Home-based versus office-based biofeedback therapy for constipation with dyssynergic defecation: a randomised controlled trial

Satish S C Rao, Jessica A Valestin, Xuelian Xiang, Shaheen Hamdy, Catherine S Bradley, M Bridget Zimmerman

Summary

Background Office-based biofeedback therapy is effective for constipation with dyssynergic defecation, but must be performed by skilled staff, is only available in selected centres, and requires multiple visits. The efficacy of home-based biofeedback therapy is unknown. We compared clinical and subjective outcomes with home-based and office-based approaches.

Methods In this randomised controlled trial, eligible patients were adult outpatients (age 18–80 years) who met the Rome III criteria for functional constipation and who had been referred to a tertiary-care centre after non-response to routine management, and who had dyssynergic defecation. Patients were randomly assigned according to a schedule generated in advance by the study biostatistician, in permuted blocks of four, to receive office-based or home-based biofeedback therapy. Office-based biofeedback comprised therapist-guided pelvic floor training for six sessions over 3 months (visits every 2 weeks). Home-based biofeedback comprised 20 min self-training sessions twice per day, in which a self-inserted probe was used to provide visual feedback via a handheld monitoring device of anal sphincter pressure and push effort. Patients recorded in diaries the time of each defecation attempt, stool consistency, straining effort, feeling of incomplete evacuation, need for digital assistance with stooling, and satisfaction with bowel function, from 1 week before enrolment to the end of follow-up. Treatment responders were defined post hoc as those with normalisation of dyssynergic defecation and an increase in the number of complete spontaneous bowel movements per week by 3 months. Cost outcomes calculated from health-care costs and loss of salary were assessed from hospital billing and medical records and questionnaires. Primary outcome measures were the presence of a dyssynergic pattern during attempted defecation, balloon expulsion time, the number of complete spontaneous bowel movements per week, and satisfaction with bowel function, assessed by intention to treat (non-inferiority) and per protocol. This trial is registered with ClinicalTrials.gov, number NCT03202771.

Findings Of 300 patients screened we enrolled 100, from Jan 7, 2005, to Jan 31, 2010. 83 patients completed training (38 [76%] of 50 in the home-based biofeedback group and 45 [90%] of 50 in the office-based biofeedback group). 34 (68%) patients in the home-based group and 35 (70%) in the office-based group were classified as responders. All primary outcomes improved significantly from baseline in the two treatment groups (all $p<0·0001$). Home-based biofeedback therapy was non-inferior to office-based therapy for number of complete spontaneous bowel movements per week, satisfaction with bowel function, and balloon expulsion time in the intention-to-treat and per-protocol analyses, and for dyssynergia in the per-protocol analysis. No adverse events were reported. The median cost of home-based biofeedback therapy was significantly lower than that for office-based treatment (US$1081·70, IQR 794·90–1399·30 *vs* $1942·50, 1621·70–2369·00, $p=0·009$).

Interpretation Home-based and office-based biofeedback therapy for dyssynergic defecation improved bowel symptoms and physiology with similar efficacy. A home-based programme could substantially broaden the availability and use of this treatment.

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Division of Gastroenterology and Hepatology, Medical College of Georgia, Augusta University, Augusta, GA, USA (Prof S S C Rao MD, X Xiang MD); **Department of Medicine** (Prof S S C Rao, J A Valestin BS) **and Department of Obstetrics and Gynecology** (Prof C S Bradley MD), **University of Iowa Carver College of Medicine, Iowa City, IA, USA; Division of Diabetes, Endocrinology, and Gastroenterology, University of Manchester, Manchester, UK** (Prof S Hamdy FRCP); **and Department of Biostatistics, University of Iowa College of Public Health, Iowa City, IA, USA** (Prof M B Zimmerman PhD)

Correspondence to: Prof Satish S C Rao, Division of Gastroenterology and Hepatology, Augusta University Medical Center, BBR 2538, Augusta, GA 30912, USA **srao@augusta.edu**

Introduction

Constipation is a common digestive complaint that affects approximately 15% of people in the USA.[1,2] A third of these have dyssynergic defecation, which is one of three overlapping subtypes of constipation.[3–6] Characteristics are impaired propulsion of stool from the rectum, paradoxical anal contraction, inadequate anal relaxation, or a combination of these mechanisms.[4,7,8]

Several randomised controlled studies have shown that biofeedback therapy is effective in normalising dyssynergic defecation and is superior to treatment with laxatives,[9] sham feedback treatment, and relaxation therapy.[10] A position paper from the American Gastroenterology Association endorsed biofeedback therapy,[4] and the American Neurogastroenterology and Motility Society and the European Society of

Research in context

Evidence before this study

We searched PubMed and Google Scholar for articles published in English up to Jan 31, 2018, with the terms "constipation", "dyssynergic defecation", "biofeedback therapy", "treatment", and "behavioral treatment". Chronic constipation affects around 15% of people in the USA, and around a third of these have dyssynergic defecation. Many of these patients do not respond to treatment with laxatives. Randomised controlled trials have shown that office-based biofeedback therapy can help to correct dyssynergic defecation, and this approach has been recommended by the American Neurogastroenterology and Motility Society and the European Society of Neurogastroenterology and Motility. In the USA, however, this treatment is only available in a small number of centres, partly because it is labour intensive, must be supervised by skilled staff, and requires multiple office visits. Whether home-based biofeedback therapy is efficacious in the management of patients with chronic dyssynergic defecation has not been assessed.

