THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 16, Number 1, 2010, pp. 47–52

DOI: 10.1089/acm.2009.0084

Functional Relaxation as Complementary Therapy in Irritable Bowel Syndrome: A Randomized, Controlled Clinical Trial

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Abstract

Objectives: Irritable bowel syndrome (IBS) is a frequently disabling and almost invariably distressing disease with a high overall prevalence. Numerous trials identified the importance of psychogenic and emotional etiological factors, and this is obvious in clinical practice. Although relaxation techniques are frequently recommended, there is still a lack of evidence for their efficacy in the management of IBS. This study therefore aims to determine the efficacy of functional relaxation (FR) in IBS.
Subjects: The subjects were 80 patients with IBS.
Interventions: Participants were randomly allocated either to FR or to enhanced medical care (EMC: treatment as usual plus two counseling interviews) as control intervention with 2 weekly sessions over the 5-week trial each. Thirty-nine (39) patients completed FR and 39 received EMC.
Outcome measures: An impairment-severity score (IS) was employed as the primary outcome parameter with assessment at baseline, after treatment, and again after 3-month follow-up.
Results: FR was significantly superior to EMC with a standardized effect size of 0.85. The achieved effects through FR remained stable in terms of psychic and bodily impairment after 3-month follow-up.
Conclusions: The results of our trial suggest a positive effect of FR training on subjective functional impairment in the IS, if provided in addition to treatment as usual (TAU). There appears to be a clinically relevant long-term benefit of FR as a nonpharmacological and complementary therapy approach in IBS.

Introduction

Irritable bowel syndrome (IBS) is a chronic, relapsing functional gastrointestinal disorder, characterized by abdominal pain, bloating, and changes in bowel habit. The precise prevalence and incidence depends on the criteria used. However, all studies agree that it is a common disorder, affecting a substantial proportion of individuals in the general population, leading to frequent consultations with both general practitioners and specialists. The overall prevalence ranges between 5% and 11%.[1] IBS is troublesome, with a significant negative impact on quality of life and social functioning in many patients,[2–5] but it is not known to be associated with the development of serious organic disease or with excess mortality. However, health care–seeking behavior is greater in patients with IBS than in patients without IBS.[6,7] Therefore, IBS generates significant health care costs, both direct, because of IBS symptoms and associated disorders, and indirect, because of time off work.[8]

The key features are abdominal complaints in the absence of structural abnormalities likely to account for these symptoms. Symptoms should be present for at least 6 months to distinguish them from those caused by other conditions such as infections, where the effects are often transient, or progressive diseases such as bowel cancer (usually diagnosed within 6 months of symptom onset). Associated nongastrointestinal symptoms include lethargy, backache, headache, urinary symptoms, and dyspareunia in women.[1] At least half

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of patients with IBS are described as suffering from comorbid depressive, anxiety, or hypochondriacal symptoms.[9,10]

Regarding the pathophysiology of IBS, abnormalities of gastrointestinal sensation, motility, autonomic function, bacterial flora, the mucosal immune system, and serotonin pathways have been advocated as underlying mechanisms.[11] Approximately two thirds of the patients show enhanced pain sensitivity to experimental gut stimulation, a phenomenon known as visceral hypersensitivity. Visceral hypersensitivity is thought to play an important role in the development of chronic pain and discomfort in patients with IBS. It appears to be partly caused by failed antinociceptive pathways.[12] Numbers of and secretions from mast cells are increased in IBS and raised concentrations of serotonin-containing enteroendocrine cells have also been reported in patients with IBS.[13] The serotonin transporter may be impaired in IBS, but this finding is contentious.[11]

Management recommendations for IBS include dietary changes and drug therapy with antispasmodics, antidiarrheals, laxatives, antidepressants, and probiotics as well as type 3 serotonin receptor antagonists and type 4 serotonin receptor agonists.[14] Furthermore, the efficacy of psychotherapeutic interventions such as cognitive behavioral therapy, psychodynamic psychotherapy, or hypnotherapeutic interventions has been validated in several trials.[15–18]

