

Official Title: Efficacy of a Health Empowerment Theory Based Health Information Literacy Promotion Intervention in Individuals with Metabolic Syndrome

NCT Number:

Date of Document: 2025-07-01

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Efficacy of a Health Empowerment Theory Based Health Information Literacy Promotion Intervention in Individuals with Metabolic Syndrome

PRINCIPAL INVESTIGATOR

Meihua Ji, PhD, RN
Capital Medical University, School of Nursing
Beijing China, 100069
Phone: 83916507/15210434269
Email:mjshouyi@ccmu.edu

Study site: Affiliated Beijing Luhe Hospital, Capital Medical University; Li Yuan Community Health Service in Tongzhou District, Beijing; Yu Qiao Community Health Service in Tongzhou District, Beijing

Ethical Approval Institution: Capital Medical University, Beijing, China;

Informed Consent Form

We are honored to invite you to participate in this study, the current study has been reviewed and approved by the Ethics Committee of Capital Medical University. Your participation of the current study is totally voluntary, and you have the right to give your opinion or withdraw during the study as you wish.

1. Purpose of the study

This study is a two arm, pre and post study examining the feasibility and preliminary efficacy of a personalized, theory-driven “ENRICH” health information literacy intervention program among patients with Metabolic Syndrome and Metabolic Component Abnormalities. Study has been approved by capital medical university, Beijing, China (Z2023SY119).

2. Study Procedures

Participants will fill in a set of self-reported questionnaires according to the researcher's requirements at baseline and at 6 weeks. The questionnaires included general information, including socio-demographic information and clinical information, as well as the Health Information Literacy Self-rating Scale (HILSS), the Newest Vital Sign scale (NVS), the self-management ability of patients with chronic diseases, the Chinese version of the Health Problem Solving Scale, the Chronic Illness Resources Survey (CIRS), the European Quality of Life Five Dimension Five Level Scale Questionnaire (EQ-5D-5L), the General Population Nutrition Literacy Survey, Chronic Disease Self-Efficacy Scale, Knowledge of Metabolic Syndrome Scale (K-MS scale). Meanwhile, participants' metabolic indicators (HbA1c and Lipid profile) will be retrieved from the medical record at enrollment and at the end of the study (approximately 6 weeks after enrollment). Patients participating in the study will also receive a 6-week health information literacy intervention including personalized assessment, group health education, online counselling, tailored feedback, use of self-monitoring tools, etc., which is designed to help patients improve their health literacy, build health management skills and support disease management.

3. Possible risks

This study will not cause any risks to endanger your health. During the study, if there were any possibility of harming patients' interests or causing harm to participants, it will lead to timely termination of this study.

4. Benefits

Through participation of this project, the information you provided will help researchers to gain better knowledge in this research area. In addition, during the study, we will be fully involved to guide you in promoting health information literacy and better disease management, which may be beneficial to the treatment of your disease.

5. Cost

This study will not impose any additional medical financial burden on you, and instead, we will provide a small gift to appreciate your participation of the study.

6. Confidentiality and Data Protection

The general information, related questionnaires and other patient-related information involved in this study will be kept strictly confidential, and the results will only be used for academic research and not for commercial purposes. We hope that you will fill in the questionnaires and complete the related activities according to the actual situation, as the truthfulness of the answers and your commitment to participate all activities in this study will affect the conclusion of the research.

7. Contact Information

If you have any questions or concerns about the study, you can contact the Principal Investigator at [Tel.+86 83916507 MJSHOUYI@ccmu.edu.cn or qxyan0626@163.com]. You also have the right to contact the institutional review board or ethics committee that approved this study if you have any concerns about your rights as a participant.

8. Consent

I have read and understood the information provided above. I have had the opportunity to ask questions and have received satisfactory answers. Therefore, I voluntarily agree to participate in this study and understand that I have the right to withdraw at any time without penalty.

Participant's Signature:

Investigator's Signature:

Date: