Trials

STUDY PROTOCOL

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The effects of a nutritional intervention on the sports nutrition knowledge and nutritional status of track and field athletes: protocol for a randomized controlled trial

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Abstract

Background Sports nutrition plays a crucial role in providing the fuel to meet the energy demands of athletes' training programmes, enhancing adaptations associated with training, and ensuring rapid recovery between workouts. However, evidence suggests that the dietary habits of many athletes are unsatisfactory when compared to sport-specific nutrition recommendations. This discrepancy is mainly due to a lack of up-to-date, evidence-based nutritional knowledge. Hence, this parallel-group, randomized controlled clinical trial aims to evaluate the effectiveness of a 16-week evidence-based, culturally appropriate, personalized sports nutrition intervention on the sports nutrition knowledge and nutritional status of track and field athletes in Sri Lanka, in comparison to a control group that does not receive this intervention.

Methods Elite and highly trained track and field athletes, competing at the national level and/or representing Sri Lanka in international competitions, will be randomly allocated to either the intervention group (IG) ($n=15$) or the control group (CG) ($n=15$). Participants in the IG will receive an evidence-based, culturally acceptable, personalized sports nutrition intervention from the principal investigator through one-to-one consultations at three-time points (zeroth, fourth, and eighth weeks), while participants in the CG will be followed up throughout the period without receiving the intervention. The primary outcome measure is the number of participants who achieve at least a 10% increase in mean sports nutrition knowledge (SNK) score at the end of the 16th week, compared to the CG. Secondary outcomes include nutrition status and sports performance-related measures at the beginning and end of the intervention.

Discussion While the primary objective is to enhance SNK, it is anticipated that improvements in nutritional status and overall health may significantly impact sports performance and career longevity of the athletes.

Trial registration Sri Lanka Clinical Trials Registry, SLCTR/2024/013. Registered on 10th April 2024. Universal Trial Number (UTN), U1111-1304–8890.

Keywords Sports nutrition, Sports nutrition knowledge, Sports performance, Track and field athletes

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Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Title {1}	The effects of a nutritional intervention on the sports nutrition knowledge and nutritional status of elite athletes: protocol for a randomized controlled trial.
Trial registration {2a and 2b}	This trial is registered under the Sri Lanka Clinical Trial Registry: SLCTR/2024/013 on 10th April 2024.
Protocol version {3}	Protocol version 1.0 (2024/05/08)
Funding {4}	This study is part of a doctoral project and will be conducted by the Department of Physiology, Faculty of Medicine, University of Colombo, Sri Lanka, utilizing their infrastructure. A part of the expenses for biochemical investigations and laboratory tests will be covered by Nawaloka Hospitals PLC, located at 23, Deshamanya H.K. Dharmadasa Mawatha, Colombo 2, Sri Lanka.
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Name and contact information for the trial sponsor {5b}	Nawaloka Hospitals PLC, contact number: +94 115 577 111, Fax: 0112 430 393, Email: nawaloka@slt.lk
Role of sponsor {5c}	A part of the expenses for biochemical investigations and laboratory tests, including serum vitamin D3, serum ferritin, full blood count, and dual-energy X-ray absorptiometry, will be covered.

Introduction

Background and rationale {6a}

Sports nutrition is an integral component in achieving optimal performance in athletes at all levels [1]. An athlete's diet plays a significant role in supplying the fuel needed to cover the energy demands of their training program, enhance the adaptations achieved during training, and ensure quick recovery between workouts [2]. Athletes generally have increased protein and carbohydrate requirements to help lean mass growth and maintain glycogen stores [3]. Optimal dietary macronutrient availability can enhance athletic performance and support skeletal muscle adaptations to endurance and resistance training [2]. An adequate intake of vitamins and minerals assists the use of macronutrients for all physiologic processes, and they are the key regulators of work performance in addition to maintaining optimum health [4]. Moreover, there is an increased requirement for certain minerals such as iron, calcium, and sodium for athletes [3]. Although there is empirical evidence to support the importance of proper nutrition to enhance performance and overall health, it is widely reported that for many athletes, dietary habits are unbalanced and nutritionally deficient [5]. Besides, the dietary practices among athletes are often reported to be unsatisfactory compared to sports-specific nutrition recommendations [6].

Although the reasons for poor dietary practices among athletes are multi-factorial, lack of up-to-date evidence-based nutritional knowledge is one of the main reasons [2]. On the other hand, responsible sports staff recognize the value of their nutrition knowledge and the possible impact it has on their athletes' performance [7]. A lack of nutrition education is one of the main reasons for the lack of sports nutrition knowledge (SNK) among athletes and coaches [8]. Boidin reported that as an athlete's SNK increases, the nutritional quality of food choices improves [9]. According to observations made by coaches and nutrition experts, athletes confident in their nutrition knowledge are more likely to incorporate this knowledge into their lifestyle by selecting accurate dietary practices to match their sports requirements [10]. Nevertheless, adherence to nutritional guidance is eventually enhancing the performance and overall health of the athletes [11].

Furthermore, the nutrition practices of Sri Lankans exhibit notable features. For example, the majority of their calories are obtained from carbohydrates, which account for more than 70% of daily intake, in contrast to protein, which accounts for only about 10% and is derived from predominantly low-quality sources [12]. In addition, the main fat source is coconut oil, which is devoid of essential fats and is high in saturated fat [13]. Moreover, only 3.5% of the population achieves the national

recommendation for fruit and vegetable intake [14], and the consumption of milk and dairy products is also below the recommendations [14]. While there is no nationally published data on the dietary habits of athletes, a study on the nutritional intake of the undergraduate Sri Lankan athletic community found that they do not get sufficient energy or protein and do not meet daily requirements for micronutrients, including vitamins B_1, B_2, B_9, B_{12}, and C and calcium, magnesium, and potassium [15]. While the majority of Sri Lankan athletes take nutrition supplements, including multivitamins (51.8%), creatine (37.3%), and protein powders (14.8%), they buy these supplements without recommendations from qualified professionals [16].

