Pilot-RCT of an integrative group therapy for patients with refractory irritable bowel syndrome (ISRCTN02977330)

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ABSTRACT

Objective: Different forms of psychotherapeutic treatments have been proven effective in irritable bowel syndrome (IBS), but disorder-oriented and integrative concepts are still rare. Therefore, we implemented and evaluated an integrative group therapeutic concept within an interdisciplinary tertiary care clinic for functional gastrointestinal disorders (FGIDs).

Aims: present our integrative group concept, assess feasibility issues, and evaluate efficacy.

Methods: A pilot-RCT with a randomized controlled wait-listed group design was conducted. The treatment concept was a disorder-oriented multicomponent group therapy (12 90-min weekly sessions) integrating interactive psychoeducation, gut-directed hypnotherapy, and open group phases. All patients received enhanced medical care and completed a short online diary as an active wait-listed control condition. Inclusion criteria: refractory IBS diagnosed as somatoform autonomic dysfunction of the lower gastrointestinal tract (SAD).

Primary outcome: IBS symptom severity (IBS-SSS).

Results: Of 294 patients, 220 had IBS (ROME III), 144 were diagnosed as SAD (ICD-10), 51 were eligible regarding inclusion/exclusion criteria, and 30 consented to participate (group intervention: n = 16, wait-listed control condition: n = 14). Only 1 patient dropped out. Intention-to-treat-analysis with repeated-measures mixed ANOVA showed that the group intervention was not significantly superior to the wait-listed control condition. Nevertheless, the calculated effect size for the between-group difference in IBS-SSS at the end of treatment (post) was moderate (d = 0.539).

Conclusion: Our disorder-oriented integrative group intervention for IBS proved to be acceptable and feasible in an interdisciplinary tertiary care setting. There is promise in this intervention, but a larger RCT may be needed to investigate efficacy.

1. Introduction

Irritable bowel syndrome (IBS) is a pattern of troublesome gastrointestinal (GI) symptoms that may be persistent or recurrent and are characterized by disturbed bowel habits, abdominal pain and bloating [1]. The IBS symptom pattern is associated with physical as well as psychological complaints and an impaired quality of life [2]. According to ICD-10, persistent IBS with distressing symptoms not sufficiently explained by peripheral organ pathology is classified as somatoform autonomic dysfunction of the lower GI tract (SAD) [3].

Evidence exists, particularly from individual settings, that IBS patients may be treated effectively by psychotherapeutic interventions [4]. A meta-analysis demonstrated cognitive behavioral therapy (CBT), hypnotherapy, multicomponent psychological therapy, and psychodynamic therapy (PDT) as effective in treating IBS [5]. Psychotherapeutic treatment improves somatic symptom severity as well as comorbid...

Abbreviations: CBT, cognitive behavioral therapy; FGID, functional gastrointestinal disorder; GI, gastrointestinal; IBS, irritable bowel syndrome; MUS, multiple unexplained symptoms; PDT, psychodynamic therapy; SAD, somatoform autonomic dysfunction

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anxiety and depression, overall with small to moderate effect sizes [4]. To improve treatment, integrative concepts are recommended. The combination of different therapeutic approaches can help to address several dimensions of body-mind-interactions: reflecting intra- and interpersonal issues (PDT), self-regulating body-related processes (gut-directed hypnotherapy), and changing behavioral avoidance (CBT elements). Combined interventions tend to be the norm, but often lack a detailed description of the integrated components [6]. Therefore, we provide our concept with differentiated elements.

Group settings are more cost-effective than individual settings [7] while being equally effective in treating IBS [8]. They additionally utilize group therapeutic factors and enable work on interpersonal issues, which may be relevant in IBS. Group therapy concepts based on CBT have proven effective in somatoform [7] and IBS patients [8–15], along with group concepts based on gut-directed hypnotherapy [16,17]. The effectiveness of PDT has been shown in individual settings for somatoform disorders in general [18], and for IBS in particular [19–21].

