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EFFECTIVENESS OF NON-INVASIVE, STATIC, MAGNETIC STIMULATION OF THE PELVIS IN THE CONTROL OF URINARY INCONTINENCE

Hypothesis / aims of study
The objective of the study was to determine the safety and effectiveness of non-invasive static magnetic stimulation (SMS) of the pelvis compared to placebo in the treatment of women aged 60 years and over with urinary incontinence.

Study design, materials and methods
A double-blind randomised controlled trial of magnetic stimulation of the pelvic area, using a commercially available product was conducted according to the CONSORT guidelines. This product consists of a garment that resembles underpants but with 15 static magnets of 800 to 1200 milliTesla anterior, posterior and inferior to the pelvis incorporated into the design. Preliminary studies conducted by the manufacturer provided data for power calculations. These calculations suggested that with an effect of 50% (for improvement of symptoms) for a power of 0.80 the sample size required for each of the two groups was 53 participants.

The sample included 122 women, aged 60 years and over, who had had urinary incontinence for at least 6 months. Subjects were randomly assigned to the active SMS group or the placebo group. The protocol specified that the treatment group should wear the undergarment at least 12 hours a day for three months. The placebo group wore the same undergarment with inert metal disks replacing the magnets. Outcome measures included the 24 hour pad test, the Bristol Female Lower Urinary Tract Symptoms – Scored Form (BFLUTS-SF) questionnaire, the Incontinence Severity Index (ISI), a Bothersomeness Visual Analogue Scale and a 24-hour Bladder Diary. Protocol adherence and adverse events were recorded daily in a Wearer's Diary.

Results
Sixty-two women were randomised to the intervention group and 60 to the control group. Fifty-one participants in the intervention group and 50 participants in the control group provided at least some follow-up data. There were no statistically significant differences in change in objective outcome measures (Pad test, frequency of continent and incontinent episodes, BFLUTS-SF, ISI, Bothersomeness Score) between the two groups by the end of the study. There was initial evidence of subjective improvement in symptoms of urinary incontinence for those wearing the pants when compared to a placebo controlled group. However, once those who could correctly identify their group allocation were removed from the analysis there were no statistically significant differences apparent between the groups. The qualitative data suggested that the garment was uncomfortable and hot to wear.

Interpretation of results
No significant differences between the magnetic and non-magnetic undergarments on the key outcome measures were found. This could be due to a variety of reasons: no magnetic effect on these outcomes, small sample size, issues related to design and protocol adherence. The qualitative data suggested that there are some design issues with the product especially for use in a sub-tropical climate. This meant that the recruitment to a clinical trial was difficult and adherence to the protocol was even more difficult. For these reasons the lack of effect seen in the intervention group must be treated with caution. It may be that there is an effect if the garment is worn as designed; however, the effectiveness of the garment cannot be confirmed from the results of this study.

Concluding message
Further research needs to be undertaken into the basic physics of the strength and flux of the magnetic field generated by the product. Once this work is completed additional animal and clinical trials may be planned. Future clinical trials would need to include 469 women with urinary incontinence to detect a difference of 15g in a 24 hour pad test to give a power of 90%. Innovative recruitment and blinding strategies would have to be used and some design modification may improve protocol adherence in sub-tropical climates.

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