

DOUBLE BLIND RANDOMISED CONTROLLED TRIAL OF PERCUTANEOUS TIBIAL NERVE STIMULATION VS SHAM ELECTRICAL STIMULATION FOR THE TREATMENT OF FAECAL INCONTINENCE IN ADULTS; CONTROL of Faecal Incontinence using Distal Neuromodulation (The CONFIDeNT Trial) Emma J Horrocks¹ S A Bremner²), Natasha Stevens², Christine Norton³), PR O'Connell⁴, Sandra Eldridge², Charles H Knowles¹ on behalf of the CONFIDeNT Study Group.

¹National Centre for Bowel Research and Surgical Innovation, Blizard Institute, Queen Mary University of London. ²Pragmatic Clinical Trials Unit, Blizard Institute, Queen Mary University of London. ³Florence Nightingale Faculty of Nursing and Midwifery, King's College London. ⁴School of Medicine and Medical Science, University College Dublin, Ireland.

Background: Percutaneous Tibial Nerve Stimulation (PTNS) is a relatively new ambulatory therapy for faecal incontinence. Case series data suggest beneficial outcomes in 50-80% patients however the effectiveness of PTNS vs. sham has not been trialled. We aimed to assess the short-term efficacy of PTNS compared to sham electrical stimulation in adults with faecal incontinence.

Methods: In this multicentre, parallel-group, double-blind, randomised controlled trial involving 17 UK specialist centres, patients aged 18 or over with significant faecal incontinence, who had failed conservative treatments, were randomly assigned (1:1) to receive either PTNS or sham stimulation. Randomisation was stratified by sex and then by centre in females. Patients and outcome assessors were masked to allocation for the 14-week duration of the trial, when the effect of the intervention on severity of faecal incontinence and quality of life was assessed using bowel diaries and validated questionnaires. A clinical response to treatment (primary outcome) was defined as a 50% or greater reduction in weekly faecal incontinence episodes.

Findings: 227 patients were randomised (from 373 screened) to receive PTNS (n=115) or sham stimulation (n=112). There were 12 trial withdrawals; seven from the PTNS group and five from the sham group. Missing data were multiply imputed. 39 patients in the PTNS group (38%) had a 50% or greater reduction in weekly faecal incontinence episodes compared to 32 in the sham group (31%) (OR 1.28, 95% CI 0.72-2.28, p=0.396). No serious adverse events related to treatment were reported.

Interpretation : PTNS did not confer significant clinical benefit over sham electrical stimulation in the treatment of adults with faecal incontinence.

Funding: This project was funded by the NIHR Health Technology Assessment programme and will be published in full in Health Technology Assessment.