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Effectiveness of acceptance and commitment therapy for irritable bowel syndrome non-patients: A pilot randomized waiting list controlled trial



Masataka Ito^{a,*}, Takashi Muto^b

- a Graduate School of Psychology, Doshisha University, 1-3 Tatara-Miyakodani, Kyotanabe, Kyoto, Japan
- ^b Faculty of Psychology, Doshisha University, 1–3 Tatara-Miyakodani, Kyotanabe, Kyoto, Japan

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ABSTRACT

Irritable bowel syndrome (IBS) is one of the most common functional disorders, and an intervention targeting IBS non-patients (with symptoms and undiagnosed) is needed. This study examined the efficacy of acceptance and commitment therapy (ACT) in IBS non-patients. A total of 26 non-patients were randomly assigned to either an intervention group (n=14) or a waiting list group (n=12). Self-reported IBS symptom severity, quality of life, psychological distress (anxiety and depression), and psychological flexibility were assessed at three time points. The intervention group completed an ACT program consisting of a one-day group session and a two-month self-help program. This program reduced depressive mood but not symptom severity. These results suggest that this ACT program is insufficient for IBS non-patients and the intervention needs further modification.

1. Introduction

Irritable bowel syndrome (IBS) is a highly prevalent disorder, with about 11% of the adult population affected in most countries (Lovell & Ford, 2012). This disease is characterized by abdominal pain, abdominal distention, and changes in bowel habits, and it severely affects quality of life (QOL; Longstreth et al., 2006). IBS is associated with psychological factors like stress and anxiety (Spiller et al., 2007). The social impact of this disease is also notable. Although IBS is not a cause of mortality, the monetary and productivity costs relating to IBS treatment tend to be very high (Inadomi, Fennerty, & Bjorkman, 2003).

Several psychological treatments for IBS have been investigated. Among these, strong evidence has emerged for the efficacy of cognitive behavioral therapy (CBT; Zijdenbos, de Wit, van der Heijden, Rubin, & Quartero, 2009). Studies have found that effective forms of CBT exert their symptom reduction and QOL improvements by means of a reduction in visceral anxiety (Labus, Mayer, Chang, Bolus, & Naliboff, 2007).

However, there are many people with IBS symptoms who do not have an IBS diagnosis; these individuals are referred to as IBS non-patients. Cañón, Ruiz, Rondón, and Alvarado (2017) reported that the prevalence of IBS symptoms among university students and staff is 24%. Although non-patients exhibit less visceral anxiety than do patients (Labus et al., 2007), they exhibit higher levels of anxiety than do people with no IBS symptoms (Hazlett-Stevens, Craske, Mayer, Chang,

& Naliboff, 2003). Therefore, the QOL in IBS non-patients also seems to suffer (Frank et al., 2002).

There are currently no studies investigating which psychological interventions are effective for IBS non-patients. In a meta-analysis of psychological treatments for IBS patients (Zijdenbos et al., 2009), 84% of studies investigated treatments implemented as part of secondary or tertiary care, and the remainder investigated those implemented as part of primary care. Although treatment for IBS non-patients is needed because about 30% of IBS non-patients become IBS patients within three years (Fujii & Nomura, 2008), many psychological treatments for IBS only target patients with severe symptoms.

Among the various forms of CBT, we propose that ACT can function as an intervention for IBS non-patients for three reasons. First, previous studies have shown that ACT for IBS patients is effective in reducing the severity of symptoms and improving QOL (Ferreira, Gillanders, Morris, & Eugenicos, 2017; Gillanders, Ferreira, Angioni, Carvalho, & Eugenicos, 2017). Second, there is evidence suggesting that ACT is effective for subclinical cases. For example, ACT was shown to improve general mental health and reduce overall distress in non-patient college students who were at risk of mental illness (Muto, Hayes, & Jeffcoat, 2011). Third, the treatment mechanism of ACT is appropriate for IBS non-patients' characteristics. ACT aims to increase psychological flexibility, which comprises acceptance, defusion, contact with the present moment, self-as-context, values, and committed action, and to facilitate behavior that accords with one's personal values (Hayes, Strosahl, &

^{*} Corresponding author. Graduate School of Psychology, Doshisha University, 1–3 Tatara-Miyakodani, Kyotanabe, Kyoto, 610-0394, Japan. E-mail addresses: ito.mstka@gmail.com (M. Ito), tamuto@mail.doshisha.ac.jp (T. Muto).

Wilson, 2012). In IBS patients, the improvement of psychological flexibility leads to better QOL (Ferreira et al., 2017). These studies suggest that ACT may be effective for IBS non-patients in reducing the severity of symptoms and improving QOL.

The current study aimed to examine the effectiveness of ACT for IBS non-patients. If this intervention is effective for non-patients, we may expect to see improvements in symptom severity, QOL, and psychological distress, along with changes in participants' psychological flexibility.

2. Materials and methods

2.1. Participants

Participants were recruited from a university population by means of a screening survey. The screening survey used the Japanese version of the irritable bowel syndrome severity index (IBSSI; Shinozaki et al., 2006). A total of 329 undergraduate students participated in the screening survey. Those who scored above the clinical cut-off score on the IBSSI at screening (200 people) were invited to participate in the study, with 169 declining to do so. Of the remaining 31, five participants recovered to the extent that they scored below the clinical cut-off on the IBSSI at a pre-intervention assessment, and thus were excluded from the study. The remaining 26 participated in this study, and their mean age was 19.9 years (SD = 1.23). Further, the majority of participants were female (61.5%). There were four exclusion criteria: (1) undergoing psychopharmacological or psychological treatment for gastrointestinal or psychiatric disorders; (2) the presence of warning symptoms which suggested the presence of organic disease at the selfreported screening and assessment (e.g., anemia, inflammatory reactions, fecal occult blood, unexplained weight loss in the past six months, or a family history of colon cancer); (3) suicidal ideation; and (4) individuals whom the investigator determined to be unsuitable as participants (e.g., unable to communicate effectively in Japanese).

