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Pilot study of Acceptance and Commitment Therapy for Irritable Bowel Syndrome

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TITLE: A pilot study of Acceptance and Commitment Therapy (ACT) for Irritable Bowel Syndrome (IBS) – A preliminary analysis of treatment outcomes and processes of change

Abstract

Objective: To investigate the efficacy and proposed processes of change of ACT in improving the outcomes of IBS. Methods: Fifty six consecutive patients recruited from a specialist clinic were included in the study and completed an ACT treatment protocol (one day group workshop plus self-help manual). Assessments of process (acceptance of IBS) and outcome variables (symptom severity, avoidance behaviours, quality of life and gastrointestinal anxiety) were carried at 4 time points (assessment, pre-treatment, post-treatment, follow-up). Results: A significant increase in the acceptance of IBS and improvement in all outcome variables was observed from pre- to post-treatment and follow-up (effect sizes medium to large). Improvements in all outcomes were associated with increases in acceptance of IBS. Changes in acceptance of IBS from pre- to post-treatment were a significant predictor of improvements in outcomes from pre-treatment to follow-up. Conclusions: Results support the efficacy of a brief ACT protocol in improving IBS outcomes and maintaining therapy effects at 6 month follow-up. Preliminary support for the treatment process proposed was also found.

KEYWORDS: IBS, Psychotherapy, Experiential Avoidance, ACT

KEYPOINTS:

1. ACT seems to be efficacious in improving IBS outcomes
2. The therapeutic effects are maintained at 6 month follow-up
3. ACT seems to work through the proposed mechanism of increasing acceptance of IBS

Introduction

With an estimated prevalence of 5-11% in the general population, Irritable Bowel Syndrome (IBS) is one of the most common functional gastrointestinal disorders in the world (Spiller et al., 2007). Based on the Rome III criteria, an IBS diagnosis includes abdominal pain/discomfort associated with altered bowel habit and stool consistency (Longstreth et al., 2006). IBS symptoms tend to be experienced intermittently with periods of remission (Spiller et al., 2007). IBS tends to be chronic and to impair the patient's quality of life when compared to healthy controls (Halder et al., 2004) or to other long-term illnesses such as asthma (Frank et al., 2002). Psychosocial factors (cognitive and emotional) have shown to significantly contribute to patient suffering (Levy et al., 2006) beyond physical symptoms. Patients report thoughts of worry about the symptoms, their consequences and duration, and experiences of anxiety, depression and shame (Schneider & Fletcher, 2008). Most commonly reported is the phenomenon of gastrointestinal specific anxiety (GSA): "the cognitive, affective and behavioural response stemming from fear of GI sensations, symptoms, and the context in which these visceral sensations and symptoms occur" (Labus, Mayer, Chang, Bolus, & Naliboff, 2007). GSA is a key feature in IBS symptom maintenance, by acting as an endogenous stressor, and higher levels of GSA have consistently been shown to be related to higher symptom severity and lower quality of life (Jerndal et al., 2010; Labus et al., 2004, 2007).

Avoidance is commonly used as the main strategy to cope with the aversive illness experiences of IBS, even in the absence of symptoms (Corney & Stanton, 1990). Situations commonly avoided include: food or food related situations; social or work related situations; leisure or travelling; personal relationships and intimate contact (Rønnevig, Vandvik, & Bergbom, 2009). Patients identify these behaviours as an essential part of the management of

their condition; however they also recognise these to be one of the main causes behind their low quality of life and psychosocial distress (Drossman et al., 2009). Recent studies have shown the use of avoidant coping in IBS to be associated with poorer quality of life, high levels of anxiety and depression (Rutter & Rutter, 2007) and to be a good predictor of psychotherapeutic treatment success (Reme, Kennedy, Jones, Darnley, & Chalder, 2010).

Although cognitive behaviour therapy (CBT) has been presented as the best evidence-based psychological treatment (Zijdenbos, Wit, Heijden, Rubin, & Quatero, 2009) for IBS, it has been shown not to be more effective than placebo (Blanchard et al., 2007) and its effects to wane at 6 months follow-up (Kennedy et al., 2006). One study also found that cognitive change (a key component of CBT) was not associated with any significant changes in IBS outcomes (Lackner et al., 2007). Therefore approaches that target mechanisms other than thought content change have been suggested, specifically Acceptance and Commitment Therapy (ACT) (Naliboff, Frese, & Rapgay, 2008).

