The Effects of Exercise upon Symptoms and Quality of Life in Patients Diagnosed with Irritable Bowel Syndrome: A Randomised Controlled Trial

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Key words
- exercise
- quality of life
- IBS
- constipation
- diarrhoea

Abstract

While it seems intuitively appealing to promote participation in regular exercise in the management of irritable bowel syndrome, limited randomised controlled trial evidence exists to support this recommendation. We examined the feasibility and effects of an exercise intervention upon quality of life and irritable bowel symptoms using a randomised controlled trial methodology. Patients with a clinically confirmed diagnosis of irritable bowel syndrome according to Rome II criteria were randomised to either an exercise consultation intervention or usual care for 12 weeks. Outcomes included irritable bowel specific quality of life, symptoms (total symptoms, constipation, diarrhoea and pain) and exercise participation. The recruitment rate of eligible patients identified from hospital records was 18.3% (56/305). Analyses revealed no differences in quality life scores between groups at 12-week follow-up. The exercise group reported significantly improved symptoms of constipation (mean difference = 10.9, 95% CI = – 20.1, – 1.6) compared to usual care at follow-up. The intervention group participated in significantly more exercise than usual care at follow-up (mean difference = 21.6, 95% CI = 9.4, 33.8). Recruitment of eligible patients into this study was possible but rates were low. Findings highlight the possibility that exercise may be an effective intervention for symptom management in patients with irritable bowel syndrome; this may be particularly the case for constipation predominant patients.

Introduction

Estimates suggest that irritable bowel syndrome (IBS) affects between 10 – 30% of the population [9,30]. IBS is likely to cause a significant reduction in quality of life (QoL) [8,10]. In recent years there has been increased interest in evaluating QoL interventions and reports suggest the majority of IBS patients use some form of self-treatment [30]. Studies involving healthy adults [26] have indicated that exercise can improve feelings and symptoms of fatigue, bloating and constipation. Thus, it seems intuitively appealing to promote participation in regular exercise in the management of IBS. Whilst IBS management programmes often suggest that exercise might be a worthwhile health promoting activity, we found no randomised controlled trials (RCT) that have evaluated the effects of an exercise intervention in patients experiencing IBS. Moreover, observational and non-randomised studies predominantly involving healthy participants have provided contradictory evidence of an association between IBS-related symptoms and exercise participation [2,6,10,15,20,28].

While the underlying mechanisms for the potential benefits of exercise on IBS symptoms are not fully understood, it has been suggested that decreased gastrointestinal blood flow, neuroimmuno-endocrine alternations, increased gastrointestinal motility and mechanical bouncing during exercise may be responsible [24]. The stress reducing effect of exercise has also been offered as a possible explanation [17] and studies [3,27] have reported reductions in feelings of stress and well-being after exercise in both healthy adults and clinical populations.

Given the nature of IBS and associated symptoms, achieving participation in regular exercise may be difficult for IBS patients. Therefore, we examined the feasibility of a brief exercise intervention that was intentionally pragmatic using a RCT methodology. This study also aimed to evaluate the effects of exercise on IBS-specific QoL, symptoms associated with IBS and participation in exercise, in previously sedentary IBS patients.

accepted after revision
March 17, 2008

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DOI 10.1055/s-2008-1038600
Published online 2008
Int J Sports Med © Georg Thieme Verlag KG Stuttgart · New York · ISSN 0172-4622

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To our knowledge this is the first published RCT of its kind and is timely given the number of patients who are now considering alternatives to traditional pharmacological interventions in an attempt to control their IBS symptoms and improve subsequent QoL [16]. We hypothesised that participants randomised to the exercise intervention would report significant improvement in QoL and IBS symptoms and demonstrate increased exercise participation levels at follow-up, relative to usual care.