2.2. Primary outcome measure

2.2.1. Japanese version of the IBS Severity Index (IBSSI)

The IBSSI (Francis, Morris, & Whorwell, 1997) was developed to assess the major symptoms of IBS, and it has been translated into Japanese (Shinozaki et al., 2006). This measure consists of 7 items relating to the severity and duration of abdominal pain, severity of abdominal distention, dissatisfaction with bowel habits, and interference in their life, with higher values representing higher levels of severity. Both the original and Japanese versions of IBSSI have pre-determined cut-off scores which indicate mild (75–174), moderate (175–299), or severe (300–500) IBS. The Japanese version of the IBSSI showed acceptable internal consistency (Cronbach's $\alpha=0.69$) and test-retest reliability (ICC = 0.86; Shinozaki et al., 2006). However, in the current study, the IBSSI demonstrated lower internal consistency $(\alpha=0.34-0.67)$ across the assessments.

2.3. Secondary outcome measures

2.3.1. Japanese version of the IBS-QOL

The IBS-QOL instrument (Patrick, Drossman, Frederick, Dicesare, & Puder, 1998) was developed to assess symptom-related QOL, and has been translated into Japanese (Kanazawa et al., 2007), with higher scores indicating a better QOL. Internal consistency was almost identical (Cronbach's $\alpha=0.96$ - 0.97) across assessments in the present study.

2.3.2. Short Form (36) Health Survey (SF-36)

The SF-36, developed based on the Medical Outcome Study, is a 36item measure assessing health-related QOL (Ware, Kosinski, & Keller, 1994) and has been translated into Japanese (Fukuhara, Bito, Green, Hsiao, & Kurokawa, 1998). We used three summary scores (Suzukamo et al., 2011): the physical component summary (PCS), the mental component summary (MCS), and the role/social component summary (RCS). Higher scores represent better QOL. Good internal consistency was shown for PCS (Cronbach's $\alpha = 0.81$ -0.86), RCS (Cronbach's $\alpha = 0.79$ -0.89), and MCS (Cronbach's $\alpha = 0.88$ -0.90).

2.3.3. Beck Depression Inventory-II (BDI-II)

The BDI-II was used to measure depression (Beck, Steer, & Brown, 1996), with higher scores representing more depressive symptoms. The Japanese version of the BDI-II is well-validated (Kojima et al., 2002). In this study, BDI-II showed good internal consistency (Cronbach's $\alpha=0.91\text{-}0.94$).

2.3.4. State-Trait Anxiety Inventory (STAI)

The STAI was used to measure state anxiety (STAI-S) and trait anxiety (STAI-T) (Spielberger, Gorsuch, & Lushene, 1983), with higher scores indicating more anxiety. The Japanese version of the STAI has been validated in previous studies (Hidano, Fukuhara, Iwawaki, Soga, & Spielberger, 2000). Good internal consistency was shown for the STAI-S (Cronbach's $\alpha=0.92$ -0.94), and STAI-T (Cronbach's $\alpha=0.87$ -0.92).

2.4. Process measures

2.4.1. Acceptance and Action Questionnaire-II (AAQ-II)

The AAQ-II was used to assess experiential avoidance, which is the key process targeted in ACT, with higher scores indicating more frequent avoidance. The AAQ-II has been found to have adequate reliability and validity (Bond et al., 2011) and has been translated into Japanese (Shima, Yanagihara, Kawai, & Kumano, 2013). The AAQ had good internal consistency (Cronbach's $\alpha=0.82\text{-}0.91$).

2.4.2. Cognitive Fusion Questionnaire (CFQ)

The CFQ is a 13-item measure of cognitive fusion, which is a component of psychological flexibility, with higher scores indicating more cognitive fusion. This scale has been shown to have good psychometric properties (Gillanders et al., 2014), and the Japanese version has shown similar psychometric properties (Shima, Yanagihara, Kawai, & Kumano, 2014). In the current study, the CFQ had acceptable internal consistency (Cronbach's $\alpha=0.73$ -0.90).

2.4.3. Five Facet Mindfulness Questionnaire (FFMQ)

The FFMQ (Baer et al., 2008) was used to measure five dimensions of mindfulness, with higher scores indicating greater mindfulness. The Japanese version of this questionnaire has been validated (Sugiura, Sato, Ito, & Murakami, 2012). In this study, the FFMQ showed acceptable internal consistency (Cronbach's $\alpha=0.56\text{-}0.69$).

2.5. Adherence quizzes

Adherence multiple-choice quizzes were administered online on six occasions to measure the participants' use of the workbook. Each quiz consisted of 10 items that were relevant to two or three chapters of the book. Quizzes examined participants understanding of book content (e.g., "In ACT, what part of the issue are you focusing on?").

2.6. Treatment protocol

The procedure used in this study followed a treatment protocol used by Ferreira et al. (2017) and published by the Association for Contextual Behavioral Science (Ferreira & Gillanders, 2012a). This protocol consists of two main elements: (1) a one-day group ACT workshop, and (2) a two-month period of self-help using a workbook. The initial workshop did not have any notable changes from the protocol, except that only one facilitator was used (see supplementary material). The first author, who is a licensed clinical psychologist, administered all

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