Informed consent form

Project Name: Exploration and Intervention of a Management Model for Cancer Recurrence Fear
Research Plan Version Number and Date: V2.0/2022-12-14
Version number and date of informed consent form: V2.0/2022-12-14

Dear participants

We invite you to participate in a study that has been reviewed and approved by the Medical Ethics Committee of Southern Hospital of Southern Medical University. Before you make a decision, we hope you can understand the reasons for conducting this study and what it requires of you. Your participation in this study is purely voluntary, which means you can choose to participate or not. The research team will explain this information disclosure letter to you and answer any questions you may have.

If you have any unclear points, please ask us a question. Welcome to discuss this study and the information contained in this document with your partner, family, friends, and doctors who are close to you.

After considering all the information related to this study and answering all your questions, if you agree to participate, the research team will ask you to sign an informed consent form and indicate the date (at the end of this document) before proceeding with any research related procedures.

1、 Research background

Fear of Cancer Recurrence (FCR) refers to the fear, anxiety, and concern about cancer recurrence or progression, which is a common phenomenon during the survival period of cancer patients. However, it is an unmet need that has not received attention and satisfaction. The high incidence and potential negative impacts of FCR require us to determine effective management strategies. Current psychological interventions are considered feasible, acceptable, and potential measures to alleviate FCR. Especially mindfulness decompression therapy is widely used and has promising intervention effects. This study compared conventional health education to investigate the efficacy of online mindfulness decompression.

2、 Research purpose

1).Through cross-sectional investigation and research, construct an FCR warning model to identify and screen cancer populations with high FCR, in order to discover predictive factors for high FCR, and study how cancer patients develop susceptibility to FCR during the diagnosis and treatment process,

Include which participating factors, explore the development trajectory of FCR, and effectively prevent the occurrence of high-level FCR.

2). Through the Randomized controlled trial, the study on psychosocial intervention of mindfulness and decompression for high-level FCR patients was carried out to verify the effectiveness of psychosocial intervention measures for domestic cancer groups, and improve and standardize the intervention methods, intervention time and treatment content.

3、 Research Product Introduction

This clinical trial will utilize a third-party online platform to achieve 8-week mindfulness reduction (MBSR) and health education, including:

1. Mindfulness Relief (MBSR)

Week 1: Introduce mindfulness theory knowledge to participants and guide them to engage in mindfulness breathing training; Week 2: Sitting meditation, explaining the essence of meditation and practicing with music;

Week 3: Explain the connotation of walking meditation, inform the participants of precautions, and guide them to practice; Week 4: Explain the connotation and requirements of body scanning, guide participants in practice;

Week 5: Introduce the connotation of hatha yoga and guide participants to practice;

Week 6: Explain the meaning of mindfulness sounds and thoughts, guide participants to practice; Week 7: Explain the characteristics of non selective perception, combined with music practice;

Week 8: Emphasize mindfulness to promote health, encourage participants to practice internalization, and develop into their own patterns. 2. Health education: Automatic tweeting, providing health knowledge related to popular science.

4、 Research process

1)How many people will participate in this study?

Recruit 440 tumor patients, collect basic patient information collection forms, FoP-Q-SF, PHQ-9, GAD-7, ISI, and SF-36 at baseline, screen out high-level FCR, and randomly assign them to the MBSR group and health education group in a 1:1 ratio, with 65 patients in each group.2. 2)Research steps

■Before the start of the study:

To check if you are suitable to participate, the following inclusion and exclusion criteria will be listed.

① Inclusion criteria

A. Adults aged ≥ 18 years old;

B. Consistent with pathological diagnosis of cancer;

C. Able to understand and comply with research protocols; D. Written informed consent can be provided;

E. Own and know how to use smart terminals (such as smartphones, tablets, computers, etc.).

② Exclusion criteria

A. Patients with definite diagnosis and no mental illness or Disorders of consciousness; B. Patients with cancer metastasis or recurrence;

C. End of life treatment for patients.

After providing informed consent, you will undergo some tests, examinations, and procedures during this study. If you have any doubts about any of the tests, please discuss with the research doctor.

■ Baseline period

If the researchers confirm that you are eligible to participate in this study, you will be included in the study and complete the relevant questionnaire, receiving MBSR or health

education for a period of 8 weeks through random allocation (similar to drawing lots). The following procedures will be carried out during this visit:

Reconfirm if you are eligible to participate in this study

Filling out the scale questionnaire

Allocate to MBSR group or health education group based on randomization results (confirm compliance with high FCR standards)

Assign you a specific identification number to participate in this study

■ Treatment period

This research plan is a randomized controlled study, which is like flipping a coin and randomly receiving MBSR or health education. To ensure that the effectiveness of your MBSR or health education treatment can be accurately recorded and evaluated, you need to cooperate in completing the following procedures during this period:

Both the MBSR group and the health education group include an 8-week core course.

■ Follow up period

After completing the visit at this stage, it is usually considered that you have completed the entire study, and the researchers will perform the following follow-up procedures during this period:

At the 8th week (i.e. completion of treatment), 1st month, and 3rd month after the start of treatment, both groups of subjects underwent the same assessment as baseline, including self-assessment questionnaires (FoP-Q-SF, ISI, PHQ-9, GAD-9, SF-36).

Although the treatment ends within 8 weeks, you can review your 4-week treatment content within 3 months.

3).How long will this study last?

This clinical study lasted for approximately 3 months. During the period of joining this study, you must cooperate with the patient after receiving treatment receive outpatient or online follow-up for 3 months.

You can choose to withdraw from the research at any time without any punishment, nor will you lose any benefits that you should have received. However, if you decide to withdraw from this study during the study, we encourage you to consult with your doctor first. Considering your security issues, it is possible that a related check will be conducted after exiting.