Methods

Participants and eligibility

Patients were recruited through hospital records at the Good Hope Hospital; a district general hospital in England. Patients who had been seen in gastroenterology clinics at the Hospital and diagnosed with IBS within the previous 12 months, aged 18 – 65 years, and not experiencing any major contraindications to exercise, were invited by letter from a consultant gastroenterologist to participate. Those interested were asked to contact the research team for further information. Once patients had agreed to participate they were screened for eligibility via a mailed screening questionnaire to further ascertain their IBS status according to the Rome II criteria [5]. Patients had to understand English due to lack of interpretation services. Patients were ineligible if a diagnosis other than IBS could have explained their symptoms or if another major illness was substantially influencing QoL. Patients who were already regularly active (defined as three or more times per week for at least 30 min per session and had been so for more than three months), known to be pregnant or unable to provide written informed consent were also ineligible. Eligible patients were then seen in a dedicated hospital research clinic by a consultant gastroenterologist who further confirmed patients' eligibility prior to randomisation. Eligible patients were then seen by the trial research assistant (CG) and written informed consent to participate in the study was obtained. Ethical approval was obtained from the South Birmingham Local Research Ethics Committee.

Random assignment to treatment and assessments

Randomisation was by telephone according to a computer-generated list and was blocked (length 6) and stratified by patients' baseline QoL score (low or high) and took place after baseline assessments had been completed. Due to the nature of the intervention, group allocation could not be blinded to participants, clinicians or researchers. The trial researcher (CG) enrolled participants. Participants were informed they had 50% chance of being randomised to one of the trial groups. The same researcher (CG) delivered all the exercise consultations.

Assessment of outcomes and masking

Participants completed the study questionnaires prior to randomisation and at 12-week follow-up. At baseline questionnaires were completed by patients while attending the trial research clinic. The 12-week follow-up questionnaires were mailed to participants with a freepost envelope for the return of the completed questionnaire at the appropriate time. Demographic data, self reported height and weight, current medication and items relating to health behaviours (e.g. smoking, drinking etc) were also recorded.

Exercise intervention

The intervention involved two individual person-centred exercise consultations over the 12-week intervention. Maxton and collegues [19] have recommended that trials of IBS treatments should be at least 12 weeks in duration. This type of intervention was chosen because if it is successful, it can be more easily integrated into current healthcare practice than supervised programmes and has been found to be efficacious in promoting exercise with other clinical populations [14 – 18]. The intervention was centred on equipping individuals with skills, knowledge and confidence so that they felt able to participate in regular exercise. In line with the current public health recommendations in the UK [3] the behavioural goal was for patients to work towards accumulating 30 minutes of moderate intensity exercise on five days of the week. Walking for health was particularly encouraged. Consultations lasted approximately 40 minutes.

The first consultation centred on uptake of exercise and focused on enhancing motivation, self-efficacy for exercise, the perceived pros and cons of becoming more physically active, overcoming barriers and developing appropriate activity plans. Participants were also given a pedometer to be used as a motivational tool and to assist participants in quantifying the amount of activity they were achieving each day/week. At week four the intervention group received a second consultation centred on the prevention of relapse back to sedentary behaviour and/or improving maintenance of an active lifestyle. A review of exercise patterns over the previous four weeks was also included. Participants were mailed postcard prompts that encouraged exercise during weeks three and nine of the intervention.

The usual care group were asked not to change their current exercise patterns over the course of their involvement in the study and offered an exercise consultation and pedometer at the end of their involvement in the study.

Outcomes

The primary outcome measure was QoL as measured by the IBS Specific Quality of Life Questionnaire [23], which is a 34 item self-completed rating scale that assesses health-related QoL among patients with IBS. The Birmingham IBS Symptom Questionnaire (11 item version) was used to assess IBS symptoms [25,30]; namely total symptoms, constipation, diarrhoea and pain. The Perceived Stress Scale [1] (14-item version) was used to assess perceptions of stress. The Godin Leisure-Time Exercise Questionnaire [7] was used to assess physical activity. This questionnaire asks participants to consider how many times per week they participate in strenuous, moderate and mild intensity exercise for more than 15 minutes during their free time. Total weekly leisure activity score is calculated in arbitrary units by summing the products of the separate components as shown in the following formula: Weekly leisure activity score = (9 × Strenuous) + (5 × Moderate) + (3 × Light).

