of life and therefore helped to keep the MS from advancing quite so quickly. With the FES and my sit-stand

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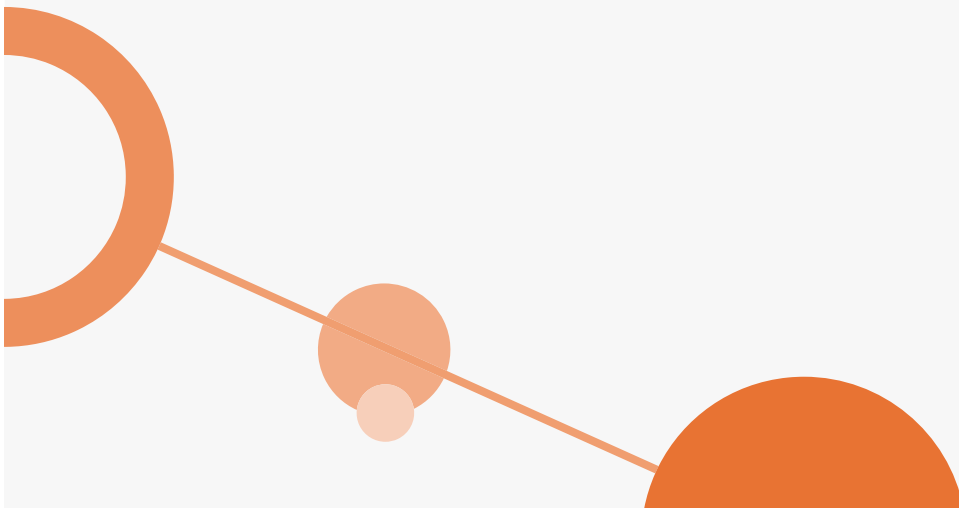
“There is so little available to help people with advanced MS, this seems something that could make a huge difference to someone’s quality of life.”

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chair I am able to run the kitchen, doing the cooking, washing up and even bake cakes. It helps to give me a purpose in life.

Without the FES I would be in a wheelchair the whole time. Could I finance an electrical wheelchair, possibly not. Would I need a carer? Food shopping would be virtually impossible, we could not live in our lovely house or in the lovely town of Berkhamsted, too many slopes. Trips to London museums and theatres would be very difficult and require much more planning. My life would be totally different.

I believe that everyone who could benefit from an FES should be given the opportunity to try one and find out if it could help their life. I am lucky to have the facilities and skilled people from Queen SQ within an hour travel by public transport but that is unfair on so many others who have not been told about the FES.”

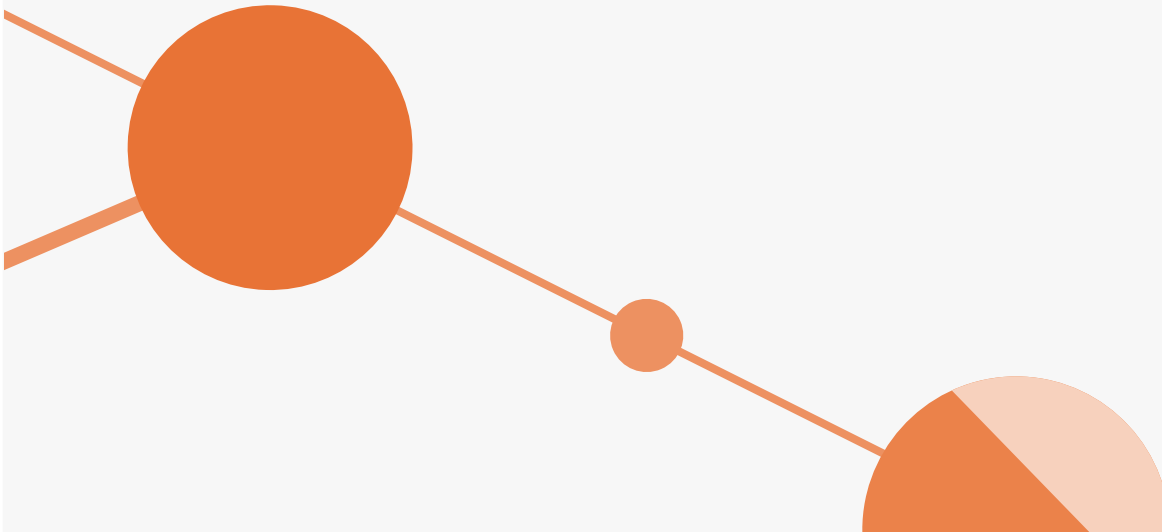


# Does FES reduce falls?

- 41 Falls in MS
- 42 Fear of falling in MS
- 43 Can FES reduce falls and fear of falling?