Successful sports nutrition interventions (SNI) should be modified according to each sport and, more importantly, considering socio-economic characteristics to achieve the best outcomes. Moreover, sports nutrition-enhancing interventions are useful in improving nutritional knowledge, eating habits, body composition, and sports performance in a diverse range of team sports athletes [17]. Evidence-based SN advice is increasingly recognized as a major contributing factor for the optimal sporting performance of any athlete competing across a range of sport types, such as strength and power: powerlifting, team: cricket, and endurance: race walking [9]. The fundamental SN strategy to enhance performance is to optimize the intake and distribution of energy, macronutrients, micronutrients, and fluids throughout the day [18]. In addition to basic nutritional advice, a culturally specific, personalized dietary intervention is likely to have a better influence on changing athletes' dietary practices and subsequently improving sports performance [19].

Therefore, it is evident that a successful dietary intervention will rely on providing up-to-date, evidence-based, personalized nutritional guidance that is tailored to the athletes' cultural values and considering socio-economic characteristics. At present, neither an evidence-based nor a culturally appropriate intervention to enhance sports nutrition knowledge, nutritional status, and sports performance has been conducted in Sri Lanka.

Objectives {7}

Study hypotheses

We hypothesize that the implementation of a 16-week evidence-based, culturally accepted, personalized sports nutrition intervention will significantly improve the sports nutrition knowledge and nutritional status of elite and highly trained athletes, resulting in enhanced performance and overall well-being when compared to a control group not receiving this intervention.

General objective

To investigate the effectiveness of a 16-week evidence-based, culturally accepted, personalized sports nutrition intervention on the sports nutrition knowledge and nutritional status of elite and highly trained athletes.

Specific objectives

1. To investigate the effectiveness of an evidence-based, culturally accepted, personalized sports nutrition intervention in enhancing the sports nutrition knowledge of elite and highly trained athletes.
2. To assess the impact of an evidence-based, culturally accepted, personalized sports nutrition intervention on various aspects of nutritional status, including anthropometry, biochemistry, body composition, physical fitness, hydration status, and overall well-being.

Trial design {8}

The research will be carried out as a parallel, randomized controlled clinical trial to evaluate the effectiveness of an evidence-based, culturally accepted, personalized sports nutrition intervention on the sports nutrition knowledge and nutritional status of elite and highly trained athletes for 16 weeks. The participants will be elite track and field athletes of both genders. Participants satisfying the eligibility criteria will be allocated to intervention ($n=15$) and control ($n=15$) groups. The intervention group will be given an evidence-based, culturally acceptable, personalized sports nutrition intervention by the principal investigator in one-to-one consultations and continued support via WhatsApp communications (WhatsApp Inc., California, USA). The control group will not receive any intervention but will be followed up throughout the period.

Methods: participants, interventions, and outcomes

Study setting {9}

Department of Physiology, Faculty of Medicine, University of Colombo, Sri Lanka.

Eligibility criteria {10}

Participants will be enrolled on a voluntary basis after conducting an appropriate screening, two weeks prior to the intervention. Sri Lankan elite track and field athletes satisfying the below-mentioned eligibility criteria will be recruited.

Inclusion criteria

1. Track and field athletes as defined by the International Olympic Committee (IOC)
2. Competing at the national level and/or representing Sri Lanka in international competitions
3. Aged 18 years and above
4. Both male and female athletes
5. Athletes with a personal WhatsApp number
6. Full-time athletes
7. Athletes who agree to participate in the 16-week sports nutrition intervention
8. Those who have the facilities and support to follow a prescribed diet and nutritional supplements

Exclusion criteria

1. Athletes with current sports-related injuries
2. Paralympic athletes
3. Individuals already following a prescribed diet
4. Athletes currently on any sports supplements
5. Individuals largely dependent on outside food
6. Athletes who have changed their sports events recently
7. Athletes addicted to alcohol and smoking
8. Pregnant and lactating athletes

Who will take informed consent? {26a}

The principal investigator (RJ) will obtain informed written consent from the participants after explaining the potential benefits and risks of participation and the right to withdraw from the study, both verbally and in writing, in their native language (Sinhalese or Tamil). The information provided will include the aims of the study, participant responsibilities, follow-up visits and procedures, potential individual and societal benefits, risks involved, and the ability to withdraw from the study at any time, without any consequences. In addition, opportunities are to be provided during this process for any clarifications required by the study participants to ensure maximal understanding. The contact details of two investigators (including the principal investigator) will be provided to study participants for immediate contact during the study (if necessary) to ask questions and register complaints. In addition, a complaint record sheet will be made available to participants to register written complaints.

If a participant indicates that he/she wants to withdraw consent during the study, his/her wishes will be complied with. Reasons for the withdrawal of consent (adverse effect, ineffective treatment, inability to comply with study requirements, etc.) will be sought only from participants who consent to provide this information. In the case of a change in the research procedure during the study, re-consent will be sought from participants of the study after explaining the need for such a change and the possible effects if any on the participant.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

The information leaflet and consent form include details of the blood samples and the tests carried out. No additional consent will be obtained from the participants since biological specimens will not be stored in future studies.

Interventions

Explanation for the choices of comparators {6b}

The control comparator used in this trial will be the elite and highly trained track and field athletes.

Intervention description {11a}

The administration of this nutritional intervention will be undertaken exclusively by the principal investigator, who is a sports nutritionist. The intervention is specifically designed for track and field athletes and incorporates evidence-based, culturally accepted, and personalized strategies to optimize performance and well-being. Personalized consultations will be conducted to provide tailored nutrition prescriptions based on individual nutritional and health parameters assessed 2 weeks before the baseline. These plans will include culturally familiar foods and meal patterns to ensure adherence and practicality while aligning with local dietary preferences and food availability. The intervention follows a scientific framework, adapting international sports nutrition guidelines to meet the specific needs of track and field athletes. Additionally, athletes will have access to the principal investigator via the WhatsApp application for ongoing support, enabling them to address nutrition-related queries remotely. They will also be provided with additional reading materials on request. A structured schedule of intervention sessions will address key nutritional areas such as energy requirements, macronutrient intake, hydration, meal timing, and competition-day strategies, ensuring a comprehensive approach to nutrition education and support.

Number of interventions

There is one intervention with three consultations.

Frequency of intervention delivery

The intervention sessions are strategically spaced, with the first session held at week 0, the second session at the end of week 4, and the third session taking place at week 8.

Approximate duration of each intervention

Typically, each intervention session is anticipated to last for 15–20 min. This concise yet focused approach ensures that participants receive the necessary guidance and support, optimizing their engagement and adherence to the study protocol.

