PARTICIPANT INFORMATION SHEET AND CONSENT FORM FOR RESEARCH SUBJECTS (ATHLETES)

1. Study Information

IRB Reference Number: NU-FULL-021

Protocol Title:
Carotenoids on vision and sport performance

2. Purpose of the Research Study

We would like to invite you to participate in this research project. It is important to us that you first take time to read through and understand the information provided in this sheet before taking part in this study. We will explain the study to you and provide you opportunity to ask any questions. You would need to sign the consent form attached with this sheet if you have decided to take part in this study.

Aim

This study aims to examine the effects of macular carotenoids, lutein, zeaxanthin and meso-zeaxanthin (LUT, ZEA and meso-ZEA), on visual function and sport performance amongst Singapore shooting population.

Background

A shooter's visual system is always under intense pressure to achieve stability of hold, timing of triggering, aiming accuracy and cleanliness of trigger, which influences shooting performance and are partly dependent on visual stimuli. Macular carotenoids, LUT, ZEA, and meso-ZEA, are micronutrients that accumulate inside the eye, at the centre of the retina, that play an important role in protecting against oxidative damage and enhanced visual performance. Humans obtain LUT, ZEA and meso-ZEA solely from their diet through certain fruits and vegetables. This study uses supplements, an alternative source, that contain natural extracts of macular carotenoids obtained from marigolds dissolved in omega-3 to improve shooter's visual function and sporting performance.

3. Study Design

This research study is a randomised placebo-controlled trial, aiming to recruit 80 healthy volunteers who are currently training in shooting (rifle and pistol). This study requires volunteers to consume either a supplement, containing the macular carotenoids with omega-3 oil, or a placebo on a daily basis for 9 months; participants are assigned to one of two groups; and neither the participants nor the investigators will know if they are consuming the supplement or the placebo until the end of the study. Randomization means assigning your order of supplement by chance, like tossing a coin or rolling dice.

Information of the Supplement

This supplement is third party tested for substances prohibited in sport based on World Anti-doping Agency Prohibited List'2022. The capsule[s] containing 10mg lutein, 10mg meso-zeaxanthin and 2mg zeaxanthin in omega-3 oil; and the placebo formulation containing sunflower oil. The supplements will be provided free of charge by the study investigators.

Participation Criteria

To participant in this study, volunteers should

1) be 18 – 50 years of age,
2) not consume carotenoids containing supplements in the past 3 months,
3) with fish and shellfish allergy,
4) able to maintain current diet throughout the studies,
5) not suffer from ocular disease, colour blindness, pancreatic disease, atrophic gastritis, insulin -requiring diabetes and gastrointestinal bleeding disorders.

4. Procedure in the Study

If you take part in this study, you will be asked to attend the Singapore Sport Institute Physiology Laboratory for a clinical assessment three times and the Safra in-door shooting range for sport performance test twice over a 9-months period. There are two main visits, at the start (first visit) and at the end (last visit) of the trial, and a short visit at month 4.5 only for a blood sample. The main visits for clinical and sport performance assessments will last approximately 1h 30 min each, whereas the study visit for blood samples lasts no more than 10 minutes. Prior to the actual sports performance testing, a practice round (1h 5min) for all participants will be arranged to familiarise shooting using air-rifle and air-pistol in an indoor range.

The anonymizing procedures will be carried out consisting of a series of clinical and sport performance testing:

1. *Blood sample:*

   A blood sample will be taken by a trained professional and analysed to measure the macular carotenoids in your blood.
2. *Questionnaires:*

   You will be asked to complete a brief questionnaire to gather information on you. These questionnaires will collect your contact details, lifestyle information, medical history, sleep health, visual function and dietary intake for analysis.
3. *Visual Function:*

   An optometrist and trained professionals will assess your visual function (acuity, contrast sensitivity, glare sensitivity and ocular dominance)

4. *Carotenoid Skin Detection:*

   A trained professional will ask you to place your palm on a non-invasive laser scanner for 30 seconds to analyse skin carotenoid concentration.

5. *Skinfold Measurement:*

   A trained ISAK technician will take skinfold measurements to analyse your body composition.

6. *Shooting Performance:*

   You will be asked to shoot, either using air-rifle or air-pistol, 60 shots within 45 minutes time frame. Total aiming time, shooting accuracy and shots grouping will be recorded for analysis.