Foot drop and other walking issues increase the risks of falls and trips<sup>46</sup>. Some research estimates that over 50% of people with MS will fall at least once within three months<sup>67</sup>. Fear of falling is a related and common issue which can lead to social isolation and deconditioning through the restriction of activities<sup>9</sup>.

Research on FES suggests that it may reduce falls<sup>27, 33</sup> and people with MS related foot drop commonly report a reduction in falls and trips<sup>24</sup>. One trial found that participants who used FES recorded 72% less falls than the comparison group<sup>26</sup>. Research also suggests that FES can reduce the fear of falling and make people feel more confident and able to participate in activities<sup>24</sup>.





# Falls in MS

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**37%**

of participants were frequent fallers<sup>67</sup>

**11%**

of recorded falls caused injuries

**28%**

of falls happened during general mobility tasks, such as standing, walking or turning

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Foot drop and other walking issues increase the risk of falls and trips<sup>46</sup>. Since walking issues are so common in MS, falls are an ever present reality for many people with MS.

A meta-analysis including data from 537 people with MS found a 56% prevalence of falls within a three month time frame. 37% of participants were frequent fallers<sup>67</sup>.

A 2014 study<sup>46</sup> looked at how often people with MS with an EDSS score between 3.5 and 6.5 fall. Over three months, the 139 participants recorded 672 falls and 3,785 near falls, which is equivalent to 18.41 falls per person year. 11% of recorded falls caused injuries.

About 28% of falls happened during general mobility tasks, such as standing, walking or turning. Falls during daily living activities were also common, including during personal hygiene activities (16.4% of falls), cleaning (7.7% of falls) and working in the kitchen (8.7% of falls)<sup>46</sup>.

# Fear of falling in MS

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**“Before FES I would frequently stumble and sometimes fall. Even with a stick I was fearful of falling. The front of my left shoe wore out after approx. 6 months.”**

David, living with relapsing remitting MS

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Fear of falling is a related issue that affects people with MS. It's an ongoing fear or concern about falling and the possible consequences, such as injury or loss of independence<sup>68</sup>.

In a study with 1,064 people with MS over the age of 45, 63% reported a fear of falling<sup>9</sup>.

To reduce the anxiety and avoid a fall, people with a fear of falling often isolate themselves more and more from physical activities and social contacts<sup>68</sup>. In one study, 83% of participants with a fear of falling said that they reduced their activities as a result

of this fear. This can lead to social isolation and affect people's quality of life<sup>9</sup>.

The decrease in physical activity can also lead to deconditioning, which can increase fatigue and in turn make other MS symptoms worse<sup>69</sup>.

Research also suggests that a fear of falling is associated with a higher risk of falling<sup>45</sup>. So reducing fear of falling is a key outcome that assistive devices such as FES need to address.

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“[FES] reduced trips and falls far more than I expected. Also less fatigue when walking, less effort to walk. [Without FES, I] would be covered in bruises and would have broken bones. I get huge benefit from FES and missed it when it broke recently. Without it I am far less confident and worry about falling and tripping. FES should be more widely available.”

Christine, 64,  
living with primary  
progressive MS

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## Can FES reduce falls and fear of falling?

Previous research suggests that FES might reduce falls. One study compared FES to an exercise intervention. The researchers found that the median number of falls per research participant over the 18-week study was 72% lower for participants in the FES group, compared to those in the exercise group (5 vs. 18)<sup>26</sup>.

Another study compared the number of falls before using FES and 8 weeks after starting FES in 24 participants (14 with MS, 10 with stroke). The researchers found that the total number of falls reduced from 10 to 2 after 8 weeks of FES use<sup>27</sup>.

Participants in a qualitative study reported that falls and trips had reduced since using FES. And also that using FES had increased their confidence and participation<sup>24</sup>.

This suggests that FES might reduce falls and counteract the activity curtailment associated with fear of falling<sup>9</sup>.

More research is needed to fully understand how FES affects trips and falls. But current studies suggest that FES might reduce trips and falls, reduce the fear of falling, and increase confidence. People with MS report feeling safer and more confident, and, in turn, more able to take part in everyday life.

# Rob

## Living with secondary progressive MS

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Rob walked with real effort as he had to lean over to the right to enable him to swing his left leg round enabling the dropped foot to clear the surface he was walking on. He tried foot up splints but these didn't work.

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Rob told us that before using FES, from 2012 to 2013, he was falling once a week at least and was falling heavily with grazes and bruises. One time he fell he dislocated his shoulder and was really concerned that he would have a more serious injury or break. Falling or having a dislocated shoulder or worse wasn't something he wanted to go through again.

His local MS group told him about FES for foot drop and fortunately, they had purchased two FES machines and were able to access private physio sessions with a physio therapist who was trained to use FES. Rob had been referred for FES on the NHS in 2013, but he still hasn't been offered an appointment.

Rob describes the impact of FES on his life as 'It is a miracle to have the machine'. The FES helps to stop his ankle from seizing up. Walking was much easier and less strenuous so he could walk further and rarely fell. FES also enabled him to keep driving until 2017.

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Even though Rob hasn't really been able to walk since 2019, his physiotherapist still uses the FES to stop the ankle seizing up and to lengthen the Achilles which, alongside physio sessions, still stops spasms and pain.

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If he hadn't had access to FES he would have ended up standing on the ball of his foot as the FES helps to lengthen the Achilles and stop it tightening up. He wouldn't have been able to carry on walking, which he was able to do until around 2019.

About the current levels of access to FES, Rob said "I wish it was more readily available as foot drop is so common in MS and Stroke. It would help prevent people falling and keep people independent for longer."



# Conclusion

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“[I have] difficulty walking more than a short distance, normal tasks such as shopping are difficult. [Because of FES, I] can walk dramatically further. It should be very easy to access and fully funded.”

Geoff, 50, living with relapsing remitting MS

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Research has shown that FES is effective for treating MS related foot drop. It can significantly improve people’s quality of life, walking ability and walking safety. They are able to walk faster and with a healthier walking pattern. And, as a consequence, are more able to take care of themselves, be independent and take part in social activities. FES can also have psychological benefits and lead to greater self-esteem and confidence.

Research also shows that FES is cost-effective. Several cost-effectiveness analyses, using different data and approaches have found FES to be cost-effective, with incremental cost-effectiveness ratios (ICERs) between £6,137 and £19,238 per quality-adjusted life year (QALY) gained.

While the available research points to clear benefits, many studies on the use of FES for MS-related foot drop have small sample sizes, or other methodological limitations.

Despite these limitations, the evidence is strong enough to support FES as an effective treatment that should be funded routinely. Every person with MS who could benefit from FES should be able to access it.

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# Appendix: Methods summary

A rapid evidence review was conducted.

Initially PubMed was searched (a data base for biomedical research literature) using combinations of the terms 'FES' 'MS', 'functional electrical stimulation' 'multiple sclerosis'. Where possible, we favoured systematic reviews and meta-analysis (for example for walking speed or quality of life measures).

The review of these search findings determined the main sections of the evidence pack. Based on these sections – such as 'FES MS quality of life' or 'FES MS quality of gait', further specific searches were carried out to capture any newer studies. Potentially relevant studies that

we identified through reading of the literature and reference lists were also searched and included if relevant.

The main limitation of this approach is that we may have missed studies since our searching was not comprehensive and systematic. While drawing primarily on systematic reviews and meta-analyses brings confidence that the main sections of the evidence pack are based on peer reviewed, quality assessed evidence, we have not applied our own quality assessment to all the studies included.



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