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Rapid Response to Cognitive Behavior Therapy for Irritable Bowel Syndrome

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Abstract

Background—We sought to determine whether the therapeutic phenomenon of rapid response characterizes patients undergoing CBT for irritable bowel syndrome (IBS). If RR is operating in IBS treatment, a significant proportion of CBT treated patients should achieve a positive response early in treatment (by week 4). We also hypothesized that rapid responders (RR) would be more likely to maintain treatment gains than non rapid responders (NRR). Our secondary goal was to characterize the psychosocial profile of RRs on clinically relevant demographic and clinical variables (e.g., health status, baseline level of IBS symptom severity, distress).

Methods—71 individuals ages 18–70 years with a Rome II IBS diagnosis and symptoms of at least moderate severity were randomized to one of 2 CBT treatments: either 10 weekly, one hour sessions (Standard-CBT) or four, one hour sessions over 10 weeks (Minimal Contact-CBT). RRs were classified as patients who 1) reported adequate relief of pain; 2), adequate relief of GI symptoms and 3) a decrease in total IBSSS scores of \geq 50 by week 4.

Results—30% of CBT treated patients achieved RR by week 4 of treatment. 90–95% of RRs maintained gains at immediate and 3 month follow-up. While RR reported more severe IBS symptoms at baseline, they achieved more substantial and sustained gains (e.g. IBS symptom reduction) than NRRs. Standard- and MC CBT yielded comparable RR rates even though MC CBT patients received 50% less clinic treatment by week 4.

Conclusions—Rapid response is a potentially important prognostic outcome indicator that has important implications for developing step care approaches for IBS treatment.

Keywords

rapid response; cognitive-behavioral therapy; irritable bowel syndrome; outcome research

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Irritable bowel syndrome (IBS) is a common, chronic, often disabling gastrointestinal (GI) disorder best understood from the perspective of the biopsychosocial model ¹. Central to this conceptualization is recognition that IBS symptoms (abdominal pain/discomfort with altered defecation) are clinical manifestations of dysregulation in the bi-directional neural connections linking the gut to the cognitive and emotional centers in the brain (i.e., brain-gut axis, ², ³). Although alterations at any level of the brain-gut axis influence motility, visceral sensation, and intestinal secretion ⁴, multiple lines of evidence highlight the importance of central processes in the perception and maintenance of symptoms, particularly in more severely affected patients.

One measure of the influence of central factors on IBS comes from outcome research testing the efficacy of psychosocial therapies. These data, as summarized in a recent metaanalysis ⁵, suggest that psychological treatments as a whole are at least moderately effective in reducing IBS symptoms. Although there was not enough data to establish the relative superiority of any one type of psychological treatment, 14 of 17 trials in the meta analysis featured cognitive behavior therapy (CBT). The therapeutic value of CBT was echoed in a recently published *New England Journal of Medicine* narrative review ⁶ that identified CBT as one of the few empirically validated treatments for IBS.

These data are important because dietary and medical treatments designed to modulate intestinal motility and decrease visceral sensitivity have proven largely unsatisfactory for IBS. Notwithstanding *impressive data supporting CBT for IBS, a sizable proportion (20–35%) of patients who undergo CBT* either do not respond or do not respond well enough for symptom change to represent clinically meaningful improvement ^{7, 8}. Identifying variables that specify for whom a treatment works or under what conditions a treatment is effective has the potential to improve clinical decision making, health care policy, and patient care. If negative prognostic indicators are identified, it may be possible to engineer protocol changes in a way that optimizes outcome for patients at highest risk for treatment failure. Specifying prognostic variables would help us move closer to answering a fundamental question that should guide all efficacy research: *What treatment, by whom, is most effective for this individual* ⁹, p. 111.

Few studies have formally examined potential modifiers (predictors, moderators, variables that alter the strength or direction of a relationship) of CBT response in IBS. The few studies that have examined predictors have focused on variables conveniently collected during baseline assessment such as demographic variables (e.g., gender), distress (depression, anxiety), and clinical characteristics (e.g. symptom severity, predominant bowel habit). These variables exert such a modest influence on outcome that "other variables …must be responsible for change in the actual GI symptoms of IBS" ⁸, ^{p. 334}.