Studies on illness beliefs in patients with somatoform disorders do not support the perspective that they poorly acknowledge emotional factors [22]. Rather, they often show multiple, mixed organic and psychosocial illness attributions [23], particularly when accompanied by comorbidity with depressive/ anxiety disorders [24]. To consequently establish a bio-psycho-social illness model that considers somatic as well as psychosocial illness factors therefore appears to lower patients’ threshold to use psychotherapeutic treatment strategies [25]. We know that addressing IBS as a functional disturbance of the nervous system and integrating interventions in medical care settings enhance acceptance from the affected patients [26]. However till now, such integrated concepts are rarely implemented.

This study aimed to address this shortcoming by establishing a disorder-oriented, integrative, multicomponent group psychotherapy within an interdisciplinary tertiary care clinic for functional GI disorders (FGID). A combination of evidence-based psychotherapeutic treatment elements was implemented within a manualized group intervention for patients with IBS diagnosed as SAD. Our study aimed (1) to present our group concept, (2) to assess feasibility issues, and (3) to evaluate its efficacy and estimate its effect sizes within a pilot-RCT.

2. Method

2.1. Study design and setting

A pilot study with a randomized controlled wait-listed group design was implemented to assess feasibility issues and efficacy of the disorder-oriented, integrative group therapy in tertiary care. The groups were conducted between 07/2014 and 06/2015 within a stepped-care model for IBS patients at the interdisciplinary FGID clinic at the Department of General Internal Medicine and Psychosomatics at Heidelberg University Hospital [27]. All of the patients received enhanced medical care (EMC) and completed a short online diary about anxiety and depression, overall with small to moderate effect sizes [4]. To improve treatment, integrative concepts are recommended. The combination of different therapeutic approaches can help to address several dimensions of body-mind-interactions: reflecting intra- and interpersonal issues (PDT), self-regulating body-related processes (gut-directed hypnotherapy), and changing behavioral avoidance (CBT elements). Combined interventions tend to be the norm, but often lack a detailed description of the integrated components [6]. Therefore, we provide our concept with differentiated elements.

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2.2. Patient recruitment and study population

Patients who visited our FGID clinic had a suspected FGID diagnosis and were refractory to basic treatment of primary care [27]. Patients visiting our FGID clinic between 06/2012 and 01/2015 were assessed for eligibility using a two-stepped process. Inclusion and exclusion criteria were assessed with a checklist. Information was gathered from physician letters and completed by telephone screening if necessary:

1. In the first step, patients were included if they had a refractory Rome III IBS symptom pattern that was diagnosed as SAD according to ICD-10 by an FGID specialist. We used the SAD concept, because stress associated somatic symptoms are a good indicator for psychotherapy [28]. Additional inclusion criteria were age between 18 and 65 years, and residing within 45-min accessibility to Heidelberg.

2. In the second step, patients were invited to the study by mail, and proceeded through further telephone screening. The study entry criteria were defined according to guideline recommendations [29]: IBS symptoms must have been refractory to previous IBS therapies (e.g., communication of the diagnosis or psyllium). Therefore, abdominal complaints during the last 7 days were assessed by a dichotomous question concerning adequate relief (AR) (AR = yes/no), and a balanced 7-point Likert scale [30] modified to subject’s global assessment (SGA) [31] (SGA 1–3; 3 to +3 scale; −3 = significantly worse, 0 = unchanged, +3 = significantly relieved). Moreover, pertinent abdominal discomfort/pain was required per an abdominal pain intensity scale [32] (≥3; 3–11-point Likert scale; 0 = no pain/discomfort; 10 = worst possible pain/discomfort). Additionally, depending on the IBS-subtype [29], stool frequency (IBS-C: ≤3 per week) or stool consistency (IBS-D: ≥1 time as type 6 or 7 on the Bristol Stool Form Scale (BSF) [33] on ≥2 days per week; IBS-M: ≥25% type 6 or 7 and ≥25% type 1 or 2 on BSF) was assessed.

3. The exclusion criteria were as follows: Recently begun antidepressants (≤1 month) or psychotherapy (≤3 months); alcohol or substance abuse; severe psychiatric co-morbidity affecting eligibility for a short-term group intervention; ongoing litigation due to disability pension; inability to read, write and speak the German language; inability to complete the questionnaires and the short daily online diary; and inability to commit to weekly group sessions. Eligible and interested patients returned a signed informed consent.

