

Cognitive behavior therapy for functional gastrointestinal disorders: is group treatment effective?

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Objective: The intention of this study was to evaluate therapy outcome of a cognitive-behavioral group treatment program for functional gastrointestinal disorders. As a particular characteristic, gastrointestinal symptoms were investigated independently from diagnostic categories on a dimensional basis, considering the persistence of symptoms as well as the aspect of severity.

Methods: A total of 64 subjects participated in the 10-week treatment program, and 49 completed the study. Subjects underwent four assessments (baseline, pre-, post-treatment, 12-month follow-up), each comprising several self-rated questionnaires on gastrointestinal, somatoform, depressive, hypochondriacal and anxious symptoms, and health locus of control, as well as a diagnostic interview of functional gastrointestinal and mental disorders at the baseline assessment. Treatment effects were controlled by subjects' waiting list period before treatment.

Results: Gastrointestinal symptoms, as well as comorbid psychopathology scores, decreased significantly during treatment and remained unchanged during the follow-up period, whereas no relevant changes were found in health locus of control. Largest effect sizes were found for gastrointestinal symptoms, which decreased by 30–50% of their initial number.

Conclusions: The group treatment investigated was effective and particularly successful with respect to functional gastrointestinal symptoms. However, the mechanisms of treatment outcome remain indistinct. Further studies comparing different setting conditions directly are required to clarify the question of whether group treatment is significantly superior or inferior to individual therapy.

Keywords: functional gastrointestinal disorders; group treatment; irritable bowel syndrome; outcome; standardized dimensional assessment

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Introduction

Functional gastrointestinal disorders (FGDs) are very frequent, and their significance for the general health care system is immense. They are characterized by various combinations of recurrent or persistent gastrointestinal symptoms, which are not due to structural or biochemical abnormalities. About 2–20% of the general population suffer from irritable bowel syndrome (IBS) (1,2), which is the principal category among functional bowel

disorders. Prognosis is unfavorable (3,4), as symptoms tend to become chronic and effective medical treatments are not available. Absence of pharmacological treatment options has encouraged the development of psychological treatment approaches during the last 20 years. Positive and clinically relevant effects of different, mostly cognitive-behavioral interventions have been demonstrated repeatedly (5–10). In addition, recent studies investigated differential effects of

treatment conditions and settings. Fernandez et al. (11) compared effects of stress and contingency management. Subjects in both experimental conditions experienced substantial improvements of characteristic gastrointestinal symptoms, but contingency management was distinctly superior to stress management. Heymann-Mönnikes et al. (12) combined medical treatment and multicomponent cognitive-behavioral treatment (CBT). The combination therapy was significantly superior to a standard medical treatment condition regarding gastrointestinal symptoms, quality of life, overall well-being, and internal locus of control. Vollmer and Blanchard (13) compared individual cognitive therapy and cognitive therapy in small groups. Both cognitive treatments were significantly superior to the control condition, whereas no difference was found between the small group and individual condition. Considering that group treatment is more economic, group therapy might be preferable according to these results. However the total number of treatment evaluations is still very small, and evidence on treatment efficacy is too limited to establish CBT as a standard therapy for FGDs (14). An insufficient empirical basis may be explained by two conceptual characteristics of FGD research. First, the categorical aspect of gastrointestinal symptomatology has been over-emphasized, while dimensional aspects have been widely neglected. As a result, FGDs are defined by more than 20 diagnostic categories, but standardized assessments for the dimensional measurement of symptom changes were not available up until a short while ago. Second, a large proportion of FGD research may be represented in research on somatoform disorders (SFDs), since boundaries between different functional and somatoform syndromes are indistinct (15, 16), and concepts are incompatible.

