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An implementation trial of ACT-based bibliotherapy for Irritable Bowel Syndrome

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Brief Empirical Report

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An Implementation Trial of ACT-Based Bibliotherapy for Irritable Bowel Syndrome

David Gillanders[a*], Nuno Bravo Ferreira[a], Eugenia Angioni[a],

Sergio A. Carvalho[b], and Maria P. Eugenicos[c]

*Corresponding author
Email: david.gillanders@ed.ac.uk
Tel: +44(0)1316513946

[a]School of Health in Social Science, University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG. e-mail: david.gillanders@ed.ac.uk; nuno.ferreira@ed.ac.uk; s0968375@sms.ed.ac.uk

[b] Cognitive-Behavioral Center for Research and Intervention (CINEICC), School of Psychology and Education Sciences, Universidade de Coimbra, Rua do Colegio Novo, s/n 3001-802, Coimbra, Portugal. e-mail: sergio.and.carvalho@gmail.com

[c] Department of Gastroenterology, Western General Hospital, University of Edinburgh, Crewe Road South, Edinburgh EH4 2XU, UK e-mail: MP.Eugenicos@ed.ac.uk

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Abstract

Background: Irritable Bowel Syndrome is a gastrointestinal disorder that is associated with pain, discomfort, constipation and diarrhoea. It affects around 20% of adults in Western countries. Reports of distress and self-consciousness, as well as experiential and situational avoidance are common. Previous studies have shown that ACT may be effective for people with IBS.

Methods: An uncontrolled trial of ACT based bibliotherapy was undertaken in a specialist motility clinic. Outcomes were measured with standardised self-report questionnaires pre-treatment, and at two and six months. Missing data was handled using maximum likelihood imputation. Data was analysed using repeated measures ANOVA.

Results: 45 participants enrolled in the study, with 36 providing data at two months, and 24 at six months. Participants were predominantly female, with an average ten-year history of IBS, and 71% of the sample had moderate or severe symptoms. At six months,participants had improved on symptom severity ($\eta_p^2 = .09$, 90% CI = .01 - .18), GI specific anxiety ($\eta_p^2 = .07$, 90% CI = .01 - .16) and IBS willingness ($\eta_p^2 = .14$, 90% CI = .04 - .24), but had not shown behavioural changes towards greater activity, ($\eta_p^2 = .01$, 90% CI = .0 - .05) or to reduce IBS avoidance behaviours ($\eta_p^2 = .05$, 90% CI = .0 = .13). Contrary to hypothesis, intervention did not reduce the impact of IBS on quality of life($\eta_p^2 = .04$, 90% CI = .0 - .09).

Discussion: Bibliotherapy interventions may be useful for people with refractory IBS, though greater contact and structured exposure may be necessary to change behaviour. The study was limited by problems with attrition, though these data suggest future research in this area would be worthwhile.

Keywords: Irritable Bowel Syndrome, IBS, Acceptance & Commitment Therapy, ACT, Bibliotherapy, Self-Help.

Introduction

IBS is a functional gastrointestinal disorder affecting around 10 – 20% of adults in Western countries, most of whom are female (Thompson, Irvine, Pare, Ferrazzi, & Rance, 2002; Wilson, Roberts, Roalfe, Bridge, & Singh, 2004). It is characterized by abdominal pain, bloating, discomfort and changes in bowel habit (Longstreth et al., 2006; Tanaka, Kanazawa, Fukudo, & Drossman, 2011). When symptoms remain after 12 months of pharmacological treatment, IBS is considered 'refractory' (NICE, 2008). People with IBS often report embarrassment and shame, and stop socialising, withdraw from intimacy, reduce working hours and reduce participation in normal community activities (Rønnevig, Vandvik, & Bergbom, 2009; Schneider & Fletcher, 2008). IBS is associated with psychiatric disorder, with rates of 17% for major depression and 32% for generalised anxiety disorder (Lydiard, 2001).