2.3. Intervention

The group concept was integrative, combining evidence-based PDT and gut-directed hypnotherapy with treatment elements from CBT in a disorder-oriented manner. The disorder-orientation was provided by introducing the brain-gut-axis as a bi-psycho-social explanatory model for FGIDs. From this model therapeutic elements were derived. The interpersonal approach of PDT [34] integrated (1) interactive psychoeducation, (2) gut-directed hypnotherapy, and (3) open group phases. The underlying psychodynamic assumption was that developmentally based and epigenetically modulated dysregulations [35] of patients’ (bodily) self-experience, stress responses and relationships constitute a pertinent basis for their symptoms [18,34,36].

The group setting is shown in Table 1. It was guided by two group leaders: A medical specialist qualified in internal medicine as well as in psychosomatics and psychotherapy and specifically trained in gut-directed hypnotherapy, and a psychologist trained in PDT. The two group leaders reflected their cooperative group leading and the group process during regular intervention.

Each session had a certain topic and was conducted according to a manual, illustrated in Table 2. More than half of the intervention time was allocated to process-oriented and interactive group work (open
group phases), reflecting the psychodynamic approach. The open group phases provided room for patients to discuss personal experiences, individual life situations and issues that emerged during gut-directed hypnotherapy. Group dynamic processes and biographical factors were rather in the background and limited if necessary; further individual psychotherapy was recommended if greater biographical burden was indicated. The remaining time was used for hypnotherapeutic training and structured, theme-centered but still interactive psychoeducation that integrated CBT elements (e.g., goal formulation, cognitive restructuring [7], and exposure [13,37]). The guided gut-directed hypnotherapy was oriented towards the Manchester Protocol [38], but utilized several adaptations as shown in Table 2. In the beginning, a long version of the adapted protocol was introduced for about 30 min. After that, it was practiced during each session in a short version of about 15 min. Patients received a CD with the hypnotherapeutic instructions and an accompanying booklet.

The group intervention was structured into several phases (Table 2) that were general phases beyond therapeutic methods:

### Table 1
Setting of the group therapy.

<table>
<thead>
<tr>
<th>Location</th>
<th>Department of General Internal Medicine and Psychosomatics at Heidelberg University Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Context</td>
<td>FGID clinic</td>
</tr>
<tr>
<td>Type</td>
<td>Out-patient, closed group</td>
</tr>
<tr>
<td>Composition</td>
<td>Disorder-oriented, homogeneous</td>
</tr>
<tr>
<td>Number of participants</td>
<td>8–12</td>
</tr>
<tr>
<td>Group leader</td>
<td>Two group leaders (medical specialist and psychologist)</td>
</tr>
<tr>
<td>Diagnostic status</td>
<td>Individual contacts within FGID clinic, information sheet, telephone screening and briefing</td>
</tr>
<tr>
<td>Sessions</td>
<td>12 sessions and 1 booster session</td>
</tr>
<tr>
<td>Frequency of sessions</td>
<td>Weekly sessions, booster session after 3 months</td>
</tr>
<tr>
<td>Duration of sessions</td>
<td>90 min</td>
</tr>
</tbody>
</table>

### Table 2
Manualized disorder-oriented group intervention.

<table>
<thead>
<tr>
<th>Ses.</th>
<th>Topics</th>
<th>Aims and intervention components</th>
<th>Gut-directed hypnotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Pre-group phase: preparing and orientation</td>
<td>Providing information about IBS, group concept and framework, and the study context; assessment of eligibility</td>
<td>Information about hypnotherapy</td>
</tr>
<tr>
<td>1</td>
<td>Beginning phase (1–3); orientation, group formation and goal formulation</td>
<td>First acquaintance; introduction of gut-brain-interactions and explanatory model</td>
<td>Imaginative relaxation technique: the safe place</td>
</tr>
<tr>
<td>2</td>
<td>Group formation</td>
<td>Group contract; confidence and appreciation; encourage interaction; group cohesiveness</td>
<td>Imaginative relaxation technique: tree-exercise</td>
</tr>
<tr>
<td>3</td>
<td>Therapy goals</td>
<td>Individual goal formulation, self-responsibility</td>
<td>Introduction of classic gut-directed hypnotherapy</td>
</tr>
<tr>
<td>4</td>
<td>Middle phase (4–9); symptom contextualization and coping and regulation</td>
<td>Understanding, mindful self-awareness → coping and regulation</td>
<td>Gut-directed hypnotherapy with individual imaginations</td>
</tr>
<tr>
<td>5</td>
<td>Diet; mindfulness</td>
<td>Food intolerances, dietary culture; raspberry (“raisin”) exercise</td>
<td>Gut-directed hypnotherapy with in-vitro exposure to avoided situations</td>
</tr>
<tr>
<td>6</td>
<td>Experiences with health care system and medication</td>
<td>Adequate use of health care services; symptom-oriented medication</td>
<td>Gut-directed hypnotherapy with in-vitro exposure to avoided situations</td>
</tr>
<tr>
<td>7</td>
<td>Symptom and resources diary</td>
<td>Contextualization</td>
<td>Gut-directed hypnotherapy with in-vitro exposure to avoided situations</td>
</tr>
<tr>
<td>8</td>
<td>Interim results; cognitive restructuring</td>
<td>Balancing therapy goals; cognitive restructuring</td>
<td>Gut-directed hypnotherapy with in-vitro exposure to avoided situations</td>
</tr>
<tr>
<td>9</td>
<td>Gut feelings; gut-brain-interactions (somatic markers – emotions – decisions)</td>
<td>Gaining trust in own body, using wisdom of unconsciousness; affects as monitor of self-experience and regulation of relationships; integration of physical and emotional experience</td>
<td>Gut-directed hypnotherapy with in-vitro exposure to avoided situations</td>
</tr>
<tr>
<td>10</td>
<td>Avoidance and exposure</td>
<td>Reducing phobic behavior; graded physical activation</td>
<td>Gut-directed hypnotherapy with in-vitro exposure to avoided situations</td>
</tr>
<tr>
<td>11</td>
<td>Final phase (10 – 12); self efficacy and transfer of health behavior</td>
<td>Increasing individual stress competence</td>
<td>gut-directed hypnotherapy with in-vitro exposure to avoided situations</td>
</tr>
<tr>
<td>12</td>
<td>Stress competence</td>
<td>Resource activation; coping with possible relapse</td>
<td>Gut-directed hypnotherapy with in-vitro exposure to avoided situations</td>
</tr>
<tr>
<td>13</td>
<td>Balance and farewell</td>
<td>Balancing goal attainment; gut-brain-interactions; planning next steps; farewell</td>
<td>gut-directed hypnotherapy with in-vitro exposure to avoided situations</td>
</tr>
<tr>
<td>14</td>
<td>Booster</td>
<td>Refreshment et résumé</td>
<td>Gut-directed hypnotherapy</td>
</tr>
</tbody>
</table>

2.4. **Pre-group phase (0)**

This is an important preparing phase in which information and orientation about IBS, the group concept and the study context was provided and the patient's eligibility was assessed. This was done within the consultation of our FGID specialty clinic and during additional telephone screening.

2.5. **Beginning phase (sessions 1–3)**

In the beginning phase, the emphasis was on forming the group. A written group contract was read and discussed together. Individual complaints were explored, while their legitimacy was emphasized. Group cohesion was supported by creating an appreciative and confident atmosphere and encouraging interaction. Psychoeducation about the brain-gut axis was delivered interactively, tied back to patients' own experiences and their subjective illness theories [39,20,40,41]. Gut-directed hypnotherapy was introduced as a technique to influence the vegetative and enteric nervous system and to enhance psycho-vegetative self-regulation [42]. Individual therapy goals were formulated in a concrete and realistic way on a specific worksheet regarding coping with physical complaints, everyday life, interpersonal behaviors, and intrapersonal issues.

2.6. **Middle phase (sessions 4–9)**

In the middle phase, the emphasis was on better symptom understanding based on symptom contextualization and mindful self-awareness with the aim of enabling improved individual coping and regulation. Using a symptom and resources diary, individual factors influencing the complaints (diet, situations, thoughts, emotions, illness behavior, and relationship contexts) were identified. They were integrated into a bio-psycho-social model of gut-brain interactions. Group discussion was used to debate adequate health care use and develop...
self-helping coping strategies [43]. Patients were motivated for graded physical activation. They were encouraged to trust in their own body and to use their feelings as signals. As an interim result, the therapy goals were evaluated. Regarding gut-directed hypnotherapy, patients were invited to implement their own imaginations; further, in vitro exposure to avoided situations was conducted under hypnotic conditions.

2.7. Final phase (sessions 10–12)

In the final phase, the emphasis was on improving self-efficacy and transferring health behaviors to everyday life by activating resources and improving individual stress competence [44]. The group experience and the individual therapy goals were evaluated. Coping with possible relapse was discussed and the next steps were planned.

A booster session (13) after three months served as refreshment and repetition to maintain the beneficial effects.

2.8. Control condition

In the control group of this RCT, all study participants received EMC based on the recommendations of our FGID clinic [27] and completed a short online diary for 12 weeks every evening (ca. 5-min duration) as the active control condition. The online diary captured symptom-specific features (IBS symptom severity, stool consistency) and selected core items on several psychosocial issues (anxiety/depression/somatizing; stress/coping/self-efficacy; fatigue/quality of sleep; daily events/quality of relationship/quality of life) for process assessment.

3. Measurements

The patients were characterized by general and IBS-specific questionnaires covering important physical as well as psychosocial features. The questionnaires were completed routinely in the FGID clinic before the patients were seen by a physician. Additional instruments were used within the screening and follow-up process.

3.1. Socio-demographic data

The following socio-demographic data were collected: age, sex, marital status (dichotomized: living with a partner vs. others), educational level (≤ 2, International Standard Classification of Education [ISCED] [45]) and professional life (paid employment, disability pension, old-age pension).

3.2. IBS-specific instruments

- The ROME III criteria [46] determined the IBS inclusion criteria, IBS subtype diagnostic classification (diarrhea, constipation, mixed, and unspecified), and functional dyspepsia (FD) categorization.
- The Irritable Bowel Severity Scoring System (IBS-SSS) [47] was used to specify the degree of symptom severity and bowel habits.
- The Bristol Stool Form Scale (BSFS) assessed the stool consistency [33].
- The Functional Digestive Disorders Quality of Life questionnaire (FDD-Qol) examined the FGID-specific quality of life [48]; it contains 8 subscores (activities, anxiety, diet, sleep, discomfort, health perception, disease coping, stress).

3.3. General instruments

- Somatic symptom severity was measured using the somatic symptom scale [49] of the general patient health questionnaire [50,51] (PHQ-15, range 0–30).
- Depression was measured using the Patient Health Questionnaire 9-item (PHQ-9) scale (range 0–27) [52].
- Generalized anxiety was assessed using the Generalized Anxiety Disorder 7-item (GAD-7) scale (range 0–21) [53].
- Illness anxiety was measured using the brief Whitley Index-7 (WI-7; range 0–28) [54]; additionally, the 5-point Likert scale was dichotomized [55] and used as an indicator of relevant illness anxiety (cut-off-score ≥ 4) [56,57].
- Health-related quality of life was assessed using the 36-item Short Form 36 Health Survey (SF-36) [58], which generated composite scores (range 0–100) for physical (PCS) and mental health (MCS).

3.4. Primary outcome of pilot-RCT

The IBS-SSS was used to assess the efficacy of the group intervention and to estimate the effect size.

3.5. Statistical analysis

The characterization of the study sample was conducted on the basis of descriptive analysis. Metric variables were reported as medians with interquartile range (IQR), because of the small sample size. Categorical variables were reported as percentages. Mann-Whitney-U tests and Chi2-test were used for analyzing differences between intervention group and wait-listed-control condition at baseline. Statistical pre-post analyses were conducted according to the intention-to-treat (ITT) principle with repeated-measures mixed ANOVA. Additionally, effect sizes (\(=Hedges' g\)) were calculated for the within- and between-group differences in the primary outcome (IBS-SSS) and reported and interpreted according to Cohen’s d [59]. Missing values were replaced using mean value imputation, provided their frequency was below 20% [60]. Patients who did not complete any questionnaire or never received the allocated intervention were excluded from the analysis. All statistical analyses were conducted using the Statistical Package for the Social Sciences, version 22.0 (SPSS Inc., Chicago, Ill., USA).

4. Results

4.1. Participants’ characteristics

The patient population of our FGID clinic (n = 294) was screened for eligibility within a two-stepped recruitment process (Fig. 1). In the first step, 150 patients were excluded due to absent ICD-10 SAD diagnoses. In the second step, patients were screened according to additional inclusion and exclusion criteria. Afterwards, 51 were eligible regarding inclusion/exclusion criteria (rate of eligibility: 51/294 = 17%), and 30 consented to participate (consent rate 30/51 = 59%). Only 1 patient dropped out of the intervention group and no patient dropped out of the wait-listed control condition (adherence rate 29/30 = 97%).

Patients that completed the group intervention condition (n = 15) attended 9 [2.16] sessions on average (range 5–12); questionnaire completion rates were > 95%.

The sociodemographic and clinical characteristics of all the study participants, separated for intervention group (IG) and wait-listed control group (WG) are presented in Table 3. No differences were found between the study participants in the group therapy and those in the wait-listed control condition. The average patient participating in our group study was female (63%), 37 years old, employed (70%), and had been experiencing GI symptoms for a median of 6.5 years. The patients showed a median degree of IBS symptom severity that correlated with the upper end of the median severity level (280.50). Regarding patient psychosocial characteristics, they showed medium somatic symptom severity (13.00) and medium depressive symptom severity (11.00), mild anxiety (8.50), but mainly considerable illness anxiety (73%) and medium symptom-specific quality of life (Qol) (50.00).
4.2. Efficacy analysis

The IBS-SSS (range 0–500) as measurement of primary outcome was compared from baseline (pre) to end of treatment (post) within an ITT analysis (Fig. 2). The descriptive results were as follows: IBS-SSS improved within the intervention group from a mean (SD) of 271.18 (104.93) to 181.5 (79.09) (effect size d = 0.956). The wait-listed control group improved less than the intervention group from a mean (SD) of 263.43 (106.05) to 231.69 (107.00) (effect size d = 0.298). Repeated-measures mixed ANOVA revealed a significant main effect of time ($F(1,25) = 10.794$, $p = 0.003$, $\eta^2 = 0.302$). The main effect of group ($F(1,25) = 0.835$, $p = 0.370$, $\eta^2 = 0.032$) and the time × group interaction did not reach significance ($F(1,25) = 1.290$, $p = 0.267$, $\eta^2 = 0.049$). The calculated effect size for the between-group difference in IBS-SSS at the end of treatment (post) was $d = 0.539$.

5. Discussion

In this study, we (1) presented the concept of an integrative IBS-specific group therapy in an interdisciplinary tertiary care setting, (2) assessed feasibility issues, and (3) evaluated the efficacy and the effect sizes within a pilot-RCT. The main evidence-based therapeutic elements were interactive psychoeducation, gut-directed hypnotherapy, and open group phases. Feasibility was limited due to a low rate of eligibility (17%), although supported by a rather high consent rate (59%), a very low drop-out rate (6%) and high questionnaire completion rates (> 95%), which proved the concept to be highly acceptable. Within this pilot-RCT, the intervention group was promising in reducing IBS symptom severity (IBS-SSS), but was not significantly superior to the wait-listed control condition.