ACT proposes that an unwillingness to contact aversive physical, cognitive and emotional experiences (also called experiential avoidance) leads to excessive attempts to try and control, change or eliminate these experiences, promoting therefore behavioural patterns that lead people away from valued activities (Hayes, Strosahl & Wilson, 1999). Ferreira et al. (2011) propose that it is the movement away from activities that are important in one's life that enhances experiences of suffering in IBS as the patient becomes stuck in a set rigid behavioural patterns that allow for less diversity of experiences, therefore curtailing the possibility of experiencing events that would be likely to enhance Quality of Life or even the symptoms themselves. ACT emphasizes the promotion of positive strategies like mindfully exposing oneself to negative private experiences (physical or psychological), choosing to accept these experiences (rather than trying to control, change or eliminate them) in the service of living a

more valued life (Hayes, Strosahl, & Wilson, 1999). Several studies have shown that increasing acceptance significantly improves outcomes in health conditions such as chronic pain (McCracken, Vowles, & Eccleston, 2005) or diabetes (Gregg, Callaghan, Hayes, & Glenn-Lawson, 2007). Two recent studies using a mindfulness and exposure ACT consistent intervention for IBS were found to be effective at improving symptoms alongside with improvements in quality of life and GSA (Ljótsson, Andréewitch, et al., 2010; Ljótsson, Falk, et al., 2010). However these studies did not assess whether the improvements in outcomes were associated with changes in processes such as acceptance or mindfulness.

With high human resource and economic costs, more emphasis is being put on the possibility of IBS patients self-managing their condition with minimal health care provider contact. Self-Help interventions such as psychological self-management are a cost-effective way to provide patients with the skills to manage their condition (Dorn, 2010). ACT has been shown to be effectively delivered in self-help formats in several studies (e.g. Gregg et al., 2007; Lillis, Hayes, Bunting, & Masuda, 2009).

The main aim of this study was to examine if an ACT protocol for IBS (with a self-management component) would improve IBS acceptance and decrease symptom severity, impact of IBS on quality of life, use of avoidant behaviours and GSA. Outcomes were evaluated both at post-treatment and at 6 month follow-up. The secondary purpose of this study was to conduct a treatment process analysis. According to the ACT model it was hypothesized that changes in IBS acceptance at post-treatment would predict changes in all outcomes at follow-up beyond the effects of demographic variables or changes in symptom severity.

Method

Participants

Participants were recruited in Edinburgh, Scotland, from a Gastroenterology outpatient clinic specialized in motility disorders between April 2009 and February 2010. Patients are usually

in the refractory spectrum of IBS, that is, they have had at least 12 months of primary care support with no significant improvement. A gastroenterology consultant (Author4) confirmed IBS diagnosis using both clinical interview and the Rome III criteria (Longstreth et al., 2006) as suggested by the British Society of Gastroenterology (Spiller et al., 2007). Exclusion criteria included pregnancy, breastfeeding, symptoms suggestive of inflammatory or neoplastic disorder, and cognitive impairment.

A total of 121 patients were referred to the study with 42 immediately declining to participate. Of the remaining 79, twenty two did not attend the group session. Reasons for non-attendance included: incompatibility of schedule, being ill or poor accessibility. One patient out of the 57 that attended the group session asked to be excluded from the study due to sudden illness. Figure 1 displays an overview of the flow of participants through the study.

This study included 56 individuals who attended the treatment session and completed post-treatment and/or 6 month follow-up measures. Participants were predominantly female (N=52), a common feature of IBS research within tertiary settings (Frissora & Koch, 2005). The mean age was 47.6 years (SD = 13.0; range 20-71) and mean time of IBS suffering was 8.7 years (SD = 8.3; range 1-30). Most participants (67.9%) had (or were currently studying for) a higher education degree while the rest had secondary education. Most were married or cohabiting (55.4%), whilst the rest were single (23.2%), divorced or separated (19.6%), or widowed (1.8%). The most frequent form of IBS was a mixed type (58.9%), alternating between diarrhoea and constipation, followed by diarrhoea predominant (21.4%), constipation predominant (8.9%) and the remainder undifferentiated type (see Longstreth et al., 2006 for IBS sub-classifications).

The local ethics committee approved the study protocol and patients gave written informed consent prior to enrolment (approval number 08/S1103/67).