The purpose of the present study was to evaluate effects of standardized CBT in patients with functional bowel and gastroduodenal disorders. As group treatment is economic and very effective in many mental and psychosomatic disorders, this setting was likewise chosen for our CBT program. In order to avoid limitations and diagnostic inconsistencies due to the coexisting concepts of SFDs and FGDs, functional gastrointestinal symptoms (FGSs) and symptom changes were investigated independently from diagnostic categories on a dimensional basis. Additionally, we evaluated changes in further somatoform, hypochondriacal, depressive, and anxious symptoms, as well as health locus of control. Furthermore, our intention was to identify predictors of decrease in FGSs, which could clarify mechanisms of maintenance and etiology of FGDs.

Methods

Sample and procedure

Subjects were recruited mainly by newspaper and internet articles describing characteristics, frequency and treatment options for functional gastrointestinal disorders and announcement of a free psychological treatment program. Another portion were referred by cooperating gastroenterologic practices. At first, subjects were informed about the content and organizational details of the treatment program in an individual screening session, and a diagnostic interview for functional gastrointestinal disorders and comorbid mental disorders according to DSM-IV was conducted. In addition, subjects had to complete questionnaires on gastrointestinal and somatoform symptoms, depression, anxiety, hypochondriasis and health locus of control within 1 week after the screening session. Self-rating instruments were applied again immediately before and after treatment, and at 12-month-follow up. A total of 103 subjects were screened for study inclusion and exclusion criteria, after informed consent had been obtained. Of these, 64 subjects met the study criteria and agreed to participate in the treatment program. As all subjects underwent the same cognitive-behavioral treatment condition, the waiting-list period between the screening session and the first treatment session served as control condition. Mean duration of the waiting list period was 123 (± 82) days.

Definitions

The diagnostic selection procedure for the study was based on the revised Rome criteria (Rome-II criteria) (17,18). In addition to that, subjects had to meet the DSM-IV (19) criteria for undifferentiated somatoform disorder or somatization disorder, since somatoform disorder definitions are characterized not only by symptom definitions but also by distress and impairment criteria, which provide significant information for psychological treatments.

All subjects included in the study suffered from symptoms of irritable bowel syndrome or other combinations of persistent and distressing bowel symptoms. This somewhat uncommon definition was used to cover relevant gastrointestinal symptomatology beyond the narrow definition of IBS, considering that boundaries between various functional gastroduodenal and bowel disorders according to the Rome-II criteria are indistinct, and syndromes are overlapping.

Subjects were excluded from the study, if they had not attended a physical examination by a specialized physician to exclude relevant medical conditions within 12 months before the screening session, or if they suffered from severe or predominant organic disease. Furthermore, subjects with primary mental disorders requiring intense psychological care (e.g. major eating disorders) and psychotic disorders were excluded.

Assessments

Functional gastrointestinal disorder diagnoses were investigated using a checklist interview developed on the basis of the Rome-II criteria (17,18). Furthermore, a diagnostic interview for mental disorders of DSM-IV axis I (including somatoform, anxiety, affective, substance use and eating disorders) was conducted using the International Diagnostic Checklists (IDCL) (20), which is a well evaluated, reliable and economic instrument recommended by the World Health Organization for the assessment of mental and behavioral disorders.

For the psychometric assessment of treatment effects, a self-rated questionnaire was applied, comprising several standardized instruments on various aspects of the general psychopathology and cognitions. Characteristics investigated were functional gastrointestinal and further somatoform symptoms, depression, hypochondriasis, trait anxiety and health locus of control.

Functional gastrointestinal symptoms were measured dimensionally using a recently developed instrument, the Gastro-Questionnaire (21). This instrument includes 27 gastrointestinal symptoms derived from the Rome-II criteria, which are rated on four-point (0 = 'not at all' to 3 = '(nearly) always') and five-point (0 = 'no distress' to 4 = 'very severe distress') scales by symptom persistence and distress induced by the symptom. While ratings refer to a 12-month period corresponding to the Rome-II criteria in the basic version, 14 days were defined as reference period for the present study to adapt the instrument to repeated measurement. Furthermore, the questionnaire contains several additional questions required for categorical screening diagnoses and exclusion of organic disease. Diagnoses of 20 gastrointestinal disorders according to the Rome-II classification can be derived directly from the questionnaire combining symptom ratings and additional questions.