We developed our integrative IBS-specific treatment model, which combines evidence-based treatment elements for IBS [5] and other functional somatic syndromes within a new multicomponent group therapy, integrating PDT, gut-directed hypnotherapy, and CBT elements. Thereby, we followed an integrative approach promoted by Klaus Grawe [61]. The elements were implemented along a themecentered manualized concept and followed an interpersonal PDT approach [34]. Therefore, more than half the time was used for process-oriented and interactive group work; furthermore, we focused on emotions and relationships. This approach was analogous to our preceding specific collaborative group intervention for functional somatic syndromes (speciAL) [62]. With gut-directed hypnotherapy, we used a well-studied [16] and IBS-specific technique for improving self-regulation and reducing avoidance behavior through in vitro exposure, which has been evaluated by a 10-session group therapy for IBS patients [17]. The intervention was combined with established CBT elements such as goal formulation, cognitive restructuring [7], and exposure [13,37]. Previous multicomponent approaches for IBS proved effective
who are predominantly female (69%), middle-aged (mean: 41.1 years; median: 37 years old, and had been enduring symptoms for a median of 5 years). These observations are typical characteristics for IBS patients, who are predominantly female (69%) [65], middle-aged (mean: 41.1 years) [65] and have chronic GI symptoms (e.g., in primary care on average for 5 years) [66]. The markedly impaired quality of life of the enrolled patients supports the indication for psychotherapeutic intervention.

As a focus of our study, feasibility issues were analyzed. The main reason for lacking eligibility during the patient recruitment phase was no ICD-10 diagnosis of SAD (51%) in the first step. In the second step, among patients diagnosed as SAD, the major exclusion criterion was residing too far away (56%) and (almost) full remission (25%) since their first consultation in the FGID clinic.

To be eligible, patients had to fulfill the ROME III IBS symptom pattern and be diagnosed as SAD by an FGID specialist. Perhaps the inclusion criteria could be eased in the future, considering that the non-reliable differentiation between medically explained and unexplained symptoms has been removed in the revision process towards DSM-5 [67]. Additionally, gut-directed hypnotherapy also proved efficient in patients with somatic diseases, e.g., ulcerative colitis [68,69].

In the second step, the main reason for the low eligibility rate of 17% was that patients resided too far away from Heidelberg. To extend the catchment area and to ensure better care of rural areas, further attention should be paid to internet-based interventions, which have already been examined for CBT-based interventions [4], but may have limited adherence rates [70].

The fact that one quarter of patients had (almost) full remission may be sufficient to improve well-being [17].

Regardless, we had a rather high consent rate (59%). Only 17 of 51 eligible patients refused to participate, mainly because of no time (41%) or too great an effort (29%) concerning the group therapy. Our consent rate is lower than the rate reported by Speckens [71] (81%) although it is comparable to that of Arnold [72] (58%), who evaluated the feasibility of 12-session group CBT for MUS in secondary care. In their study, 26% of patients were excluded because of symptom improvement or full remission.

To further improve the consent rate, shorter interventions might be preferable in light of evidence that 5 sessions of gut-directed group hypnotherapy may be sufficient to improve well-being [17].

As a focus of our study, feasibility issues were analyzed. The main reason for lacking eligibility during the patient recruitment phase was no ICD-10 diagnosis of SAD (51%) in the first step. In the second step, among patients diagnosed as SAD, the major exclusion criterion was residing too far away (56%) and (almost) full remission (25%) since their first consultation in the FGID clinic.

To be eligible, patients had to fulfill the ROME III IBS symptom pattern and be diagnosed as SAD by an FGID specialist. Perhaps the inclusion criteria could be eased in the future, considering that the non-reliable differentiation between medically explained and unexplained symptoms has been removed in the revision process towards DSM-5 [67]. Additionally, gut-directed hypnotherapy also proved efficient in patients with somatic diseases, e.g., ulcerative colitis [68,69].

In the second step, the main reason for the low eligibility rate of 17% was that patients resided too far away from Heidelberg. To extend the catchment area and to ensure better care of rural areas, further attention should be paid to internet-based interventions, which have already been examined for CBT-based interventions [4], but may have limited adherence rates [70].

The fact that one quarter of patients had (almost) full remission may be sufficient to improve well-being [17].

