INTRODUCTION

Ischemic heart disease (IHD) is considered the foremost reason for fatality in widespread diseases and the foremost single cause of mortality and loss of disability adjusted life years (DALYs) globally. Low- and middle-income countries are highly affected by IHD, accounting for nearly 7 million deaths and 129 million DALYs annually. Furthermore, the patients who have survived myocardial infarction (MI) are at massive risk for recurrent infarctions and have at least five- to six-fold higher annual mortality rates than individuals who do not have IHD.

Non-adherence to treatment remains a crucial challenge, limiting overall benefits and often leading to poor health outcomes, lower quality of life, and increased demand for healthcare. The prognosis of IHD patients can also be compromised by poor adherence to physical activity, diet, and medications. As per the definition of the World Health Organization, adherence is the level at which a person adjusts his/her behavior according to the instructions and the recommendations given by the health-care provider. These behavioral changes may cover areas that increase compliance to medications, dietary requirements, and lifestyle modifications.
In adherence interventions, addressing multiple health behaviors have proven to be more effective than addressing single health behaviors, particularly when addressing affective and cognitive elements. Further, the psychological approach of Motivational Interviewing has proved to be effective in changing maladaptive health behaviors, thus reducing the risk of IHD. Motivational interviewing is described as “a client-centered, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence”. The patient’s inconsistency or discrepancy between his central beliefs and ill health behavior could be reduced or eliminated with motivational interviewing, motivating the patient to change. Furthermore, goal setting and problem-solving are some other methods frequently used in cardiac rehabilitation programs leading to desired health behaviors. Moreover, numerous studies have found that cardiac outcomes can be enhanced with targeted patient education and better-quality communication skills in the health-care provider as it is shown to improve patients’ health literacy levels.

The incidence of IHD in Sri Lanka has increased considerably over the past two decades. Further, recent studies have revealed a growing increase in IHD among the younger generation in Sri Lanka and its risk factors are concentrated among urban populations and those in the higher socioeconomic classes. Moreover, IHD was the leading cause of hospital death in the country during the past 10 years, accounting for nearly 10% of all hospital deaths. However, western countries report a considerably low death rate due to technically advanced interventional procedures, which are very expensive for lower-income countries like Sri Lanka. Therefore, this study suggests a socio-culturally applicable cost-effective health counseling intervention for improving adherence to physical activity, diet, and medication in patients with IHD in Sri Lanka.

**Aims and objectives**

The study aimed to develop a socio-culturally appropriate health counselling intervention protocol to enhance the adherence of prescribed physical activity, diet and medication among IHD patients attending medical clinics in Sri Lanka.

**MATERIALS AND METHODS**

**Content of the protocol**

This protocol is a health counseling intervention aimed at increasing the adherence to physical activity, medication adherence, and dietary adherence of patients who are clinically diagnosed with IHD. Further, it was developed to be used by the health education nurses at the delivery of care on the patients diagnosed with IHD. This protocol combines knowledge from psychology, nursing, nutrition, physical education, and pharmacology. The protocol consists of two sections – (A) Assessment and primary interventions, and (B) intervention.

1. **Assessment and primary interventions**

The first section of the assessment consists of two subsections and was developed based on the self-regulation model. In the first subsection, the nurse is guided on how to assess the patients’ knowledge on IHD, such as the patient’s ideas about the identity, cause, timeline, and consequences of IHD. This assessment criterion was developed based on the Brief Illness Perception Questionnaire (Brief IPQ: 28). In the second subsection, the nurse is guided on obtaining the patient’s perception regarding the symptoms of IHD. Making sense of the IHD symptoms, assessing the health risk and determining patients’ actions regarding IHD symptoms are significant concerns of this subsection. Further, the readers are explained on assessing patients using the 0–10 rating scale. Moreover, they are, further, guided on carrying out the primary interventions by providing health education and correcting misconceptions based on the answers that the patients given to these questions.

2. **Intervention method**

The second section of the protocol – intervention method – integrates four subsections; communication skills, motivational interviewing, goal setting, and problem-solving.

**Communication skills**

The subsection “communication skills” guides nurses on effective verbal and non-verbal communication techniques to deliver the intervention content clearly, factually, and relevantly. Verbal communication is described as the human interaction through the use of words or messages in linguistic form, and it includes attending behaviors, active listening, summarizing, paraphrasing, confrontation, and open-ended and specific questioning. Non-verbal communication is described as any form of communication apart from language, and it includes facial expressions, body movement and posture, gestures, eye contact, therapeutic touch, and spacing between the patient and the nurse.

**Motivational interviewing**

The application of five central principles of motivational interviewing is summarized by the acronym “DEARS” (developing discrepancy, expressing empathy, amplifying ambivalence, rolling with resistance, and building self-efficacy) which is discussed in this subsection.
The discrepancy between the patients’ personal goals and patient’s present behavior is elicited by asking open-ended evocative questions, exploring the pros and cons of behavioral change, inquiring about extremes of the impact of treatment adherence, and by looking back and forward on patient’s treatment adherence. The nurse would be trained in empathy to enhance the therapeutic effectiveness of the intervention. Appropriate use of empathy as a communication tool honors the patient, enhances the acceptance, and facilitates the change. By recognizing and verbalizing ambivalence, the nurse would facilitate the patient to acknowledge his/her contradictory ideas about treatment adherence and work on overcoming these contradictions. According to motivational interviewing, directly challenging resistance is useless, and the patient has to roll with it to diminish it. Therefore, the nurse would guide to work on the person’s own health behavior choices and help the patient get control over his/her life. Further, it teaches nurses how to assess a patient’s motivational state accurately, pitch the approach according to the patient, and work in partnership. Finally, the concept of self-efficacy is introduced to the protocol such that the nurse is imparted with techniques such as discussing past patient successes and empowering personal strengths and providing support for them. These five principles of motivational interviewing are thoroughly discussed in this protocol, with examples to facilitate the nurses to use them effectively in the intervention. However, there are no fixed locations, where these principles and their associated techniques are used in the intervention, and the nurses are expected to decide where to use them according to the patient’s requirements throughout all the counseling sessions.