Measures

Participants completed self-report assessment instruments at 4 time points: T1-assessment; T2-pre-treatment; T3-post-treatment and T4 – six month follow-up. T2 measures were collected on the day the participants came for the group session, before this began. Average time between assessment and pre-treatment was 55 days (SD = 13.2). T3 measures were collected two months after the group session (expected amount of time that would take for patients to work through the self-help manual given at the end of the group session).

Demographic variables of gender, age, education, marital status and length of illness were collected via an ad-hoc questionnaire. IBS status and type of IBS was collected from the ROME-III criteria IBS module (Longstreth et al., 2006). Treatment compliance was checked via a question in the T3 and T4 questionnaire packs regarding the use of the self-help manual. Assessment instruments relating to the key outcome and process variables were collected at all time points and included the following:

IBS Acceptance and Action Questionnaire (IBSAAQ)

The IBSAAQ is 20 item scale that assesses the acceptance of IBS. The items explore the main factors of willingness to experience difficult IBS experiences without the need to control or change them and engagement with valued activities in the presence of IBS aversive experiences. Higher scores indicate greater acceptance. This scale has shown to have good reliability ($\alpha = .89$) and good validity (Ferreira, Eugenicos, Morris, & Gillanders, 2012).

Irritable Bowel Syndrome Symptom Severity Scale (IBSSSS)

The IBSSSS (Francis, Morris, & Whorwell, 1997) is a symptom severity assessment composed of 5 questions (scored from 0-100) that assess Pain (severity and duration), Distension, Bowel Satisfaction and Interference with Life Activities. The maximum score is 500 and patients may be considered to have mild IBS (75–174), moderate IBS (175–299) or severe IBS (300–500). Scores below 75 indicate normal bowel function. This scale has been shown to have satisfactory reliability and to be sensitive to change (Gonsalkorale, Miller, Afzal, & Whorwell, 2003).

Irritable Bowel Syndrome impact on Quality of Life Scale (IBS36)

The IBS36 is a 36 item illness specific measure of Quality of Life that assesses the impact of IBS on quality of life in areas as diverse as food, symptoms, family relations, emotional impact, work/school/daily activities impact, social impact, sleep/fatigue, and sexual relations. Each question is scored on a 7 point Likert-type scale ranging between 0 (“Never”) and 6 (“Always”) with higher scores indicating greater impact on Quality of Life. The scale has a high internal consistency ($\alpha = 0.95$), high test-retest reliability and is responsive to change (Groll et al., 2002)

Irritable Bowel Syndrome-Behavioural responses questionnaire (IBS-BRQ)

The IBS-BRQ assesses the frequency of use of specific avoidant coping behaviours by IBS patients. Twenty eight coping behaviours are described and scored on a Likert scale from 1 (“Never”) to 7 (“Always”) indicating how often the behaviour is carried out. The items cover situations such as the avoidance of certain foods, social situations, intimate situations, exercise or work. Other situations relate to efforts to control the bowel function by using medication, food or cigarettes or by changing toilet habits. Higher scores indicate more use of attempts to

control symptoms. This scale has a good internal consistency ($\alpha=.86$) and validity (Reme, Darnley, Kennedy, & Chalder, 2010).

Visceral Sensitivity Index (VSI)

The VSI is a 15 item scale that assesses GSA, that is, fear, anxiety and hyper-vigilance responses to common GI specific sensations (Labus et al., 2004). Each item asks the responder to state how much he/she agrees (“Strongly agree” – 1, “Strongly Disagree” - 6) with the statement presented. The items are then reverse scored, and summed to yield a possible range of scores between 0 (no GSA) to 75 (severe GSA). The scale has good internal consistency (Cronbach's $\alpha = 0.93$) and validity (Labus et al., 2007).

Treatment

The treatment consisted of two elements:

1. Attending a one day group session of ACT for IBS. All sessions were delivered by two trained clinical psychologists (N.B.F and D.G.) and lasted approximately 6 hours, divided into four 1.5 hours blocks. Each group session was attended by 6-12 participants
2. Working with a self-help manual of ACT for IBS. At the end of the group session participants were given a self-help manual to work with for the following 2 months. During this time one of the researchers (N.B.F.) would make 2 telephone calls to provide any additional support in the use of the manual.

Both the session and the manual had a similar structure in terms of content and were based on the ACT model (See Table 1 for more information). A series of metaphors, experiential and exposure exercises were developed to target the main processes of ACT. The main aim of the treatment was to improve IBS outcomes by increasing psychological flexibility. This mainly

involved undermining experiential avoidance and promoting acceptance of IBS aversive experiences (physical and psychological) within the context of living a more successful life according to one's own values. Individual sections of treatment focused on more particular aspects of the model. The first section addressed basic education about IBS and the biopsychosocial model. This was followed by an analysis of how useful control strategies had been for relief of aversive IBS experiences, both on the short and long term and how this had impacted their quality of life. Patients were then led through a series of exercises designed to clarify and contact their valued life directions with particular attention paid to how experiential avoidance had got in the way of living these values. A series of mindfulness based exercises were then used to promote present moment and self-as-observer awareness. A series of metaphors and exercises were then used to promote cognitive defusion (i.e. distancing from thoughts that might influence behaviour in a non-valued direction) and acceptance of IBS (i.e. willingness to contact aversive IBS experiences). Finally, participants were asked to make a plan of action directed at performing values consistent behaviours. This plan included the use of exposure to difficult trigger situations while acting in a values consistent manner. The session was essentially used to familiarize the patients with the ACT model. The self-help manual contained all the material used in the session and more exercises consistent with the model and provided the main treatment support. It included also 2 CD's with some exercises in audio format.

None of the content of the group session or the manual was designed or directed at removing, controlling or altering physical symptoms or distressing cognitive content, but rather at promoting in patients a new relationship with these experiences. The main delivery style of this content was experiential rather than didactic and no elements of cognitive restructuring or relaxation training were explicitly addressed. The treatment philosophy and methods were

congruent with similar successful ACT protocols previously used in chronic illness settings such as chronic pain (McCracken et al., 2005) and diabetes (Gregg et al., 2007).

Treatment fidelity was maintained by using a session protocol and producing a self-help manual. Detailed information on the session protocol can be found in the Association for Contextual Behavioural Science website (<http://tinyurl.com/buklhjy>) and the manual is now commercially available (Ferreira & Gillanders, 2012).

Statistical analysis

Preliminary analyses investigated possible differences in demographic, outcome and process measures between participants who completed measures at all time points and those who missed at least one time point. We used paired-samples t-tests to investigate improvements over time for all variables and within-subject Cohen's *d* (Cohen, 1988) effect sizes were calculated for the changes between pre- and post-treatment, and between pre-treatment and follow-up. Intent to treat (ITT) analyses are reported with the data of patients who attended the treatment session (missing either T3 or T4 measures) using the Last Observation Carried Forward (LOCF) imputation method. Treatment compliance was described by percentage of patients who reported making use of the self-help manual at post-treatment and follow-up. Descriptive analyses investigated changes in IBS status and transitions between symptom severity descriptor groups at follow-up. A set of hierarchical multiple regressions assessed the ability of the change score in the process measure (pre- to post-treatment) to account for variance in the change scores from the outcome variables (pre-treatment to follow-up) while controlling for relevant demographic variables and symptom severity (pre to post-treatment). All statistical analyses were conducted using SPSS19.0.

Results

Preliminary analyses

A series of *t*-tests or non-parametric equivalents (Mann-Whitney U, Pearson χ^2 , Fisher's exact test) investigated possible differences between participants who completed measures at all time points ($n=36$) and those who missed at least one time point ($N=20$). No differences were found (all $p<.05$) for any of the demographic variables. Regarding the process and outcome variables there was only a marginally significant difference for GSA ($t=2.05$, $p=0.46$) with non-completers reporting higher GSA.

Impact of treatment

Table 2 presents a summary of all outcome and process measures at assessment, pre-treatment, post-treatment and 6 month follow-up. There were no significant changes in the baseline period, all $t(55)<1.61$, all $p>.05$. Between pre- and post-treatment, there was a significant improvement in all outcomes, all $t(55) > 3.13$, all $p<.01$, with a small to moderate reduction in use of avoidant behaviours ($d=.32$), a moderate reduction in symptom severity ($d=.41$) and in IBS impact on quality of life ($d=.41$), and a large reduction in GSA ($d=.76$). IBS acceptance significantly increased, $t(55)=5.09$, $p<.001$, although the effect size was only small to moderate ($d=.32$). The same pattern of improvement in all outcome variables was observed for the period between pre-treatment and follow-up (all $t(55)>3.66$, all $p\leq.001$), with a small to moderate effect size for the use of avoidant behaviours ($d=.39$); a moderate effect size for symptom severity ($d=.47$) and IBS impact on quality of life ($d=.55$); and a large effect size for GSA ($d=1.10$). There was also a significant increase in IBS acceptance, $t(55)=6.38$, $p<.001$ with a moderate effect size ($d=.50$). These results suggest that treatment had an impact on all outcome and process variables, and that the magnitude of impact increases through time.

