

**Effect of acceptance and commitment therapy
on stigma in college students with irritable
bowel syndrome: a randomized controlled study**

October 18, 2022

Study Protocol

1. Integrity Statement

(1) Ensure that the operation is in strict accordance with the test protocol and the authenticity of the data records; (2) No conflict of interest with other projects.

2. Title of the study

Effect of acceptance and commitment therapy on stigma in college students with irritable bowel syndrome: a randomized controlled study

3. Flow chart of the implementation of the study

Specific implementation contents of the intervention programme

Module topics	Module objectives	Intervention contents	Homework
Week 1 Building relationships understanding ACT	Understanding the ACT content	<ol style="list-style-type: none"> 1. The researcher and the patient introduce themselves, get to know each other and establish a good relationship. (5 minutes) 2. Understand the patient's psychological state and encourage each patient to tell their experience of IBS, their views on IBS and their knowledge of IBS health. (10 minutes) 3. Introduce the six core components of ACT and the treatment process, and explain the application of ACT to help patients realize that they can improve their current psychological state and enhance their confidence through intervention. (15 minutes) 4. Teach patients to mindfulness breathing. (10 minutes) 5. Live answer: answer patients' questions and start a discussion. (10 minutes) 	Perform Positive Exercises 1-2 per day and record a video to upload to WeChat group.
Week 2 Acceptance of disease	Positive acceptance Abandon confrontation	<ol style="list-style-type: none"> 1. Live discussion: encourage patients to express their thoughts, describe the reasons for their worries or fears, their inner feelings, etc., after experiencing the disease, and share the measures taken to cope with these thoughts or feelings and their effects. (10 minutes) 2. Live video broadcast: explain the metaphor of "Tug-of-War with Monsters" to convey to patients that in difficult situations, the more they struggle, the worse the situation will be, and to promote the acceptance of negative emotions by patients, and to correctly face the disease and pain. "Struggle Switch": give up the struggle against physical and emotional pain and accept the true feelings. (20 minutes) 	Patients are encouraged to keep a diary every day, take photos and upload them to email to exchange ideas with researchers. Record your struggles with painful thoughts or emotions and think about how cognitive dissociation strategies should be used to regulate emotions.

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		<p>3. Establish correct knowledge of IBS and acceptance of IBS. Tell patients to face painful experiences with an open attitude of acceptance, avoidance will only deepen the bondage of suffering. (10 minutes)</p> <p>4. Live answer: answer patients' questions and start a discussion. (10 minutes)</p>	
Week 3	Reducing the problematic dominance of patient cognition over behavior	<p>1. Explaining to patients the importance of rationally coping with negative emotions, carrying out cognitive dissociation exercises, helping patients to identify "thoughts" and "reality", and making patients realize that "thoughts" are not "facts per se", and guiding patients to normalize their painful emotions by separating negative thoughts from reality. (10 minutes)</p> <p>2. Live video: "I am having this thought" exercise to reduce or get rid of emotional pain. (20 minutes)</p> <p>3. Use the metaphor of "leaves floating down the stream" to help patients separate the ideal from the reality, so that they can learn to look at the stigma of IBS from an observer's point of view with a more relaxed mindset, and not to get caught up in it. (10 minutes)</p> <p>4. Live answer: answer patients' questions and start a discussion. (10 minutes)</p>	<p>Practice "Leaves Floating in the Stream" every day, write down your own experience, take photos and upload them to email to exchange ideas with researchers.</p>
Week 4	Dissociation from the conceptualized self	<p>1. Change the patient's concept of "self" and guide the patient to positively accept IBS. (10 minutes)</p> <p>2. Conduct a "checkerboard metaphor" exercise to guide patients</p>	<p>Patients are guided to empty themselves, to be in the present moment, to be</p>

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		<p>to focus on their lives in the present, accept their own emotions, and pay attention to their true selves in the present moment. (20 minutes)</p> <ol style="list-style-type: none"> Facilitate self-expression without being held back by conceptualizations of self or others. (10 minutes) Live discussion: think about the changes brought about by IBS and guide patients to practice body scanning. (10 minutes) 	<p>consciously aware of their thoughts, to think about the changes brought about by the illness, and to record them.</p>
Week 5	Focus on your core values	<ol style="list-style-type: none"> Introduce the values in ACT, use interviews with IBS patients to help them clarify their values, guide them to identify "what is most important to them", and develop a list of goals based on their own values and use them as goals and directions for action. (10 minutes) Picture display: using the metaphor of "Donkey, Stick and Carrot" to introduce values. (10 minutes) Compass Metaphor: work with the patient to understand the importance of values and to guide patients to develop confidence in improving levels based on their own values. (20 minutes) Live answer: answer patients' questions and start a discussion. (10 minutes) 	<p>Write out their own value goals, reflect on the values, and share ideas with the researcher and peers during the next intervention session.</p>
Week 6	Guided by values toward a meaningful life	<ol style="list-style-type: none"> Introduce the importance of commitment to action: according to their own values, guide patients to clarify "what kind of person they want to be", think about the goals they want to achieve, and consider the problems and solutions they may encounter in the process of implementation, and help them to develop a practical 	<p>Encourage patients to think about what they want to achieve. What is the specific process for achieving it?</p>

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Module topics	Module objectives	Intervention contents	Homework
		<p>plan together. (10 minutes)</p> <ol style="list-style-type: none">2. Set SMART behavioral goals: S-Specific; M-Measurable; A-Achievable; R-Realistic; T-Time-bound. (10 minutes)3. Live discussion: summarize and review the whole process of the ACT intervention, and invite each member to share their own gains and feelings during the intervention. (10 minutes)4. Encourage each member to strengthen the use of ACT in their future study and life. (15 minutes)	