There is a growing belief that treatment effects are not strictly defined by the personal characteristics patients bring to treatment but are rather shaped by factors that occur during the course of treatment^{10–13}; one such predictor is the rapidity of treatment response. Contrary to the commonly held view that patients undergoing psychological therapies improve gradually and incrementally over time and therefore require extended treatment in order to show meaningful change ^{7, 14}, a wealth of research over the past two decades shows that a significant proportion of patients undergoing CBT for a variety of conditions achieve rapid, substantial, and sustained symptom improvements relatively early in treatment (e.g., first four weeks). ¹³.

The significance of the rapid response phenomenon lies partly in its prognostic value. Rapid responders are significantly more likely to do better at the end of the acute phase of CBT and long term follow up than non rapid responders ¹⁵. Prognostic information obtained

before treatment has run its course has the potential to provide clinicians guidance for determining which patients are likely to respond to treatment and when treatments are "working" or "not working" ¹⁶. Patients who quickly achieve treatment gains (e.g., IBS symptom relief) may be spared the cost and inconvenience of follow up care of marginal therapeutic value. This scenario may lead to the development of self guided treatments based on multimedia technology (e.g., web, DVD, Smartphone) and free up a dearth of trained clinicians to focus on more severely affected patients. Conversely, patients who do not respond within a set number of sessions early on could be immediately identified and triaged or "stepped up" to potentially more powerful treatment(s) (e.g. combining CBT with pharmacotherapy) rather than bearing the cost, demoralization, and frustration that comes with treatment failure to insufficient unimodal therapies. The phenomenon of rapid response is not of interest only to behavioral researchers. Once the most powerful "ingredients" of behavioral treatments are distilled, biologically oriented clinical researchers in academia and industry can harness the clinical benefit of CBT to maximize the therapeutic value of pharmacological treatments.

With the assumption that the rapid response phenomenon observed in other CBT interventions would apply to IBS, we predicted that a significant proportion (25–40%) of IBS patients undergoing CBT would achieve a positive response early in treatment (by week 4). We also predicted that early responders would be more likely to maintain their treatment gains than non rapid responders at the end of acute treatment phase and through follow up 3 months after the end of treatment. A secondary goal was to characterize the psychosocial profile of rapid responders on clinically relevant cognitive processes.

Patients and Methods

Study Design

This study is a secondary analysis of a single site, three arm randomized clinical trial pitting CBT delivered in either 4- or 10-session "doses" against a waiting list control (WLC). Both CBT versions were comparably efficacious and superior to WLC in improving IBS symptoms, reducing quality of life impairment and delivering adequate relief from both pain and bowel symptoms. Additional details about the results and design of this study (e.g., CONSORT statement) are published elsewhere ¹⁷.

Participants

Participants were 75 adults between the ages of 18 and 70 years who were diagnosed with IBS according to Rome II criteria without comorbid GI disease. Four subjects were excluded because their data was not suitable for analysis. Detailed description of eligibility criteria are found in our original report¹⁷

Treatment Conditions

CBT was delivered in 2 doses: either 10 weekly, one hour sessions (S-CBT) or four, one hour sessions over 10 weeks (MC-CBT). MC-CBT covers the same range of procedures featured in S-CBT but is largely patient administered and relies extensively on self-study materials ¹⁸. The passive control subjects were wait listed (i.e. placed on a 10-week delayed treatment wait list, during which time they monitored the severity of GI symptoms on a daily basis).

Measures

Efficacy endpoints—Participants completed 2 binary (Yes/No) adequate relief measures (Adequate of relief of pain, other IBS symptoms such as diarrhea, constipation, bloating)

and the Irritable Bowel Syndrome Severity Scale¹⁹ (IBSSS). The IBSS requires the patient to evaluate on 100 point scales each of five items: severity of abdominal pain, frequency of abdominal pain, severity of abdominal distension, dissatisfaction with bowel habits, and interference with quality of life. All five components contribute equally to the total score, yielding a range of 0–500, in which a higher score indicates a more severe condition.

