Official Title: Effectiveness of dietary intervention strategies among athletes with gastrointestinal symptoms in Perak: A study protocol of three-arm randomized controlled trial

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Introduction

Gastrointestinal (GI) symptoms are highly prevalent among athletes across different levels, including elite, national, and recreational populations, with reported symptoms such as bloating, abdominal pain, diarrhea, nausea, and reflux frequently occurring during or after exercise. These symptoms are increasingly recognized as a significant concern due to their negative effects on athletic performance, recovery, and quality of life. Globally, gastrointestinal (GI) symptoms among athletes have been widely reported, with ranges between 11.5% and 80%, and approximately one in two female athletes and one in three male athletes experiencing symptoms around training or competition. In Asia, 26.1% to 50.4% of the endurance runners experienced GI symptoms while racing, and those symptoms varied according to the stage of the race, with symptoms being most prominent during the middle stage. In Malaysia, the available evidence on GI disorders draws primarily from general population studies or specific clinical groups rather than athletic cohorts. Among the dietary strategies proposed to manage GI symptoms, the low fermentable oligo-, di-, monosaccharides and polyols (FODMAP) diet has gained considerable attention. The low FODMAP diet involves a structured three-phase approach, restriction, reintroduction, and maintenance, aimed at reducing fermentable carbohydrate intake to minimize luminal distension and osmotic effects in the gut. However, its implementation is often challenging due to dietary restriction, potential nutritional inadequacy, and adherence difficulties, particularly among athletes with high energy demands. Alternatively, butyrate, a short-chain fatty acid (SCFA), has emerged as a promising therapeutic strategy. Butyrate is produced in the colon through microbial fermentation of dietary fiber and serves as a primary energy source for colonocytes, playing a vital role in maintaining gut barrier integrity and anti-inflammatory responses. Currently, butyrate is available in several forms for consumption, including sodium butyrate, calcium/magnesium butyrate salts, and encapsulated formulations designed for targeted colonic release. Encapsulated butyrate has gained attention due to its improved stability and tolerability compared to other forms (Caban et al., 2025). However, research on its application among athletes remains limited, highlighting a critical gap in literature. Despite growing evidence, there is a lack of comprehensive research in Malaysia examining the effectiveness of dietary strategies among athletes with most existing studies have been conducted in Western populations, limiting the applicability of findings to Malaysian athletes. Therefore, the aim of the study in this trial protocol is to determine the effectiveness of a low FODMAP diet and oral butyrate supplementation in reducing GI symptoms among athletes in Perak.

Methods

Study design
This is a single-blind, three-arm randomized control, parallel trial in which the participants will be randomized into a 1:1: 1 ratio.

Athletes who report at least one gastrointestinal symptom according to the Gastrointestinal Symptom Rating Scale (GSRS) will be an eligible participant and will be randomly assigned to receive either a low FODMAP dietary intervention, oral butyrate supplementation, or general healthy eating advice (control) for 12 weeks. Gastrointestinal symptoms will be assessed at baseline and at weeks 4, 8, and 12 using the GSRS questionnaire. Appropriate statistical analysis will be performed to compare the effectiveness of dietary interventions.

Study setting
This study will be conducted at Majlis Sukan Negeri Perak (MSNPk), Perak where eligible athletes will be recruited. Questionnaire administration, informed consent, hydration assessment, and follow-up assessments will be conducted at designated facilities within MSNPk. For the intervention phase, individualized dietary counselling sessions and outcome assessments will be conducted at MSNPk.

Participants
Healthy athletes aged 18 years and above, currently undergoing structured training at Majlis Sukan Negeri Perak (MSNPk), Perak for at least four weeks and are involved in moderate- or vigorous-intensity, ability to understand the study procedures, provide written informed consent and willing to comply with all study procedures will be invited to participate in this study. Additionally, athletes identified with at least one gastrointestinal symptom and willing to participate in the 12-week intervention will be involved.

However, participants currently consuming probiotics or have followed a gastrointestinal-specific dietary regimen (e.g., low FODMAP diet) within the previous three months, have used non-steroidal anti-inflammatory drugs (NSAIDs) or stool-altering medications (e.g., laxatives) within one month before enrolment, have a diagnosed gastrointestinal disease or disorder (e.g., inflammatory bowel disease, coeliac disease, gastrointestinal infection), have been with diagnosed psychological disorder requiring active medical treatment and are unable or unwilling to comply with the study procedures will be excluded (Scrivin, 2025).

