🏆 Best in Category Prize – Anorectal / Bowel Dysfunction

259

McClurg D[1], Goodman K[1], Hagen S[1], Manokian S[1], John N[2], Treweek S[2], Emmanuel A[3], Donnan P[4], Norton C[5], Harris F[6], Rauchhaus P[4], Doran S[1]

1. *Nursing, Midwifery and Allied Health Professions Research Unit, Glasgow Caledonian University,* ***2.*** *University of Aberdeen,* ***3.*** *University College London,* ***4.*** *University of Dundee,* ***5.*** *Kings College London,* ***6.*** *University of Stirling*

ABDOMINAL MASSAGE FOR NEUROGENIC BOWEL DYSFUNCTION IN PEOPLE WITH MULTIPLE SCLEROSIS (AMBER - ABDOMINAL MASSAGE FOR BOWEL DYSFUNCTION EFFECTIVENESS RESEARCH)- PRELIMINARY RESULTS OF A RANDOMISED CONTROLLED TRIAL

Hypothesis / aims of study

Multiple sclerosis (MS) is the commonest disabling neurological disease affecting younger adults. Neurogenic bowel dysfunction (NBD) occurs in 50-80% of these patients and is the term used to describe constipation and faecal incontinence (FI) which often coexist with MS. A pilot study of 30 people with MS found benefits with an intensively supported programme of abdominal massage (weekly home visits by a nurse)(1). We undertook a pragmatic randomised controlled trial (RCT) to determine clinical and cost-effectiveness of abdominal massage in the management of NBD with fewer supervised sessions which may be deliverable within existing United Kingdom national health services.

Study design, materials and methods

This was a parallel group multicentre RCT. People with MS who had reported constipation symptoms as being bothersome, and had no confounding 'red flags' e.g. rectal bleeding, were invited to take part. Participants (and a carer if assisting with massage) in the intervention group were randomised to a one-to-one session of instruction on abdominal massage. They were provided with training materials demonstrating the technique including a video and written/diagrammatic information, and were given a lifestyle advice leaflet for the alleviation of symptoms of constipation. Participants in the control group were also seen once when the advice leaflet alone was provided. During the six weeks of intervention, all participants were telephoned weekly and offered support regarding abdominal massage (intervention group) and discussion of lifestyle changes (both groups).

Randomisation was by computer allocation using a remote randomisation service. Minimisation variables were: centre, disability level of the participant (walking unaided, aided, wheelchair). A daily bowel diary was completed a week prior to randomisation, during the whole six weeks of treatment and during week 23. A diary recording the massage undertaken was also completed by the intervention group participants. Questionnaires were administered at baseline, 6 and 24 weeks post-randomisation. The primary outcome was the Neurogenic Bowel Dysfunction (NBD) Score (2), a clinician-administered questionnaire validated in spinal cord injured patients, at 24 weeks. The NBD score is a 10 item questionnaire covering: frequency of bowel movements; headache, perspiration or discomfort during defaecation; medication for constipation; time spent on defaecation; frequency of digital stimulation or evacuation; frequency of FI; medication for FI; flatus; and perianal skin problems. The NBD score ranges from 0 to 47; scores over 14 are considered severe. Secondary outcomes included a bowel diary, constipation scoring system (3), adherence to the intervention, bladder function and quality of life (EQ-5D-5L) (4). A process evaluation was undertaken alongside the trial. Analysis was by intention-to-treat. NBD scores were compared between trial groups using repeated measures mixed models with adjustment for gender, minimisation variables and (if applicable) baseline measurements. A sample size calculation (using a 5% level of significance (two-sided), 90% power and allowing for 20% dropout. indicated a trial of 150 was necessary to detect a difference in the primary outcome measure of 4.2. The funders recommended this was increased to 200 to allow for higher attrition. We report here results of the analysis of the primary outcome measure.

Results

In total 191 participants were randomised, of which 189 provided data (2 participants withdrew immediately post-randomisation). The trial group characteristics were well-balanced at baseline. Mean age was 52 years (SD 10.83 years). Most participants were able to walk unaided (n=79, 41.8%) or with a walking aid (n=89, 47.1%), the remainder using a wheelchair (n=21, 11.1%). The majority were female (n= 154, 81.5%). Massage was self-administered in 84% (n=73). At 24 weeks 71% (n=51) were continuing with the massage, all except one of whom were undertaking self-massage, with 80% (n=44) reporting that they felt a benefit. The response rate for the NBD score at 24 weeks was 81% (n=153).

There was no significant difference between the intervention and control groups in the NBD score at 24 weeks (Table 1) (mean difference in NBD score -1.64 95% CI -3.32 to 0.04, p=0.0558), nor immediately post intervention (6 weeks) (mean difference in NBD score -0.58 95% CI -2.38 to 1.22, p=0.5236).

Table 1

	Intervention			Control			Effect size (95% CI)*	
NBD	Baseline N=86	6 weeks N=62	24 weeks N=69	Baseline N=94	6 weeks N=83	24 weeks N=84	6 weeks	24 weeks
Mean (SD)	7.6 (5.31)	8.4 (6.2)	7.4 (5.23)	8.6 (5.08)	9.1 (5.72)	8.7 (5.7)	-0.581 [-2.378 – 1.216]	-1.64 [-3.321-0.041]
Median (range)	6 (0-21)	7 (0-25)	7 (0-24)	9 (0-22)	8 (0-34)	7.5 (0-24)	p-value 0.5236	p-value 0.0558

*Adjusted for centre, sex, level of disability and baseline. Centre was used as a random coefficient

There were 10 serious adverse events requiring hospitalisation but none were related to the abdominal massage (3 MS relapses, one myocardial infarction 1 myocardial infarction, 3 infections, 3 falls).

Interpretation of results

There is weak evidence of a small effect (<2 units on NBD scale) at week 24 and many participants continued to self-massage. However, the 95% confidence interval of -3.3 units rules out the minimally important clinically difference of 4.2 that we originally estimated.

Concluding message

From the preliminary analysis of the data a home programme of abdominal massage may offer a small reduction in some of the symptoms of neurogenic bowel dysfunction in patients with multiple sclerosis. Analysis of the other outcomes is underway and may offer further insights.

References

1. McClurg D, Hagen S, Hawkins S, Lowe-Strong A. (2011) Abdominal Massage for the Relief of Constipation in People with Multiple Sclerosis. Multiple Sclerosis. 17(2):223-33
2. Krogh K, Christensen P, Sabore S, Laurberg A. (2006). Neurogenic Bowel Dysfunction Score. Spinal Cord. 44(10):625-631
3. Agachan F, Chen T, Pfiefer J et al. (1996). A constipation scoring system to simplify evaluation and management of constipated patients. Diseases of the Colon and Rectum. 39(6):681-685

Disclosures

Funding: This abstract presents independent research funded by the National Institute for Health Research (NIHR) under the Health Technology Assessment Programme Project:12/127/12 and the views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health **Clinical Trial:** Yes **Registration Number:** ISRCTN85007023. **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** West of Scotland Research Ethics Committee, 14/WS/0111 **Helsinki:** Yes **Informed Consent:** Yes