Added value of this study

This randomised controlled trial involved a well characterised cohort of patients with dyssynergic defecation and assessed a new portable biofeedback device and probes that can be used at home. Because a diagnosis of dyssynergic defecation is based on symptoms and manometric criteria, we included post-hoc assessment of subjective and objective outcome metrics to define treatment responders. With rising health-care costs, as well as being efficacious, treatments must be cost-effective. Thus, we additionally did a cost-effectiveness analysis.

Implications of all the available evidence

Home-based biofeedback therapy was non-inferior to office biofeedback therapy in remedying bowel symptoms associated with constipation and in correcting dyssynergic defecation in around 70% of patients. The home device was well tolerated without adverse events. Additionally, the overall cost of home-based biofeedback therapy was significantly lower than that for office-based biofeedback therapy. Our findings should help to guide the use of objective metrics of clinical outcomes in future research. Given the ease of administering the home biofeedback treatment and cost implications, this approach could substantially broaden the availability of biofeedback therapy and should be the preferred setting.

Neurogastroenterology and Motility conferred a grade A recommendation for this treatment.[11] However, biofeedback therapy is not widely available, is labour intensive for patients and therapists, must be supervised by skilled personnel, and requires multiple office visits. All these factors negatively affect adherence to therapy and might contribute to personal hardship. Additionally, many insurance agencies in the USA do not provide coverage for biofeedback therapy. As health-care costs are rising, as well as efficacacious, treatments must be cost-effective. Consequently, home-based biofeedback therapy could be an attractive and cost-effective option for delivering this behavioural therapy, might offset some of the potential issues associated with office-based biofeedback therapy, and could increase availability and use of this treatment.

We tested the hypothesis that home-based biofeedback therapy would be as efficacious as office-based biofeedback therapy for patients with dyssynergic defecation but would incur lower costs. We compared the efficacy of a self-administered home-based biofeedback therapy programme using a portable device with that of office-based biofeedback therapy to improve bowel symptoms and anorectal physiology in patients with constipation and dyssynergic defecation. Additionally, we did a prospective cost-effectiveness comparison.

Methods

Study design and participants

We did a parallel-arm randomised controlled trial at the University of Iowa, IA, USA. Eligible patients were adults aged 18–80 years who had been referred to a tertiary-care centre as outpatients because of constipation. Inclusion criteria were Rome III criteria for functional constipation,[12] lack of response to routine management of constipation, and dyssynergic defecation diagnosed by attempted defecation with anorectal manometry,[13] either shown by balloon expulsion time longer than 1 min or delay in colonic transit (>20% retention of a radiopaque marker).[10,13–15] Exclusion criteria were evidence of structural or metabolic disease that could cause constipation, as assessed by colonoscopy or barium enema and routine haematological, biochemical, and thyroid function tests; use of drugs known to cause constipation (eg, opioids), within the previous 2 weeks; severe cardiac or renal disease, previous gastrointestinal, spinal, or pelvic surgery except cholecystectomy, hysterectomy, or appendicectomy; neurological diseases, such as multiple sclerosis, stroke, Parkinson's disease, or spinal injury; impaired cognisance (Mini-Mental State Examination score <15); rectal prolapse; anal fissure; alternating pattern of constipation and diarrhoea; legal blindness; and pregnancy. The study was approved by the University of Iowa Institutional Review Board (200209080). All patients provided written informed consent.

Randomisation and masking

We randomly assigned patients 1:1 in permuted blocks of four according to a randomisation schedule generated in advance by the study biostatistician. Allocations were placed into sequentially numbered opaque envelopes, sealed, and sent to the study coordinator for opening

after a patient met the study inclusion and exclusion criteria. Although allocation could not be masked from the therapist and patients, the manometry reader and the data analyst were unaware of patients' treatment assignments and histories.

Procedures

A standard protocol was put in place to ensure that all patients received similar general guidelines for management of their constipation. A gastroenterologist, nurse therapist, and dietitian provided advice regarding bowel habits, exercise, laxatives, dietary fibre, and fluid intake, and advice on timed toilet training given in the initial visit was reinforced in follow-up visits. All patients were advised to attempt a bowel movement for 5 min, twice per day, 30 min after eating, irrespective of their urge to defecate. The nurse therapist taught patients how to improve push effort with postural and diaphragmatic breathing techniques,[10,16,17] to be practised at home for 15 min, three times per day. At the start of the trial, patients were advised to use 15–30 mL magnesium hydroxide (Phillips, Bayer, USA) or two to four tablets magnesium gluconate (Fleming & Company, St Louis, MO, USA) per day, and were instructed to titrate doses based on passage of regular soft stools. All patients were advised to refrain from using digital assistance with stooling but to record this method if it was used. Patients who had no bowel movement for 48 h were instructed to use one glycerin suppository, followed by a tap-water enema at 72 h, and two bisacodyl tablets (rescue laxatives) taken orally at 96 h if necessary. The dietitian advised patients to consume a balanced, adequate calorie diet, increase fruit and vegetable intake to five servings per day, and consume 25 g dietary fibre from natural food sources daily.