However, most of these interventions are part of long-term treatment and therefore time-consuming and expensive.[19] Relaxation training is a brief psychosomatic intervention that be provided not only to individuals, but also to groups of patients. A small study by Blanchard et al.[20] showed promising results of relaxation training as a group intervention in IBS. In a clinical trial conducted by Boyce et al., [21] relaxation led to improvement similar to that of cognitive behavioral therapy. Van der Veek et al.[19] conducted a study and found that brief relaxation training significantly improved symptom severity, general health perception, and reduced service utilization in patients with IBS. Body awareness therapy[22] also led to an overall reduction of gastrointestinal and psychological symptoms in patients with IBS.

In the present study, we focused on an approach called *functional relaxation* (FR). This is a body-oriented psychologic intervention, which was found to be effective in previous clinical trials, particularly in tension headache,[23] noncardiac chest pain,[24] and psychosomatically influenced asthmatic diseases.[25,26] We carried out a randomized, controlled trial, aiming to compare the brief relaxation technique of FR with enhanced medical care (EMC, treatment as usual plus two counseling interviews) as a control intervention in IBS.

Materials and Methods

Participants

Eligible patients with a diagnosis of IBS were identified and invited to participate in the study project at a German university medical outpatient center for gastroenterology within a 6-month period. Eighty-four (84) patients met the inclusion criteria: diagnosis of IBS according to the Rome-II criteria[27] established by a consultant gastroenterologist including investigations to exclude organic disease: full blood works, stool diagnostics, colonoscopy, and gastroduodenoscopy at least within the previous 2 years. Exclusion criteria were defined as follows: fewer than 18 or over 70 years of age, severe psychiatric or somatic disease other than IBS, gastrointestinal allergy, any specific current medication for IBS, and previous experience in body-psychotherapy or psychotherapy within the last 3 months before inclusion in the trial.

Current mental illness was excluded within a clinical face-to-face interview. Potential participants received a comprehensive description of the study specifics and 80 patients gave their written informed consent. Those included were simply randomized to FR or EMC. Randomization was carried out in confidence by a study nurse, with allocation concealment using a randomization list created before the study. The flow chart of the trial is given in Figure 1.

Power calculation was based on the Impairment Score (IS) as primary outcome measure and an assumed effect size of 0.65 (error probability = 0.05, two-tailed; power = 0.80). According to Cohen's convention for research in social sciences, this is the average value between medium (0.5) and large (0.8) effect sizes. It could be assumed in consideration of the effect sizes obtained in former trials with functional relaxation in other psychosomatic conditions.[24,28] The detection of effect sizes of 0.65 requires a sample size of at least $n = 39$ per group. Eighty (80) patients were randomized with a loss to follow-up of 16 patients due to incomplete or missing questionnaires.

Assessment

The degree of psychosomatic impairment was assessed by trained and clinically experienced interviewers using the IS, which is well-known in German scientific literature as *Beeinträchtigungs-Schwere-Score* and was established by Schepank et al.[29] The interviewers were blind to treatment group and were instructed only to assess the degree of impairment and not to ask for the patients' experience with the intervention. The IS allows a trained clinician to assess the severity of psychologic (respectively psychosomatic) impairment in three areas with specific scores: bodily ("bod"), psychic ("psy"), and social ("soc") impairment. These subscores are ranging on a 5-point Likert scale from 0 (not at all) to 4 (extreme). The sum-score ranges between 0 (no impairment) and 12 (extreme impairment). The benchmark dividing those individuals with clinical conditions from healthy individuals is a cumulative value of all three scores of ≥ 5; the inter-rater reliability ranges between 0.85 and 0.92.[29,30]

Furthermore, the patients were asked to assess their subjective overall impairment by IBS symptoms as well as their subjective impairment due to abdominal pain and tenderness, diarrhea, and/or constipation and bloating on a scale ranging from 10 (marginally impaired) to 50 (highly impaired).