Somatoform symptoms were measured by the Screening for Somatization Symptoms (SOMS-7) (22), a 53-item self-rating scale including all soma-

toform complaints listed in DSM-IV and ICD-10. The patients also completed the German version of the Whiteley Index (23), a 14-item scale to measure hypochondriasis, the Beck Depression Inventory (BDI) (24), the trait anxiety subscale of the German version of the State-Trait-Anxiety Inventory (STAI) (25), and the German version of the Multidimensional Health Locus of Control Scales (MHLC) (26).

Definitions of functional gastrointestinal symptoms

For the evaluation of changes in gastrointestinal symptomatology, two different definitions of clinically relevant symptoms were applied. This distinction was introduced to control for associations between symptom definitions and dimensions of treatment effects. In the more inclusive version, closely oriented at the Rome-II criteria, a gastrointestinal symptom was defined as a bodily complaint being present more than 25% of days. In addition to that, symptoms had to be at least distinctly distressing following the more restrictive definition.

Standardized manual-guided treatment

All subjects obtained the same standardized manual-guided treatment, consisting of 10 90-minute group sessions over a 10-week period. Group size ranged between six and nine subjects. The following cognitive-behavioral standard interventions and techniques were applied.

Symptom diaries. Subjects were asked to complete daily diaries including ratings of symptom severity, symptom-related distress, general well-being, quality of sleep, and activities or incidents inducing symptom changes. Diaries were regularly discussed at the beginning of each session.

PMR. Three PMR exercises were conducted during the treatment sessions; subjects were motivated to practice at home regularly and obtained a cost-free CD with PMR instructions for the long and the short version.

Stress management. Subjects were presented with a model of the stress reaction and its components. Exercises on muscular and autonomic stress and relaxation correlates were conducted; behavior change towards a more regular and stress-reducing lifestyle was supported, and stress-inducing cognitions were identified and modified continuously.

Attention deflection. Influence of attention and perception effects on physical sensations was discussed on the basis of the concept of somatosensory amplification, demonstrated by practical exercises, and instructions for attention defocusing were given to the subjects.

Cognitive restructuring. Symptom-related catastrophizing cognitions following the exacerbation of gastrointestinal symptoms, as well as non-specific dysfunctional cognitions activating physical symptoms, were identified, and subjects were taught to change them systematically into more adequate cognitions. These new cognitive skills were also used as a basis for systematic problem-solving regarding distressing social situations.

Furthermore, education on gastrointestinal functioning, FGDs, gut-brain interactions, and their associations with stress, and modification of unhealthy and irregular eating behavior were applied as interventions specifically aimed at gastrointestinal complaints.

In order to prevent relapse after the treatment program, subjects obtained extensive written material about each practical exercise and treatment component, and were recommended to use them as a self-administered manual for the post-treatment period.

Statistical analyses

Treatment effects were determined by MANOVAS with repeated measures and subsequent paired *t*-tests. As additional measure for the clinical relevance of changes in the characteristics investigated, effect sizes were calculated by dividing the difference between the pretreatment and the follow-up score by the pretreatment standard deviation.

Results

The sample

Of 64 subjects initially included in the treatment program after the screening procedure, 49 completed the study until follow-up assessment, while 15 subjects dropped out of the treatment program early or refused to complete post-treatment or follow-up questionnaires.

Mean age and gender proportion were comparable to other psychosomatic treatments, whereas the sample was untypical regarding educational status. One reason for the large proportion of well-educated subjects may be that the program was offered by newspaper and internet, and

subjects had to be willing to go to a psychological department, i.e. they had to have at least a basic understanding of the psychosomatic aspects of their gastrointestinal disorder. This interpretation corresponds to the fact that more than one-third of the subjects had attended previous psychotherapies, and about one-third had experienced a depressive episode (Table 1).