Patients assigned to the office-based biofeedback group had an initial training session with a nurse specialist that was followed by 1 h sessions every 2 weeks at the hospital, up to a maximum of six therapy sessions over 3 months. During the office visit, a solid-state anorectal manometry probe (Konigsberg Instruments, Pasadena, CA, USA) and Nanologger data recorder and Amb B software (Gaeltec Ltd, Dunvegan, UK) were used to obtain, display, and analyse manometric data. Biofeedback therapy consisted of three components. First were the diaphragmatic breathing techniques to improve the push effort.[17] These techniques were continuously monitored throughout therapy sessions and appropriate feedback was given. Second, the patient was trained to use increased push effort to improve rectoanal coordination, which was seen as a rise in intra-abdominal or intrarectal pressures synchronised with anal relaxation (decrease in anal sphincter pressure) on the manometric data display. While seated on a commode, patients watched the manometric tracings on a computer monitor and received visual and verbal instructions to correct the dyssynergic pattern.[7,16] Third, the patient was trained to efficiently expel a 50 mL artificial stool over three attempts.[7,16,18]

Patients assigned to the home-based biofeedback group attended one session to receive instructions on how to use the home-training device consisting of a reusable dual-sensor probe that was connected to a handheld pressure monitor (Anatoner, Protech, Hyderabad, India) that displayed the patient's response. Each patient was shown how to place the probe into her or his rectum. Next, the patient was asked to sit on a commode, and attempt 10–15 push manoeuvres whilst monitoring the anal and rectal pressure changes on the handheld device. Pressure was indicated by lights. When the anal sphincter pressure decreased, the number of lights illuminated on the anal panel of the device would increase. If the patient could not relax the number of lights decreased. With increasing push effort the number of lights illuminated on the rectal panel would increasex. Patients were asked to insert the probe at least twice daily, practice for 20 min, and record the results. They returned to the hospital for follow-up visits after 4 and 8 weeks to have the device sensitivity adjusted and new goals set dependent on progress.

Assessments

All patients were assessed at baseline and at the end of treatment with anorectal manometry, a balloon expulsion test,[10,14,19,20] and a colonic transit study in which three different shaped radiopaque markers (Sitzmark, Konsyl Pharmaceuticals, Fort Worth, TX, USA) were administered on 3 consecutive days and a plain abdomen x-ray was done on day 6.[10,21]

Patients were asked to keep a prospective stool diary from 1 week before enrolment to the end of follow-up, in which they recorded the time of each defecation attempt, stool consistency (Bristol Stool Scale, from type 1=hard pellets to 7=watery stools[22]), straining effort (1=normal, 2=moderately excessive, and 3=severe), feeling of incomplete evacuation (yes or no), and need for digital assistance with stooling (yes or no). Satisfaction with bowel function was measured on a 100 mm visual analogue scale (VAS).[10] Progress and adherence to therapy were monitored through telephone calls every 2 weeks.

After completion of treatment, during the final visit, patients in both groups answered a survey designed for the study that assessed tolerability and acceptance of the biofeedback therapy. The instructions on device use and social issues associated with the treatments were also assessed.

Outcomes

Because dyssynergic defecation is a heterogeneous condition without adequate defining features to optimise assessing clinical outcome,[10,14,23] we used a range of physiological and subjective measures of bowel function to assess outcomes in this study. The physiological primary outcome measures were the presence of a

dyssynergic pattern during attempted defecation[7,14] and balloon expulsion time. The subjective primary outcome measures were the number of complete spontaneous bowel movements per week and satisfaction with bowel function. A spontaneous bowel movement was defined as a bowel movement that had occurred naturally or without use of suppositories, enemas, or rescue laxatives in the previous 24 h. A complete spontaneous bowel movement was defined as a bowel movement reported in the stool diary as not being associated with a feeling of incomplete evacuation. A positive change of 20 mm or more on the bowel function VAS was used as an index of global bowel satisfaction. All primary outcomes were assessed by intention to treat (ITT)—ie, all patients who were randomly assigned to a treatment group and who underwent at least one session of treatment—and per protocol—ie, patients who completed the required number of biofeedback sessions. For patients with missing end-of-study data in the ITT analysis, we used the last recorded values.

Secondary subjective outcome measures included stool frequency, stool consistency, straining effort, and the proportion of patients who used digital assistance with stooling. The secondary physiological outcome measures were anal residual pressure, intrarectal pressure, defecation index (an overall measure of rectoanal coordination) during attempted defecation, volume thresholds for first sensation, desire to defecate, and urge to defecate, and the proportion of patients with slow colonic transit time.[14,20,21]

Cost analysis

Costs were estimated with a microcosting analysis based on patients' electronic medical records, hospital billing records, and study questionnaires. We captured direct (health-care system costs) and indirect (lost salary due to treatment) costs to the patient. We estimated the total cost in each treatment group from hospital costs, physician costs, equipment costs (home-based group only), home-treatment costs (home-based group only), work loss costs, travel time costs (loss of salary), and transportation costs.

The hospital costs for all patients took into consideration the patient's age and insurance reimbursement rate (age ≥65 years=Medicare, age <65 years= private insurance). In the home group, one 1 h visit was needed for training in how to use the device and other visits were brief follow-up visits. Therefore, the cost of a single visit was calculated for hospital costs. In the office-based group hospital costs were multiplied by six (number of office visits). Physician costs were assigned a value of US$90·00 per visit and multiplied by one for the initial training visit in the home-based biofeedback group and by six for the hospital therapy sessions in the office-based biofeedback group. The equipment cost in the home-based group was assigned $280·00 (rental fee for one home device and 1·5 probes per patient) in the home-based group. Home treatment costs in the home-based group took into account salary per h (based on the US Bureau of Labor and Statistics 2007 data and the patient's job description and US state of residence), and time spent on practice at home (20 min twice per day) multiplied by 0·5 salary per h. The cost of loss of work in both treatment groups was calculated by multiplying patients' salary per h by the number of visits and the time spent at hospital, including time around the appointment (waiting time, car parking, etc). Travel time in one direction was estimated with MapQuest, which we multiplied by two for the round trip and the patient's number of sessions and salary per h. Transportation costs were estimated by distance of the round trip multiplied by 0·35 for costs (fuel, fares, etc).