Sample size
The sample size in this study is calculated based on the formula developed by Chan (2003). The estimation was based on the proportion of participants reporting positive effects following dietary intervention (Wiffin et al., 2019). For a two-sided test of 5%, where c = 7.9 for 80% power and 10.5 for 90% power, π_1 and π_2 are the proportion estimates. Thus, from the above proportion, $\pi_1 = 0.25$ (proportion reporting positive effects in high FODMAP group) and $\pi_2 = 0.69$ (proportion reporting positive effects in low FODMAP group). Using 80% power, the calculated sample size is n = 16. After accounting for a 20% non-response rate, n = 20 for each trial arm. Hence, 20 x 3 = 60 subjects will be needed.

Data collection procedure and randomization

Athletes identified with at least one gastrointestinal symptom according to the Gastrointestinal Symptom Rating Scale (GSRS) and meeting the inclusion criteria will be invited to participate in the intervention study. Following written informed consent and baseline assessment using the GSRS, participants will be randomly allocated into one of three interventional groups. The participants will be randomized by using a computer-generated block randomization stratified by GI symptom severity (moderate vs. severe). Allocation concealment using sealed opaque envelopes. To prevent bias, participants will not be informed of their group's assignment to the treatment or control group. Allocation will follow a 1:1:1 ratio.

Group 1: Low FODMAP diet group, participants will receive individualized dietary counselling to follow a low FODMAP diet for 12 weeks. Compliance will be monitored using 3-day food records at Weeks 4, 8, and 12.

Group 2: Oral butyrate supplementation group, participants will receive oral microencapsulated calcium butyrate supplementation sachet (3g/day) for 12 weeks while maintaining their usual dietary intake. Compliance will be monitored through sachet counts and participant self-report.

Group 3: Control group, participants will continue their habitual diet and receive individualized general healthy eating advice for 12 weeks.

Gastrointestinal symptoms will be evaluated using the GSRS at baseline and at Weeks 4, 8, and 12. Participants may withdraw from the study at any time without any consequences. All collected information will be kept confidential and used solely for research purposes.

Outcome measurement

Personal data

In this section, personal data and training information such as age, sports type (endurance, non-endurance and mixed), self-reported exercise intensity of training sessions (on a scale of 1 to 7), weekly training frequency (number of sessions per week), length of each training session (in hours) will be collected to classify participants as moderate or vigorous intensity group. Participants that reported performing intense, very intense, and maximal physical exercise were grouped in physical exercise of vigorous intensity group (Lira et al., 2019).

Gastrointestinal Symptom Rating Scale (GSRS) for GI symptom assessment

The GSRS consists of 15 items and assesses GI complaints in the 7 days prior to filling out the questionnaire. The 15 items (1: upper abdominal pain; 2: heartburn; 3: acid reflux; 4: hunger pains; 5: nausea; 6: rumbling in the stomach; 7: bloated; 8: burping; 9: passing gas or fatus; 10: constipation; 11: diarrhea; 12: loose stools; 13: hard stools; 14: urgent need to defecate; 15: incomplete emptying of bowels) assessed the extent of discomforts of GI symptoms based on a 7-point Likert scale, with higher scores reflecting more severe discomforts. A total score with no complaints would result in 15 points, whereas the maximal score would result in 105 points (Wardenaar, 2025). In addition, the GSRS outcomes were categorized into three main categories based on the 7-point Likert scale as no symptoms (1), moderate symptoms (2–4), and severe symptoms (5–7) (Wardenaar et al., 2023)

The primary outcome of this study will be able to determine the number of athletes reporting GI symptom improvement, while the secondary outcome is able to determine the significance difference in gastrointestinal symptoms among Perak athletes receiving low FODMAP diet and oral butyrate supplementation intervention.

Participant timeline

Measures	**Intervention Follow-Up**			
	Visit 1 (Week 0)	**Visit 2 (Week 4)**	**Visit 3 (Week 8)**	**Visit 4 (Week 12)**
Explanation of the study	X			
Inform consent	X			
Eligibility screening	X			
Gastrointestinal Symptom Rating Scale (GSRS)	X	X	X	X
Demographic and training information	X			
Randomization	X			
Primary outcome				
GI symptoms improvement		X	X	X
Secondary outcome				
Significance difference in GI symptoms		X	X	X

Recruitment

In achieving adequate participant enrolment to reach the targeted sample size, the data collection will be coordinated with Majlis Sukan Negeri Perak (MSNPk) and coaching staff to schedule study visits at times that minimize disruption to training activities. To improve compliance rate particularly receiving the low FODMAP dietary intervention which may vary due to individual food preferences, limited availability of suitable foods, and athletes existing dietary practices, individualized dietary counselling, culturally appropriate meal plans, educational materials, and regular follow-up sessions will be provided. Compliance will be monitored using 3-day food records for the low FODMAP group and sachet counts together with self-reported adherence for the oral butyrate group. To minimize loss to follow-up during the 12-week intervention which may reduce statistical power, regular communication and appointment reminders will be provided, and study visits will be scheduled to coincide with athletes' routine training sessions whenever possible. The sample size calculation has also incorporated an anticipated attrition rate.