Design

The course of the trial was identical for all conditions. After giving written informed consent, the patients were randomized to FR or EMC. The interventions were carried out twice weekly over a period of 5 weeks in small groups of 3 people. The functional impairment of the participants was evaluated by patients' self-assessment as well as assessed by an independent rater with the IS[29] directly before (t0) and after finishing the therapies (t1) and again 3 months later (t2). The study was completed according to plan.

Interventions

All participants received their treatment in an outpatient clinic. FR was carried out by a psychotherapist certified in

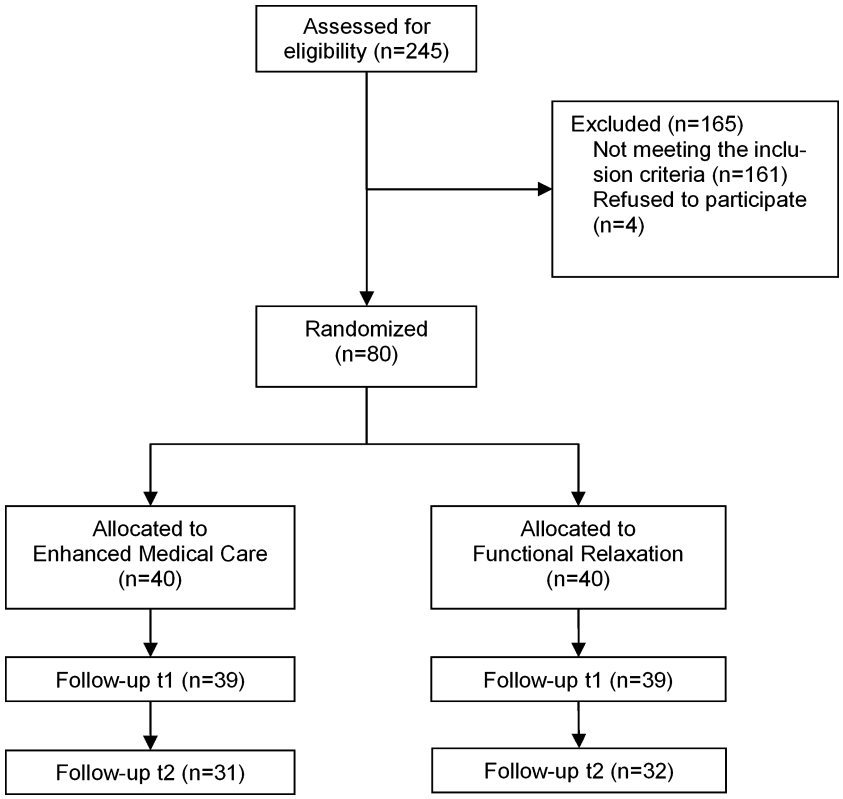


FIG. 1. Flow diagram of trial progress.

functional relaxation. EMC was delivered by a consultant physician, experienced in gastroenterology and psychosomatic medicine in close collaboration with the staff of the university medical outpatient center for gastroenterology. In the interest of minimizing potential therapist bias, all therapy sessions were videotaped and adherence was rated by an independent researcher also certified in FR. The FR condition consisted of twice-weekly 60-minute sessions in a group setting.

FR is a somatopsychotherapeutic intervention technique commonly used in Germany, Austria, and Switzerland for the treatment of psychosomatic disorders.[24] The therapeutic effects are delivered through the assumed mechanism of positive stimulation of the autonomic nervous system, as well as facilitation of proprioreceptive awareness.[31] Hardly noticeable for observers, diminutive movements of small joints are performed during relaxed expiration, accompanied by focusing on and exploring the perceived differences of body feelings triggered by the movements. The focus of attention is thereby directed toward the way the person relates to the environment, particularly the floor as the foundation, as the "outer support" to the bony skeleton. The latter is referred to in FR as "the frame," the "inner support," whereas the interior regions of the body and the skin are regarded as an "outer border."