Statistical analysis

Based on our previous study,[10] we estimated that with the paired *t* test at the 0·025 significance level, a sample size of 50 patients in each study group would be adequate to detect a mean change in anorectal function measures of at least 0·45 SD with 0·80 power. This difference would correspond to at least a 39% decrease in balloon expulsion time, a 103% increase in defecation index, a mean increase of 8 mm on the satisfaction with bowel function VAS, and an increase of 2·2 in the number of complete spontaneous bowel movements per week. For the non-inferiority study, 50 patients per study group would provide 0·70 power to reject at the 0·05 significance level the null hypothesis that the mean change in primary outcome measures would be smaller with home-based biofeedback therapy than with office-based biofeedback therapy by at least 0·44 SD. This hypothesis was tested against the alternative null hypothesis that the mean change due to home-based biofeedback therapy would be no more than 0·44 SD lower than that achieved with office-based biofeedback therapy. We judged home-based biofeedback therapy to be non-inferior if median values of at least 58 s decrease in balloon expulsion time, 1·0 increase in defecation index, 41 mm increase in satisfaction with bowel function VAS, and 1·3 increase in the number of complete spontaneous bowel movements per week were seen compared with balloon expulsion time 111 s (SD 120), defecation index 1·4 (SD 0·9), bowel function satisfaction VAS score 49 mm (SD 17), and 3·4 complete spontaneous bowel movements per week (SD 4·8) in the office-based group.

Based on variations in insurance reimbursement cost per session of office-based therapy ($150–425), and assuming a range of three to six office sessions, we expected the total cost of office-based biofeedback therapy to be between $450 and $2550. Assuming this range represents 95% of cost values, we estimated that the total cost SD would be $525, calculated as (2550–450) / 4. With the proposed sample size of 50 patients per group, the two-sample *t* test at the 0·05 significance level would detect a difference in mean cost of at least $270 with 0·80 power.

We did within-group and between-group comparisons. Within groups, we investigated whether symptoms and anorectal and colonic physiology differed significantly from baseline after biofeedback training. The null hypothesis was that no change would be seen from baseline following biofeedback training. If the null hypothesis were rejected, the result would indicate a significant change from baseline.

Between groups, we compared the effects of biofeedback treatment to assess whether home-based biofeedback therapy was non-inferior to office-based therapy. The null hypothesis was that the mean change from baseline after home-based therapy would be worse than that after office-based therapy by a degree judged to be clinically important by the study team and based on the literature. This hypothesis was tested against the alternative non-inferiority hypothesis that the mean change from baseline following home-based therapy would be no worse or better than that after office-based therapy.

A standard way of testing for non-inferiority of means is the one-sided *t* test with a bound (margin) added to the null value. If the null hypothesis was rejected in favour of the alternative hypothesis, we would conclude that the mean change in measurement following home-based biofeedback therapy was non-inferior to office-based therapy. We used the Farrington-Manning score to test non-inferiority of the difference between two independent proportions. The non-inferiority bounds for the home-based biofeedback therapy were set as follows: 0·70 for the number of complete spontaneous bowel movements per week; 0·75 for the number of stools per week; 0·25 for the stool strain score, which represents an eighth of the score range of 1–3; –0·50 for stool consistency, which represents a twelfth of the score range of 1–7; –13 mm for the satisfaction with bowel function VAS score; 1·70 s for balloon expulsion times; 5 percentage points for digital assistance and abnormal balloon expulsion time; 10 percentage points for dyssynergic defecation and slow transit; and –10 percentage points for response to treatment. The non-inferiority bound for the continuous outcome measures was set at 0·44 of the SD, as was used for the sample size calculation.

The TTEST procedure in SAS version 9.2 was used to test the difference in outcomes at baseline and at the end of treatment and non-inferiority of home-based biofeedback therapy versus office-based biofeedback therapy. Some measures, such as balloon volumes for first sensation, balloon expulsion time, and defecation index, typically have a log normal distribution and, therefore, were log-transformed for the analyses. For the number of complete spontaneous bowel movements and stool frequency per week, we used the generalised mixed model analysis for Poisson counts (GLIMMIX procedure) in SAS, and for prevalence outcomes we used the FREQ procedure.

Effects for the continuous variables were expressed as mean changes from baseline with 95% CIs calculated for within-group changes, and as mean differences between groups with one-tailed 95% CI lower limits (or upper depending on the direction of the non-inferiority bound) for tests of non-inferiority of home-based biofeedback therapy. These are also expressed as two-tailed 90% CIs. For the log-transformed variables and the complete spontaneous bowel movement and stool frequency counts, effects were calculated as mean ratios, either for after treatment relative to baseline or for home-based relative to office-based therapy.

We did a post-hoc analysis of response rates in the two groups. Response to treatment was defined as an increase of more than 1·0 in the number of complete spontaneous bowel movements from baseline and normalisation of the dyssynergic pattern of defecation after 3 months. We used these two measures because a diagnosis of dyssynergic defecation is based on symptoms and altered anorectal manometry,[13,14] and we felt the combined outcome would provide a robust method of assessing treatment success.

