

FEASIBILITY OF ABDOMINAL MASSAGE FOR THE ALLEVIATION OF SYMPTOMS OF CONSTIPATION IN PEOPLE WITH PARKINSON'S

Hypothesis / aims of study

One in 500 people in the UK have Parkinson's and it has been demonstrated that patients are nearly five times more likely to meet the Rome Criterion for constipation than partner/career controls (odd ratio 4.80, 95% CI 1.61-14.04), with constipation-related problems causing daily concern for significant numbers of people. It has however been reported that there is a need for further research into optimal management regimens, including robust trials to provide an evidence-base for practitioners. The aim of this feasibility study is to develop appropriate methods for a randomized controlled trial of abdominal massage for the alleviation of symptoms of constipation and collect pilot data to inform sample size calculation within this patient population.

Study design, materials and methods

This was a prospective two-group single blind randomized controlled trial (n=32). Patients were recruited from 3 out-patient clinics and were included if they were over 18 years of age, reported they were constipated and did not have a medical history of bowel disease or recent change in bowel functions. Participants were randomly allocated to the Intervention Group (n=16) undertaking 6 weeks of daily abdominal massage and receiving lifestyle advice or to a Control Group (n=16) receiving lifestyle advice.

Intervention: A physiotherapist visited all the participants in their own home weekly during the 6 weeks of intervention. Participants in the Intervention Group 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. Both groups received lifestyle advice relevant to constipation such as adequate fluid intake and defaecation position.

Outcome measures: Data on outcome measures were collected prior to group allocation (week 0) and at 6 and 10 weeks by a research assistant blinded to group allocation. The primary outcome measure was the Gastro-intestinal Rating Scale (GRS)², secondary outcome measures included the Neurogenic Bowel Dysfunction Score (NBD)³, and the Constipation Scoring System (CSS)⁴. A bowel diary which also recorded Laxative use was undertaken.

Data Analysis: The results were entered and analysed using SPSS V 18. Analysis was on an intention to treat basis and was undertaken before unblinding of group allocation. Changes in scores from pre to post intervention (from week 0 to week 6 and week 10) 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.

32 patients were recruited, one participant withdrew due to the demands of the study being too much for him; seven were female and 25 were male. The mean age was 72 years (SD 7) and the mean time since diagnosis 5 years (SD 4). Hoen and Yahr ranged from 1-4 with a median of 2.4. Trial groups were comparable at base-line.

Primary Outcome Measure: The GRS is a 15 item scale with higher scores indicating increased severity. The results demonstrated a non significant reduction in score from a mean of 34.37 (SD 10.99) at baseline to 26.86 (SD 12.71) at Week 6 (p=0.089), and a significant reduction to 24.3 (SD 6.56) at Week 10 (p=0.008) in the Intervention Group. A non-significant reduction from 28.88 (SD 12.78) at baseline to 22.60 (SD 6.24) at Week 6 (p=0.111) and to 24.45 (SD 5.22) at Week 10 (p=0.371) was observed in the Control Group. There was however no significant difference between groups in the reduction in score from baseline to either Week 6 or Week 10 (Independent sample t-Test at Week 6, mean diff 4.267; 95% CI -3.226 to 11.759; t 1.167; df 28; p=.253 and at Week 10 mean diff -.147; 95% CI -5.235 to 4.943; t -.060; df 22; p=.953).

Secondary Outcome Measures: Similarly the NBDS (Independent sample t-Test at Week 6; mean diff 2.333; 95%CI -1.282 to 5.949; t=1.322; df =28; p=.197 and at Week 10 mean diff 2.469; 95% CI -1.669 to 6.606; p=.229) and the CSS (Independent sample t-Test at Week 6; mean diff 2.333; 95%CI -1.282 to 5.949; t=1.322; df =28; p=.197 and at Week 10 mean diff 2.469; 95% CI -1.669 to 6.606; p=.229), did not demonstrate significant difference between groups at either time point.

	Intervention Group			Control Group		
	Wk 1 \bar{x} , SD	Wk 6 \bar{x} , SD	Wk 10 \bar{x} , SD	Wk 1 \bar{x} , SD	Wk 6 \bar{x} , SD	Wk 10 \bar{x} , SD
Gastrointestinal Rating Scale (GRS)	34.37, 10.99	26.86, 12.71 .089	24.3, 6.56 .008	28.88, 12.78	22.60, 6.24 .111	24.45, 5.22 .371
Neurogenic Bowel Dysfunction Score (NBDS)	8.0, 4.7	3.6, 2.69 .003	4.2, 3.49 .007	5.38, 4.031	2.80, 2.70 .101	3.54, 2.69 .347
Constipation Score System (CSS)	12.25, 4.05	9.2, 4.75 .021	8.92, 4.7 .016	9.13, 5.488	6.86, 4.91 .006	6.45, 5.02 .001

Both groups reported increased frequency of passing stool with less time spent on the toilet. Laxative use did not appear to change.

Interpretation of results

Recruitment was slower than anticipated but retention was excellent and the intervention was delivered by protocol. Of those in the intervention group a carer performed the massage in 13/15 and 80% performed it daily. Eight of those undertaking the massage were continuing at the 10 week follow-up appointment. Age, gender or severity of disability (Hoen and Yahr scale) did not impact on the amount of improvement in either group.

Concluding message

The feasibility of undertaking a randomised controlled trial was established and data will allow power calculations to establish the sample size. Lifestyle advice was greatly appreciated and adhered too in both groups. Abdominal massage may be an option for those with more intractable constipation and a randomised controlled study is required to establish effect.

References

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3. Svedland J, Sjodin I, Dotevall G. Gastro-intestinal Rating Scale - a clinical rating scale for gastro-intestinal symptoms in patients with irritable bowel syndrome and peptic ulcer disease. (1988). *Dig Dis Sci*. 33:129-139.

Disclosures

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