Regardless, we had a rather high consent rate (59%). Only 17 of 51 eligible patients refused to participate, mainly because of no time (41%) or too great an effort (29%) concerning the group therapy. Our consent rate is lower than the rate reported by Speckens [71] (81%) although it is comparable to that of Arnold [72] (58%), who evaluated the feasibility of 12-session group CBT for MUS in secondary care. In their study, 26% of patients were excluded because of symptom improvement or full remission.

To further improve the consent rate, shorter interventions might be preferable in light of evidence that 5 sessions of gut-directed group hypnotherapy may be sufficient to improve well-being [17].
High drop-out rates often hamper the feasibility and acceptance of group interventions. By calculating a pooled drop-out rate of the seven comparable IBS group therapy studies [8–13,17] we found a mean of 18.2% (SD = 12.1; range 4.9–34.9%) drop-outs. In our study, we had substantial adherence with very low group drop-outs (6%). Our adherence rate of 100% in the control condition and 93% in the study condition is very high. Patient adherence may have been strengthened by the attachment to our FGID clinic. Furthermore, patients completed a short online diary every evening, which may have increased the study adherence in the wait-listed control group as well. Overall, an IBS-specific group format within an interdisciplinary FGID clinic appears to be highly accepted, whereas general psychotherapy has been reported to be insufficiently accepted by IBS patients [73,74].

The third aim of the study was to evaluate the efficacy according to our pilot RCT. The intervention group showed a greater improvement in IBS-SSS, but also the wait-listed control condition showed a positive trend. The trend of the wait-listed control condition was not expected to be only an effect of time, because it was an active control condition, combining EMC based on the recommendations of our FGID clinic and a short online diary every evening. Overall, ITT analysis with repeated-measures mixed ANOVA showed that the group intervention was not significantly superior to the wait-listed control condition. As this was a first pilot study with a small sample size (n = 30), it was expectable not to find significant results, but to calculate the effect sizes. There was a large within-group difference in the intervention group (d = 0.956) and the between-group difference at the end of treatment was moderate (d = 0.539). According to these effect sizes, there is promise in this intervention, but efficacy has to be validated in a larger RCT.

This study has several strengths: First, the treatment concept is disorder-oriented and focused, combining elements of evidence-based treatment strategies in an integrative manual. Second, the emphasis on a consequent bio-psycho-social model is an important focus, which is also reflected in the two group leaders: a medical specialist and a psychologist. Third, our evaluation of feasibility issues may help to improve future therapeutic offers because it indicated the main barriers for study participation, that is, no diagnosis of SAD and residing too far from the venue of the group sessions. Finally, the first results suggest the group intervention to be promising in reducing IBS symptom severity and the estimated effect sizes help to calculate the sample size of a larger intervention study.

The following limitations should be considered. First, the patient population was selective because it was recruited from our FGID specialty clinic in a tertiary care setting. Although this selectivity indicates a higher frequency of psychosocial afflictions [28], which may impact positively the acceptance of therapeutic options, it also indicates that we encounter patients with chronic, refractory IBS symptoms in that setting. Second, we considered only IBS patients diagnosed as SAD for our group therapy, which should be considered regarding the generalizability of our results. Third, no blinding was possible. Finally, we mainly used an adapted and shortened version of gut-directed hypnotherapy in our study, which may have decreased its efficacy. Overall, a high demand exists for psychotherapeutic interventions that are feasible in medical care, accepted by IBS patients and effective in reducing GI symptoms. The evaluated feasibility issues of our group concept are a cornerstone for implementing a larger randomized controlled intervention study. A shortened group intervention for all IBS patients regardless of the presence of a SAD diagnosis should be conducted. An internet-based intervention may fulfill the need to reach more patients within a large catchment area. Furthermore, in line with Laird’s suggestions [6], future research should focus on dismantling studies to identify effective mechanisms of an intervention across different therapeutic approaches.

In conclusion, our disorder-oriented integrative group intervention for IBS proved to be acceptable and feasible in an interdisciplinary tertiary care setting. As efficacy could not be proved in this pilot RCT, but effect sizes suggested promising effects, there is a need for a larger RCT. Our disorder-oriented, integrative group concept can help to bridge an important gap in the management of patients with refractory IBS.

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The authors have no competing interests to report.

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