Several psychological therapies have been trialled for IBS. Hypnotherapy and cognitive behavioural therapy (CBT) have the strongest evidence (Lee, Choi, & Choi, 2014; Li, Xiong, Zhang, Yu, & Chen, 2014). The focus of hypnotherapy is upon reduction of stress via relaxation and suggestion, leading to better symptom control (Whorwell, 2005; Webb, Kukuruzovic, Catto-Smith, & Sawyer, 2007). Recent meta analyses show hypnotherapy to be effective at short term, but the pattern of results is not conclusive as to the effects at follow-up. In addition, mechanisms of action are unclear (Lee et al., 2014).

In CBT for IBS, patients are educated about the physiological, cognitive, behavioural and emotional influences on their condition, and are taught self-control strategies to enhance coping behaviours, reduce stress and alter dysfunctional thinking about IBS. Meta-analyses have shown that CBT is effective for IBS, when compared to non-active controls, but not superior to standard medical care or basic support (Li et al., 2014; Lackner, et al., 2007).).

CBT has been used to design self-help interventions for IBS. Hunt, Ertel, Coello, & Rodriguez (2015) reported benefits as did Sanders, Blanchard, & Sykes (2007), though attrition was high in both studies. Everitt, et al. (2010) found a web based self-help intervention to be comparable to medication, but neither outperformed a 'no treatment' control condition.

What is shared in both CBT and hypnotherapy for IBS is a focus on gaining control over IBS symptoms. For many patients, not only does this strategy not reliably lead to symptom control, it has the unintended consequence of further restricting normal functioning (Ferreira, Eugenicos, Morris, & Gillanders, 2011). Acceptance and Commitment Therapy (ACT) (Hayes, Strosahl, & Wilson, 2012) challenges the need to use control-based strategies. Instead, client and therapist work together to construct overarching life goals, and behavioural strategies are used to move towards these goals. Mindfulness, acceptance and perspective taking skills are taught to facilitate goal oriented behaviour in the presence of difficult symptoms, thoughts and emotions; hence Acceptance *and* Commitment.

ACT is effective for other long-term health conditions, including chronic pain (Graham, Gouick, Krahé, & Gillanders, 2016; Hann & McCracken, 2014) and there is preliminary evidence that ACT may be applicable to IBS. Whilst not described as ACT, Ljótsson et al. (2010, 2011) reported benefits of an internet delivered exposure and mindfulness treatment. Treatment was highly structured, was supported by an online peer chat room and asynchronous weekly therapist support. It used mindfulness to facilitate patients' exposure to

avoided situations and sensations, whilst reducing control oriented behaviours. Large effect sizes were reported across measures of symptoms and quality of life, with gains maintained at 15 to 18 month follow up (Ljótsson et al., 2011). Ljótsson and colleagues' study reflected a trend within other areas of CBT to use principles such as exposure and mindfulness, without naming the intervention as 'ACT' (e.g. Arch & Craske, 2008). Such a strategy has allowed studies to remain identified with the broader CBT tradition whilst incorporating elements of the 'third wave'.

Finally, Ferreira, Gillanders, Morris, & Eugenicos (in press) reported a trial of ACT for IBS. Participants took part in a one-day group workshop, combined with a self-help book and audio CD to modify their approach to IBS (Ferreira & Gillanders, 2012). Ferreira and colleagues showed that participants' acceptance of IBS increased, and that this mediated improvements in symptoms, stress, quality of life and avoidance behaviours.

The current study aimed to extend Ferreira et al. (in press) by testing the impact of bibliotherapy alone. The primary outcome was the impact of IBS on quality of life. The book explicitly targeted avoidance and acceptance and so it was predicted that the intervention would lead to improvements in both. If participants began to live more effectively with IBS, improvements in gastrointestinal specific anxiety and IBS symptom severity were also predicted. These improvements were expected to be seen at the two-month assessment and to have continued to improve at the six-month follow up.

Materials and Methods

Design
An uncontrolled implementation trial of self-help was conducted in a specialist motility clinic. Participants were new or return attenders who were diagnosed with refractory IBS by a consultant gastroenterologist with expertise in IBS (author M.E.), using ROME III criteria (Longstreth et al., 2006). Participants completed standardised self-report measures prior to intervention, at two months and six months later. The study was designed and conducted in accordance with the Code of Human Research Ethics of the British Psychological Society (British Psychological Society, 2014) and approved by a UK National Health Service Local Research Ethics Committee (Approval reference #12/SS/0133).

Sample size
The study by Ferreira et al. (in press), using self-help and a group workshop showed an effect size of .55 for the primary outcome of IBS Quality of Life. The GLIMMPSE (http://glimmpse.samplesizeshop.org) software was used to calculate a sample size sufficient to detect equivalent effects (Guo, Logan, Glueck, & Muller, 2013). At an alpha of .05, 23 participants would be needed to have 80% power to detect such effects. More conservatively, 81 participants would have 80% power to detect effect sizes of .3 and above.

Recruitment
Recruitment took place between December 2014 and July 2015. Inclusion criteria were: Diagnosis of IBS, aged 18 years and older, and fluency in English. Exclusion criteria were: Women who were pregnant or breastfeeding, symptoms suggestive of inflammatory bowel disease (or similar), and inability to understand study consent procedure. These criteria were assessed by both the consultant gastroenterologist and the research assistant (author E.A.). Eligible patients met with the research assistant, who took written informed consent and administered pre-intervention measures. Some participants took the information sheets and

questionnaires away to consider involvement and were given prepaid postal envelopes to return assessment measures. Follow up measures were posted to participants at two and six months, along with a pre-paid return envelope. Participants were prompted by telephone to return questionnaires, when necessary.

Intervention
The intervention consisted of giving participants the self-help book "Better Living with IBS" (Ferreira & Gillanders, 2012) and the accompanying audio exercises on CD. The book contained information about IBS, stress and symptoms, exercises to reflect on use of control strategies, values exercises, and exercises to develop skills in mindfulness, defusion and willingness. Participants were encouraged to engage in the book, by their consultant in gastroenterology and by the research assistant. No specific protocol was used for this encouragement, instead the benefits of regular practice with the intervention were outlined. Participants were asked to work through the book at their own pace and they would likely complete all sections within the first two months. Participants received two telephone calls from the research assistant during the first and second months following recruitment. They typically lasted between five and 20 minutes and covered practical problems of engagement, clarification of information in the book, and encouragement to use the intervention strategies. All participants reported using the book and exercises at least to some degree, though this was not formally measured.

Measures

Demographic Variables
At pre-treatment, information was collected on age, sex, marital status, education and duration of IBS symptoms.

ROME III Questionnaire IBS Module (ROMEIII)

The IBS module of the ROME III questionnaire (Longstreth et al., 2006) contains 10 questions to aid diagnosis of IBS and determine subtype: Diarrhoea predominant, constipation predominant, mixed or unspecified.

IBS36 Impact on Quality of Life Scale (IBS36)

The primary outcome was the IBS36 (Groll et al., 2002). It is a 36-item measure of the impact of IBS on eating, social relationships, emotions, daily activities, school or employment, fatigue, sleep disturbance and sexual functioning. Higher scores represent greater impact of IBS on Quality of Life, i.e. worse functioning. Cronbach's α in the current sample was .95.

Visceral Sensitivity Index (VSI)

A secondary outcome, the VSI measured gastrointestinal specific anxiety (Labus et al., 2004). It has 15 items that assess cognitive and behavioural aspects of fear, anxiety and hypervigilance to gastrointestinal (GI) sensations. Higher scores represent greater GI specific anxiety. Cronbach's α in the current sample was .92.

IBS Symptom Severity Scale (IBS-SSS)

The IBS-SSS (Francis, Morris, & Whorwell, 1997) contains five items assessing pain severity, pain duration, bowel distension, satisfaction with bowel habit and impact on quality of life. The IBS-SSS was considered a secondary outcome. Cronbach's α in the current sample was .82.

IBS Acceptance and Action Questionnaire (IBS-AAQ)

The IBS-AAQ is a 19-item measure of acceptance of IBS (Ferreira, Eugenicos, Morris, & Gillanders, 2012). It was considered a process measure. It contains two factors: Activity Engagement and IBS Willingness. Higher scores represent greater acceptance. Cronbach's α in the current sample was .92 for the total scale, .89 for activity engagement and .89 for IBS willingness.