FR treatment, in this group-therapy setting, is guided by a manual generated during previous investigations.[23,24] This concept has been adapted to special features of patients with IBS.

The patients in EMC were treated in a university medical outpatient center for gastroenterology, receiving "enhanced medical care." This means that in addition to treatment as usual, they took part in two counseling interviews. The goal of these interviews was to promote personal care skills and shared decision making. Patients assigned to EMC were informed of their diagnosis and were encouraged to pass this information on to their general practitioner in order to initiate primary care or specialty treatment without restrictions. Due to the difference between the study arms regarding the time spent with each patient, this design does not control for unspecific effects of this factor.

Statistical analysis

Statistical analyses were performed using SPSS software version 17.0 (SPSS Inc., Chicago, IL). Patients' basic data were characterized by descriptive statistics. Kolgomorov-Smirnov test was applied for testing normal distribution of dependent variables. Chi-square test and Mann-Whitney *U t*est were used for exploratory comparisons of social demographic data between intervention groups. To fulfill the principle of intention to treat and to avoid a possible bias in our data, all missing values of the interviewer and patient ratings were replaced by the SPSS Missing Values 17.0 procedure using a linear regression model. Analysis of covariance (ANCOVA) was employed for analyzing differences in change of the primary outcome parameter IS between EMC and FR, using baseline scores as covariates in order to adjust for baseline values. Calculation of the standardized effect sizes (SES) is based on the estimated marginal means of the ANCOVA and on the pooled standard deviations. All statistical analyses were performed two sided at a 0.05 level of

Table 1. Baseline Characteristics at Time of Randomization

Variable	*Treatment condition*		p-*value*
	Enhanced medical care (N = *40*)	*Functional relaxation* (N = *40*)	
Age (years) (SD)	47.9[a] (11.9)	49.7[a] (10.6)	0.260
Gender (female)	24 (60.0%)	29 (72.5%)	0.237
Living in a partnership	39 (97.5%)	36 (90.0%)	0.166
Blue-collar worker	10 (25.0%)	5 (12.5%)	
White-collar worker	25 (62.5%)	20 (50.0%)	0.027
Homemaker	5 (12.5%)	15 (37.5%)	
Duration of complaints (years) (SD)	14.8[a] (11.2)	12.9[a] (9.8)	0.525
Diarrhea predominant	12 (30.0%)	9 (22.5%)	
Constipation predominant	6 (15.0%)	7 (17.5%)	0.744
Alternating diarrhea and constipation	22 (55.0%)	24 (60.0%)	
Burden of pain (0 = none – 4 = very strong)	3.9 (0.9)	3.7 (0.9)	0.409
Psychotherapy within last 3 years	8 (20.0%)	4 (10.0%)	0.210

[a]Mean value.
SD, standard deviation.

significance. Statistical evaluation was carried out according to the intention-to-treat principle.

Source of funding and ethical considerations

The study was planned and conducted in accordance with the Declaration of Helsinki and ethical laws pertaining to the medical professions. The design was approved by the ethics committee of the responsible university medical school. This study was conducted independently of any institutional influence and was not funded externally.

Results

The study sample consists of 80 patients. Figure 1 shows patient flow through the study. The patient's baseline characteristics at the time of randomization are presented in Table 1. All dependent variables showed normal distribution. Participants had a very long history of complaints (more than 12 years on average). Statistically significant occupation-group differences were found at t0. However, because this variable revealed no significant effects on any of the primary or secondary outcome variables within the treatment groups, this difference can be disregarded.

For the scale "bodily complaints" of the IS, significant treatment effects in the FR group could be found at the end of therapy (t1): $F(1; 77) = 14.3$; $p < 0.001$; SES = 0.85. This effect remained significant at the end of the follow-up (t2): $F(1; 77) = 4.7$; $p = 0.034$; SES = 0.48. The scale "psychic impairment" of the IS improved significantly at t1 ($F(1; 77) = 8.9$; $p = 0.004$; SES = 0.67), but did not reach the level of significance at t2: $F(1;77) = 3.0$; $p = 0.089$; SES = 0.39. No significant effects were found with regard to social impairment subscale of the IS, neither at t1 nor at t2.

