Peninsula Cerebra Research Unit PenCRU Childhood Disability Research

What's the Evidence? Functional Electrical Stimulation (FES) to improve gait in children with cerebral palsy

Key findings

- Functional electrical stimulation (FES) is a way to stimulate nerves to make specific muscles contract during a particular activity such as walking.
- Most research has focused on using FES to help the foot clear the ground when walking.
- FES is only appropriate for children with an adequate range of motion to alter their walking pattern.
- There is limited evidence that FES improves walking patterns in some children with cerebral palsy.
- There is better evidence for improvement in ankle movement, strength, balance, and range of motion. However, it is unclear whether FES is more or less effective than other treatment options.
- FES is generally well-tolerated, but it can be uncomfortable or burdensome to some children.
- More research is needed to determine the effectiveness of FES for children with cerebral palsy.
- An assessment and a chance to try a device in a specialist clinic can help to determine if it is likely to help.

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What were we asked?

A physiotherapist asked us whether there is any evidence that Functional Electrical Stimulation (FES) is effective for improving the gait (walking pattern) of children with cerebral palsy in <u>Gross Motor Function</u> <u>Classification System (GMFCS) levels I and</u> II, who walk independently.

What did we do?

We structured the question using the <u>PICO</u> format: Is Functional Electrical Stimulation more effective than other treatment options to improve the gait (the way a person walks) in children and young people with cerebral palsy with GMFCS levels I and II?

We searched the following evidence databases: NHS Evidence, the Cochrane Library, Trip, NICE (National Institute for Health and Care Excellence), and PubMed, and brought the information together in this summary. The searches were last updated in February 2017.

Experts in gait and FES and members of our <u>Family Faculty</u> reviewed the accuracy and accessibility of the summary.

What did we find?

What is the Gross Motor Function Classification System?

The Gross Motor Function Classification System (GMFCS) describes a child's ability to sit, stand and walk, and whether they use mobility devices.

Children with GMFCS level I can walk, run, and jump, but their speed, balance, and coordination are limited.

Children with GMFCS level II can walk in most settings and climb stairs holding a railing. They may use a mobility device to walk long distances and are limited in their ability to run and jump.

What are gait problems associated with cerebral palsy and how are they treated?

Cerebral palsy affects a child's movement and co-ordination which may lead them to develop a different gait, find walking tiring, and be more likely to trip. However, cerebral palsy affects each child differently. Some treatments help people with cerebral palsy become more independent.

Walking problems are identified using gait analysis and treated with physiotherapy, drugs, surgery and/or orthoses. Orthoses are a type of brace that helps to align the leg and provide stability. <u>Botulinum toxin type</u> <u>A injections</u> may be used to relax overactive muscles for a few months at a time. Surgery to change muscles and bones may be appropriate in some cases. In many cases more than one of the above interventions is used in combination.

What is Functional Electrical Stimulation?

Functional electrical stimulation (FES) has been used as an alternative option for children who have gait problems. FES is a way to stimulate nerves to make specific muscles contract during a particular action, such as walking.

FES is only appropriate for children with an adequate range of motion to alter their walking pattern. For example, being able to flex their foot into a right angle with their ankle with assistance from a therapist.

Children referred for FES could have hemiplegia or cerebral palsy affecting both sides of their body, but would need to be able to stand from sitting independently or with aids. They would also need to be able to comply with treatment with support from family or carers as needed.

Children who meet these criteria would attend a clinic for an assessment and to try using an FES device. If it seems appropriate and likely to be effective, the child and his or her parent carer will return to the clinic to have a device set up and to learn how to use it. Regular follow-up appointments will then be arranged as needed.

FES has been used with children as young as three years old. Younger children may need more support to use the device.

An FES device consists of a stimulator, a pair of electrodes, a lead connecting the stimulator to the electrodes, and a pressure or tilt (trigger) sensor.

- The stimulator is where the user can control the device, turning it off or on and adjusting its settings.
- The electrodes stick to the skin over the nerve which stimulates the muscles.
- The trigger sensor is usually placed under the user's foot, inside their shoe, where it can detect when the foot lifts up and down from the ground, but can also be placed elsewhere on the leg to sense movement.
- In the different models on the market, some use a wire connecting the trigger sensor to the stimulator, whereas others perform this wirelessly.
- Similarly, some systems have the option of the child wearing the stimulator on a cuff close to the electrodes.

The device senses the point in a walking stride in which a muscle needs to contract and activates the electrodes at that point to stimulate the muscle.¹

Is there any evidence that FES is effective in improving the gait pattern in children with cerebral palsy?

Most of the evidence for FES is to overcome the difficulty lifting the front of the foot when walking causing tripping. This is due to spasticity, tight calf muscles and/or weakness of the muscles that lift the foot.

NICE guidance states that current evidence adequately supports the use of FES for this

type of gait problem, and that patients should be considered for FES by a multidisciplinary team.

NICE state that there are various FES devices, and that the technology is evolving, so effectiveness will vary.²

However, NICE guidance was based more on research studies of adults with stroke.

A <u>systematic review</u> of studies of adults with stroke found that FES resulted in effects that were just as positive as those from using ankle-foot orthoses.³ The evidence specifically for children with cerebral palsy is more limited.