4. Background

Acceptance and commitment therapy (ACT), as a new cognitive intervention therapy, emphasizes value-oriented goal setting, which mainly includes six core processes: acceptance, cognitive dissociation, experiencing the present moment, self-as-context, clarifying values and committed action, which is conducive to solving the psychological disturbances existing in patients with chronic pain, HIV, cancer, epilepsy, irritable bowel syndrome, etc., and increasing the degree of self-acceptance and reducing the stigma of illness. Through diverse therapeutic approaches, psychological flexibility is increased and the impact of unrealistic thoughts on daily life and goal achievement is limited. There are many reports of domestic studies related to ACT on reducing the sense of shame in patients with chronic diseases, but there have been no intervention studies on ACT to reduce the sense of shame in patients with IBS, and there is a lack of applied research on systematic intervention programs. Therefore, in this study, we used ACT as the basis for developing an intervention program to reduce the stigma, and explored the effectiveness of ACT in reducing the stigma in IBS patients, with the aim of enhancing their mental health and improving their quality of life.

5. Research purpose

The purpose of this study was to construct a stigma intervention program for college students with Irritable Bowel Syndrome (IBS) based on the Acceptance and Commitment Therapy (ACT) theory and to investigate the effectiveness in reducing stigma in IBS patients with the aim of enhancing their mental health and improving their quality of life.

6. Inclusion and Exclusion Criteria

Inclusion criteria: (1) Patients with IBS who meet the Rome IV diagnostic criteria; (2) Duration of IBS disease \geq 0.5 years; (3) The Perceived Stigma Scale in IBS (PSS-IBS) total score \geq 80; (4) Patients can proficiently use WeChat and participate in remote follow-ups; (5) Understand the research content, participate voluntarily and sign the

informed consent. Exclusion Criteria: (1)Patients with other intestinal diseases or serious primary diseases; (2) Patients with comorbid psychiatric diseases; (3) Patients who engaged in psychological workers or received psychological counseling within 3 months; (4) Patients who have recently participated in or are currently participating in other similar studies.

7. Intervention process

From June 2023 to January 2024, college students with irritable bowel syndrome (IBS) accompanied by a sense of shame who met the inclusion and exclusion criteria were selected from a comprehensive university in Yangzhou City. The control group implemented conventional health education on IBS, and the intervention group implemented psychological intervention program based on ACT theory on top of the control group.

8. Sample size estimation

The required sample size was calculated by comparing the means of the two samples, applying the following formula: $n=2[(Z\alpha/2+Z\beta)\sigma/\delta]^2$, the test level was taken as two-sided $\alpha=0.05$ and $\beta=0.10$, which resulted in $\mu\alpha=1.96$, and $\mu\beta=1.282$, the two-sided test was used, reviewing the literature, $\sigma=5.15$ and $\delta=4.01$, the calculation was made that $n1=n2=35$ cases, and the 20% loss of visit rate was considered. Finally, there were 42 cases in each group, and the total sample size was 84 cases. In the process of the study, there were 2 cases of lost visits in the control group, of which 1 case withdrew in the middle of the study and 1 case was interrupted; there were 2 cases of lost visits in the intervention group, of which 1 patient withdrew due to aggravation of the disease and 1 case was interrupted, and the final sample size included in the statistical analysis was 80 cases, with 40 cases in each group.

9. Randomisation

Participants were identified through related questionnaire survey, and participants signed a written consent form to participate in the study. After the baseline assessment, using a randomized grouping approach, patients who met the inclusion and exclusion

criteria were numbered and randomly divided into a control group and an intervention group by a computerized random number procedure.

10. Measurement index

General information questionnaire: baseline (T0); perceived stigma scale in IBS (PSS-IBS) (primary indicator): baseline (T0), 1 month post intervention (T1), 3months post intervention (T2); acceptance and action questionnaire-II (AAQ-II) (secondary indicator): baseline (T0), 1 month post intervention (T1), 3months post intervention (T2); self-acceptance questionnaire (SAQ) (secondary indicator): baseline (T0), 1 month post intervention (T1), 3months post intervention (T2); IBS quality of life (IBS-QOL) (secondary indicator): baseline (T0), 1 month post intervention (T1), 3months post intervention (T2).

11. Ethical consideration

The study was ethically approved by the Ethics Committee of the College of Nursing of Yangzhou University (YZUHL20220044).

12. Statistical analysis of data

SPSS 25.0 software was applied for data analysis. Measurement data conforming to normal distribution were described by mean \pm standard deviation, those not conforming to normal distribution were described by median (inter-quartile spacing), and count data were expressed by frequency and constitutive ratio. The t-test was used for between-group comparison of measures that met normal distribution, the Mann-Whitney U test was used for between-group comparison of measures that did not meet normal distribution, the χ^2 test was used for categorical variables, and Mauchly's test of sphericity was used, and if the covariance matrix did not satisfy the sphericity symmetry, the correction coefficient (Epsilon) was used to correct for the degrees of freedom, and the Greenhouse-Geisser was used for correcting results. Trends in PSS-IBS, AAQ-II, SAQ, and IBS-QOL scores over time were analyzed using ANOVA of repeated measures data for both study groups at pre-intervention, 1 month post-intervention, and 3 months post-intervention.