

Prof. Bawantha Gamage,
Professor in Surgery,
The Department of Surgery,
Faculty of Medical Sciences,
The University of Sri Jayawardenapura.
22.12.2023

Hon. Secretary,
Sri Lanka Clinical Trials Registry
Sri Lanka Medical Association
6. Wijerama Mawatha
Colombo 07.

Dear Sir/ Madam,

Request for Amendment of Sri Lanka Clinical Trials Registry Committee Approval – Research Project: SLCTR/2020/022 [Impact of Mindfulness-based Trimodal Prehabilitation on Functional Recovery and Selected Surgical Outcomes of Patients with Colorectal Cancer; A Randomised Control Trial.]

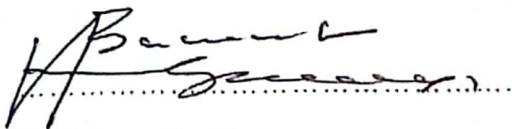
I wish to request protocol amendments of the Sri Lanka Clinical Trials Registry Committee approval for our ongoing research project mentioned above.

In support of this request, I have attached the following documents:

1. The annual progress report.
2. Obtained approval letters from the Ethics Review Committee of the Faculty of Medical Sciences for all protocol amendments.

Thank you

Yours faithfully,



Prof. Bawantha Gamage
(Principal Investigator)



Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2020/022

Scientific title of trial: Impact of Mindfulness-based Trimodal Prehabilitation on functional recovery and selected surgical outcomes of patients with Colorectal Cancer; A randomised control trial

Date of commencement (enrolment of first participant):

Progression: 6 months 1 year 2 years **3 years**
 At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: **Yes**

Any changes to trial outcomes after commencement: **Yes. Official approval has been obtained from the Ethics Review Committee of the Faculty of Medical Sciences for all protocol amendments. Enclosed herewith are the approval letters for your reference and records.**

Category	Amendment
Title	Impact of Mindfulness-based Trimodal Prehabilitation on functional recovery and selected surgical outcomes of patients with Colorectal Cancer; A randomised control trial
Study setting	The study will be conducted at the following locations: 1. The Surgical Professorial Unit of Colombo South Teaching Hospital 2. Apeksha Hospital in Maharagama 3. Kings Hospital 4. The Mindfulness-Based Wellbeing Centre of the University of Sri Jayewardenepura.
Target number/sample size	The preceding sample size amounted to 150 participants (75 individuals in each group); however, it has currently been reduced to 72 participants (36 in each group).
Time of assessment	Initially, outcome will be measured at 05 different time intervals for each patient. But now at 04 different time intervals for each patient: 1. At the start of the trial 2. Four weeks after prehabilitation or Day prior to surgery (upon admission) 3. 4 weeks postoperatively 4. 8 weeks postoperatively (at the end of the trial)
Secondary outcomes	Hand grip strength has recently been incorporated into the nutritional assessment protocol. Consequently, nutritional assessment will be conducted utilizing the Malnutrition Universal Screening Tool (MUST), Body Mass Index (BMI), Serum Albumin, Blood Hemoglobin (Hb) level, and the measurement of hand grip strength. Biomarker assessment will only be conducted by measuring: 1. Serum β -endorphin 2. Serum Cortisol."

2. Current status

Recruitment status: recruiting

Number assessed for eligibility: 72 participants (36 in each group)

Number recruited and allocated/randomized: 39 participants

Number allocated/randomized to each intervention/arm (please edit as relevant):

Arm 1: 19 participants (Intervention Group)

Arm 2: 20 participants (Control Group)

Losses/exclusions after allocation/randomization (please edit as relevant):

Arm 1: 04 participants (Intervention Group)

Arm 2: 05 participants (Control Group)

3. Trial output

Date of trial completion ("last patient, last visit"): Not applicable

Final sample size: Not applicable

Summary of Interim/Final data (if available):

Not applicable

Abstract presentations of results at scientific meetings

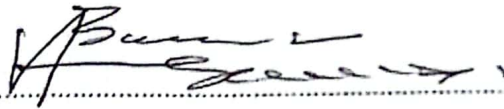
Note: please include a URL link or scanned copy of the abstract

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
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Publications

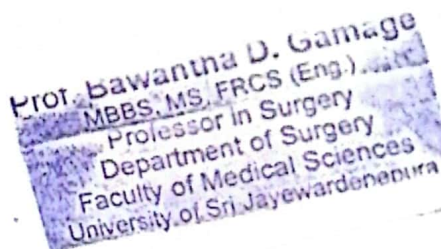
Note: please include a URL link or scanned copy of the publication

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)
Study protocol: Impact of Mindfulness-Based Tri-Modal Prehabilitation on Functional Recovery and Select Surgical Outcomes of Patients with Colorectal Cancer: The First International Randomised Control Trial for Mindfulness-Based Tri-Modal Prehabilitation.	Manuscript submitted to Journal of BMJ Open. Pending confirmation. (bmjopen-2023-080192)
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Principal Investigator
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Date: 22.12.2023



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