The cost-outcome analysis included only patients who had complete diary and questionnaire data and, therefore, had completed the study. Due to the lack of normal distribution of data, we used the Wilcoxon rank sum test to evaluate significance. This trial is registered with ClinicalTrials.gov, number NCT03202771.

Role of the funding source

The funder of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had the final responsibility for the decision to submit for publication.

Results

From Jan 7, 2005, to Jan 31, 2010, we enrolled 100 patients (96 women and four men) with constipation and dyssynergic defecation, of whom 50 patients were randomly assigned to each study group. Apart from sex, the characteristics of the two groups at baseline were similar (table 1). 83 (83%) patients completed the study (38 [78%] of 50 in the home-based biofeedback and 45 [90%] of 50 in the office-based biofeedback therapy group; figure). The main reasons for not completing treatment were loss to follow-up and transportation issues (figure). The non-completion rate did not differ between groups (p=0·21), but a type II error could not be excluded. All 100 enrolled patients were included in the ITT analysis.

The mean number of therapy sessions attended by patients in the office-based group was five (range four to six). In both treatment groups the number of complete spontaneous bowel movements per week increased significantly compared with baseline (p<0·0001 in each group) and the groups did not differ significantly after treatment (table 2, appendix p 1). Home-based

See Online for appendix

	Home-based biofeedback therapy group (n=50)	Office-based biofeedback therapy group (n=50)
Sex		
Women	50 (100%)	46 (92%)
Men	0	4 (8%)
Median (IQR) age (years)	35 (16)	42 (21)
Ethnicity		
White	44	42
Black	2	3
Other	4	5
Mean (range) duration of constipation (years)	12 (2–37)	15 (3–33)
Number of stools per week	5·06 (0·5)	5·71 (0·7)
Stool consistency	3·41 (0·15)	3·24 (0·2)
Stool straining effort score	1·89 (0·08)	1·98 (0·09)
Number of CSBM per week	0·68 (0·17)	1·2 (0·29)
Use of digital manoeuvres to assist stooling	24 (48%)	24 (48%)
Satisfaction with bowel function VAS score (mm)	16·3 (2·4)	18·4 (2·9)

Data are n (%) or mean (SE) unless stated otherwise. CSBM=complete spontaneous bowel movements. VAS=visual analogue scale.

Table 1: **Baseline characteristics**

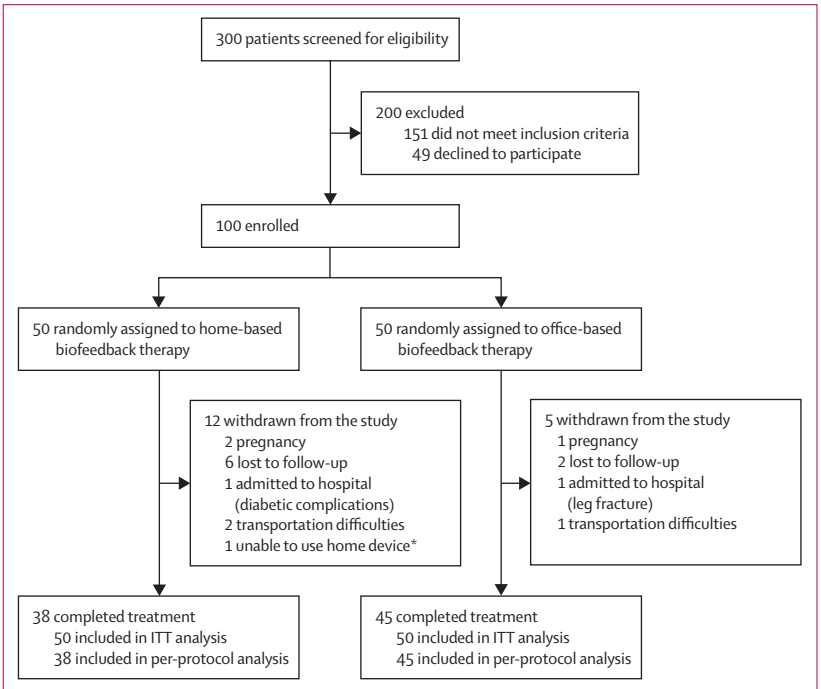

Figure: **Trial profile**

*One patient was a student who lived in a dormitory and found using the device at home difficult. ITT=intention-to-treat.

biofeedback therapy was non-inferior to office-based therapy for this outcome (table 2). Satisfaction with bowel function significantly increased in the two treatment groups (both p<0·0001), with home-based therapy non-inferior to the office-based group (table 2).

After treatment, the mean stool frequency per week increased from baseline more in the office-based group than in the home-based biofeedback group (table 2), but the home-based therapy group was not non-inferior to the office-based group (table 2). Straining effort improved from baseline significantly in the home-based and the office-based groups, with non-inferiority shown between groups, and a small improvement in stool consistency seen by the end of treatment (table 2). The use of digital assistance with stooling lessened significantly in both treatment groups compared with baseline (p<0·0001 in each), but the change in the home-based group was not non-inferior to that in the office-based group (table 2). Laxative use in the home-based and office-based biofeedback therapy groups did not differ significantly: none in 17 (34%) of 50 versus 13 (26%) of 50 (p=0·38); magnesium, senna, or stool softener in 26 (52%) versus 30 (60%, p=0·42); bisacodyl, polyethylene glycol, or lubiprostone five (10%) versus six (12%, p=0·75); and enema or suppository use in two (4%) versus one (2%, p=0·56).

Dyssynergic defecation significantly improved from baseline in the home-based and office-based biofeedback groups (both p<0·0001; table 2, appendix p 1), and was corrected in 36 (72%) of 50 and 40 (80%) of 50 patients, respectively, although non-inferiority of home-based treatment was not shown (table 2).

Balloon expulsion time decreased significantly from baseline in both groups (both p<0·0001, table 2), as did the proportions of patients with abnormal balloon expulsion times (both p<0·0001). The change in balloon expulsion time, but not the difference in proportion of patients with abnormal balloon expulsion times, with home-based biofeedback therapy was non-inferior to office-based therapy (table 2).

The defecation index improved significantly from baseline in both treatment groups (both p<0·0001; table 2, appendix p 1). The mean increase in the home-based biofeedback therapy group was non-inferior to that in the office-based group (table 2). Slow colonic transit time was seen in significantly fewer patients than at baseline in the home-based biofeedback group after treatment (p=0·0002), but not in the office-based group (p=0·109; table 2); nevertheless, home-based therapy was not non-inferior to office-based therapy (table 2).

Sensory thresholds for first sensation significantly decreased from baseline in the two treatment groups, but no significant changes were seen in desire or urgency to defecate in either group. Difference between the home-based and the office-based biofeedback therapy groups in change in median sensory threshold was about 5 mL for first sensation, 5 mL for desire to defecate, and 30 mL for urge to defecate (table 3).

34 (68%) of 50 patients who received home-based biofeedback therapy responded to treatment compared with 35 (70%) of 50 who received office-based

	Home-based biofeedback therapy group (n=50)	Office-based biofeedback therapy group (n=50)	Test of non-inferiority		p value
			Home-based biofeedback therapy bound	Mean difference* or ratio† (90% CI)	
Number of CSBM per week					
Baseline	0·68 (0·17)	1·20 (0·29)	..	..	..
After treatment	3·34 (0·37)	4·74 (0·57)	<0·70	0·70 (0·54 to 0·92)	0·484
Ratio‡	4·91 (3·19 to 7·56)§	3·95 (2·55 to 6·12)§	<0·70	1·24 (0·75 to 2·07)	0·032
Number of stools per week					
Baseline	5·06 (0·49)	5·71 (0·71)	..	..	..
After treatment	5·94 (0·53)	8·36 (0·86)	<0·75	0·71 (0·57 to 0·89)	0·654
Ratio‡	1·17 (0·96 to 1·43)	1·46 (1·09 to 1·96)§	<0·75	0·80 (0·60 to 1·07)	0·352
Straining effort					
Baseline	1·89 (0·08)	1·98 (0·09)	..	..	..
After treatment	1·68 (0·08)	1·72 (0·08)	>0·25	–0·04 (–0·22 to 0·14)	0·004
Change¶	–0·21 (–0·36 to –0·06)§	–0·26 (–0·45 to –0·07)§	>0·25	0·05 (–0·15 to 0·25)	0·050
Stool consistency					
Baseline	3·41 (0·15)	3·24 (0·20)	..	..	..
After treatment	3·45 (0·14)	3·41 (0·19)	<–0·50	0·04 (–0·35 to 0·43)	0·012
Change¶	0·04 (–0·27 to 0·34)	0·17 (–0·27 to 0·60)	<–0·50	–0·13 (–0·57 to 0·31)	0·083
Satisfaction with bowel function VAS (mm)					
Baseline	16·3 (2·4)	18·4 (2·9)	..	..	..
After treatment	56·3 (3·9)	57·5 (3·8)	<–13	–1·2 (–10·2 to 8·0)	0·017
Change¶	40·0 (31·0 to 49·0)§	39·1 (30·7 to 47·5)§	<–13	0·9 (–9·3 to 11·1)	0·013
Digital assistance					
Baseline	24 (48%)	24 (48%)	..	..	..
After treatment	6 (12%)§	5 (10%)§	>5 percentage points	2% (–9 to 13)	0·317
Dyssynergia (%)					
Baseline	50 (100%)	50 (100%)	..	..	..
After treatment	14 (28%)§	10 (20%)§	>10 percentage points	8% (–6 to 22)	0·638
Balloon expulsion time (s)‖					
Baseline	64·1 (12·3)	57·8 (11·4)	..	..	..
After treatment	17·5 (3·1)	17·5 (3·0)	>1·70	1·00 (0·66 to 1·51)	0·018
Ratio‡	0·27 (0·18 to 0·40)§	0·30 (0·21 to 0·44)§	>1·70	0·90 (0·58 to 1·40)	0·010
Abnormal balloon expulsion time					
Baseline	28 (56%)	26 (52%)	..	..	..
After treatment	8 (16%)§	8 (16%)§	>5 percentage points	0% (–13 to 13)	0·249
Defecation index score‖					
Baseline	0·48 (0·04)	0·47 (0·04)	..	..	..
After treatment	1·64 (0·24)	1·77 (0·24)	<0·65	0·92 (0·66 to 1·29)	0·042
Ratio‡	3·43 (2·50 to 4·71)§	3·74 (2·82 to 4·95)§	<0·65	0·92 (0·65 to 1·30)	0·051
Slow transit					
Baseline	31 (62%)	23 (46%)	..	..	..
After treatment	18 (36%)§	17 (34%)	>10 percentage points	2% (–14 to 18)	0·200
Responder					
After treatment	34 (68%)	35 (70%)	<–10 percentage points	–2% (–17 to 13)	0·193

Data in home-based and office-based biofeedback therapy group columns are mean (SE), mean (95% CI), or n (%). CSBM=complete spontaneous bowel movements. VAS=visual analogue scale.*Percentage difference between home and office. †Home / office. ‡After treatment / baseline. §P values <0·0001 incidate significant change from baseline. ¶After treatment – baseline. ‖Log-transformed data.

