

Double-blind randomised controlled trial of percutaneous tibial nerve stimulation versus sham electrical stimulation in the treatment of faecal incontinence: **CONtrol of Faecal Incontinence using Distal NeuromodulaTion (the CONFIDeNT trial)**

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Plain English summary

The CONFIDeNT trial

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Plain English summary

Faecal incontinence occurs when a person passes faeces (stools) without the usual control. It is a distressing and common condition, although it is under-reported because of embarrassment. There are few treatment options available. Percutaneous tibial nerve stimulation (PTNS) is a relatively new treatment, which involves electrically stimulating a nerve at the ankle using a very small needle (similar to acupuncture). Few studies have been performed to quantify how successful it is, but early results of PTNS suggest that it is as good as other more expensive and invasive treatments.

The aim of this research was to determine how effective PTNS is in the treatment of patients with faecal incontinence by comparing it with sham treatment (fake stimulation). This was carried out by comparing the number of people who experienced successful treatment in the PTNS group with the sham group. Treatment was considered 'successful' if faecal incontinence episodes were reduced by half or more.

In total, 227 patients in 18 UK specialist centres took part. They were randomly allocated, 115 to PTNS and 112 to sham stimulation. Each patient filled in bowel diaries and questionnaires before and 2 weeks after treatment to compare the arms.

The results showed that the proportion of patients in whom treatment was successful was similar in both groups (38% in the PTNS group compared with 31% in the sham treatment group). This means that PTNS is not significantly better than sham stimulation. This results will be important in guiding whether or not PTNS should be made available to patients in the NHS and beyond.

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