Anticipated Benefits and Risk

Participants included in this study may benefit from increased awareness of their gastrointestinal health and dietary practices. Participants enrolled in the randomized controlled trial may experience improvement in gastrointestinal symptoms following the low FODMAP dietary intervention or oral calcium butyrate supplementation. The results will provide evidence to support the development of effective nutritional strategies for the prevention and management of gastrointestinal symptoms and may assist sports dietitians, healthcare professionals, coaches, and sports organizations in improving athlete health, well-being, and sports performance among Malaysian athletes.

In addition, this study is considered to pose minimal risk to participants. Participants may choose not to answer any question they find uncomfortable and may withdraw from the study at any time without penalty. Participants assigned to the low FODMAP diet may experience temporary dietary inconvenience, challenges in food selection, or minor gastrointestinal changes during dietary modification. These risks will be minimized through individualized dietary counselling, culturally appropriate meal plans, and regular follow-up throughout the intervention period. Participants receiving oral butyrate supplementation may experience no or minimal gastrointestinal side effects. Participants will be monitored throughout the intervention for any adverse events, and supplementation will be discontinued if clinically indicated. Participants experiencing persistent or significant adverse effects will be referred to an appropriate healthcare professional for further evaluation. All participant information will be kept confidential and stored securely. Only the primary investigator will have access to identifiable data, and study findings will be reported in aggregate form without revealing participants identities.

Data handling and statistical analysis

Intention-to-treat analysis will be analyzed. Statistical analyses will be conducted using the Statistical Package for the Social Sciences software programme (SPSS, Version 30). Descriptive statistics will be used to determine the prevalence of gastrointestinal symptoms improvement among athletes throughout the intervention period. Repeated measures ANOVA to assess changes in occurrence of GI symptoms outcomes across groups and time points (Wiffin et al., 2019). Post-hoc pairwise comparisons with Bonferroni correction will be analyzed. Statistical significance will be set at $p < 0.05$.

Ethical clearance

This study was approved by Universiti Tunku Abdul Rahman (UTAR) Scientific and Ethical Review Committee (SERC), U/SERC/56(B)-106/2026.

Confidentiality

The research procedures will be carried out by the primary investigator (PI). The PI will be responsible for participant recruitment, obtaining informed consent, administering questionnaires, providing dietary counselling, monitoring participant compliance, collecting outcome data, and managing the study database. All research data will be stored securely by the PI. Hardcopy documents, including signed informed consent forms and data collection forms, will be kept in a locked filing cabinet in the PI's office at Universiti Tunku Abdul Rahman (UTAR). Electronic data will be stored on a password-protected computer and backed up on an encrypted, password-protected external storage device. Each participant will be assigned a unique study identification number to maintain confidentiality and the access to identifiable research data will be restricted to the PI only. Research data will be retained for a minimum period until the research is completed. After the research study period, hardcopy documents will be shredded using a secure document disposal service, and all electronic files will be permanently deleted from computers and storage devices using secure data deletion methods. Similarly, signed informed consent forms will be retained securely for the required research study period. Following the completion of research study period, all consent forms will be destroyed by secure shredding.

Discussion

This trial will provide evidence on the comparative effectiveness of a low FODMAP diet and oral butyrate supplementation in reducing GI symptoms. The findings will contribute to the development of evidence-based nutritional management strategies for athletes experiencing exercise-associated gastrointestinal symptoms. This project is expected to contribute to the fields of sports nutrition and gastrointestinal health by providing one of the first comprehensive investigations of GI symptoms among Malaysian athletes. Additionally, the findings may assist sports dietitians, nutritionists, healthcare professionals, coaches, and sports organizations in developing targeted nutrition interventions to improve athlete health, gastrointestinal well-being, and training performance. This study will also provide baseline data for future multicenter studies and support the development of nutrition guidelines and policies for athlete care in Malaysia.