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ABDOMINAL MASSAGE FOR THE ALLEVIATION OF CONSTIPATION IN PEOPLE WITH MULTIPLE SCLEROSIS: A RANDOMISED CONTROLLED FEASIBILITY STUDY

Hypothesis / aims of study

Abdominal massage has been used in several patient populations to relieve the symptoms of constipation[1,2] however, although constipation is a major problem in people with multiple sclerosis(MS)[3], there have been no studies on the use of the technique in this population. Therefore this study aimed to assess the effectiveness of undertaking abdominal massage within an MS population and develop the methods for a multi-centre randomised controlled trial of abdominal massage for constipation. As part of the study, pilot data were collected to test questionnaires and inform sample size calculations in preparation for undertaking the full multi-centre trial.

Study design, materials and methods

Thirty people with MS were recruited over a 6 month period. Patients self-referred following advertisement through local MS charities and were included if they were over 18 years of age, had a confirmed diagnosis of MS, fulfilled the Rome II criteria for constipation, did not have a medical history of bowel disease or recent change in bowel function and were able to provide informed written consent. Participants were randomly allocated to Group 1 (Intervention) undertaking 4-weeks of daily abdominal massage and receiving lifestyle advice (n=15), or to Group 2 (Control) receiving lifestyle advice (n=15).

Intervention

A physiotherapist visited all the participants in their own home weekly during the 4 weeks of intervention. Participants in Group 1 were taught how to administer the abdominal massage themselves or their carer was taught the technique. It was recommended that the massage was undertaken daily, each session lasting for 15 minutes. A DVD was also provided which demonstrated the abdominal massage. Participants in both groups received lifestyle advice relevant to constipation such as adequate fluid intake and defaecation positions.

Outcome measures

Data on outcome measures were collected prior to group allocation (week 0) and at 4 and 8 weeks by a research assistant blinded to group allocation. The primary outcome measure was the Constipation Scoring System (CSS); secondary outcome measures included the Neurogenic Bowel Dysfunction Score (NBD), Qualiveen Questionnaire, the MSIS-29 and a bowel diary.

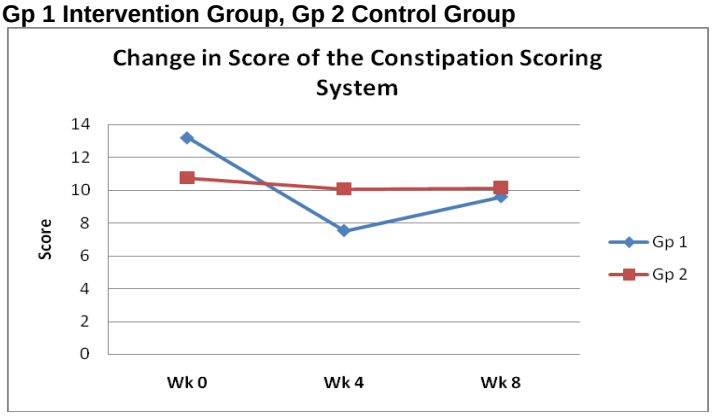
Data Analysis

Data were entered into SPSS 17 and analysed before unblinding. Comparison of the baseline characteristics of the two study groups was undertaken using the independent sample t-test or the chi square test. Changes in scores from pre to post intervention (from Week 0 to Week 4 and Week 8) were compared between study groups using the independent sample t-test. The distribution of study variables was assessed for normality to ensure the use of parametric tests was appropriate. A 5% level of significance was used throughout.

Results

Constipation Scoring System**:** Both groups' CSS scores decreased on average from week 0 to week 4 indicating an improvement in constipation symptoms, however the intervention group [Gp 1] improved significantly more than the control group [Gp 2]; (mean difference between groups in score change -5.0 (SD 1.5), 95% CI -8.1, -1.8; t=-3.28, df=28, p=0.003). There was no difference between groups however in CSS score improvement between Week 0 and Week 8 (mean difference between groups in score change -1.6 (SD1.5), 95% CI -5.6, 0.6; t=-2.64, df =28, p=0.112).

Figure 1 Graph showing the change in the Constipation Scoring System score
Gp 1 Intervention Group, Gp 2 Control Group



Neurogenic Bowel Dysfunction Score**:** The NBD score decreased (improved) on average in the intervention group but increased (worsened) in the control group, the difference between groups being statistically significant for the change from Week 0 to Week 8 (mean difference between groups in score change 7.35 (SD 2.4), 95% CI -12.45, 2.25; t=-2.95, df=27, p=0.006), but not for Week 0 to Week 4 (mean difference between groups in score change 4.4 (SD 2.5), 95% CI -9.6, 0.68; t=-1.77, df =28, p=0.086).

Table 1 Change in Neurogenic Bowel Score (NBS)

Change	Group	n	Mean difference	SD	Independent sample t-Test *p* value
Baseline - Week 4	Gp I Intervention	15	-4.2667	7.8	0.086
	Gp 2 Control	15	.2000	5.8	
Baseline – Week 8	Gp1 Intervention Gp 2 Control	15 14	-5.0000 2.35711	6.1 7.2	0.006

***Bowel Diary*:** The frequency of defaecation increased (improved) in both groups but the intervention group improved more than the control group, the difference between groups being statistically significant for the change from Week 0 to Week 4 (mean difference between groups in score change 2.2, (SD.58), 95% CI-.98,.97; t = 3.7, df=27, p=.001**).** There was no significant change in the use of laxatives, stool consistency or bladder function.

Interpretation of results

This is the first study of abdominal massage for the relief of constipation which has exclusively involved patients with MS. Despite the small sample size there were interesting findings from the analysis of the pilot data suggesting that abdominal massage may be of benefit to some patients with MS and constipation with those participants in the intervention group demonstrating significantly more improvement in the relief of the symptoms of constipation and in the number of defaecations per week when compared to the control group. More importantly, it would also appear that it is a feasible intervention for people with MS to undertaken and is amenable to being evaluated within a randomised controlled trial design. All participants remained in the study up to the end of the intervention period (Week 4), one participant from the control group withdrew due to a MS relapse, before the final outcome measures were completed at Week 8. There were no adverse incidents reports.

Concluding message

This paper describes a feasibility study of the effectiveness of abdominal massage in relieving constipation in people with MS. Questionnaire response rates and compliance with treatment were high and data analysis results indicated a potential positive effect of the intervention on the symptoms of constipation. Further research is now warranted in the form of a multi-centre randomised controlled clinical trial

References

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3. Chia YW, Fowler C, Kamm M et al. (1995). Prevalence of bowel dysfunction in patients with multiple sclerosis and bladder dysfunction. Journal of Neurology. 242:105-108.

Specify source of funding or grant	**Multiple Sclerosis Trust**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ISRCT NO 1328898**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**The Office for Research Ethics Committees, Northern Ireland**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**