IBS Behavioural Response Questionnaire (IBS-BRQ)

The IBS-BRQ (Reme, Darnley, Kennedy, & Chalder, 2010) is a 26-item scale that assesses unhelpful behavioural responses to IBS, such as behaviours to control IBS, eating specific foods, avoiding certain foods, avoidance of normal activities, work, socialising, making plans, as well as repeated asking for reassurance, being hypervigilant to symptoms and the risk of bowel accidents etc. It was considered a further process measure. Cronbach's α in the current sample was .90.

Analytic Plan

Data were analysed using SPSS version 20 (IBM corporation, 2011). Effect sizes and confidence intervals were calculated using the MBESS package for R (R Core Team, 2016; Kelley, 2016). Data were tabulated by missing patterns and cases and visually assessed for missing data patterns. Histograms and distribution statistics were used to confirm parametric assumptions. Baseline data were examined between completers and those lost to follow up using independent t-tests and chi-square tests. Intervention effectiveness was analysed using repeated measures analysis of variance (rmANOVA) and further probed using *t*-tests. Completer status was examined as a significant moderator of response. As it was not significant for any variable, the data were presented without this covariate analysis. A related samples McNemar test was used to ascertain if the proportion of people no longer meeting diagnostic criteria following intervention was significant.

Results

Missing Data

Within assessment phases there was no obvious pattern to missing data. Between phases however, if a participant did not provide data at post treatment they were also unlikely to provide it at follow up. In addition, completers had less severe IBS symptoms and higher levels of education at baseline. The data were considered missing at random (MAR), meaning that the probability of missing-ness is likely a function of other observed variables, though *may* not be a function of the missing data value itself (Enders, 2011). Following recommendations from Enders (2011), maximum likelihood estimation was used to impute missing data. It was chosen as it is easily implemented within SPSS, is a relatively conservative approach, and leads to similar estimates as more complex solutions such as multiple imputation (Enders, 2011).

Participants

Seventy participants met eligibility criteria and were invited to enrol in the study, forty-five participants (64.2%) agreed to take part and provided data at baseline, with 36 (80%) completing measures at two months and 24 (53.3%) at six months.

Parametric assumptions were met. Participants had been diagnosed with IBS for an average of ten years (Table 1). The ratio of females to males (87% female) is typical of the IBS population (e.g. Reme et al., 2010). Pre-treatment, two participants (4.4%) scored in the range of 'Normal Bowel Function', 11 (24.4%) reported 'Mild IBS', 21 (46.7%) reported 'Moderate IBS', and 11 (24.4%) reported 'Severe IBS'. At two months, two participants (4.4%) reported 'Normal Bowel Function', 20 (44.4%) reported 'Mild IBS', 13 (28.9%) reported 'Moderate IBS', and ten (22.2%) reported 'Severe IBS'. At six-months, four (8.9%) participants reported 'Normal Bowel Function', 16 (35.6%) reported 'Mild IBS', 15 (33.3%) reported 'Moderate IBS', and ten (22.2%) reported 'Severe IBS'. A related samples marginal homogeneity test showed that these changes were not significant at two months ($p = .07$) or at six months ($p = .10$).

Insert Table 1 here

Treatment effects

Table 2 shows the results of rmANOVA and *t*-tests. Contrary to prediction, participants did not show changes in the impact of IBS on quality of life. Participants did show improvements in GI specific anxiety, IBS symptom severity, and acceptance of IBS. The component of acceptance that reflected this change was the IBS willingness scale, and not activity engagement. Participants did not show significant changes in either activity engagement or in unhelpful behavioural responses to IBS, contrary to predictions. Finally, four (9%) participants no longer met criteria for an IBS diagnosis at Stage 3, though this change was not significant (Related samples McNemar test, $\chi^2_{(1)} = 4$, $p = .13$, *ns*).

Insert Table 2 Here

Discussion

This study investigated ACT-based self-help for participants with treatment refractory IBS. Contrary to predictions, bibliotherapy did not reduce the impact of IBS on quality of life, the primary outcome measure. The intervention did lead to changes in IBS symptom severity, GI specific anxiety (secondary outcomes), and increased acceptance of IBS (process measure). That such changes occurred with minimal therapist contact is encouraging for the potential of this low-cost intervention to benefit many patients.