Proposed sample size and analysis plan

Previous estimates [25] of variance for QoL [23] indicated that 23 patients per group would be sufficient to detect an effect size of 0.8 SD with power of 80% ($p < 0.05$). A 10 – 12% dropout rate ($N = 6$) was assumed, therefore 56 patients needed to be randomised. Differences in age and deprivation [22] (as measured by postcode linked index of multiple deprivation quartile rank) between responders and non-responders/those not interested in participating were analysed using an independent *t*-test and χ-squared analysis respectively. Analyses of covariance (ad-

justed for baseline scores) were performed to compare mean scores between the groups at 12-week follow up [29]. Residual plots were performed to check for normality. Analysis was performed by intention to treat for all outcomes.

Results

Recruitment of patients and characteristics of responders and non-responders

A total of 305 patients were identified from hospital records as potentially eligible; 11 participants were not interested in participating (3.6%), 79 agreed to take part (25.9%) and 215 did not respond (70.5%). Of those who responded, 61 were fully eligible and 56 were randomised. Therefore, the recruitment rate of eligible patients was 18.4% (56/305). Non-responders and those not interested (mean age = 38.4 years) in participating were significantly younger than responders (mean age = 44.1 years), although there were no significant differences between these groups for deprivation (according to IMD quartile rank score).

Demographics

Socio-demographic characteristics of the sample can be found in **Table 1**. On average participants were aged 43.1 (SD = 12.4) and 73.2% of the sample were female. Most participants were of white ethnicity, did not smoke and were overweight/obese (58.9%). The majority of participants were in paid employment (66.1%). Participants' flow through the trial is described in **Fig. 1**.

Symptoms, QoL and exercise participation

The exercise intervention group participated in significantly more exercise than usual care at follow-up (mean difference = 21.6, 95% CI = 9.4 to 33.8). The exercise group reported significantly improved symptoms of constipation (mean difference = 10.9, 95% CI = – 20.1 to – 1.6) compared to usual care at 12-month follow-up. No other significant differences between the groups were found (**Table 2**).

Table 1 Baseline demographic characteristics and trial outcomes

Demographics	Usual care (N = 28) N (%)	Exercise (N = 28) N (%)
Gender		
▸ female	19 (67.9)	22 (78.6)
Ethnicity		
▸ White	26 (92.9)	26 (92.9)
Employment status		
▸ in paid employment	19 (67.9)	18 (64.3)
▸ unemployed	1 (3.6)	1 (3.6)
▸ looking after family/home	2 (7.1)	1 (3.6)
▸ retired	1 (3.6)	6 (21.4)
▸ sick/disabled	3 (10.7)	2 (7.1)
▸ other	1 (3.6)	0
▸ missing	1 (3.6)	0
Smoking status		
▸ yes	5 (17.9)	3 (10.7)
▸ no	23 (82.1)	23 (82.1)
▸ missing	0	2 (7.1)
Body mass index		
▸ under/normal weight	16 (57.1)	13 (46.4)
▸ overweight	7 (25.0)	5 (17.9)
▸ obese	4 (14.3)	9 (32.1)
▸ missing	1 (3.6)	1 (3.6)
Taking prescribed medication[1]		
▸ yes	11 (39.3)	17 (60.7)
▸ no	15 (53.6)	9 (32.1)
▸ missing	2 (7.1)	2 (7.1)
Trial outcomes	**Mean(SD)**	**Mean (SD)**
Symptoms (score range = 0 – 100)		
▸ pain	44.3 (19.1)	49.4 (18.4)
▸ diarrhoea	28.5 (19.3)	31.0 (13.2)
▸ constipation*	37.4 (29.9)	38.8 (16.9)
▸ total symptom score	36.6 (14.6)	25.2 (13.0)
Quality of life (total score range = 0 – 100)	39.1 (17.5)	33.4 (15.3)
Perceived stress (score range = 0 – 70)	28.7 (7.8)	23.0 (6.8)
Leisure time exercise index score	9.5 (10.4)	8.9 (8.5)

[1] Refers to medication for abdominal pain or bowel movement in the previous three months

Discussion

IBS symptoms and quality of life

As the prevalence of IBS is high and many patients have reduced QoL, it is important to identify interventions that are acceptable to patients and which can have positive health outcomes. In previously sedentary patients with IBS, a consultation based exercise intervention delivered in a hospital setting significantly improved symptoms of constipation and increased exercise levels, relative to usual care. Our findings for constipation are not consistent with some small observational studies which have failed to report positive associations between exercise and constipation [15,20], but results do support several other observational studies and related RCTs. Donald and colleagues [4] have shown that physically active elderly participants were less likely to be constipated than their less active counterparts. Physical activity has also been shown to reduce mouth-to-anus transit time [21] and among individuals with constipation, higher levels of physical activity were found to be associated with improved physical functioning and health perceptions [28]. Similarly, Keeling [11] reported that orocecal transit time was accelerated during mild exercise. Of some relevance to the findings reported here is a recent RCT [12] that found walking to be an effective intervention for improving the degree of bowel cleansing in preparation for a colonoscopy.

In contrast to observational evidence [28] we did not find that exercise participation improved QoL in IBS patients. The exercise intervention in this trial lasted for 12 weeks and it might be that even longer interventions are required to be able to demonstrate measurable changes upon QoL; this is because changes in exercise may not be spontaneous and may take some time to occur and impact upon patients' lives. The intervention as applied may not have been adequate to induce improvements in QoL.

Exercise participation

Given that IBS patients may avoid participating in exercise because of their symptoms, the significant increases in the amount of exercise achieved by the intervention group relative to usual care was encouraging. Intervention participants reported significantly greater amounts of exercise participation, relative to usual care demonstrating that brief exercise promotion strategies

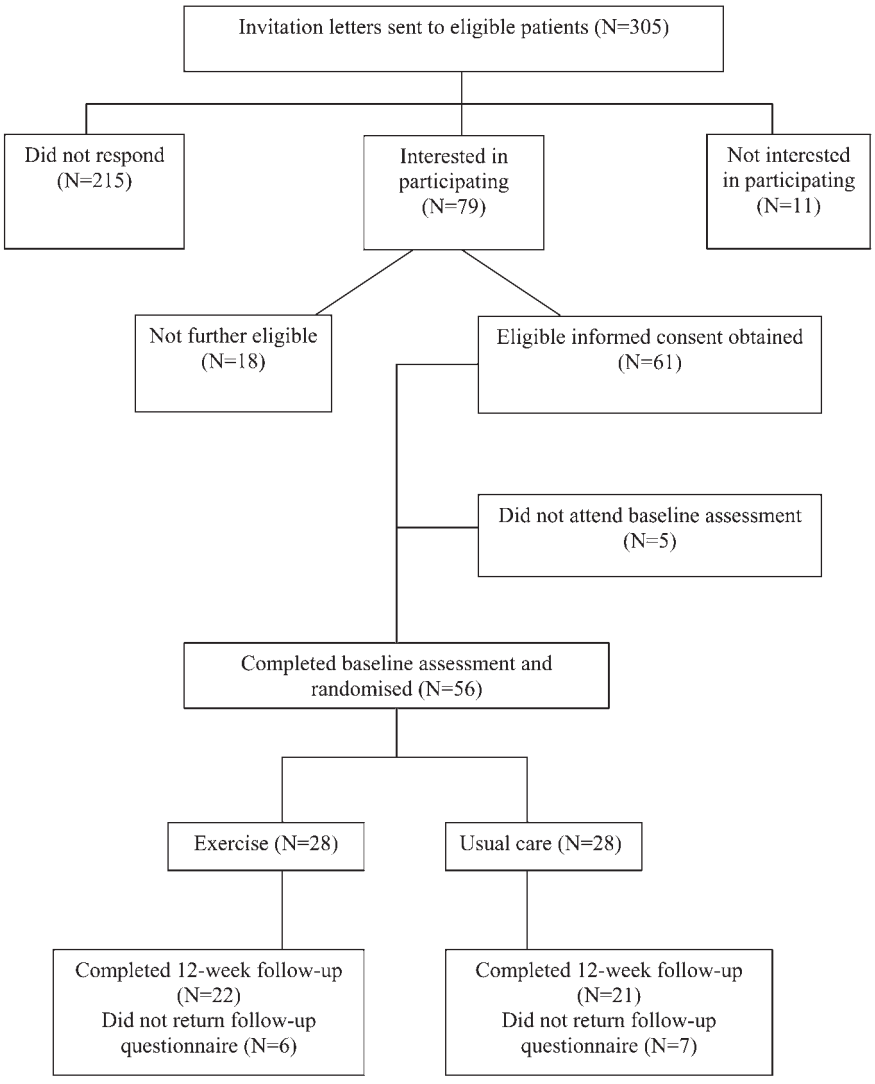

Fig. 1 Participant trial flow.

Table 2 Trial outcome data at follow-up (adjusted for baseline scores)

	Usual care (N = 22) Mean (SE)	Exercise (N = 21) Mean (SE)	Mean difference	95 % CI
Symptoms (score range = 0 – 100)				
▶ pain	46.4 (3.4)	49.3 (3.2)	3.8	– 5.8, 13.4
▶ diarrhoea	30.6 (2.8)	31.1 (2.7)	0.5	– 7.3, 8.4
▶ constipation*	32.8 (3.2)	21.9 (3.3)	– 10.9	– 20.1, – 1.6
▶ total symptom score	28.3 (2.3)	25.4 (2.3)	– 2.9	– 9.5, 3.7
Quality of life (total score range = 0 – 100)	35.9 (2.9)	31.5 (2.9)	– 4.4	– 12.9, 4.2
Perceived stress (score range = 0 – 70)	24.5 (1.9)	22.4(1.8)	– 2.1	– 7.6, 3.3
Leisure time exercise index score*	15.0 (4.3)	36.7 (4.2)	21.6	9.4, 33.8

* Denotes significant difference between the groups ($p < 0.05$)

delivered to IBS patients within a hospital setting might be a worthwhile strategy for clinicians and health professionals to pursue with their patients.

Recruitment rate of eligible patients

The low trial recruitment rate of eligible patients was disappointing at about 18 %. Not only does this affect the generalisability of the findings, but it might highlight that exercise as an intervention is not appealing to this population. In addition, the low recruitment rate might indicate limited interest in exercise as a therapeutic intervention in IBS patients, or that our recruitment strategies were not as effective as they might have been. Further work regarding optimum methods of recruitment may be needed as part of subsequent research.

Limitations and strengths

Blinding of the assessments was not possible, although we do not consider this to be a substantial limitation as the questionnaires were self-administered. Exercise was self-reported and patients may have overestimated the amount of exercise they were achieving. While the significant effect for constipation was encouraging, the non-significant effects for QoL and other symptom outcomes should not be ignored; some caution should therefore be applied when interpreting the overall contribution that exercise may have in improving the general well-being of IBS patients. Larger trials may be better positioned to detect changes in these outcomes.

This study was not statistically powered to detect differences in subgroups of IBS patients (i.e. constipation predominant, diarrhoea predominant and alternating patients). It is possible that the inclusion of a heterogeneous sample has led to an underestimation of the potential effects of exercise upon constipation. Future studies should consider examining the effects of exercise interventions specifically in patients with constipation predominant symptoms since they may benefit the most. No long-term follow-up of outcomes was included, so we have no indication whether the significant improvements in constipation symptoms remained, or whether there might have been a delayed or accumulative effect upon other symptoms and QoL. Attrition level was acceptable with 76.9% of the sample providing follow-up data. It will be important for future research to consider the role of any potential changes in medication between assessments of outcomes as this may impact subsequent symptoms reporting. Previous studies have been observational so do not provide any evidence of causality. The use of a RCT methodology in this study is therefore an important advancement of previous research. Previous studies have tended to include healthy participants, who are likely to respond more favourably to behaviour change advice than might be the case in patients with chronic disease. It is important that studies examine effects of exercise interventions in patient groups and this trial makes an important contribution towards achieving this goal.

Conclusions

This study has demonstrated the feasibility and efficacy of a brief, pragmatic and low cost exercise consultation intervention delivered to IBS patients within a hospital setting. Larger trials are now required to confirm these findings particularly given there are plausible mechanisms by which exercise might provide benefit. Future research should focus on recruiting constipation predominant patients since they may have the most to gain from participation in regular exercise.

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