Gait problems in children with cerebral palsy are fundamentally different than those of adults with stroke. This is due to cerebral palsy being caused by damage to the developing brain. These children will learn ways of walking that make it easier or more comfortable for them, rather than experiencing a sudden change in gait.

One systematic review found that FES is more effective than no intervention in improving walking in children with cerebral palsy GMFCS levels I and II, but that FES was not more effective than practising the activity without FES.⁴ This review included studies using FES on different muscles to address a variety of gait problems.

However, one recent <u>randomised controlled</u> <u>trial</u> found some evidence of improvement in gait with FES as compared to usual orthotics and therapy for children with spastic hemiplegia.⁵

A recent systematic review found limited evidence for a reduction in toe-drag and falls, but better evidence for improvement in ankle movement, strength, balance, and range of motion.⁶

Another review suggested that the majority of studies of FES with children with cerebral

palsy found it to be effective and welltolerated by patients in general.⁷

One randomised controlled trial also found that FES may reduce walking speed as a result of a more controlled gait.⁸

What does the evidence tell us about the safety of FES?

NICE guidance noted that a small percentage of patients reported skin irritation and device malfunction. They also noted potential for several risks: increase in seizures among patients with epilepsy; sudden increases in blood pressure in patients with spinal cord injuries; increased spasticity or spasms (involuntary muscle contractions); and skin intolerance.²

Are children able to use FES devices and are they happy with them?

As with any intervention, not all children will take well to using an FES device. One study found that, out of 21 children, 18 were able to regularly use the devices.

• One child was unable to use the device because they could not tolerate the sensation of the electrical stimulation.

- Another child did not experience a benefit in their walking pattern.
- A third child stopped using the device because the benefit was not felt to be worth the effort of putting on and removing it every day.⁹

Another study reported technical problems with the devices, particularly fitting them to children and adapting them for activities such as sports.⁸ These issues were mainly related to the trigger sensors and wires, which are not present in all FES devices.

Is there any evidence of a long-term 'training effect' of FES?

A training effect would be an improvement in gait pattern without using FES after having used it for a period of time.

A few studies have looked into whether FES might result in a training effect in the long term, but most have not found evidence of this in children.^{4, 10}

An exception is one small randomised controlled trial, which found improvements in spasticity, mobility, and balance six weeks after an eight-week trial using FES as compared to usual orthotics and therapy.⁵

Is there any evidence about the impact FES may have on any other outcomes for children with cerebral palsy?

There is some evidence that FES may be effective for maintaining trunk control to improve sitting balance in children with cerebral palsy when applied to trunk muscles, although more research is needed on this application.^{11, 12}

There is also some evidence that FES may improve muscle strength in some children, but treatment may need to be continued for the effects to be maintained.^{6, 13, 14}

Is FES available on the NHS for children and young people with cerebral palsy in UK?

FES is available on the NHS in some areas. Families will need to talk with their GPs or hospital consultants to find out whether it is a treatment option in their own area.

In some locations, it is available only for adults or only for other conditions such as stroke or multiple sclerosis.

Patients are typically referred to a trained healthcare professional, normally a physiotherapist, to be assessed to see if an FES device is suitable and effective for them.

A NICE briefing on two devices that are used in the NHS reported that the devices

themselves cost £670 for the ODFS (Odstock Dropped Foot Stimulator) Pace and £995 for the ODFS Pace XL. A total cost over five years, including the costs for consumables such as new electrodes and other parts and appointments at a specialist clinic, was estimated to be £3,320 and £4,325 for each device respectively.¹

In some cases, clinicians may recommend that FES be provided in conjunction with physiotherapy and/or Botulinum toxin type A injections as a programme to improve range of motion and reduce spasticity, with the overall aim of improving gait.

What do we think?

FES is a treatment option that is wellestablished for patients with stroke, but more research is needed to determine its suitability and effectiveness for gait problems in patients with cerebral palsy.

It is unclear whether FES is more effective than orthoses for improving walking.

FES may not be more effective than practising walking, but for some children, it may be a more suitable or accessible intervention than an exercise programme.

More research is needed to determine whether FES leads to a lasting training effect and improvement in gait pattern when walking without an FES device.

FES may not improve walking in all children, and some children may not take well to wearing them or may find that they cause skin irritation or other discomfort, although most children participating in studies have continued to use them.

An assessment by a specialist professional, including a chance to try a device in a clinic, can help to determine whether FES is appropriate and likely to be effective for a specific child with cerebral palsy.

Signposts to other information

NHS Choices information on foot drop: http://www.nhs.uk/conditions/footdrop/Pages/Introduction.aspx

NICE explain their guidance on FES: <u>https://www.nice.org.uk/guidance/IPG278</u> /informationforpublic

University College London Hospitals information leaflet on FES: <u>https://www.uclh.nhs.uk/PandV/PIL/Patie</u>

nt%20information%20leaflets/FES%20and %20NMES.pdf

The Salisbury NHS Foundation Trust information page: <u>http://www.odstockmedical.com/about-fes</u>

We would like to hear your feedback on this summary – please email us at <u>pencru@exeter.ac.uk</u> if you have any comments or questions.

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Note: the views expressed here are those of the Peninsula Cerebra Research Unit (PenCRU) at the University of Exeter Medical School and do not represent the views of the Cerebra charity, or any other parties mentioned. We strongly recommend seeking medical advice before undertaking any treatments/therapies not prescribed within the NHS