Bibliotherapy did not however, lead to improvements in activity engagement or reduction of IBS avoidance behaviours. These were targets in the intervention, so it is concerning that they did not change. It is possible that further time and practice of acceptance, mindfulness and defusion skills were needed for these overt behaviours to be influenced. Bibliotherapy may have led to 'acceptance' as a change in stance or perspective on IBS, but not 'acceptance' as a behavioural choice. It is possible that from this more willing stance, 'accepting behaviour' may emerge, though given that participants were followed up at six months, this is considered less likely.

The current study built on the study of a workbook plus face to face group workshop intervention by Ferreira et al. (in press), by testing only the bibliotherapy component. Current results are comparable to the previous study in terms of improvements in symptom severity and acceptance, though the previous study produced improvements in the primary outcome of quality of life (d = .55). The previous study also showed significant reductions in behavioural avoidance (d = .39). This could suggest that public commitment is required to produce overt behaviour changes. The face to face study also produced larger reductions in GI specific anxiety (d = 1.1), suggesting that safely sharing IBS experiences is an important component. This could be considered a form of exposure.

This is consistent with the studies by Ljótsson et al. (2010, 2011), which used therapist and peer support, greater structure and more explicit exposure to a variety of avoided situations. It could be that interpersonal contact, greater structure, more explicit focus on exposure or the combination of factors is required to create changes in behavioural avoidance and quality of life. A further dismantling study by Ljótsson et al. (2014) provided evidence that structured exposure strategies are indeed key to treatment success.

There are several limitations to the current study. Firstly, the study is uncontrolled and it is possible that participants may have improved regardless of intervention. This interpretation is considered unlikely, given participants' long histories of IBS. Changes could also be due to being in a trial per se, rather than due to engagement in the intervention. A further limitation concerns sampling bias. Participants were self-selected, which may limit generalisability. A further limitation concerns attrition. Forty-seven percent of participants were lost to follow up, the conservative assumption would be that these participants did not benefit. In addition, the sample size reduced the study's power to detect smaller changes. Small samples can also lead to spurious non-null findings and to overestimation of the magnitude of effects (Button et al., 2013). Furthermore, underpowered studies can compound sampling biases that would be likely to be improved in a larger sample. This can lead to failures to replicate in future studies.

Hunt et al. (2015), reported an attrition rate of 76%, making our study favourable in comparison, and comparable to Sanders et al. (2007). It is of note that except for Everitt et al. (2010), all self-help studies in IBS suffer from problems of high attrition. For the field to progress, explicit strategies need to be developed to retain participants, without undermining the minimal contact aspect of these interventions. In addition, future research could compare pure self-help versus guided self-help.

Those lost to follow up scored higher for IBS symptom severity at baseline. It is possible that for those with more severe IBS, the bibliotherapy approach is not sufficient. A further limitation of the study is that we did not measure treatment fidelity / engagement. We therefore do not know the degree to which participants engaged in the approach and whether greater engagement lead to greater change. During telephone support, participants reported that they were using the intervention, though this was not formally measured.

The effect sizes seen in the current study, and in other self-help for IBS studies, were modest. Notwithstanding, self-help interventions appear to be achieving similar effects as medications (Everitt et al., 2010). They are low cost and easily disseminated. Given that many patients have tried unsuccessfully to treat their IBS for an average of 10 years, it is our opinion that a modest effect size is worth pursuing.

The current study does represent a first step in testing ACT based self-help for IBS, and suggests a larger, better controlled trial is needed to address the limitations outlined. Future research could also incorporate economic analyses, and could assess mediation of treatment effects by changes in process variables, such as IBS willingness.

Conclusions

Bibliotherapy for people with refractory IBS led to changes in acceptance, symptom severity and GI anxiety, but not overt behaviour changes or improved quality of life. Confidence in these findings is provisional, given the limitations, though further study is warranted.

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Table 1: Descriptives

Variable	Completers baseline $n = 24$		Lost to follow up baseline $n = 21$		$\chi^2_{(3)}$
	Frequency		Frequency		
	Female	Male	Female	Male	
Sex	20	4	19	2	.65, *ns*
Education					7.88*
None	0		1		
Primary school	1		0		
Secondary school	3		10		
College / University	19		11		
Marital Status					1.08, *ns*
Single	6		4		
Living as married	14		15		
Separated / Divorced	2		2		
Widowed	1		2		
IBS Subtype					3.4, *ns*
Diarrhoea Predominant	6		6		
Constipation Predominant	6		8		
Mixed	3		0		
Unspecified	9		7		
	Mean (*SD*)		Mean (*SD*)		$t_{(43)}$
Age (years)	55.9 (10.4)		49.3 (14.9)		1.7, *ns*
Duration of IBS (years)	11.1 (11.7)		9.4 (8.9)		.56, *ns*
IBS Symptom Severity	207.08 (97.6)		275.7 (114.2)		2.2*
IBS36 Quality of Life Impact	84.1 (44.5)		105.6 (48.8)		1.5, *ns*
IBS AAQ Total	57.4 (17.5)		51.1 (23.8)		1.0, *ns*
IBS AAQ Activity Engagement	32.5 (9.3)		27.5 (12.9)		1.5, *ns*
IBS AAQ Willingness	24.9 (10.6)		23.6 (13.1)		.37, *ns*
Visceral Sensitivity Index	38.8 (17.7)		45.2 (19.6)		1.2, *ns*
IBS Behavioural Responses Questionnaire	87.1 (27.5)		97.9 (34.2)		1.2, *ns*

*$p<.05$

Table 2: RmANOVA and *t* test analysis with maximum likelihood imputed missing data

Variable	Pre Intervention Mean (SD)	2 month follow up Mean (SD)	6 month follow up Mean (SD)	$F_{(2, 88)}$	Effect Size $(\eta_p^2)^c$ (90% CI)	Pre to 2 months $t_{(44)}$	Effect size $(d)^d$ (95%CI)	Pre to 6 months $t_{(1, 44)}$	Effect size (d) (95%CI)
IBS36 Quality of Life Impact	94.1 (47.3)	83.4 (49.7)	94.4 (68.8)	1.2, *ns*	.04 (0 - .09)	1.7, *ns*	.25 (0 - .48)	.04, *ns*	.01 0 - .20)
Visceral Sensitivity Index	41.8 (18.7)	34.6 (14.2)	40.4 (23.4)	3.5[a]*	.07 (.01-.16)	2.8**	.43 (.11 - .73)	.46, *ns*	.07 (0 - .34)
IBS Symptom Severity	239.1 (110)	202 (122.6)	206.2 (124.8)	4.5[a]*	.09 (.01-.18)	2.5*	.38 (.06 - .57)	2.2*	.33 (.02 - .53)
IBS AAQ Total	54.5 (20.6)	59.8 (14.4)	57.3 (20.7)	4.0[a]*	.08 (.01-.17)	2.7**	.46 (.06 - .47)	1.3, *ns*	.19 (0 - .35)
IBS AAQ Activity Engagement	30.2 (11.3)	30.3 (9.9)	31.0 (11.3)	.44, *ns*	.01 (0 - .05)	.15, *ns*	.01 (0 - .23)	.82, *ns*	.12 (0 - .35)
IBS AAQ Willingness	24.3 (11.7)	29.5 (7.0)	26.4 (11.9)	7.3[a]***	.14 .04 - .24)	3.8***	.65 (.21 - .76)	1.3, *ns*	.20 (0 - .43)
IBS Behavioural Responses Questionnaire	92.1 (30.9)	84.1 (34.6)	94.0 (38.8)	2.4, *ns*	.05 (0 - .13)	1.8, *ns*	.26 (0 - .53)	.37, *ns*	.06 (0 - .34)
Meets ROME III Criteria	45 / 45 100%	41 / 45 91%	41/45 91%	$\chi^2_{(1)} = 4$, [b]*p*=.13, *ns*					

n = 45, **p*<.05 **p<.01 *** *p*<.001 [a]Greenhouse-Geisser corrected [b]Related samples McNemar Test, [c]effect size conventions for η_p^2 are: small > .01, medium >.06 and large >.14 (Lackens, 2013), [d]effect size conventions for *d* are: small>.20, medium >.50, large >.80 (Cohen, 1992).