Official title: A Randomised Controlled Study to Evaluate the Effectiveness of the Combined Psychological Resilience and Self-efficacy Intervention for Oesophageal Cancer Surgery Patients

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Informed Consent Form

Dear Friend:

We invite you to participate in a study approved by Anhui Medical University to enhance the level of psychological resilience and self-efficacy and reduce anxiety and depression in patients with oesophageal cancer, which is conducted by Shuwen Li at the School of Nursing, and in which 123 subjects are expected to participate voluntarily. This study has been reviewed and approved by the Biomedical Ethics Committee of Anhui Medical University.

This notice will provide you with information to help you decide whether or not to participate in this clinical study. Whether or not you participate in this study is completely voluntary and your decision will not affect your normal rights and entitlements of treatment at our hospital, so please rest assured! If you choose to participate in this study, our research team will endeavour to ensure your safety and rights during the study!

Please read these instructions carefully and if you have any questions, please ask the researcher who is responsible for explaining the informed consent form to you.

I. Background of the study

The burden of anxiety and depression is the heaviest among the negative emotions present in oesophageal cancer surgery patients, and the current status of psychological resilience and self-efficacy is not optimistic. Psychological resilience, as an important component of positive psychology, and self-efficacy, as an important protective factor with the largest indirect predictive effect of psychological resilience, have both been shown to be effective in reducing anxiety and depression in cancer patients. By implementing one-on-one, face-to-face and online interventions, this study facilitates patients' adaptation to life after cancer and provides a scientific basis for the management of their psychological symptoms.

II. Study process

The interventions lasted for about one month, 1-3 days before surgery, 3-4 days after surgery, 7 days after surgery (on the day of discharge), 14 days after surgery (1 week after discharge), 3-4 weeks after surgery (2-3 weeks after discharge), and 5 weeks after surgery (4 weeks after discharge) for a total of 6 thematic interventions, and the subjects only needed to cooperate in truthfully filling

out the questionnaires, watching the videos to learn about the implementation, and completing the homework assignments.

III. Alternative treatment

This study is an observational study only and does not involve any treatment.

IV. Possible Risks and Discomfort

Participation in this study will not cause you any discomfort or danger.

V. Expected benefits

The implementation of the intervention will contribute to your post-operative rehabilitation and promote your physical and mental health.

VI. Free treatment

This group has fixed and sufficient funding, and subjects will not be required to pay any fees during the course of the study.

VII. Compensation

This is an observational study only and does not involve any invasive operation or examination, which will not incur any extra cost to the subjects.

VIII. Reimbursement

This study does not involve any invasive operation and will not cause any related damage or injury to the subjects.

IX. Precautions before, during and after the study

In order to ensure the validity of the results of the study, the study subjects are required to fill in the questionnaire truthfully according to their recent status before, during and after the study.

X. Confidentiality

If you decide to take part in this study, all of your personal information about you and your participation in the study will be kept confidential. For example, your questionnaire results will be identified by the study number rather than your name. The study ensures that all information is collected and stored in a secure and confidential manner. The results of the study will not be published in a way that reveals your privacy.

XI. Retaking Informed Consent

This study does not require subjects to re-sign an informed consent form.

XII. Voluntary

As a subject, you can keep informed of the information and progress of the study and decide voluntarily whether to (continue) or not to (continue) participate. After participation, you may choose to notify the researcher at any time to request withdrawal from the study, and ultimately your data will not be included in the results of the study, and any of your medical treatment and rights and interests will not be affected as a result.

XIII. Rights and Obligations of Subjects

As a subject in this study, you have the following responsibilities: to provide truthful information about your medical history and current physical condition; to tell the researcher about any discomfort you experience during this study; and to tell the researcher whether you have recently participated in other studies or are currently participating in other studies.

XIV. Contact Information

If you have any questions related to this study, or if you experience any discomfort or injury during the study, or if you have any questions about the rights of participants in this study, you may contact Shuwen Li at +8615156032927.