Psychopathological characteristics and changes during the treatment and follow-up period

At the baseline assessment, subjects reported a mean number of 9.1 (± 4.6) gastrointestinal symptoms, as defined as being present for more than 25% of the days during the last 2 weeks; and 7.3 (± 4.4) gastrointestinal symptoms when distinct distress was defined as an additional criterion for the presence of symptoms. Regarding further psychopathology measures, the score for somatoform symptoms as measured by the SOMS was distinctly elevated, while depression, hypochondriasis, and trait anxiety scores, as well as health locus of control ratings, were within or very close to the normal spectrum. As a consequence, the scope for improvements in the clinical characteristics investigated was limited from the start (Table 2).

Regarding gastrointestinal symptoms, significant global improvement was found for both symptom definitions between the baseline and the follow-up period. However gastrointestinal symptomatology already improved significantly in the waiting-list period due to non-specific factors. During the treatment period, the number of gastrointestinal symptoms decreased significantly by more than 50% using the more restrictive symptom definition, and by 38% for the alternative definition. During the follow-up period, symptom number remained nearly unchanged, which is of particular importance considering that gastrointestinal symptoms may be fluctuating

Table 1. Sample characteristics ($n=64$)

	Original sample ($n=64$)	Completers ($n=49$)
Age (years)	47 \pm 13	45 \pm 13
Gender – female	65.6%	63.3%
Education – secondary school or higher degree	79.7%	81.6%
Enduring partnership	78.1%	77.6%
Previous psychotherapies	36.0%	34.7%
Major depressive episode (lifetime)	32.9%	34.7%
SSI-8 (somatization syndrome)	40.6%	42.9%
Drop-out rate	23%	

Table 2. Treatment effects

	T0 M (SD)	T1 M (SD)	T2 M (SD)	T3 M (SD)	MANOVA	f-test			Effect size T1–T3
						T0–T1	T1–T2	T2–T3	
FGS-1	7.3 (4.4)	5.9 (4.6)	2.8 (3.4)	3.1 (3.5)	$F = 27.2^{**}$	$T = 2.9^{**}$	$T = 4.8^{**}$	$T = -0.5$; NS	0.6
FGS-2	9.1 (4.6)	7.5 (4.8)	4.7 (4.0)	4.8 (3.7)	$F = 22.3^{**}$	$T = 3.1^{**}$	$T = 3.9^{**}$	$T = -0.3$; NS	0.6
SOMS	28.9 (16.0)	26.8 (16.6)	18.8 (14.3)	20.0 (14.8)	$F = 16.2^{**}$	$T = 1.8$; NS	$T = 4.6^{**}$	$T = 0.4$; NS	0.4
Whitely	4.7 (3.2)	4.5 (3.6)	3.7 (3.2)	3.7 (3.2)	$F = 4.5^{**}$	$T = 0.6$; NS	$T = 2.3^*$	$T = -0.6$; NS	0.2
BDI	9.7 (7.1)	9.2 (8.5)	6.3 (5.0)	6.4 (6.9)	$F = 9.4^{**}$	$T = 1.1$; NS	$T = 3.2^{**}$	$T = -0.2$; NS	0.3
STAI	46.2 (10.1)	44.9 (10.8)	40.3 (9.0)	41.5 (9.3)	$F = 13.0^{**}$	$T = 1.1$; NS	$T = 5.9^{**}$	$T = -0.4$; NS	0.3
MHLC internal	3.9 (0.6)	3.8 (0.7)	3.8 (0.6)	3.8 (0.7)	$F = 0.9$; NS				
MHLC powerful others	2.8 (0.8)	2.6 (0.8)	2.4 (0.8)	2.5 (0.9)	$F = 4.2^{**}$				
MHLC chance	2.8 (0.7)	2.7 (0.8)	2.7 (0.7)	2.6 (0.7)	$F = 1.8$; NS				

FGS-1, number of gastrointestinal symptoms being present for more than 25% of days; FGS-2, number of gastrointestinal symptoms being present for more than 25% of days, and being associated with distinct, severe or very severe distress.

NS, not significant.

* $p < 0.05$, ** $p < 0.01$.

and significant symptom changes were identified during the waiting list period. The same effect size was found for both gastrointestinal symptom definitions between the pretreatment and the follow-up assessment (Table 2).

Comorbid psychopathology scores decreased distinctly during the treatment period without exception, whereas no changes occurred during the waiting list and the follow-up period. Changes in health locus of control scales were only small and clinically not relevant (Table 2).

Although a large number of possible predictors were tested with different regression-analytic models, only the number of gastrointestinal symptoms at the pretreatment assessment was (positively) associated with gastrointestinal symptom reduction, with an r^2 -coefficient of 0.48.

Changes in distress ratings

The most distressing symptoms for the subjects in our sample were bloating, distension, abdominal pain, stool urgency and flatulence. All distress ratings decreased significantly between the baseline

Table 3. Distress ratings of most distressing symptoms

	T0 M (SD)	T1 M (SD)	T2 M (SD)	T3 M (SD)	MANOVA	Effect size T1 to T3
Bloating	2.3 (1.4)	2.1 (1.5)	1.0 (1.2)	1.3 (1.4)	$F = 16.6^*$	0.5
Distension	1.7 (1.6)	1.5 (1.6)	0.7 (1.2)	0.9 (1.4)	$F = 10.9^*$	0.4
Abdominal pain	1.8 (1.6)	1.4 (1.5)	0.7 (1.3)	0.6 (1.1)	$F = 14.5^*$	0.5
Stool urgency	1.5 (1.5)	0.9 (1.3)	0.3 (0.9)	0.5 (1.1)	$F = 13.8^*$	0.3
Flatulence	2.0 (1.5)	1.8 (1.6)	1.0 (1.2)	1.0 (1.1)	$F = 14.6^*$	0.5

* $p < 0.05$, ** $p < 0.01$.

and the follow-up assessment, with corresponding effect sizes amounting to 0.3–0.5 (Table 3).

Results including outcome estimates of non-completers

In order to evaluate effects of unfavorable outcome in subjects who dropped out of the study, an intention-to-treat analysis was conducted on the basis of the 64 subjects originally willing to participate in the treatment program. As the intention was to obtain a conservative estimate, pretreatment ratings were used instead of missing post-treatment and follow-up ratings, assuming that symptoms in subjects not adhering to the study would have remained unchanged compared with pretreatment ratings.

Treatment effects in the intention-to-treat analysis were almost identical with the completer analysis. Significant global reductions of gastrointestinal symptoms and the comorbid psychopathology were found for all symptom scores. The number of gastrointestinal symptoms decreased by either 40% or 31%, depending on the definition applied. For functional gastrointestinal, hypochondriacal, and depressive symptoms, effect sizes remained unchanged, while effect sizes in somatoform and anxious symptoms were slightly lower (Table 4).

Discussion

The primary intention of the present study was to investigate efficacy of a standardized cognitive-behavioral treatment for functional gastrointestinal disorders conducted in a group setting. Up until now, only a handful of studies have focused on group therapy. However, standardized group

Table 4. Intention-to-treat analysis

	T0 M (SD)	T1 M (SD)	T2 M (SD)	T3 M (SD)	MANOVA	Effect size T1 to T3
FGS 1	6.9 (4.4)	6.5 (4.1)	3.5 (3.6)	3.9 (3.9)	$F = 21.1^{**}$	0.6
FGS 2	8.6 (4.6)	8.1 (4.3)	5.3 (4.2)	5.6 (4.2)	$F = 16.8^{**}$	0.6
SOMS	29.2 (17.0)	26.5 (17.9)	19.3 (16.0)	20.8 (16.3)	$F = 19.5^{**}$	0.3
Whitely	4.5 (3.1)	4.4 (3.7)	3.7 (3.2)	3.7 (3.4)	$F = 5.4^{**}$	0.2
BDI	10.4 (7.8)	9.9 (8.6)	7.5 (6.1)	7.6 (7.9)	$F = 9.3^{**}$	0.3
STAI	46.7 (10.8)	45.6 (11.6)	41.7 (10.4)	42.8 (10.7)	$F = 13.8^{**}$	0.2