5、 Risks and/or discomfort

1).The main goal of the research team is to always ensure your safety. The clinical interviews, questionnaire surveys, etc. involved in this plan are non-invasive and will not cause direct damage to the subjects' bodies.

2). Risks and Discomforts Caused by Treatment:

MBSR or health education treatment are non drug and non-invasive Sex therapy, and the course of treatment is safe and reliable.

3). Other risks and discomfort brought about by the research process, such as:

Electrocardiogram (ECG): When performing ECG, some sticky small patches will be placed on different parts of your body. The wires connected to the patch will send electrical activity information back to the instrument for recording and measurement. This test only takes a few minutes and is painless, but the patch placed on the body uses adhesive, so it may slightly irritate your skin.

6、 What are the benefits of participating in research?

Your participation in this study may result in your disease being controlled or alleviated. We hope that the information obtained from your participation in this study will contribute to the development of new therapies for patients with this disease in the future.

During the research period, you need to visit the hospital on time for follow-up, which will take up some of your time and may cause trouble or inconvenience to you.

7、 Use of research results and confidentiality of personal information

At the end of the research, we will write a report and send it to government regulatory agencies. The results of this study may also be published in journals or reported at meetings, but will not contain any information that may identify you.

To ensure privacy, records or samples published for research purposes will not include your name or other identification information. On the contrary, your information will be identified by only one code. Only research doctors and authorized personnel can associate this code with your name through a list that will be securely stored at the research center.

To ensure that the research is conducted correctly at the research center, if necessary, applicants, ethics review committees, and government management departments may have access to your information in accordance with regulations. They are bound by confidentiality obligations and will not infringe on your privacy.

You have the right to control the use and disclosure of your personal information. If permitted by national laws, you can request to view your medical information at any time. You have the right to view all information collected about you through a research doctor and request correction (if applicable).

8、Research related new information

During the research period, if there are changes in research procedures, newly discovered side effects, or significant situations that may affect your health or willingness to participate, the research team will notify you. The research doctor will immediately notify you and discuss with you whether you want to continue participating in this study. If you decide not to continue participating in this study, the research doctor will make arrangements to continue your diagnosis, treatment, and care. If you decide to stay in this study, the research doctor may require you to sign a new informed consent form.

9、Regarding research costs and compensation

1). Treatment and related examination costs used in the research institute

During the research period, interviews, physical examinations, scale assessments, MBSR, or health education interventions involved in the entire project implementation process are free of charge. During the project implementation process, research doctors can provide assistance to patients and their families/

Caregivers provide free consultation services related to diseases, and can also provide disease and symptom management for patients through online platforms.

2). Compensation for participating in research

You will receive a transportation fee compensation of two hundred yuan (one hundred yuan will be distributed after each follow-up) for participating in this study.

3). Compensation for damages

This study will not provide any treatment measures, and your diagnosis and treatment will be judged by the research doctor according to routine practice. If you really suffer damage due to participating in the study, you can get free treatment provided by the South Hospital of Southern Medical University, and will make compensation according to law.

10、 Rights and responsibilities of subjects

1). Your Rights

Throughout the entire process of participating in the study, you were voluntary. If you decide not to participate in this study, it will not affect the other treatments you should receive. If you decide to participate, you will be required to sign this written informed consent form. You have the right to withdraw from the trial at any stage without discrimination or unfair treatment, and your corresponding medical treatment and rights will not be affected.

2). Your responsibilities

Need to provide true information about one's medical history and current physical condition; Please inform the research doctor of any discomfort you have discovered during this study and inform them immediately; Accept follow-up on time, complete questionnaire filling and relevant examinations.

11、 Related contact information

If you have any questions related to this study, please call the outpatient department of psychology at Southern Hospital

Contact Luo Xian on 020-61642066.

If you have any questions related to your rights/interests, or you want to reflect the difficulties, grievances and concerns encountered in participating in this study, or you want to provide opinions and suggestions related to this study, please contact the Medical Ethics Committee of Southern Hospital of Southern Medical University at 020-62787238, e-mail: nfyyec@163.com.

Subject signature page

Informed consent statement

I have been informed of the purpose, background, process, risks, and benefits of this study. I have enough time and opportunities to ask questions, and I am very satisfied with the answers to the questions.

I have also been informed who to contact when I have questions, want to reflect difficulties, concerns, suggestions for research, or want to obtain further information or provide assistance for the research.

I know that I can choose not to participate in this study or withdraw from this study at any time during the study period without any reason. In addition, the researchers did not use deception, inducement, coercion or other means to force me to agree to participate in the study.

I already know that if my condition worsens, or if I experience serious adverse reactions, or if my research doctor feels that continuing to participate in the study is not in my best interest, he/she will decide to withdraw me from the study. Without my consent, the sponsor or regulatory agency may also terminate the study during the research period. If this situation occurs, the doctor will promptly notify me, and the research doctor will also discuss my other options with me.

I have read this informed consent form and agree to participate in this study.

I will receive a copy of this informed consent form, which includes my and the researcher's signatures.

Subject Signature: Date:

Contact Phone:

Signature of legal representative: Date:

Contact number:

(Note: If the subject has no or restricted behavioral ability and is included in vulnerable groups such as mental disorders/unclear consciousness, the legal representative must sign at the signature of the legal representative below)

Fair Witness Signature: Date:

Contact Phone:

(Note: only when it is possible to include subjects who have the ability to know but cannot read the text (such as illiterate, Visual impairment), the signature of the fair witness is required. When the witness is informed, the researcher had better retain video materials as evidence of knowledge).

I have accurately informed the subject of this document, and he/she has accurately read this informed consent form and demonstrated that the subject had the opportunity to raise questions, and he/she voluntarily agreed.

Researcher's signature: Date:

Contact phone number: