Impact of Adapted Mindfulness Training Integrating Interoception on Diabetic Patients with Impaired Awareness of Hypoglycemia: A Randomized Controlled Trial

May 6, 2026

Informed Consent Form (ICF)

Dear Patient:

We would like to invite you to participate in a randomized controlled study on the effects of adaptive mindfulness training combined with interoception on patients with impaired awareness of hypoglycemia in diabetes. The study protocol has been reviewed and approved for clinical research by the Ethics Committee of the School of Nursing, Yangzhou University. Before you decide whether to participate in this study, please read the following content as carefully as possible. It will help you understand the study and why it is being conducted, the study procedures and duration, as well as the potential benefits, risks, and discomforts that may arise from participating in the study. If you wish, you may also discuss it with your relatives and friends, or ask the doctor for further explanation to help you make a decision.

Research background and research purpose

Research background: Hypoglycemia is a frequent complication in diabetes treatment, and recurrent episodes often lead to impaired awareness of hypoglycemia (IAH), affecting up to 25% of insulin-treated patients. IAH severely diminishes a patient's ability to perceive the early physiological signals of low blood sugar, an issue closely linked to impaired interoceptive awareness. Without these internal warning signals, patients lose control over their physical condition and face a 17-fold higher risk of severe hypoglycemia, which can trigger fatal arrhythmias, cognitive dysfunction, and even death. These severe physical and psychological burdens remain inadequately addressed by current medical technologies. Consequently, there is an urgent need to explore psychological interventions, such as interoception-integrated adapted mindfulness training, to restore patients' body awareness, reduce severe hypoglycemic events, and improve clinical outcomes.

Research purpose: To investigate the effects of an adaptive mindfulness training program for patients with impaired awareness of hypoglycemia in diabetes on their interoceptive awareness and impaired awareness of hypoglycemia.

Target population: Patients with impaired awareness of hypoglycemia in diabetes who meet the relevant inclusion criteria and voluntarily participate.

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:_____