As depicted in Fig. 1 below, during the baseline session, participants will receive comprehensive advice on both general and sports nutrition, hydration, and sleeping habits. In addition, recommendations for micronutrient supplements will be provided if there are signs of clinical deficiency or abnormal biochemical reports. It is important to note that, as part of the intervention, we

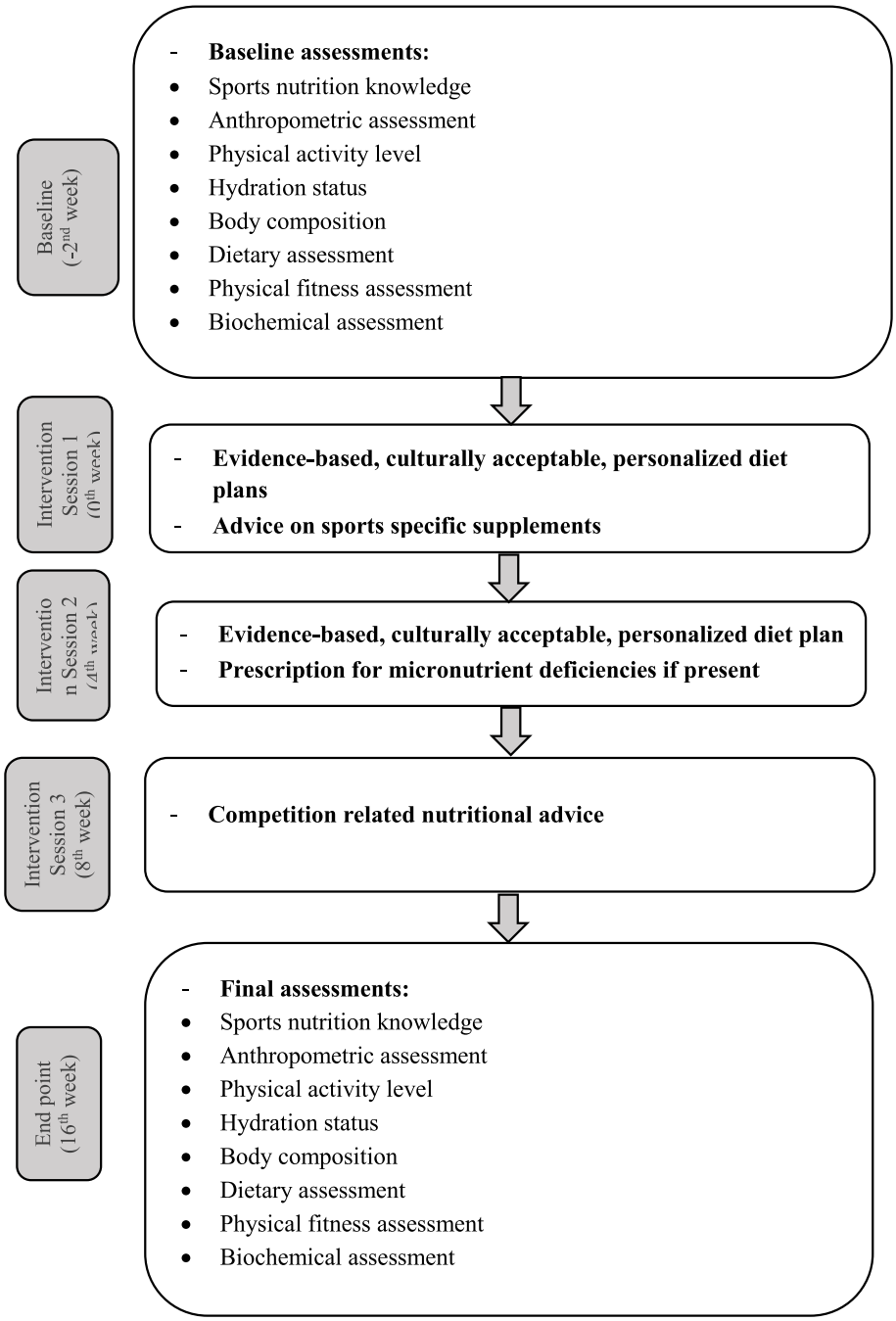

Fig. 1 Flow of the intervention

will not directly provide any micronutrient supplements. Instead, we will offer prescriptions and details of reputable suppliers.

Trial framework (superiority trial)

This randomized controlled trial (RCT) is designed as a superiority trial to assess the effectiveness of a sports nutrition intervention in improving SNK and nutritional status in track and field athletes. The primary outcome is to determine if the intervention leads to a statistically significant improvement in SNK, measured by using the Sri Lankan Sports Nutrition Knowledge Questionnaire (SLn-SNKQ), compared to the control group. The secondary outcomes focus on improvements in nutritional status and sports performance-related measures.

At the second intervention session (fourth week), participants will receive further nutrition advice on both general nutrition and sports nutrition topics, hydration advice, and sports-specific nutritional guidance, including recommendations on the accurate intake of sports supplements if needed according to their current nutritional status. In addition, we will provide training to understand food labelling. No supplements will be provided as part of the intervention during this session. However, details of recommended products and suppliers will be provided.

During the third intervention session (eight week), participants will receive additional nutritional advice aimed at enhancing their sports nutrition knowledge and performance. This advice will include nutritional advice focused on competition. In addition, event-specific ergogenic supplements will be recommended to enhance performance. It is essential to clarify that, as part of the intervention, we will not supply any ergogenic sports supplements but will provide advice on their accurate consumption.

The CONSORT diagram (Fig. 2) illustrates the flow of this RCT.

Criteria for discontinuing or modifying allocated interventions {11b}

It will be very unlikely for a participant to have an adverse effect from nutritional consultations. However, if there is an adverse effect from prescribed nutritional supplements, the participant will be advised to immediately notify the safety monitoring team and to discontinue the supplement. In addition, they will receive appropriate medical attention. Participants are allowed to withdraw from the study for any reason at any time.

Strategies to improve adherence to interventions {11c}

This study population is highly motivated and therefore likely to maintain adherence to the prescribed intervention since it could enhance their SNK, nutritional status, and potentially their performance.

To assess subject compliance with the intervention, a comprehensive approach will be employed. All participants will be engaged through direct communication via personal WhatsApp to address their queries and provide necessary support throughout the study period.

Relevant concomitant care permitted or prohibited during trial {11d}

Both groups will be advised to refrain from seeking any special nutrition advice or taking supplements from other health or nutrition professionals.

