Impact of Mindfulness-based Tri-modal Prehabilitation on functional recovery and selected surgical outcomes of patients with Colorectal Cancer; Randomized control trial.

CONSENT FORM FOR PARTICIPATION IN A CLINICAL TRIAL

Study Title: Impact of Mindfulness-based Tri-modal Prehabilitation on functional recovery and selected surgical outcomes of patients with Colorectal Cancer; Randomized control trial.

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take your time to read this form and ask questions about anything that is unclear. Your participation is entirely voluntary. You may refuse to participate or withdraw from the study at any time without affecting your current or future medical care.

Prof. Bawantha Dilshan Gamage is the principal investigator of this study. The purpose of this research is to investigate the impact of Mindfulness-Based Trimodal Prehabilitation on the functional recovery and selected surgical outcomes of patients diagnosed with colorectal cancer. You have been selected as a potential participant because you meet the criteria outlined in the study protocol.

1. What are we doing?

The Prehabilitation programme for colorectal cancer patients awaiting surgery has shown numerous benefits to the patient in the postoperative faster recovery and improve quality of life. This method is currently being practiced in many institutes worldwide. Therefore, we as a Surgical Unit have decided to implement the same programme in our unit and to assess if there is a significant benefit to patients from implementing the Prehabilitation programme when compared to the traditional practice of our unit. This will result in mild deviations from the traditional practice of our unit.

2. Why you?

As the doctors in the ward/clinic have informed you in prior, you are to undergo a Surgery for Colorectal cancer. Participation for this trial is strictly on voluntary basis and you are able to leave the trial at any given time without prior warning. If at any point you have concerns or clarifications to be made about the trial, you are at liberty to ask questions. And if any complaint is needed to be made, it will not affect your treatment in any way. We will keep the details obtained from you confidently and proper measures have been taken to store the details obtained so that unintended parties will not have access to them.

3. What we do and what is expected of you?

Once it has been decided that you require a Surgery for your colorectal cancer, in order to ensure adherence to the programme, a checklist will be filled by the doctor and you will be given all the instructions. If you agree to participate, you will be randomly assigned to either the intervention group or the control group. Participants in both groups will receive trimodal prehabilitation for four weeks before surgery. The intervention group will receive additional mindfulness-based sessions during this period. Your participation in the study will involve attending scheduled appointments, completing questionnaires, and undergoing assessments as outlined in the study protocol.

4. Benefits

• Direct benefit – It has been shown that this Prehabilitation programme is associated with faster recovery, shorter hospital stays and quicker return to normal functional activities while reducing the cost burden on the patient and the institution.

• Indirect benefit – you will be able to contribute to the advancement of scientific knowledge which will be useful to improve the future management of similar patients.

• There will be no financial benefits by taking part in this trial will not contain any reimbursements.

• You will not be penalised if you decide not to take part in this trial or decide to leave early. The routine care that is provided to all colorectal cancer patients awaiting surgery will be given to you.

5. Risks

• There will be mild deviations from the traditional practice of our unit. However, this will not result in any harm to you. In addition, if the consultant surgeon deems it to be harmful, you will not be subjected to the above protocol.

6. Sample collection

• Blood will be collected at each data collection time interval. This will be in addition to the routine investigations that are currently being performed to all patients who will undergo colorectal surgery. Blood drawn will be about 5ml. The blood collected will be used to assess Serum Albumin, Blood haemoglobin level, Serum β-endorphin, Serum Cortisol.

• After performing necessary test, the remaining sample will be discarded.

7. Confidentiality

Your privacy and confidentiality will be protected throughout the study. All data collected will be kept confidential and will only be accessible to authorized study personnel.

8. Voluntary Participation

Participation in this study is voluntary. You are free to refuse to participate or withdraw from the study at any time without penalty or affecting your medical care.

9. For further Information

You can read this information sheet and clarify any queries before you give consent. If you have any questions or concerns about the study, you may contact Ms. Nilushika Perera at +94 713 312 963.

This study has been approved by the Ethics Review Committee of the Faculty of Medical Sciences, University of Sri Jayewardenepura. If you have any queries or complaints about the conduct of the study, please contact the ERC Office on +94 112 758 253 If you have any concerns regarding this, you can also contact the Ethics Review Committee (ERC) of Colombo South Teaching Hospital Tel: 0112763262 e-mail: ercсsth@gmail.com.

If you wish to be a part of this study, you may give the consent by filling out the section below.

Name _____

Surgical procedure _____

I have read the information sheet and have had adequate time to make my decision. I also had the opportunity to clarify my queries.

I understand that the confidentiality of my personal information will be maintained at every level.

I have understood the samples which will be collected, the method of collecting the samples and the fate of the samples.

I hereby give my consent to be included in this study and for any publications that follow.

I understand that I can revoke my consent at any time before the surgery, and that I won't be affected in any way in terms of my care and follow up.

Participant Signature: _____ Date: _____

Investigator Signature: _____ Date: _____