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

May 22, 2023

Informed Consent Form (ICF)

Dear Patient:

You have been invited to participate in a clinical study of irritable bowel syndrome. This informed consent form provides you with information to help you decide whether or not to participate in this clinical study. Please read it carefully and ask the investigator in charge of the study if you have any questions.

Your participation in this study is voluntary. This study has been reviewed by the Institutional Ethics Review Board.

Research background and research purpose

Research background: The prevalence of irritable bowel syndrome (IBS) has continued to rise in recent years in response to changing lifestyles. The sense of shame is a common negative emotion in patients with IBS, and negative emotions can trigger multiple disorders of neurological and humoral immune responses through psychological stress, affecting the intestinal flora and leading to the aggravation of IBS patients' conditions. During the exacerbation period, the normal physiological functions of IBS patients are severely damaged, and they lose control of their bodies, and in severe cases, even suffer from fecal incontinence, resulting in feelings of embarrassment and social stigmatization. These negative feelings bring a heavy psychological burden to the patients, who gradually and consciously alienate themselves from social relationships, affecting their quality of life and treatment outcome.

Research purpose: In-depth research on the status of stigma in patients with irritable bowel syndrome (IBS) was conducted to explore the factors affecting stigma, with a view to providing a rational basis for positive and effective interventions for such patients in the future.

Target population: patients with irritable bowel syndrome who are voluntary subjects meeting the appropriate inclusion criteria.

Research process: We will administer the questionnaire to each subject without any risk to the subject. If you agree to participate in this study, all information will be kept confidential.

Benefits:

1. The questionnaire-based survey of you will help to make a diagnosis of the disease, provide necessary recommendations for your treatment, or provide useful information for research on the disease.

2. We will bear the costs associated with this study, which will provide the basis for your future treatment and care. The study will not add to your financial or psychological burden and is entirely at your discretion.

As a subject, you have the following responsibilities:

Provide truthful information about your medical history and current physical condition; tell the researchers about any discomfort you experience during this study; and tell the researchers if you have recently participated in other research studies or are currently participating in other research studies.

Privacy:

If you decide to participate in this study, your participation in the study and your personal information during the study will be kept confidential. Information that identifies you will not be disclosed to members outside of the research team unless you give your permission. All study members and the study sponsors are asked to keep your identity confidential. Your file will be kept

in a locked filing cabinet and will be accessible only to researchers. To ensure that the research is conducted in accordance with the regulations, members of the government administration or the Ethical Review Committee will be given access to your personal data at the research unit, if necessary and as required.

The results of this study will be published when they are available. The results of this study will be published without disclosing any of your personal information.

You may choose not to participate in this study and your data will not be included in the study results, and any medical treatment and rights you may have will not be affected.

You will have access to information about this study and the progress of the study, and you may contact the investigator by telephone if you have questions about this study or about the rights of participants in this study.

Affirmation of consent

I have read the above description of this study and have had the opportunity to discuss and ask questions about this study with the research team. All of the questions I asked were answered to my satisfaction.

I fully understand the information on medical research and the specifics of this study. I understand that participation in the study is voluntary and I confirm that I have had sufficient time to consider this and understand;

- I can ask the research team for more information at any time.

- I can withdraw from this study at any time without discrimination or retaliation, and that my medical treatment and rights will not be affected.

Finally, I give my consent for the drug regulatory authority, ethics committee or sponsor's representative to have access to my research data and decide to consent to participate in this study.

Subject's signature (or handprint):_____ Date:_____

Subject contact number:_____

I confirm that I have explained the details of this study to the patient, including their rights and benefits.

Researcher's signature:_____ Date:_____

Researcher contact number:_____