Figure 2 displays the mean values of the subscales of all participants at the three points of assessment. Exploratory, paired-sample t tests within the treatment group showed highly significant reductions ($p \leq 0.001$) in the bodily complaints and psychic impairment subscale between t0 and t1 (end of therapy phase); as well as significant reductions ($p \leq 0.050$) between t0 and t2 (follow-up). There were no significant results for the EMC group. No significant changes could be found regarding the social impairment subscale of the IS in any condition.

Patient ratings of gastrointestinal symptoms by treatment condition can be seen in Table 2. The patient's global assessment of impairment improved significantly over the course of the trial, an effect sustained during follow-up. This effect was found for bloating as well, which similarly improved significantly at t1, and again at t2. Patients perceived their bowel habits as significantly improved at t1, but this effect was not sustained over the follow-up period. Also, although significant improvements resulted, both in global evaluation and with regard to bloating and bowel habits, subjective pain-related impairment registered no significant change in the course of the study.

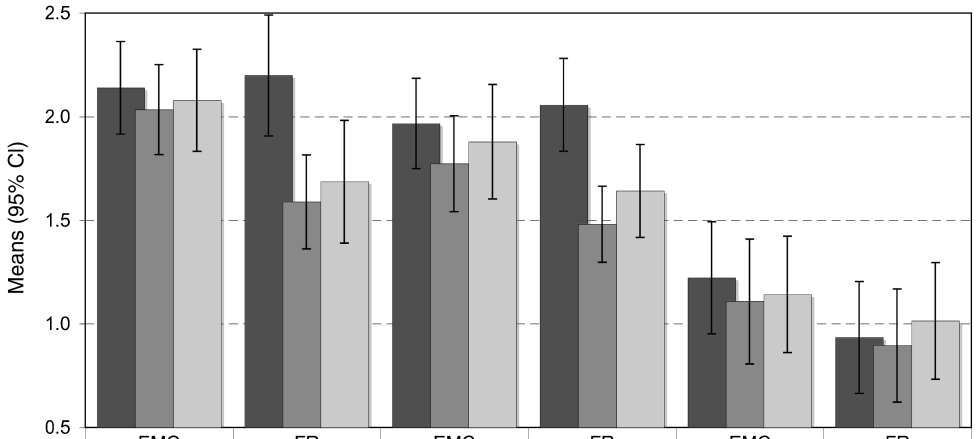
No side-effects of the interventions were reported by any of the patients, nor did any patients report difficulties with implementation of the body-oriented psychotherapeutic technique of FR.

Discussion

The results of this study concur with clinical experience, showing a positive effect of relaxation training on clinical impairment in patients with IBS.

In line with our hypotheses and consistent with the effects observed for relaxation therapies in other studies, we found that the addition of FR to treatment as usual led to medium to large effects on impairment scores. Regarding the outcome, it seems of particular importance to take the long history of complaints into consideration. The most pronounced and statistically significant and clinically relevant effects of FR in comparison to EMC were the reductions in "bodily" and "psychic" impairment scores at the end of the therapy phase (t1). Regarding the variable "social," no relevant change could be found in any condition, which came as no surprise. The significant differences post-treatment dissipated at follow-up (t2). This is partly explained by decline of the achieved improvement within the FR group at t2 compared to t1, but also an effect of smaller sample size at t2 due to a dropout rate of 20%, which reduces the explanatory power.

Nevertheless this study has several methodological limitations. First, the sample size was relatively small, consisting



	Bodily Impairment		Psychic Impairment		Socio-commun. Impairment	
	EMC	FR	EMC	FR	EMC	FR
t0	2.14 (0.72)	2.20 (0.94)	1.97 (0.70)	2.06 (0.72)	1.22 (0.87)	0.94 (0.87)
t1	2.03 (0.70)	1.59 (0.73)	1.77 (0.75)	1.48 (0.59)	1.11 (0.97)	0.90 (0.88)
t2	2.08 (0.79)	1.69 (0.95)	1.88 (0.89)	1.64 (0.72)	1.14 (0.91)	1.01 (0.91)

FIG. 2. Measurement of impairment-severity score subscales over the course of the trial (EMC, group with enhanced medical care [$n = 40$]; FR, group with functional relaxation [$n = 40$]; subscales of the impairment scale: bodily, psychic, and socio-communicative impairment; values are mean values with standard deviations in parentheses and 95% confidence interval [CI] in graphic application).

of only 40 patients in every treatment condition, with a dropout rate of 20% at follow-up. Given that the body-oriented therapy sessions were carefully designed and matched for possible nonspecific effects (e.g., attention given by the trainer, or learning effects), it is difficult to claim that outcome variables were influenced by nonspecific ingredients of FR. However, one possible influence may be seen in the fact that the study was not, and cannot be, conducted in an entirely double-blind setting, since it is not feasible that an experienced therapist does not know what kind of technique she/he is applying. However, a potential bias could arise from not checking blinding of the patients. Although patients were not informed to which intervention they were allocated, we did not ask the participants which intervention they believed themselves to be allocated to. Furthermore, although adherence of therapists to the treatment manual was controlled by continuous supervision, the adherence of patients to the given instructions was not measured in the trial. Another source of a potential bias might be the fact that EMC was not conducted by the same therapist as FR, which might have led to an unbalanced distribution of nonspecific therapist effects between the intervention groups. However, this was impossible to avoid due to the fact that EMC had to be applied by a specialist for gastroenterology, whereas FR had to be carried out by a psychosomatic specialist trained in the technique of FR.

Conclusions

Even considering the above limitations, the results of our study are promising because they show that body-oriented therapy such as FR, provided to patients with chronic IBS, can lead to a significant reduction of bodily and psychic impairment. The observed benefits of treatment are the result of only 10 sessions of complementary body-oriented treatment.

Table 2. Patients' Ratings of Gastrointestinal Symptoms by Treatment Condition

Rating	*Time*	*Treatment condition*		*ANCOVA*	*SES*
		Enhanced medical care (N = *40*)	*Functional relaxation* (N = *40*)	$F_{(1;77)}$; p	
Overall IBS symptoms	Pre	31.0 (6.4)	31.8 (6.3)		
	Post	29.8 (5.3)	23.5 (6.7)	35.0; <0.001	1.32
	Follow-up	30.6 (6.1)	26.2 (6.8)	13.1; 0.001	0.81
Abdominal pain and tenderness	Pre	31.4 (10.3)	33.0 (9.8)		
	Post	29.7 (9.6)	27.0 (8.9)	3.6; 0.063	0.42
	Follow-up	27.3 (10.5)	25.7 (9.9)	1.0; 0.325	0.22
Diarrhea and/or constipation	Pre	32.4 (7.2)	33.4 (8.8)		
	Post	31.0 (6.0)	27.3 (7.2)	12.2; 0.001	0.78
	Follow-up	29.2 (7.8)	29.1 (7.5)	.042; 0.838	0.05
Bloating	Pre	34.9 (8.2)	35.4 (7.7)		
	Post	32.0 (8.5)	27.0 (7.6)	11.0; 0.001	0.74
	Follow-up	33.2 (7.5)	28.1 (7.6)	13.2; <0.001	0.81

ANCOVA, analysis of covariance; SES, standardized effect sizes; IBS, irritable bowel syndrome.

The treatment can hence be regarded as a feasible and time-economical intervention. Additional research is needed to determine whether these results can be replicated, how long-lasting the benefits are beyond a 3-month-follow-up, and whether the regular complementary use of FR leads to clinically relevant improvements in the long term.

Disclosure Statement

No competing financial interests exist.

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