Table 2: **Intention-to-treat analysis of bowel symptoms and physiological characteristics**

	Median (IQR)		Median difference (90% CI)
	Home-based biofeedback therapy group (n=50)	Office-based biofeedback therapy group (n=50)	
First sensation (mL)			
Baseline	20 (10 to 30)	20 (10 to 30)	..
After completed treatment	15 (10 to 30)	20 (10 to 20)	–5 (–10·5 to 0·5)
Change from baseline	0 (–10 to 0)*	0 (–10 to 0)*	0 (–3·9 to 3·9)
Desire to defecate (mL)			
Baseline	75 (60 to 130)	80 (70 to 120)	..
After completed treatment	75 (70 to 120)	80 (50 to 100)	–5 (–21·4 to 11·4)
Change from baseline	0 (–40 to 20)	0 (–30 to 30)	0 (–7·8 to 7·8)
Urge to defecate (mL)			
Baseline	170 (100 to 250)	160 (110 to 220)	..
After completed treatment	170 (100 to 200)	140 (110 to 180)	30 (4·2 to 55·9)
Change from baseline	0 (–30 to 20)	–5 (–50 to 30)	5 (–10·9 to 20·9)

*P values p <0·01 indicate significant change from baseline.

Table 3: **Intention-to-treat analysis of rectal sensory thresholds**

therapy. However, based on the non-inferiority bound of 10 percentage points, home-based therapy was not non-inferior to office-based therapy (table 2).

Results of the per-protocol analysis of the outcome measures are presented in the appendix (pp 2–4). Findings were similar to those in the ITT analysis for number of complete spontaneous bowel movements per week, satisfaction with bowel function, balloon expulsion time, and for all secondary subjective measures. Physiological outcomes were better in the home-based biofeedback therapy group in the per-protocol analysis than in the ITT analysis. Dyssynergic defecation was corrected in 35 (92%) of 38 patients who received home-based therapy compared with 38 (84%) of 45 who received office-based therapy, showing non-inferiority of home-based therapy (appendix p 3). Home-based therapy was non-inferior to office-based therapy for all other physiological measures except slow transit (appendix p 3). The difference between home-based and office-based biofeedback therapy for a change in median sensory threshold was greater in the per-protocol analysis than the ITT analysis, with a 95% CI upper limit for median difference of 10 mL for first sensation, 10 mL for desire to defecate, and 30 mL for urge to defecate (appendix p 4). Post-hoc responder analysis showed that 32 (84%) of 38 patients in the home-based therapy group responded to treatment compared with 35 (78%) of 45 in the office-based therapy group, with a percentage difference that was not less than 8% for the home-based group (90% CI –8 to 21).

Overall, both treatments were well tolerated, and patients found the training and instructions to be helpful and rewarding (appendix p 5). 35 (92%) of 38 patients in the home-based biofeedback therapy group reported that they would recommend biofeedback therapy. Significantly more patients in the home-based group than in the office-based group (p=0·008) reported that home training created social issues and device use could be messy, whereas significantly more in the office-based group (p=0·03) had to make special arrangements to receive office treatment. No other survey responses differed between groups.

No device-related or procedure-related adverse events were reported. As expected, a few patients reported anal discomfort from probe placement. Two serious adverse events occurred that were unrelated to the study treatment: one patient in the home-based biofeedback therapy group was admitted to hospital for 3 days because of diabetic complications and one patient in the office-based group had a leg fracture and stayed in hospital for 2 days.

38 patients in the home-based biofeedback therapy group and 45 patients in the office-based group completed the trial and were included in the cost outcome analysis. Home-based therapy incurred a significantly lower total cost per patient than did office-based therapy (p=0·009, table 4), yielding a median saving of $860·80 (IQR 826·80–969·70).

Discussion

In this randomised, controlled, parallel-arm trial, home-based biofeedback therapy was non-inferior to office-based biofeedback therapy in terms of the number of complete spontaneous bowel movements per week, satisfaction with bowel function, and balloon expulsion time for patients with chronic constipation and dyssynergic defecation. Patients in both treatment groups had significantly increased numbers of complete spontaneous bowel movements and improved satisfaction with bowel function compared with baseline. Likewise, the response rates in the home-based and office-based groups were similar. Our study confirms the findings of previous randomised controlled trials[11] but also provides new information about the non-inferiority of biofeedback therapy when administered at home as a stand-alone treatment rather than as an adjunctive treatment to office-based biofeedback therapy.[24]

Unlike previous randomised controlled trials of biofeedback therapy,[9–11] we used a stringent composite measure that included symptoms of constipation with difficult evacuation together with a manometric dyssynergic pattern of defecation,[4,13–15] both of which are needed to confirm diagnosis and, therefore, to assess treatment success. We additionally assessed several subjective outcome measures. Satisfaction with bowel function significantly increased and stool straining effort significantly decreased from baseline in both treatment groups. Stool consistency did not change but use of digital assistance with stooling decreased significantly from 48% at baseline in both groups to 12% in the home-based group and 10% in the office-based group.