* $p < 0.05$, ** $p < 0.01$.

treatment is very common and effective in many mental and psychosomatic disorders, and treatment is less expensive under economic aspects. Many persons affected by FGD experience distinct distress but maintain a high level of functioning. In these cases, application of individual psychotherapy as standard treatment would be too costly. Therefore, efficacy of group treatments is of special relevance in the field of FGDs.

A special aim of the study was the standardized dimensional measurement of the total spectrum of functional gastrointestinal symptoms independent of the narrow focus of IBS or other specific FGDs. Standardized dimensional measurement is of special importance, since non-standardized symptom diaries, which were used in most former studies, limit the comparability of the findings of different studies.

The cognitive-behavioral treatment investigated produced significant and enduring reduction of FGSs, which amounted to 30–50% of the initial number of symptoms. Effect sizes of about 0.60 are good, considering that these refer to chronic physical symptoms. Moreover, significant improvement was found not only in the number of symptoms, but also in the distress associated with these symptoms. This component is very important, since dysfunctional behaviors, like excessive health care use and sick-leave days, might be associated with subjective distress rather than with the mere presence of a symptom. Regarding comorbid characteristics, all psychopathology scores including further bodily symptoms, as measured by the SOMS, decreased significantly, although the initial symptom levels were moderate. However, symptomatic changes were not associated with changes in health-related locus of control and we were not able to identify specific predictors of gastrointestinal symptom outcome apart from the number of FGSs at the beginning of treatment. This means that the specific mechanisms of reduction in FGSs remain unclear, although the treatment program seems to be effective.

One limiting point of the present study is the fact that outcome was controlled by subjects' waiting-list period instead of a placebo control group or an alternative treatment condition.

This aspect becomes problematic with respect to the significant decrease in FGSs during the waiting-list period, which cannot be attributed to a specific intervention. One possible explanation is that gastrointestinal symptomatology was influenced by non-specific effects of the screening session, which also served to inform subjects about the study and to convince them to participate in a psychological treatment program. However, specificity of treatment effects is confirmed by the fact that lowered symptom levels were enduring over a 1-year follow-up period, without significant changes in any of the measures applied.

The drop-out rate of 23% during the treatment and follow-up periods was moderate, considering that subjects participated on a voluntary basis and most of these had to be convinced of a psychological approach for physical symptoms. Nevertheless results might be distorted towards a more positive outcome excluding treatment non-completers. In order to obtain a conservative estimate of negative outcome effects of the drop-outs, data were re-analyzed using an intention-to-treat analysis. Even assuming that symptomatology in non-completers would have remained unchanged starting from the beginning of treatment, therapy outcome of the initial sample differs only marginally from the completers, underlining the efficacy of the approach investigated.

In summary, the findings of the present study elucidate the efficacy and practical significance of cognitive-behavioral group treatment, which is not only an effective approach in the therapy of FGDs, but also an economic one. Outcome of FGDs in this study was quantified by standardized dimensional assessment providing the basis for the calculation of comparative effect sizes and meta-analytic research. A similar approach was presented by Boyce et al. (27). However their instrument covers only bowel symptoms, while the Gastro-Questionnaire refers to a much broader spectrum of symptoms of the entire gastrointestinal tract. Such an approach might promote the development of conventions, standards and definitions of successful treatment in FGDs, and is essential for comparative studies on differential effects of competing methods and interventions.

As the design of the present study comprised only group treatment but no alternative treatment condition, the next step towards more effective therapies could be the direct comparison of cognitive-behavioral individual and group treatment to determine the best setting for psychological treatments in FGDs.

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