Additional Measures-Several other psychometrically validated measures were administered on the same testing schedule as the IBSSS to assess the psychosocial dimension of treatment response. Our selection of measures reflected our interest in the cognitive aspects of IBS that could potentially influence rapidity of treatment response. The 25-item IBS Management SE scale^{20, 21} (IBS-SE) measures patients' confidence in their ability to control and manage IBS episodes using a 7 point Likert scale (1 = strongly disagree, 7 = strongly agree). The IBS-Specific Locus of Control Scale (IBS-LOC, ^{22, 23}) is a 33 item scale (5 point, 1 = strongly disagree, 5 = strongly agree) that measures patients' beliefs that IBS symptoms are internally controlled, controlled by health care professionals, or dictated by chance, respectively. The IBS version of the Treatment Self Regulation Questionnaire ²⁴ (TSRQ-IBS) assesses the reasons for adopting behavioral strategies to manage IBS symptoms. Patterned after previous self regulation questionnaires ²⁵ that focus on a person's motivation for engaging in a targeted health behavior (e.g., control of glucose level), the TSRQ-IBS focuses on motivation for learning behavioral self management strategies for IBS. The TSRQ-IBS presents 15 sentence stems ("The reason I would learn self management skills for managing IBS symptoms is") that are followed by items that represent either autonomy-oriented ("I feel that I want to take responsibility for my own stomach problems"), control-oriented oriented ("Because I feel pressure from others to do so"), or amotivation ("I really don't know why") motivation. Each reason is rated on a 5 point scale ranging from not true at all to very true. The Irritable Bowel Quality of Life (IBS-QOL, ²⁶) is a 34-item disease-specific HRQOL measure assessing the subjective wellbeing of patients with IBS. Psychological distress was measured using the Global Severity Index (GSI) of the Brief Symptom Inventory ²⁷. All measures were administered at baseline, at week 4 of treatment, 2 weeks after treatment ended (week 12) and at 3 month follow up with the exception of adequate relief measures that were obviously not completed at baseline.

Criteria for treatment response

Based on Rome guidelines ²⁸ we classified treatment responders as patients who 1) provided an affirmative response to *both* AR questions (pain and bowel habits); <u>and</u> 2) demonstrated a decrease in total IBSSS score of \geq 50 points from baseline. Previous research defines a reduction of \geq 50 points on the IBSSS as "clinically important" ¹⁹. Patients who met these criteria for treatment responders at week four were classified as rapid responders. Patient who did not meet both of these criteria at week 12 were classified as non rapid responders (NRR).

Results

Statistical analyses

We used an intent-to-treat approach to examine the data. A last observation carried forward techniques was used to handle missing data. The technique^{29, 30} of replacing participant's missing values after dropout with the last available measurement is a widely accepted strategy for dealing with missing data due to attrition in IBS clinical trials^{3132, 33}. One-way analyses of variance (ANOVAs) and chi-square analyses were used to assess differences between responder type on demographic and pre-treatment variables. Repeated-measures MANOVAs (RR status x time) were conducted for the IBS-LOC subscales; and the IBS-SE

and TSRQ-IBS subscales. We grouped the IBS-SE and the TSRQ together because of their theoretical and statistical relationships. MANOVAs were conducted to reduce the possibility of Type II errors. If the MANOVAs were significant, post-hoc ANOVAs were conducted to explore differences between the groups on each measure at each phase of administration, and repeated measures ANOVAs examined within group differences over time, with each controlling for multiple comparisons.

Characteristics of rapid responders

Demographic characteristics and pre-treatment psychological distress of the RR and the NRR are shown in Table 1. Rapid responders did not differ significantly from non rapid responders on psychological distress or demographic characteristics (age, education level, marital status or ethnicity) with the exception of gender (females who comprised a large proportion of the sample were more likely to be RRs). Also, RR rated their pre-treatment symptoms as more severe (IBSSS: RR = 330.3 vs. NRR = 274.6, p < .01, see Table 2)

Rapid responders across the sample over time

Of the 71 patients randomized to CBT, 21 (29.6%) showed a rapid response by the fourth week of the 10 week treatment phase. Week four corresponded to clinic session 2 of treatment for patients assigned to MC-CBT and clinic session 4 for patients undergoing S-CBT. The average reduction of IBSSS total score at week 4 was 132.5 (SD = 53.0) points for rapid responders and 19.7 (SD = 69.7) points for NRR. The two CBT conditions did not differ significantly in the proportion of participants who met criteria for a rapid response at week 4. Thirty one percent of the S-CBT patients and 27% of the MC CBT patients met criteria for RR at week four.