Provisions for post-trial care {30}

If there is an improvement in their nutrition status and performance, we will redirect them to the Centre for Sport and Exercise Medicine, University of Colombo, Sri Lanka, for continued support.

Outcomes {12}

Primary outcome

The number of participants who achieved a 10% increase in mean sports nutrition knowledge scores at the end of the 16th week in the intervention group compared to the control group.

Secondary outcomes

Nutrition status and sports performance-related outcome measures will be collected at the beginning and the end of the 16th week in the intervention group and control group. However, basic anthropometry measurements such as weight and height will be assessed in all four-time points (0W, 4W, 8W,16W) only for the intervention group.

Participant timeline {13}

Screening

- Participants will be screened 2 weeks prior to the scheduled intervention, and the participant timeline is shown in Table 1.
- Individuals will be invited through contacts from coaches, and fellow athletes, and open advertisements in social media groups and drawn from the national-level athlete pool.
- Potential participants will be contacted by a research team member who will explain the details of the

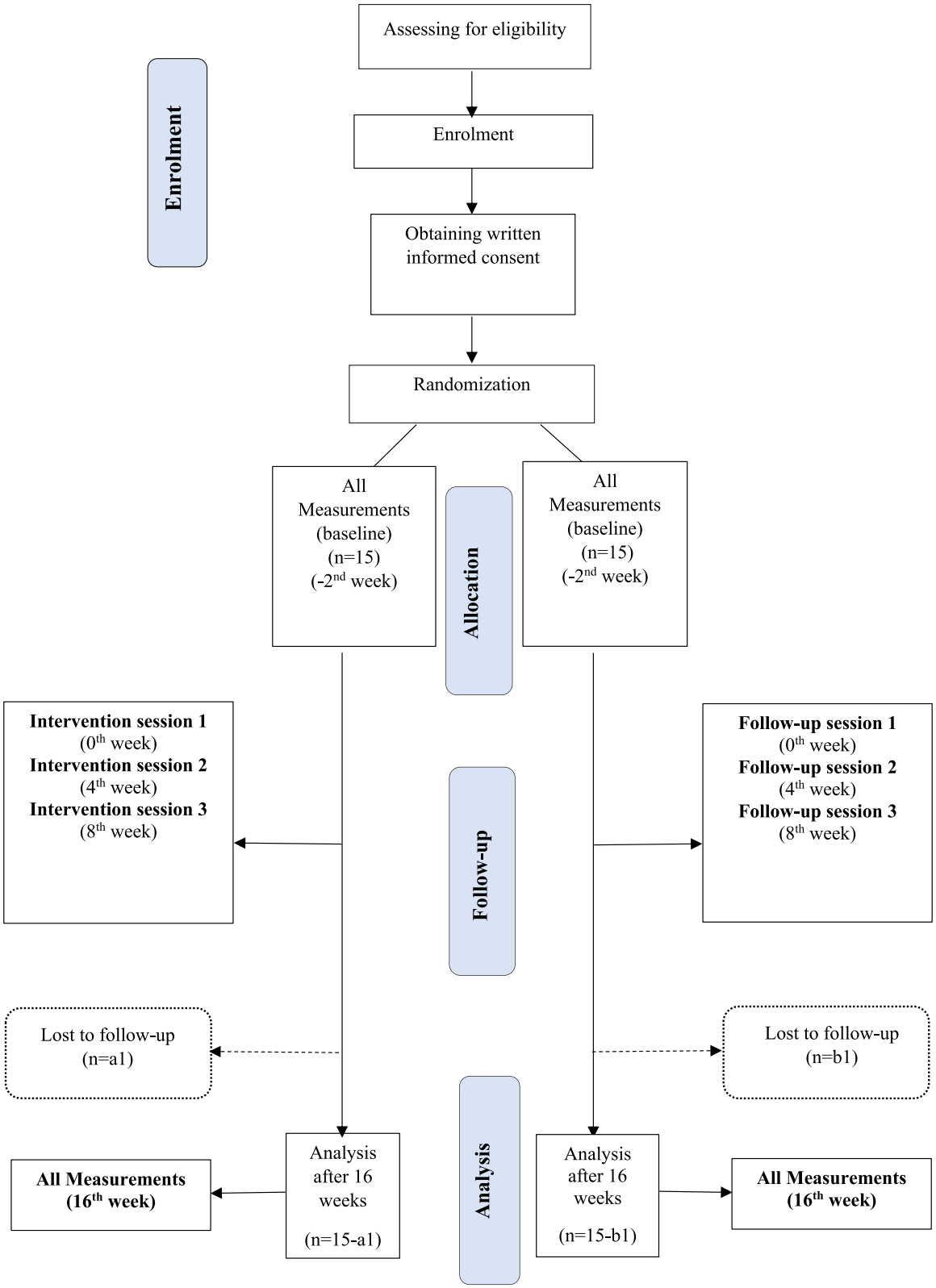

Fig. 2 CONSORT diagram

Table 1 Participant timeline

	Study period				
	Enrolment, measurement of baseline data and intervention phase I		**Intervention phase II**	**Intervention phase III**	**Close-out and post-intervention data collection**
TIMEPOINT**	***−2W***	***0W***	***4W***	***8W***	***16W***
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation	X				
BASELINE INFORMATION:					
Demographics details	X				
Sports related variables	X				
Health history	X				
Sports-related injuries	X				
INTERVENTIONS:					
Evidence-based, culturally acceptable, personalized diet plans		X	X	X	
ASSESSMENTS:					
Demographics	X				
SNK scores	X				X
Dietary status	X				X
Biochemical parameters	X				X
Anthropometry and body composition	X				X
Hydration	X				X
Hand grip strength assessment	X				X
Physical activity and training log	X				X

study and verbal consent will be taken from them to participate in the study.

- All relevant parties such as athletes, coaches, and parents will get an opportunity to clarify any queries regarding the study. To facilitate direct communication and support, the contact details of two investigators, including the principal investigator, will be made available to study participants.
- A dedicated phone number will be used to contact the research team members throughout the study period.
- Potential study participants will be identified by a research member using a checklist of inclusion and exclusion criteria. All participants will be selected by the principal investigator.
- The selected participants will be communicated further and obtain verbal consent to share relevant materials such as a booklet of a 7-day food diary, a 7-day physical activity diary, and urine collection bottles.
- All items will be posted to each individual, and a detailed explanation of filling the 7-day food diary and the 7-day physical activity diary will be provided through individual phone calls.
- Almost daily communication will be established with all individuals by the research team to clarify their queries about filling diaries, and one-to-one support will be provided.
- After a week, potential participants will be asked to visit the research centre with an early morning urine sample.
- At this point, potential study participants will receive comprehensive information both orally and in written form, presented in their native language (Sinhalese or Tamil).
- Also, they will receive a detailed information sheet containing the objectives of the study, participant responsibilities, the schedule of follow-up visits and procedures, potential benefits for both individuals and society, associated risks, and the right to withdraw from the study at any point.
- Furthermore, ample opportunities will be provided during this process for study participants to seek clarifications, ensuring a comprehensive understanding of the study. Those who provide written informed consent will be considered for the study.
- Additionally, a complaint record sheet will be accessible, enabling participants to register written com-

plaints. If a participant expresses a desire to withdraw consent during the study, their wishes will be promptly accepted.

- Participants who are willing to provide reasons for their withdrawal of consent, whether due to adverse effects, perceived ineffectiveness of treatment, inability to comply with study requirements, or other factors, will be invited to share their insights.

Sample size {14}

The sample size was calculated to detect a 10% mean score difference in sports nutrition knowledge measured by the SLn-SNKQ between the intervention and control groups after the intervention (at 16 weeks). A 10% difference was chosen as it represents a meaningful improvement in sports nutrition knowledge based on prior studies and expert consensus, reflecting a minimum effect size that would justify the intervention's practical significance.

The calculation was performed with 80% power and a 95% confidence interval, accounting for a 20% drop-out rate. This gives a required sample size of 30 participants. Hence, a total of 30 participants will be recruited for the study, with participants randomly and equally assigned into either the control or intervention groups (15 each).

The formula used for sample size calculation is presented below:

$$N = [(1/q1 + 1/q0) * (Za + Z\beta)\ 2] / [(E/S)\ 2] \quad (1)$$

Where,

N = Sample size.

$q1$ = Proportion of participants in the intervention group (0.5).

$q0$ = Proportion of participants in the control group (0.5).

$Z\alpha$ = Critical value of the normal distribution at α (α is 0.05 and the critical value is 1.96).

$Z\beta$ = Critical value of the normal distribution at β (β is 0.2 and the critical value is 0.84).

E = Effect size (10%).

S = Standard deviation of knowledge in the population (10%).

Recruitment {15}

After successful screening, suitable participants will be recruited to the study after obtaining written informed consent. Then they will be randomized by a third party for intervention and control groups.

Throughout the study, both the intervention and control groups will undergo assessments of their nutritional status, including biochemical and other relevant parameters. Moreover, all participants will receive their blood test results and other investigative findings. After the intervention, the control group will receive the nutritional advice.

Assignment of interventions: allocation

Sequence generation {16a}

Participants satisfying the eligibility criteria will be allocated to control and intervention groups equally (1:1). A computer-generated random numbers sequence will be used for randomization, facilitated by the Randomization Tool provided by the National Cancer Institute (https://ctrandomization.cancer.gov/tool/) [21]. Eligibility evaluation and enrolment will be conducted by one independent investigator, while randomization will be performed by an independent researcher.

Concealment mechanism {16b}

Sealed opaque envelopes, each indicating the allocation of a participant in accordance with their recruitment number, will be prepared in advance by an independent researcher who is not involved in any part of the study. These envelopes will be provided to the researcher responsible for participant enrolment at the time of recruitment. The sealed envelope corresponding to the participant's recruitment number will then be opened, revealing the assigned group (intervention or control). This ensures the concealment of allocation until the participant is ready to be assigned to a group.

Implementation {16c}

Eligible participants will be informed of their randomized assignment once everyone has completed the screening and baseline assessments. The allocation sequence for assigning participants according to the corresponding randomly generated numbers will be produced by a member of the study team who is not involved in participant recruitment.

Assignment of interventions: blinding

Who will be blinded {17a}

The outcome assessors and data analysts will be blinded to the intervention assignment.

Procedure for unblinding if needed {17b}

Participants will not be blinded, given the nature of the study intervention. Single blinding of the outcome assessors and data analysts will be maintained throughout the study.

Data collection and management

Plans for assessment and time collection of outcomes {18a}

The research team will provide sufficient training to the data collectors to minimize intra- and inter-observer variations. This includes being familiarized with the research questionnaire and data collection instruments, as well as receiving training on the usage of equipment and measurement techniques. A pre-test will be undertaken using a small group and data will be collected by a research team.

1. Demographic details, events/sports-related variables, and health history.

An interviewer-administered semi-structured questionnaire will be used to collect detailed demographic information, events/sports-related variables, and health history. The demographic details will include age, sex, educational level, occupation, and residential area. Events/sports-related variables such as sports category, main event, number of years of sports experience, competitiveness, personal best, seasonal best, records, and performance targets will also be collected. The health history section will assess any previous injuries, chronic illnesses, dietary habits, and supplement use to provide a comprehensive profile of the participants.

2. Assessment of sports nutrition knowledge.

SNK will be assessed pre- and post-intervention using the newly developed and validated Sri Lankan Sports Nutrition Knowledge Questionnaire (SLn-SNKQ) [22, 23]. The SLn-SNKQ comprises 32 questions across 12 sub-sections, with a total of 123 individual items. These questions cover two primary sections: the General Nutrition Knowledge (GNK) section, which includes 15 questions with sub-sections on macronutrients ($n = 4$), micronutrients ($n = 3$), energy balance ($n = 4$), hydration ($n = 3$), and weight management ($n = 1$); and the SNK section, which contains 17 questions under 7 sub-sections, including carbohydrate loading ($n = 1$), pre-training meals ($n = 1$), training meals ($n = 1$), post-training meals ($n = 2$), sports supplements ($n = 6$), supplement label reading, alcohol, isotonic drinks, and doping ($n = 4$), and energy intake and food habits ($n = 2$).

The included questions have three options—'agree', 'disagree', and 'unsure'—while some questions offer five response options, with the most accurate answer being considered for scoring. A correct answer will be awarded a plus 1 mark, while an incorrect answer will receive a minus 1 mark. An unsure response will receive a score of 0. Each item will be scored individually without additional weightage, as per author consensus [24]. To assess the nutrition knowledge of each athlete, the mean total score will be calculated across all questions.

In the case of participants facing difficulties in understanding the questionnaire due to low literacy levels or other reasons, an investigator will clarify the questions. The questionnaire will be administered online and in the participants' native language to ensure ease of understanding.

3. Assessment of dietary status.

This will be assessed at the pre-intervention (-2nd week to 0 week) and the post-intervention (end of the 16th week) via 7-day food diaries. A particular training season (off-season or in-session games) has not been specifically focused on dietary assessment. It is ensured that both groups are assessed under similar conditions, with food records being collected consistently at the same points in time across all participants. By avoiding the inclusion of a particular training season, any potential variations in dietary intake due to seasonality or specific training phases are controlled. Consequently, the intervention's effect on dietary status can be assessed without confounding seasonal influences.

Total intake for 7 days will be then averaged and given as pre- and post-intervention. The subjects will be given written and verbal instructions in a booklet for completing a 7-day food record. The portion sizes for each food item will be estimated using a local food atlas [25], which will help ensure accuracy in portion estimation and reflect the local dietary patterns. The total intake for the 7 days will be averaged to provide both pre- and post-intervention dietary assessments.

Standard energy values based on the local food atlas and typical portion sizes will be used to calculate the energy content of the foods. The daily energy intake will be determined using Nutri-Survey 2000 software (EBI-Spro). Additionally, the intake of macronutrients and micronutrients will be analyzed with the Nutri-Survey Software, modified to include Sri Lankan food composition data, to ensure the analysis reflects the local food types and nutritional context.

4. Anthropometry.

Anthropometric measurements will be performed using calibrated equipment by trained research assistants adhering to international recommendations.

Body weight will be measured to the nearest 0.1 kg using a calibrated digital weighing scale (seca 874, Hamburg, Germany) with the participants wearing indoor light clothing and emptying the bladder. Two measurements will be taken for each person and the average

weight will be considered as the actual weight for each person.

Height will be taken to the nearest 0.1 cm, as the maximum distance to the uppermost position on the head from heels, with the individual standing barefoot and in full inspiration using a calibrated stadiometer (seca 213 portable stadiometer) adhering to a consistent technique.

Mid upper arm circumference (MUAC): the measuring point of MUAC will be marked at the midpoint between the acromion and the olecranon process in the right upper arm when the right elbow is 90° flexed placing the forearm palm down across the trunk. The measurement at the marked site will be taken using a plastic flexible tape (seca 201, Germany) to the nearest 0.1 cm when the right arm is extended alongside the body with the palm facing upwards.

Waist circumference will be measured using a non-elastic measuring tape (seca 201, Germany) to the nearest 0.1 cm midpoint between the lower rib margin and the top of the iliac crest, and the measurement will be taken at the end of normal expiration. A mean value will be recorded after three consecutive measurements.

Skinfold thickness: triceps skinfold thickness will be assessed using a Harpenden skinfold calliper (Model HSC-4, British Indicators, West Sussex, UK). Each skin fold measurement will be taken in duplicate on the non-dominant side, and the average of two readings will be recorded following the standard ISAK protocols using a consistent technique [26].

5. Body composition

Bio-electrical impedance analysis (BIA): total body water will be assessed, and total body fat predicted using resistance, reactance, phase angle, and impedance values (Bodystat 1500, Bodystat Ltd., Isle of Man, British Isles). Participants will be instructed to lie supine while electrodes from the BIA device are attached to the right hand and foot [27]. All metal objects will be removed from the body, and measurements will be conducted at room temperature. Fat-free mass (FFM) and body fat percentage (BF%) will be calculated using resistance and reactance values applied to an ethnicity-specific prediction equation designed for Asians [28].

Dual-energy X-ray absorptiometry (DEXA): DEXA will be used to derive bone mineral density, BF%, and FFM. DEXA scans (QDR 4500A, Waltham, USA) will be conducted at the accredited radiography unit, Nawaloka Hospital, Colombo, Sri Lanka, at both the 0^{th} week (baseline) and the 16^{th} week of the study.

6. Hydration

Urine samples will be collected from each participant before the intervention (from 2 weeks to immediately before starting) and at the end of the intervention (16 weeks) for assessing urine-specific gravity using a clinical refractometer (model 300 CL; Atago Company Ltd., Tokyo, Japan). To conduct this procedure, an early morning mid-stream urine sample will be collected and transported within 2 h to the data collection centre.Additionally, participants will assess their urine samples in relation to urine colour against a standardized urine colour chart [29] prior to and after training on three typical training days, for a total of four instances, as instructed by the data collectors. Participants' thirst levels before and after training during three typical sessions will also be evaluated using a seven-point Likert scale (ranging from 1, 'Not Thirsty at All,' to 7, 'Very, Very Thirsty') [30]

Hand grip strength

Hand-grip strength will be measured in kilogrammes using a pre-calibrated hydraulic hand dynamometer (Model SH5001®; SAEHAN Corporation, Yangdeok-Dong, Masan, South Korea), with a resolution of 2 kg. This measurement will follow the guidelines established by the American Society of Hand Therapists [31].

Measurements will be obtained in standardized conditions with the participants in the seated position, elbow at 90°, handle adjusted to the second position, after receiving an explanation of the procedures, and after familiarizing themselves with the instrument, they should apply the maximum grip strength for 3 to 5 s. The procedure will be performed three times with each hand alternately, with an interval of 1 min between each measurement.

7. Physical activity and training

Total energy expenditure estimate: activity diary records will be kept for seven consecutive days. A modification of the method originally described by Bouchard et al. will be used in this study [32].

Activities will be categorized into nine levels according to their average energy costs, representing multiples of basal metabolic rate (BMR) (physical activity ratio = PAR), from the lowest activity level, 1, representing sleep or rest in bed, to the highest level, 9, during very intense manual work or maximal sports activity. Each day will be divided into 96 periods of 15 min each. All 96 periods will be represented by squares in the pre-printed diary form, with four squares in each row representing

1 h. For each 15 min, the participant entered into the appropriate square the categorical value corresponding to the dominant activity of that period. A list of common activities together with their categorical value will be printed on the record form. When an activity is not listed, the participant will be instructed to apply a categorical value closest to an activity of comparable intensity or to write an alphabetic code in the square and to write this code together with a description of the activity in 1 ± 2 words in a section for notes in the record form. Each participant will be given a detailed explanation and demonstration of the activity diary form and method. He or she completes a retrospective recording of the last 2 days' activities. The record will be then discussed with the investigators. Special emphasis will be placed on the choice of appropriate categorical values for different activities. Participants will be encouraged to contact the investigators by telephone at any time during the following 7 days if in any doubt about the recording. After 7 days, the activity records will be scrutinized and discussed.

Currently, there is no specific Sri Lankan formula for calculating basal metabolic rate (BMR). The BMR prediction formulae used in this study are based on international compendiums and have been widely validated across various populations. Therefore, the international formulas used in this study [33], BMR = 0.074 × kg BW + 2.754 MJ/days for men, and BMR = 0.056 × kg BW + 2.898 MJ/days for women, are appropriate for estimating BMR in the study participants [34].

8. Laboratory procedures/evaluations

Serum vitamin D_3

Serum will be separated from the 5.0 mL venous blood sample collected and tested within 3 h using MAGLUMI 2000 analyser by competitive chemiluminescence immunoassay (CLIA) (Snibe; Shenzhen, People's Republic of China). This test quantitatively measures the sum of both 25-(OH) vitamin D_3 (cholecalciferol) and 25-(OH) vitamin D_2 (ergocalciferol) in the specimen.

Serum ferritin

This will be measured in Cobas e601 device with ECLIA technology (Roche Diagnostics International AG Rotkreuz, Switzerland).

Full blood count (FBC)

The FBC will be analyzed using the SYSMEX XE-2100 Haematology Automated Analyser (Block Scientific Inc., US). Several blood parameters relevant to potential nutrition-related deficiencies will be examined, particularly focusing on haemoglobin levels, which are indicative of anaemia. Additional parameters, such as mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), and mean corpuscular haemoglobin concentration (MCHC), will be assessed. These parameters are crucial for differentiating between types of anaemia, such as microcytic hypochromic anaemia, commonly associated with iron deficiency, and macrocytic anaemia, often linked to deficiencies in vitamin B_{12} or folate.

All biochemical parameters will be carried out at an accredited laboratory (Nawaloka Metropolis laboratory, Nawaloka Hospital PLC) following the standard procedures.

Plans to promote participant retention and complete follow-up {18b}

All participants will be engaged through direct communication via personal WhatsApp to address their queries and provide the necessary support throughout the study period. Compliance will be evaluated weekly by telephone communication and follow-up consultations. It is believed that frequent communication will increase the compliance and retention rate. In general, this population is highly motivated and determined to follow sports nutrition advice.

Data management {19}

Data will be collected and recorded by a well-trained team of data collectors. Any data collected as part of this research project will be stored in a locked filing cabinet at the Department of Physiology, Faculty of Medicine, University of Colombo for 5 years, under the supervision of the principal investigator (RJ). The data will be stored in a de-identifiable format. Simultaneously, softcopies will be kept password-protected for the above-prescribed period. Following the completion of the due period, the documents will be shredded and the softcopies will be permanently deleted.

Confidentiality {27}

The data sheets and electronic data files will not contain any personal information. Each participant will be given a unique study code. The document containing the information on the study code and the identity of the patient will be kept separate from the study data files and data sheets.

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

None of the blood samples will be utilized for any other purpose outside the intended tests, and no genetic or

molecular analysis will be done. Blood samples will not be given to external bodies and sent abroad. All blood samples will be stored for a month to allow for the completion of the tests and safely destroyed.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

For each group in this study, summary statistics will be calculated and reported. Continuous variables will be described using means and standard deviations, while categorical variables will be summarized as proportions. To compare baseline and end-of-study characteristics between the groups, independent sample*t*-tests will be used, and to assess changes within each group, paired *t*-tests will be utilized for normally distributed continuous variables. The normality of these variables will be evaluated using the Kolmogorov–Smirnov test.

For continuous variables that do not follow a normal distribution, differences between and within groups will be assessed using the Mann–Whitney *U* test for independent samples and the Wilcoxon signed-rank test for paired comparisons. These non-parametric tests will be employed to handle asymmetrical data distributions.

Interim analysis {21b}

There is no interim analysis in this study.

Methods for additional analysis (e.g. subgroup analysis) {20b}

There is no additional analysis in this study.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Each participant's adherence to the research procedure will be periodically monitored via direct phone calls and WhatsApp. Through this method, any queries regarding the research procedure will be addressed, and participants will be encouraged to adhere to the intervention. Additionally, monthly follow-up sessions will be conducted during the fourth and eight weeks to monitor their progress both quantitatively and qualitatively.

If a participant is unable to adhere to the intervention procedure continuously for more than 7 days due to any reason, they will be considered "non-adherent" to the intervention and categorized as a 'drop-out.' However, for the analysis, an intention-to-treat (ITT) approach will be employed to include all randomized participants, regardless of their adherence status. A per-protocol analysis will also be conducted to evaluate the effects of the intervention among participants who fully adhered to the protocol. Both sets of results will be presented to provide a comprehensive assessment of the treatment effects.

If any data points are missing, we will first attempt to contact participants to retrieve the missing information. If this is not possible, we will use multiple imputations as the primary method to handle missing data. The nature and extent of missing data will be assessed to ensure that multiple imputations are appropriate, and sensitivity analyses will be conducted to evaluate the impact of missing data handling on the study outcomes.

Plans to give access to the full protocol, participant-level data, and statistical code {31c}

Full protocol, participant data, and statistical code will be available from the principal investigator upon reasonable request after the publication of the study results.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

The coordinating centre is located at the Department of Physiology, Faculty of Medicine, University of Colombo. The principal investigator and the data collection team are responsible for ensuring the protocol is implemented as planned, reviewing the study progress regularly, and upholding good clinical practice at all times. The principal investigator, coinvestigators, and research assistants will be responsible for all aspects of the logistics and organization of the trial.

Composition of the data monitoring committee, its role, and reporting structure {21a}

An independent board of senior researchers who have no competing interests will be appointed as the data safety monitoring committee. The accumulated study data for participants' safety and study progress will be reviewed and evaluated on a monthly basis by the data safety monitoring committee. Serving in an individual capacity, their expertise and recommendations will be provided throughout the study. Recommendations concerning the continuation, modification, or termination of the trial will be made to the research team by the committee.

Adverse event reporting and harms {22}

It is very unlikely to get an adverse event in this kind of behavioural intervention in very healthy young adults.

Frequency and plans for auditing trial conduct {23}

The independent data safety monitoring board and investigators will communicate throughout the trial period to notify the Ethics Review Committee of the Faculty of Medicine, University of Colombo, if there are any issues. Any protocol amendments will be properly notified to the Ethics Review Committee, and approval will be obtained prior to the implementation.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Any amendment to the protocol will be submitted by the principal investigator to be approved by the Institutional Ethical Review Committee, Faculty of Medicine, University of Peradeniya, Sri Lanka.

Dissemination plans {31a}

The findings of the trial will be published in peer-reviewed scientific journals and presented at international scientific conferences.

Discussion

To the best of our knowledge, this study will be the first RCT to conduct a nutritional intervention aimed at improving SNK among the sports population in Sri Lanka. While the primary objective is to enhance SNK, it is anticipated that improvements in nutritional status and overall health may have significant implications on sports performance and career longevity of this population [35].

A previous study assessing a 7-week nutrition education intervention among UK national and international adolescent swimmers revealed a significant increase in SNK [36]. Post-intervention, the mean total SNK score increased by 8.3% (SD = 8.4%, 95% CI = 4.1–12.6; $p = 0.006$; effect size = 1.0). Additionally, knowledge regarding hydration showed a substantial improvement of 22.2% (SD = 20.6%, 95% CI = 11.8–32.6, $p = 0.004$, effect size = 1.1) over the intervention period [36].

Another study, conducted on Malaysian team sports athletes, evaluated the effects of a 7-week sports nutrition education intervention on sports nutrition knowledge, attitudes, and practices (KAP), as well as dietary intake [37]. This study reported a significant increase in the intervention group's post-intervention mean scores for knowledge (6.21 ± 2.95), attitude (9.04 ± 6.65), and practice (4.39 ± 4.27) compared to the control group, which experienced declines in these areas (-2.15 ± 1.45 ; -1.72 ± 5.06; -0.74 ± 2.32). This intervention also led to marked improvements in total energy intake and intakes of carbohydrates and proteins. These findings demonstrate the efficacy of sports nutrition education interventions in enhancing the KAP scores and nutritional status of team sports athletes [37].

Research has demonstrated that dietary modifications, coupled with improved SNK, can enhance the nutritional biomarkers of athletes [38]. Debnath and colleagues conducted a study examining the effects of dietary modifications on nutritional biomarkers in footballers and hockey players [38]. Their findings indicated a significant increase in total serum protein (5.6%, $p < 0.001$), haemoglobin (3.9%, $p < 0.001$), and vitamin E (2.9%, $p < 0.001$), along with notable improvements in serum levels of vitamin C (6%, $p = 0.004$), folate (4.5%, $p = 0.004$), ferritin (4.8%, $p = 0.003$), calcium (4.2%, $p = 0.009$), vitamin B_{12} (3.9%, $p = 0.012$), and vitamin D (12.3%, $p < 0.001$) [38]. They concluded that the enhanced blood levels of nutritional biomarkers observed after 8 weeks of controlled dietary modification were supported by positive correlations with daily nutrient intakes.

A unique aspect of this proposed study is its comprehensive approach to providing nutritional advice, integrating both general and sports-specific nutrition information not only based on the current evidence but also tailored to cultural practices. Unlike studies focused solely on supplementing specific nutrients and observing nutritional status changes, this intervention will offer athletes a package of advice. This includes dietary modifications, label reading skills, micronutrient supplementation, and sports supplements, thereby ensuring the study's outcomes have greater practical validity in real-world settings.

The challenges of this study are multifaceted. The primary challenge will be recruiting suitable participants, as most elite-level athletes are already receiving professional nutritional advice and are using sports supplements. Another challenge involves minimizing contamination, as many athletes train in groups and often follow dietary practices within the same premises.

To address these challenges, we plan to invite and screen a large pool of athletes, selecting participants with great care. Furthermore, continuous motivation will be essential to maintain the confidentiality of the dietary advice provided.

One of the main limitations of this study is the inability to assess changes in competition-level performance directly. It is hypothesized that improved SNK leads to healthier dietary practices, which, in turn, may enhance athletic performance. A long-term follow-up and the collection of qualitative data could be beneficial in understanding the impact of the nutritional intervention on competition results.

Trial status

The most recent approved protocol is version 2.0, dated 20th October 2023. Ethical approval for this protocol was granted on 15th February 2024 by the Ethics Review Committee, Faculty of Medicine, University of Peradeniya, Sri Lanka. The study recruitment is planned to begin on 30th May 2024 and is expected to be completed by 30th June 2024.

Abbreviations

BCAA	Branched-chain amino acids
BIA	Bio-electrical impedance analyzer
BMI	Body mass index

BMR	Basal metabolic rate
DEXA	Dual-energy X-ray absorptiometry
DSMB	Data and safety monitoring board
FBC	Full blood count
IOC	International Olympic Committee
MUAC	Mid-upper arm circumference
PI	Principal investigator
RCT	Randomized controlled trial
SN	Sports nutrition
SNK	Sports nutrition knowledge
SNI	Sports nutrition interventions
W	Weeks

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Authors' contributions {31b}
RJ is the principal investigator; he conceived the study and led the proposal development. KW and RJ contributed to the examination, screening, and recruitment of study participants. KW contributed to the data acquisition. All authors read and approved the final manuscript.

Funding {4}
This study is part of a doctoral project and will be conducted by the Department of Physiology, Faculty of Medicine, University of Colombo, Sri Lanka, utilizing their infrastructure. A part of the expenses for biochemical investigations and laboratory tests will be covered by Nawaloka Hospitals PLC, located at 23, Deshamanya H.K. Dharmadasa Mawatha, Colombo 2, Sri Lanka.

Data Availability {29}
The principal investigator RJ will have access to the final trial dataset. Any data required to support the protocol can be supplied on request.

Declarations

Ethics approval and consent to participate {24}
Ethical approval was obtained from the Institutional Ethics Review Committee, Faculty of Medicine, University of Peradeniya, Sri Lanka (2023/EC/71). Informed written consent will be obtained from each participant prior to recruitment.

Consent for publication {32}
The model consent form will be available upon request.

Competing interests{28}
The authors declare that they have no competing interests.

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