Official Title: Evidence-Based Practice Research on the Management of Musculoskeletal Symptoms in Breast Cancer Patients Undergoing Endocrine Therapy from a Multicultural Perspective

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Informed Consent Form

Study Title:

Evidence-Based Practice Research on the Management of Musculoskeletal Symptoms in Breast Cancer Patients Undergoing Endocrine Therapy from a Multicultural Perspective

Lead Institution:

School of Nursing, Fudan University

Collaborating Institutions:

Fudan University Shanghai Cancer Center; Dali University Affiliated Hospital; Dharmais Cancer Hospital (Indonesia)

You are being invited to participate in a clinical research study. This informed consent form provides information to help you decide whether to participate in this clinical study. Please read it carefully, and if you have any questions, do not hesitate to ask the researchers responsible for the study.

Your participation in this study is entirely voluntary.

This study has been reviewed and approved by the Ethics Committee of the institution conducting the research.

Background and Purpose of the Study:

The purpose of this study is to help breast cancer patients undergoing endocrine therapy better manage musculoskeletal symptoms related to their treatment. By analyzing the current symptom management practices of patients from tertiary hospitals in Shanghai (China), Dali (China), and Jakarta (Indonesia), we aim to develop and evaluate a series of personalized management plans. These plans include strategies for self-monitoring and reporting, medication adherence, diet and nutrition, exercise and rehabilitation, and health education, with the goal of improving patients' symptoms and quality of life. Through evidence-based practice research, we hope to implement these management plans in different regions and

enhance the overall quality of breast cancer care through cross-cultural collaboration. This study seeks to provide targeted nursing support for patients and promote international nursing cooperation along the Belt and Road Initiative.

Study Procedures:

If you agree to participate in this study, you will be asked to:

1. If technically feasible, download and use the intelligent symptom management app provided by the research team.
2. Regularly record your musculoskeletal symptoms, including data such as pain levels and quality of life.
3. If you are unable to use the app due to technical issues or other reasons, the research team will provide paper records or telephone follow-ups as an alternative.
4. This study will last for six months, with three months of intervention and three months of follow-up. During the intervention phase, you will participate in the symptom management plan, and during the follow-up phase, you will be contacted for follow-up once a month.
5. Your participation is voluntary, and you may withdraw at any time without impacting the medical care you are currently receiving.
6. Additional information: During the course of the study, new information related to the research methods may emerge. If this occurs, your study physician or nurse will inform you promptly and discuss whether you wish to continue participating. If you decide to continue, you may be required to sign a new informed consent form. During the follow-up phase, your physician or nurse may contact you via text messages, phone calls, or clinic visits to check on your condition.

Potential Benefits:

While we cannot guarantee direct health benefits from participating in this study, we hope that the intelligent symptom management plan will help improve your ability to manage musculoskeletal symptoms. Furthermore, your participation will contribute to the development of better symptom management tools for other breast cancer patients undergoing

endocrine therapy.

Costs and Compensation:

There will be no additional medical costs incurred by participating in this study. The research team will reimburse you for any transportation costs associated with participating in the study. All expenses related to data collection and analysis will be covered by the research team.

The research team will make every effort to prevent and address any harm caused by the study. If adverse events occur, a medical expert committee will assess whether they are related to the study. If deemed study-related, the sponsor will provide compensation and cover any necessary medical treatment in accordance with relevant regulations.

Information and Consultation:

You are free to ask questions about the study at any time, and these questions will be addressed promptly. If new information arises during the study that might affect your decision to continue participating, your doctor or nurse will notify you immediately.

Privacy and Data Confidentiality:

We will maintain strict confidentiality regarding all of your personal information. All health data provided, including symptoms recorded through the app or other means, will be stored anonymously on encrypted servers, accessible only to the research team. Upon completion of the study, all data will be destroyed in accordance with legal and ethical guidelines, and will not be used for other studies. Your privacy will be protected to the fullest extent possible.

Right to Withdraw:

You have the right to withdraw from the study at any time, without it affecting the breast cancer treatment you are currently receiving. Upon withdrawal, your data will no longer be used and will be destroyed as per legal and ethical requirements. If you wish to withdraw, please contact the research team at any time.

Contact Information:

If you have any questions or require further information regarding this study, you may contact the lead researcher:

Cao Yuling (Phone:+86 13961102420; Email: caoyulingedu@163.com).

Consent Statement:

I have read and understood the information provided above, and the research team has answered my questions.

I understand that participation in this study is voluntary, and I can withdraw at any time without affecting my medical care.

I agree to participate in this study.

Participant's Name: _____

Participant's Signature: _____

Date： _____ Month _____ Day _____ Year

I have accurately explained this document to the participant, who has read the informed consent form thoroughly and has been given the opportunity to ask questions.

Researcher's Name： _____

Researcher's Signature： _____

Date： _____ Month _____ Day _____ Year

(Note: If the participant is legally incapacitated, a legal representative must sign.)