Global IBS Symptom Relief—At week 12 (two weeks after the end of treatment), 37 out of the 71 (52.1%) participants met the criteria for treatment responder. Of the 21 RR, 19 (90.5%) were acute treatment responders. Of the 50 NRR, 18 (36.0%) were treatment responders. RRs reported significantly less symptom severity on the IBSSS than the NRR (127.2 vs. 215.2, p < .001) even though they had more severe symptoms at baseline (RR = 330.3 vs. NRR = 274.6 scores on the IBSSS). The magnitude of the difference between RRs and NRRs at post treatment well exceeded the 50 point reduction index regarded as a sign of clinical improvement³⁴. At 3 month post-treatment follow up, 34 out of the 71 (47.9%) participants maintained their status as treatment responders as defined by the same criteria used at four week and immediate post-treatment. There was a significant differences between RR and NRR with 20/21(95.2%) of RR and 14/50 (28%) of NRR ($\chi^2 p < .001$) maintaining treatment gains at 3 months post-treatment. RR continued to report significantly less symptom severity on the IBSSS (131.7 vs. 214.1, p < .01).

Locus of Control-IBS—A repeated measures MANOVA on the IBS-LOC subscales revealed a significant interaction effect for group X time [F (6, 64) = 5.33, p < .001]. For the individual subscales of the IBS-LOC, significant interactions were found for Internal [F (2, 138) = 10.22, p < .001] and Chance [F (2, 138) = 8.50, p < .001] but not for Health Care subscales. Repeated measures ANOVAs revealed that the RR group improved significantly from pre-treatment to post-treatment and from pre-treatment to 3-month follow-up on both the Internal [pre-post: F = 32.01, p < .001; pre-3-month: F = 26.23, p, < .001] and Chance [pre-post: F 33.21=, p < .001; pre-3-month: F = 28.21, p < .001] subscales. There was no significant difference between the post-treatment and 3-month follow-up scores on either scale. Similar results were found for the NRR group (see Table 2).

Tests of simple effects at each assessment period revealed that there were no significant differences between the RR and NRR groups on either the Internal or Chance LOC

Lackner et al.

subscales at pre-treatment. However, the RR group scored significantly better than the NRR at post-treatment on the Internal subscale [F (1, 69) = 4.32, p < .02] and the Chance subscale of the IBS LOC scale [F (1, 69) = 5.68, p < .02]. These data suggest that RR had stronger perceptions of internal control and lower perceptions that their symptoms were dictated by chance than NRR. At 3 months post-treatment, RR continued to score better than the NRR on the Chance LOC subscale [F (1, 69) = 6.69, p < .01], but the difference on the Internal LOC subscale disappeared.

IBS-Self Efficacy and Treatment Self Regulation (Motivation)—A repeated measures MANOVA on the IBS-SE and the TSRQ-IBS subscales revealed a significant interaction effect for group x time [F (8, 60) = 3.13, p < .005] with planned follow-up ANOVAs demonstrating significant interactions for the IBS-SE [F (2, 134) = 6.35, p < .005] and the Amotivation subscale of the TSRQ [F (2, 134) = 5.57, p < .005], but not for the Autonomous and Controlled subscales. Repeated measures ANOVAs revealed that the RR group improved significantly from pre-treatment to post-treatment and 3-month follow-up on both the IBS-SE [pre-post: F = 64.31, p < .001; pre-3-month: F = 57.26, p, < .001]and Amotivation [pre-post: F 4.03=, p < .01; pre-3-month: F = 5.88, p < .01]subscale. There were no significant differences on the Autonomous or Controlled subscales of the TSRQ, nor were there differences between the post-treatment and 3-month follow-up scores on the IBS-SE and the Amotivation subscale. For the NRR group, the only significant difference over time was from pre-treatment to post-treatment and 3-month follow-up scores on the IBS-SE intervented in the post-treatment and 3-month follow-up scores on the IBS-SE intervented in the post-treatment and 3-month follow-up scores on the IBS-SE and the Amotivation subscale. For the NRR group, the only significant difference over time was from pre-treatment to post-treatment and 3-month follow-up on the IBS-SE [pre-post: F = 38.31, p < .001; pre-3-month: F = 35.06, p, < .001].

Tests of simple effects at phase of administration revealed that there were significant differences between the RR and NRR groups on the Autonomous [F (1, 67) = 6.25, p < .01] and Amotivation [F (1, 67) = 5.80, p < .01] subscales of the TSRQ at pre-treatment, with RR reporting more autonomous motivation to learn behavioral self management skills for IBS than NRR and NRR reporting a greater lack of motivation (amotivation). There were no differences between groups on the IBS-SE or the Controlled subscale at pre-treatment. Also, there were no differences between groups on any of the TSRQ subscales at post-treatment or at the 3-month follow-up. However, there were significant differences between groups on the IBS-SE at post-treatment [F (1, 69) = 7.31, p < .01] and at the 3-month follow-up [F (1, 69) = 6.00, p < .01], with the RR group reporting significantly greater self-efficacy for managing IBS symptoms.

IBS-Quality of Life—For the IBS-QOL, a repeated measures ANOVA revealed a significant interaction effect for group X time, F (2, 138) = 4.20, p < .01. Post-hoc tests showed that the RR group improved significantly from pre-treatment to post-treatment [F = 24.71, p < .001] and 3-month follow-up [F = 22.08, p < .001], with similar results for the NRR group (see Table 2). Tests of simple effects revealed that there was a significant difference between the RR and NRR groups at pre-treatment [F (1.69) = 5.71, p < .01], but this difference disappeared at both post-treatment and 3-month follow-up.

Discussion

Of 71 Rome diagnosed IBS patients randomized to CBT, 21 (29.6%) showed a rapid response by the 4th (session 4 and 2 of the S-SCT and MC-CBT, respectively) week of treatment. Rapid responders were significantly more likely than non rapid responders to meet criteria for a treatment responder at post-treatment, as outlined by the Rome II committee and to maintain this response at 3 month follow up. We are not inclined to believe the rapidity of response is simply a manifestation of a milder IBS condition. Rapid responders had more *severe* IBS symptoms and QOL impairment than other patients. Nor do we believe that rapid responders were less psychologically distressed than their NRR

Our study highlights patient and treatment factors that may promote rapid response to CBT in this population. With respect to patient factors, we found a strong connection between personal control beliefs and rapid response at interim and follow up assessment periods. In comparison with non rapid responders, rapid responders were more likely to have a high internal locus of control (i.e. attribute their symptoms to their own specific behavior), express more confidence in their ability to make specific behavior changes necessary to control IBS symptoms and have stronger motivation to participate in a self management program.

Some might have predicted that the therapist-directed, time intensive and highly structured demands of weekly CBT would promote a more rapid response. This prediction dovetails with the dose-effect model of therapy ³⁵ which linearly links the number of therapy sessions that clients receive to the magnitude of symptomatic improvement. In fact, a similar proportion of patients were classified as rapid responders regardless of whether they received 1 or 4 hours of face to face therapist time. This finding does not comport with the notion that "any benefit [psychologically treated IBS patients] may derive [is] from.....the quantity of contact time with the provider" ³⁶, p. S²⁵. Conversely, others may predict that the structure and format of a brief self administered CBT program contains specific features (strict time limit, time alone, elapsed time between clinical visits) that act as "catalytic" triggers for rapid response ³⁷. Neither of these hypotheses was verified, although, as a feasibility study, the present was not powered to detect between group differences on rate of rapid response.

Nor do our data suggest that early response is a transient placebo effect as placebo responders typically show an abrupt and early treatment response that decays over time ³⁸. In our study, only 2 subjects "reversed" a rapid response at post-treatment. The great majority of rapid responders (92.5%) showed an enduring benefit that lasted well over 3 months with little evidence of deterioration. This suggests that rapid response is a relatively robust, clinically meaningful and enduring clinical phenomenon. Indeed, RR maintained or continued to improve on the gains made in treatment after termination

This study has important health care policy implications that extend well beyond the problem of IBS. The existing health care crisis has crystallized the importance of conducting treatment efficacy research to improve the quality of health care in the United States⁴¹. Fundamental to improving health care is conducting outcome research that asks "which treatments work best for which patients"^{39, 40}. This has been an elusive goal in part because of the paucity of "hard data" identifying reliable predictors of outcome. In a recent study published in these pages⁴¹, we found that pre treatment clinical (e.g., predominant bowel type, abuse history, illness, duration, pain severity, psychological distress, etc) and demographic variables were for the most part poor predictors of outcome. This is not an isolated finding⁴¹. Researchers would be wise to disband a singular focus on pre treatment factors in favor of a wider one that characterizes the prognostic value of biobehavioral factors that occur during treatment if they want to best position themselves for tackling the question of which treatments works best for which patients. In this respect, this study introduces an innovative conceptual approach that has important implications for tackling some pressing health outcome questions facing us. As clinical researchers, we find gratifying increased attention paid to the importance of treatment efficacy research. As consumers of medical outcome research, we would be more confident that a large federal investment in clinical research will achieve its ambitious goals if it moves beyond solely