**Goal setting**
The primary work of goal setting is facilitating patients to set goals to bring about lifestyle change with enhancing the adherence to physical activity, diet, and medication. Therefore, the primary work of this section of the intervention is to impart knowledge on how to facilitate patients to set goals to help bring lifestyle change on adherence to physical activity, diet, and medication. Moreover, guidance is given on using specific, measurable, attainable, relevant, and time-bound goals to achieve targets such as losing weight.

**Problem solving**
Problem solving is a process, where a problem is effectively dealt with using five steps; identifying the exact problem, listing all the solutions for the identified problem, selecting the best solution, deciding the steps needed to solve the problem using the chosen solution, and evaluating illness-related improvement due to the selected solution, and developing the indicators to measure these improvements. In this subsection, the nurses are guided on supporting patients in dealing with problems effectively while reaching the expected behavior change.

**Session summaries**
The counseling intervention would be delivered by eight counseling sessions and three booster sessions in a 6-month duration. Therefore, a separate section named “session summaries” was added to the protocol to document the work done in each session by the nurse.

**The Delphi review by the experts**
Each section/subsection of the protocol was reviewed by an expert panel consisting of a consultant physician, two clinical psychologists, a nursing director at the national level (nursing educator), and a nurse in charge of the health education unit in a base hospital. Further, each section/subsection was rated, on a scale of 0 (total disagreement) to 9 (total agreement) on (i) the usefulness to improve the treatment adherence of patients with IHD, (ii) appropriateness to be used with patients with IHD, (iii) the cultural relevancy to be used in Sri Lanka, and (iv) whether understood by nurses who would implement the intervention. Moreover, expert comments were obtained on any changes to be made in each section/subsection. Each section/subsection was removed or revised if 70% or more of the re-ratings were in categories 0–3 and kept as the same if 70% or more of the re-ratings were in categories 4 and above. The Delphi ratings received from stage one was evaluated and resent for a second round after the modifications. Then, the re-ratings were re-evaluated for the degree of consensus. The content of the protocol was revised with the comments which were given by the experts.

**Ethical concerns**
The ethical approval was obtained by the Ethics Review Committee, Faculty of Medicine, University of Colombo. In addition, the study intervention was approved by the Research and Higher Degrees Committee (RHDC), Faculty of Medicine, University of Colombo, Sri Lanka.

**RESULTS**
All the ratings were in categories of four and above. Therefore, no section/subsection was removed, and all the sections/subsections were retained. However, the content was revised based on the further minor expert comments given in each section/subsection.

**DISCUSSION**
The patients with cardiovascular conditions are supported through various psychological and psychosocial interventions ranging from organizational efforts to enhance patient-
directed communication and psychotherapies. Moreover, these psychological and psychosocial interventions are usually coupled with other components of cardiac rehabilitation like risk factor modification (i.e., diet and lifestyle advice, or exercise); in some cases, the intervention is explained as “psychological” only to the extent that psychological techniques are utilized to further other treatment goals through promoting behavioral change.

A systematic review conducted on psychological interventions for patients with IHD revealed that the psychological interventions for patients with IHD were found to improve health-related quality of life, blood pressure, knowledge, and satisfaction with care for patients, and anxiety, knowledge, and satisfaction with care for partners. However, such an institutionalized psychological intervention is not established in Sri Lanka yet. Therefore, the main objective of the present study was to develop a socio-culturally appropriate health counseling intervention protocol to enhance the adherence of prescribed physical activity, diet, and medication among IHD patients attending medical clinics in Sri Lanka which could be implemented in the hospitals in the near future.

The health counseling intervention protocol was evaluated in a Delphi forum by five health experts through a consensus method. Consensus methods are commonly used in cross cultural development/adaptation of programs or scales predominantly in the medical and nursing disciplines. It aims to achieve an agreement on particular concept/s, by experts (i.e., those persons working in a particular discipline and can give evidence that the concepts/s are applicable in the second culture). In the Delphi technique, experts are polled individually and anonymously, usually with a self-administered instrument, to provide opinions/ratings on two or more consecutive rounds. At the second round (and subsequent, if any), they will be shown the ratings of the other experts and allowed to change their original opinions/ratings, if required, by considering the other’s opinions. The Delphi technique has been used extensively in developing concepts and protocols in cardiac rehabilitation and have gained good outcomes. The present study also received good consensus results from the two rounds of Delphi review. The lengthy time duration in reviewing the protocol during the two rounds of the Delphi review is been a limitation of the protocol development.

Limitations of the study
A considerable time has been elapsed to finalize the protocol with a delphi review consisted of two rounds.

CONCLUSION
The Delphi consensus method was found to be effective when developing the counseling intervention protocol in improving treatment adherence of IHD patients. The finalized protocol would be initially implemented in selected hospitals in Galle district as a quasi-experimental study in the near future.

DATA AVAILABILITY
The data used to support the findings of this study are available with the corresponding author upon request.

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CRWG- Concept and design of the study, manuscript preparation, reviewed the literature, statistical analysis and interpretation of results. PTZ, AB, NFJF- Overall Supervision and revising the manuscript.

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