Treatment compliance

At post-treatment 82.2% (n=46) of patients reported to have used the manual. At 6 month follow-up 70% (n=40) of patients were still making regular use of the manual. Higher frequency of use of the workbook was significantly associated with greater reductions in GSA ($r=.31$; $p=.03$), but not with the remaining outcome or process variables.

IBS status and symptom severity changes at 6 month follow-up

At 6 month follow-up, 11 patients (19.6%) no longer met the criteria for IBS as assessed by the ROME III criteria IBS module. Also, 35% (n=20) of patients had moved to a lower categorization of their symptom severity (e.g. from severe to moderate).

Treatment Process analysis

Hierarchical multiple regressions were carried out to investigate the unique contribution of the residualized change score of IBS acceptance from pre- to post-treatment in accounting for variance in the change scores of outcome measures from pre-treatment to follow-up. At the first step, demographic variables were tested for entry as a block using the stepwise method and retained based on statistical criteria (probability of F to enter $p<.05$ and to remove, $p>.10$). On the second step, symptom severity was entered to statistically control its contribution to the explained variance in the changes in outcomes. This was done due to IBS symptom fluctuation over time (Spiller et al., 2007). Residualized change score of IBS acceptance from pre- to post-treatment was entered into the equation as the final step. As shown in Table 3 most background variables had no significant contribution to the explained variance of any of the outcomes, except for education accounting some variance in the change score of GSA (however this became non-significant when accounting for IBS acceptance). When changes in symptom

severity from pre- to post-treatment were entered as a second step, these accounted for an average of 16% of explained variance across all outcomes. Adding the changes in the process measure of acceptance as a final step resulted in a significant (all $p < .05$) increment of the total variance explained by the equations with an average total of 32% (range 17% IBS impact on quality of life to 40% on use of avoidant behaviours). IBS acceptance contributed with an average 14.3% of the variance in all outcome measures, even after controlling for the change in symptom severity. It is interesting to note that although on its own symptom severity made a significant contribution to the explained variance of all outcomes, this became non-significant ($p > .05$ for all β) once IBS acceptance was entered in the model. Therefore IBS acceptance was the only variable to make a unique significant contribution in accounting for changes in the outcome variables.

Discussion

In this study we set out to evaluate the impact that an ACT protocol promoting IBS acceptance (delivered as a 1 day group session plus self-help manual) would have on IBS outcomes. During the baseline period, no significant changes were detected in any of the outcomes. Significant improvements in symptom severity, IBS impact on quality of life, use of avoidant behaviours and GSA were observed immediately at post-treatment and at 6 month follow-up. Effect-sizes were between small to medium at post-treatment but increased to medium at follow-up. The exception was GSA, for which a very large effect-size was immediately observed after treatment and that increased even further at follow-up. These results support the findings of two recent studies evaluating the efficacy of ACT informed interventions in improving IBS outcomes (Ljótsson, Andréewitch, et al., 2010; Ljótsson, Falk, et al., 2010) and also add to the evidence base of psychological approaches for IBS (Zijdenbos et al., 2009).

Regarding IBS acceptance which was the main target of the intervention, this initially had a small effect size change however 6 months after treatment it had increased to a medium level. This seems to be in line with ACT's proposal that acceptance is defined as a behaviour that is passable of being trained, therefore passable to grow with continuous use (Hayes et al., 1999). Similar increases in acceptance over time have been previously observed in chronic pain (McCracken & Gutiérrez-Martínez, 2011).

Although the efficacy of ACT consistent interventions has already been reported in previous studies (Ljótsson, Andréewitch, et al., 2010; Ljótsson, Falk, et al., 2010), these did not address the issues of process of change. This study shows that changes in IBS acceptance from pre- to post-treatment were a significant predictor of all outcomes changes from pre-treatment to follow-up even when possible fluctuations in symptom severity were accounted for. In fact, changes in symptom severity lost their significance in explaining variance in the changes in outcomes when IBS acceptance was accounted for. Taken together, these results seem to suggest that the hypothesised treatment process, in which targeting acceptance will lead to improvements in outcomes, is valid. This study further supports the growing literature of the efficacy of ACT interventions through their hypothesized processes in health contexts (Gregg et al., 2007; McCracken & Gutiérrez-Martínez, 2011).

The use of process change analysis also sets this study apart from literature that has focused mainly on efficacy of psychological treatments for IBS. With recent challenges (Lackner et al., 2007) to the basic processes of CBT (cognitive change) it is clear how studies like this one are essential for the development of evidence-based interventions for IBS.

The large effect size of the treatment on GSA seems to suggest that re-framing the relation patients have with their GSA, by having a more accepting stance, might be one of the key aspects of treatment. Ljótsson et al. (2010) suggest these changes in how patients deal with

GSA have an impact on behaviour and quality of life, however this type of path analyses were not conducted in the present study. Also important to note is patients held their initial post-treatment effects and continued to improve at 6 month follow-up. This is consistent with the findings of Ljótsson and colleagues (2010) at 3 month follow-up and with the behavioural tenets of ACT, in which it is reasonable to expect that a continuous engagement with accepting and valued behavioural patterns will lead to better outcomes therefore sustaining the effects of treatment by the positive consequences of these new behavioural patterns. Finally it is also important to highlight that improvements were also clinically significant in some cases, with almost 20% of patients not meeting criteria for diagnosis at follow-up and 35% of patients improving their symptom severity classification. Although symptom reduction is not a key target in ACT, it is not uncommon for ACT studies to report these reductions (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). This is thought to occur because ACT interventions look to disturb the naturally occurring “Aversive experience → Control behaviour → Immediate relief” cycle by introducing acceptance as an alternative. So it is thought that some of the aversive features of the symptoms might be removed by lowering their functional importance, therefore resulting in a lower reporting of symptoms.

Empirical support for psychological interventions for IBS is growing (Zijdenbos, Wit, Heijden, Rubin, & Quartero, 2009), however, due to economic costs self-management approaches are being put forward as viable alternatives (Dorn, 2010). The results presented here are encouraging as the intervention designed can be delivered in a brief (6 hours) group session and followed by a self-management program, therefore reducing the number of therapist contact hours. However, a full economic cost analysis would have to be conducted in the future to ascertain the economic benefits of this approach. Further to that, there is the necessity of

evaluating whether the group session is an essential part of the treatment or whether patients are likely to benefit equally from the self-management component only.

Some limitations include the fact that the study used a self-selected sample (only 46% of patients approached agreed to participate in the study) that was predominantly female and had attended higher education, therefore curtailing any generalization of the results to the whole population of IBS patients. Future studies should address issue of acceptability and efficacy of this approach with male (commonly underrepresented in IBS studies) or patients with lower attained education (given the potential complexity of the self-help materials presented). However this sampling method could be seen as a strength as it was done in a naturalistic context and allowed for a comprehensive assessment using gold standard criteria (Spiller et al., 2007). The second limitation pertains to the absence of a formal control group condition, however using a baseline period similar to the intervention length could be seen as an adequate control as it is unlikely that changes post-treatment could be accounted by passage of time or coincidental events at the time of treatment in a population that had not benefitted from previous standard care approaches. A third limitation would be that only one of the six proposed ACT processes (Acceptance) was assessed in this study. Although, as reported by Ferreira et al. (2012), the measure used (IBSAAQ) encompasses elements of IBS willingness and engagement with important life activities future studies could investigate the role of processes such as present moment awareness (using a mindfulness scale like the Five Facet Mindfulness Questionnaire; Baer, et al., 2006) or Cognitive Fusion (using the Cognitive Fusion Questionnaire; Gillanders et a., 2014). Further limitations include the lack of a more comprehensive assessment of treatment fidelity or the fact that two of the study authors conducted all the interventions. Therefore, potential issues of bias in the delivery and assessment of the intervention should be accounted for in future studies. Finally, it should be

noted that although the pilot data presented here suggests that changes in acceptance are potentially related to changes in outcomes the current design and analyses cannot provide a robust proof of this mechanism of action.

Regarding clinical applications, data seems to support the effectiveness of this intervention, but also suggested that it worked through the theoretically hypothesized processes. This study has shown that ACT has the potential to be integrated in clinical practice as an alternative form of psychological treatment that can be delivered quickly and with low costs to large number of patients attending tertiary services. This study also implies that symptom reduction might not always have to be the target of interventions with IBS populations and that targeting the relation patients have with their symptoms can be an effective way to produce changes in both physical and psychological outcomes. Alternatively this study suggests that ACT might be indicated for cases in which improvements either plateaued or were not obtained via the normal symptom focused approach. Given that implementing this intervention will potentially involve a relatively low level of human and economic investment, it is suggested that it could be made available as part of the standard treatment for these patients.

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Table 1 – Summary of treatment protocol content and how it relates to self-help manual chapters

Module	Theme(s)	Exercises/Metaphors used	Self-Help Manual Chapter
1	IBS Symptoms and Diagnosis	Psychoeducation about IBS, Brain-Gut connection and mutual influence between symptoms and emotional reactions to symptoms.	1 & 2
2	Creative Hopelessness Acceptance	Exploring the short-term and long-term effects of strategies directed at controlling/eliminating or avoiding symptoms through the “Costs of my avoidance” exercise. Introducing Acceptance as an alternative. - Chinese finger cuffs exercise - “Uncle Jack” metaphor	3 & 7

3	Values	Exploring the patient's valued paths through: <ul style="list-style-type: none"> - The compass metaphor - "100th Birthday" exercise 	4
4	Defusion	Exploring how minds work (fusion and relating): <ul style="list-style-type: none"> - 2 cavemen metaphor - "What are the numbers?" Exercise - "Mary had a little lamb" Exercise Introducing Defusion: <ul style="list-style-type: none"> - Milk, milk, milk Exercise - "Kicking your butts!" Exercise 	5
5	Defusion Observer-Self Present moment awareness	Extended version of the "Buses on the street" Exercise, used to point out the observer perspective, seeing thoughts as thoughts, and being aware of experiences here and now. Introduction to small mindfulness exercises that can be used in daily life (e.g. mindful eating).	5 & 6
6	Committed Action	Revisiting the constructs of acceptance and values to frame what you are willing to experience and what is that in service of. Filling in the "Committed Action Form" Getting participants to stand up and declare their committed action.	7 & 8

Note: All Exercises/Metaphors between inverted commas were developed by the authors for this study and can be found in "Better Living with IBS" (Ferreira & Gillanders, 2012).

Table 2. Mean values and standard deviations for all measures over time, and Cohen's *d* effect sizes for T2-T3 and T2-T4 changes

	Time Point Mean (SD)				Cohen's <i>d</i>	
	T1 Assessment	T2 Pre-treatment	T3 Post-Treatment	T4 6 Month Follow-up	T2-T3	T2-T4
Symptom Severity	264.13 (101.14)	264.55 (94.38) ^a	223.07 (107.51) ^b	214.77 (115.45) ^c	.41	.47
IBS Impact on Quality of Life	97.05 (38.56)	99.07 (37.06) ^a	81.66 (45.95) ^b	76.07 (45.64) ^c	.41	.55
IBS Avoidant Behaviours	102.10 (24.29)	102.46 (23.33) ^a	93.89 (29.27) ^b	92.28 (28.50) ^c	.32	.39
GSA	61.19 (2.02)	60.24 (2.16) ^a	53.94 (2.48) ^b	51.51 (2.63) ^c	.76	1.10
IBS Acceptance	54.86 (17.46)	56.82 (18.65) ^a	64.06 (20.17) ^b	66.64 (20.43) ^c	.32	.50

Paired samples *t*-tests significance: ^a Non-significant difference ($p > .05$) between T1 and T2; ^b Significant difference ($p < .01$) between T2 and T3;

^c Significant difference ($p \leq .001$) between T2 and T4.

Table 3. Hierarchical multiple regression analyses predicting pre- to follow-up change scores in outcome measures

Dependent variable	Step	Predictor Variables	ΔR^2	β_{final}
Impact on Quality of Life	2	Symptom Severity	.08*	-.10
	3	IBS Acceptance	.10*	.37*
Total R ²			.18*	
GSA	1	Background variables	.07*	
		Education		.09
	2	Symptom Severity	.17**	.22
	3	IBS Acceptance	.14**	-.44**
Total R ²			.38**	
IBS Avoidance Behaviours	2	Symptom Severity	.21**	-.21
	3	IBS Acceptance	.19**	.50**
Total R ²			.40**	

Notes: *p<0.05, **p<0.001. ΔR^2 is used to highlight the specific contribution each step of the regression model to the explained variance. β_{final} is the coefficient of the regression equation.