Lackner et al.

answering "horse race questions" of whether treatment X works better than Y to more complex and nuanced questions that bear directly on improving treatment efficacy and efficiency. This answer is not necessarily revealed simply through head to head comparisons of treatments. Pressing answers to the question of "which treatments work best for which patients" calls for <u>both</u> dedicated investment in medical efficacy research as well as the adoption of novel conceptual and methodological approaches that are beyond the scope of conventional clinical trials.

To our knowledge, this IBS study is the first to systematically investigate the role of motivation in IBS treatment using a theory based measure with sound psychometric properties. Motivation is often regarded as essential to shaping the outcomes of IBS therapies ^{7, 42} but has received little empirical study from IBS researchers. We found that rapid responders reported more autonomous motivation to learn behavioral self management skills for IBS than NRR, while NRRS reported higher levels of amotivation. According to self determination theory, amotivation (sample TSRQ-IBS item: "I really don't know why I would learn self management skills for managing IBS symptoms") occurs in individuals who lack the intention and willingness to engage in a specific behavior. Self perceptions of incompetence and uncontrollability can account for amotivation, which is linked to behavioral disengagement. The TSRQ-IBS appears to be a psychometrically validated measure of treatment motivation that may be useful in better understanding how motivation impacts IBS treatments whether they are pharmacological or behavioral in nature.

Interestingly, rapid response occurred *before* patients were formally introduced to cognitive techniques (e.g., prediction testing, evidence based logic, formal problem solving training) that has been characterized ⁴³ as the most powerful behavioral strategy for IBS. This invites speculation about what is going on in during the first 4 weeks sessions that fosters such dramatic and enduring change in a sizable sub set of patients. It is possible that rapid responders were especially responsive to relaxation exercises emphasized during two of the first four week of treatment. This interpretation must be weighed against outcome research showing a mixed track record of efficacy for relaxation as a standalone behavioral technique for IBS ^{44, 45}. Even the studies that support the efficacy of relaxation procedures administered a much longer training schedule (e.g., 6 weeks) than our protocol (2 weeks).

We suspect that symptom monitoring had a stronger hand in expediting early treatment gains. At the first session both CBT treatments, patients were assigned a rather intensive self monitoring regimen (see Appendix for self monitoring record) which included careful tracking of individual GI symptoms, flare ups, the circumstances in which they occurred, and the antecedent and consequent events such as emotional, cognitive, and physical responses. This is called a functional analysis and was carried out on a daily basis through at least week 4. For patients who "spend a lot of time in their heads" worrying about day to day events ("If only...., "what if ...?"), the task of monitoring situational triggers of IBS flare ups may force them to step outside of themselves and appraise the environment in a more objective, present oriented, flexible, and logical (non threatening) manner. Self monitoring may expedite rapid symptom improvement by fostering cognitive changes (awareness, self reflection, and objective appraisal of the relationship between symptoms fluctuations and situational influences) critical to self regulation,^{1646, 47}. The cognitive demands of conducting a functional analysis goes beyond the often recommended task of tracking daily symptoms. Successful completion of self monitoring may reveal interactive patterns of cognitions, bodily sensations, emotions, behaviors and the external cues that trigger these response, which sets the stage for self initiated behavioral change. Assignment of self monitoring is a simple, efficient, and potentially beneficial technique that medically oriented IBS practitioners could easily adopt in practices where behavioral medicine treatments are not routinely available.

There are important limitations to this study. As is the case in many psychotherapy trials, our sample included subjects who volunteered for a behavioral treatment for a medical problem. It is possible that our subjects were more psychologically minded, motivated and open to a biobehavioral formulation of their condition than those who did not seek psychological treatment for their IBS. While we did identify differences between rapid responders and non rapid responders on key clinical parameters (e.g. GI symptom relief/ improvement, quality of life), our major findings may not necessarily generalize to a broader set of treatment seeking IBS. This trial was designed as a feasibility study and therefore not powered to detect differences between doses of CBT treatments on rapid response. Whether rapid response is (1) more likely to occur in a brief, home based or more intensive, clinic

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based form of CBT and (2) is unique to CBT (vs. common ingredients of therapies including

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pharmacological ones⁴⁸) is an important task of a larger RCT.

Abbreviations

RR	rapid responder
NRR	non-rapid responder
CBT	cognitive behavioral therapy
QOL	quality of life

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Lackner et al.

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Table 1

Baseline Characteristics of Study Sample

	Rapid Responders (N = 21)	Non Rapid Responders (N= 50)
Age	47.3 (17.7)	46.0 (16.2)
% Female [*]	100%	80%
Education		
Some High School	1	1
High School Grad	2	4
Some College	4	8
College Degree	8	17
Some Post-Grad	1	4
Master's Degree	5	11
Doctoral Degree	0	5
Marital Status		
Single	5	12
Married	8	26
Divorced	4	10
Widowed	2	0
Co-habitating	2	2
Ethnicity		
Caucasian	20	47
Asian-American	0	1
African-American	1	1
Hispanic	0	1
BSI		
Anxiety	57.9 (9.2)	56.6 (10.3)
Depression	55.8 (10.8)	55.3 (9.6)
Somatization	59.3 (7.8)	59.3 (9.7)
Overall Distress	60.0 (8.7)	58.1 (9.3)

Note:

*p < .05

** p < .01

Table 2

Rapid Responders and Non Rapid Responders Over Time on Key Clinical Variables

	Pre-Treatment		Post-Tx		3-Month Post-Tx	Tx
	RR	NRR	RR	NRR	RR	NRR
	M (S.D.)					
IBS-LOC						
Internal	36.7 (10.6) ^{a1}	38.6 (9.8) ^{c1}	47.6 (7.5) ^{b2}	42.3 (10.4) ^{d3}	45.7 (8.4) ^{b4}	41.9 (10.5) ^{d4}
Chance	33.4 (9.4) ^{a1}	32.2 (8.5) ^{c1}	18.8 (7.1) ^{b2}	25.2 (11.4) ^{d3}	19.1 (8.2) ^{b2}	25.8 (10.4) ^{d3}
Health Care	$26.1 (6.9)^{al}$	29.1 (7.6) ^{c1}	22.3 (9.2) ^{b2}	25.3 (8.6) ^{d2}	20.7 (8.4) ^{b3}	25.8 (8.4) ^{d4}
IBS-SE	96.5 (25.0) ^{a1}	100.2 (25.0) ^{c1}	152.5 (18.1) ^{b2}	131.7 (33.1) ^{d3}	146.7 (19.9) ^{b2}	127.8 (32.7) ^{d3}
TSRQ-IBS						
Autonomous	39.4 (2.6) ^{a1}	35.7 (6.4) ^{c2}	39.3 (3.6)a3	37.8 (5.6) ^{c3}	$39.4 (4.1)^{a4}$	37.1 (5.8) ^{c4}
Control	$14.6 \ (6.8)^{al}$	13.3 (6.6) ^{c1}	16.3 (8.9)a3	$13.1 \ (6.7)^{c3}$	$15.6(9.1)^{a4}$	13.5 (7.1) ^{c4}
Amotivation	3.5 (1.4) ^{a1}	5.4 (3.5) ^{c2}	5.1 (3.1) ^{b3}	5.4 (3.8) ^{c3}	5.1 (3.0) ^{b4}	5.2 (3.6) ^{c4}
IBS-QOL	$49.0(21.1)^{a1}$	60.6 (17.7) ^{c2}	69.4 (16.2) ^{b2}	73.3 (17.7) ^{c2}	71.0 (17.5) ^{b2}	73.0 (18.2) ^{c2}
IBS-SSS	329.9 (63.5) ^{al}	278.4 (79.9) ^{c2}	127.2 (58.5) ^{b3}	215.2 (96.3) ^{d4}	131.7 (66.4) ^{b3}	214.1 (97.4) ^{d4}

Note. Within group values with similar alphabetic superscripts for each measure are statistically equal. Between group values with similar numeric superscripts are statistically equal at each phase of administration. IBS-LOC = IBS Locus of Control; IBS-SE = IBS Management Self Efficacy Scale; IBS-SSS = IBS Symptom Severity Scale; TSRQ = Treatment Self Regulation Questionnaire for IBS; IBS-QOL = IBS Quality of Life