	Home-based biofeedback group		Office-based biofeedback group	
	Basis for calculation	Actual or median (IQR) costs (US$)	Basis for calculation	Actual or median (IQR) costs (US$)
Hospital costs	NA	0	Six sessions × cost per session	732·78
Physician costs	One session × cost per session	90·00	Six sessions × cost per session	625·50
Equipment costs	$280 ($100 for device + 1·5 probes × $120)	244·00	0	..
Home treatment costs	SPH × (estimated data) × 0·5	185·80 (112·30–325·20)	0	..
Loss of work salary due to appointments	1·75 h × four sessions × SPH	142·20 (79·17–402·50)	2·25 h × six sessions × SPH	134·73 (101·79–357·21)
Travel time costs	Round-trip distance × four sessions × SPH	149·40 (71·50–276·00)	Round-trip distance × six sessions × SPH	132·50 (56·60–345·60)
Transportation costs	Round-trip distance × four sessions × 0·35	179·20 (78·10–259·80)	Round-trip distance × six sessions × 0·35	203·70 (48·50–424·00)
Total*	..	1081·70 (794·90–1399·30)	..	1942·50 (1621·70–2369·00)

NA=not applicable (no charges incurred for room and equipment use and nurse time). SPH=salary per h, based on the US Bureau of Labor and Statistics 2007 data and the patient's job description and US state of residence. *p=0·009.

Table 4: **Treatment costs per patient**

In addition to bowel symptoms, anorectal and colonic function improved in both treatment groups. Correction of dyssynergic defecation was seen in 72% of patients in the home-based biofeedback therapy group and 80% in office-based group overall, and in 92% and 84%, respectively, of patients who completed the treatments. Manometric indices of dyssynergic defecation (eg, the defecation index and balloon expulsion time) significantly improved from baseline to the end of treatment in the two groups. Over 60% of patients with dyssynergic defecation have coexisting slow transit constipation,[5,7,25] as was seen in our home-based biofeedback therapy group. Although the proportion of patients with slow colonic transit time improved in both treatment groups, the change was significant only in the home-based therapy group.

A post-treatment survey of patients who completed treatment indicated that they would recommend biofeedback training and that it was rewarding in both the home-based and office-based therapy groups. Although the home device was felt by some to be messy to use, overall it was very well tolerated, and no patients had adverse events.

The cost of home-based biofeedback therapy was significantly less than office-based therapy, with an overall saving of $860·80 per patient. This assessment did not take into account all the other inconveniences involved with a hospital appointment including effects on quality of life and difficulties with transportation or parking. Thus, home-based therapy seems to be a more cost-effective treatment option for dyssynergic defecation than office-based therapy. Few centres in the USA offer office-based biofeedback therapy, and across the USA reimbursement is problematic. Consequently, a less costly home-based option could substantially broaden the availability of this treatment.

Our study has limitations, including small sample size, and referral bias because we only included patients referred to a tertiary care centre. Additionally, we had high numbers of screening failures and dropouts. Only four men were included and, therefore, our findings might not be generalisable to men, although they are similar to those in previous trials of office-based biofeedback therapy.[10,11] This study was a single-blind randomised controlled trial, which might have biased the selection of patients, but random assignment of patients to treatment groups was done by a study coordinator with a concealed allocation method in which the physician investigators were not involved. At baseline, the groups had similar findings for the subjective characteristics of constipation, and patients in the home-based biofeedback therapy group possibly had more severe dyssynergic defecation because the number of complete spontaneous bowel movements were lower, suggesting that bias is unlikely. Our composite definition of responders was developed post hoc, although before the data analysis, and thus is a new outcome measure for dyssynergic defecation that needs to be validated in future studies. Finally, biofeedback treatment programmes are labour intensive and require motivation and multiple hospital visits. Many of our patients lived at least 2 h away from the treatment centre. These factors contributed to non-adherence and drop out. A more detailed cost-effectiveness analysis is being done that includes quality of life and quality-adjusted life-years.

Home-based biofeedback therapy was as efficacious as office biofeedback therapy, and both treatments were effective in relieving chronic constipation in approximately 70% of patients. Importantly, home-based therapy cost less than the office-based treatment programme and should be the preferred treatment option for patients with dyssynergic defecation.

Contributors

SSCR conceived the study, obtained grant support, and was the principal investigator. SSCR, SH, and CSB designed the study with statistical design input from MBZ. JAV was the study coordinator. CSB recruited patients. Biofeedback therapy was provided by JAV and overseen by SSCR. JAV collected the data. SSCR, XX, and MBZ did the data analysis and XX and MBZ did the statistical analysis. SSCR interpreted the data and supervised preparation of the report. SSCR, SH, CSB, and MBZ contributed to the preparation of the manuscript, SSCR provided critical revision, and XX and MBZ prepared the tables and figures. All authors have approved the final version of the paper.

Declaration of interests

SSCR holds a patent (US20130018308) for the Anotoner and software display used for home-based biofeedback in this study. SH has received funding from Academic Health Sciences Network, UK, for the development of a diagnostic device to assess faecal incontinence. CSB and MBZ received grants from NIH during the conduct of the study. JAV and XX declare no competing interests.

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