5. ***Summary of Assessments during First to Final Visits***

Study Procedure	Baseline	4.5 months	9 months
Clinical Assessment @ SSI Physiology Lab	**1 hr 30 min**	**10 mins**	**1hr 30 min**
• Demographic and lifestyle questionnaire	●		
• Subjective Visual Function and Sleep Health questionnaires	●		●
• Dietary carotenoid questionnaire	●		●
• Visual Function Assessments	●		●
• Skinfold Assessment	●		●
• Blood Sample	●	●	●
• Skin Carotenoid analysis	●		●
Shooting Performance @ SAFRA in-door shooting Range (Yishun)	**2 hr 35 min**		**1 hr 30 mins**
• Day 1: Practice Round *(Total duration of 1 hr 5min)*	●		
• Day 2: Actual Shooting Test *(Total duration of 1 hr 30 min)*	●		●

Incidental Findings:

"Incidental findings" are findings that have potential health or reproductive importance to research participants like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of current and future studies. There will not be any incidental findings arising from this research; hence you will not be re-identified for this purpose.

6. Responsibilities

If you agree to participate in this study, you should follow the advice given to you by the research team. You should be prepared to undergo all the procedures that are outlined above. You should also inform the Principal Investigator as soon as possible about any side effects that you may have encountered.

7. *Possible Risks and Side Effects*

You may experience some discomfort or inconvenience:

1) While drawing blood samples, there may be a minimal risk of haematoma or discomfort caused by venepuncture. However, no risks to subjects participating in this research undergoing these procedures are foreseen. All safety procedures will be followed with regards to phlebotomy and all blood draws will be performed by trained personnel. Participation in this trial is not a substitute for standard medical care or eye care.
2) Mandatory use of mask for all testing, except during sport performance testing, in accordance with Covid safe management measures.

8. *Benefits*

If you participate in this study, the investigators will provide a full report on the evaluations on vision status, macular carotenoid level in blood and nutritional information to you at the end of the study.

9. *Alternative to Participation (where applicable)*

There is no alternative procedure or treatment to the study procedures. You can choose not to take part in this study. The study procedures will not be carried out.

10. *Costs & Payments*

You will be reimbursed for your time, inconvenience and transportation costs as follows:

- If you complete the study, you will be paid *(SIN$125).*
- If you do not complete the study for any reason, you will be paid *SIN$20* / session you have attended.

11. *Confidentiality*

Your participation in this study will involve the collection of contact information provided by you, use and disclosure of data, human biological materials in an individually identifiable form (or "Personal Data"). "Personal Data" refers to data about you, which makes you identifiable from (i) such data, and/or (ii) other information which we have or likely have access to. This includes medical conditions, medications, investigations, and treatment history. Anonymity will be assured through encrypting the data by assigning an identification code to you. Both your contact information and identification code will only be accessible to the Co-investigator and the Principal Investigator.

All data collected including human biological materials will remain completely confidential and stored for a maximum of 10 years in a secured environment within SETU and a minimum of 7 years within SSI, with restricted access given only to the study research team and School Administrators. Data may

be used in scientific reports in a manner that does not reveal your identity. All data and human biological materials collected will be destroyed and discarded after the stipulated time.

However, the government ministries or regulatory agencies will be granted direct access to your Personal Data or medical records to check study procedures and data, without making any of your information public. Your Personal Data may be shared with government bodies when acquisition by law or when ordered to do so by a court or legislations.

By signing the Informed Consent Form, you (or your legally acceptable representative, if relevant) are authorizing (i) collection, access to, use and storage of your Personal Data, and (ii) disclosure to, and use and storage by, authorised service providers and relevant third parties, whether located in Singapore or overseas, for the only purposes of this study.

Data collected are the property of Singapore Sport Institute and the Nutrition Research Centre Ireland of SETU. In the event of any publication regarding this study, only aggregated research data without indefinable personals details will be used, and your identity will remain confidential.

Your Personal Data will not be used for future research, unless otherwise consented by you in the accompanying Consent Form.

12. Occurrence of Injury

If you follow the directions of the investigators in charge of this study and you are physically injured as a result of taking part in this study, without any prejudice or any admission of liability, will compensate or provide medical treatment for the injuries arising from your participation in the study without proving Singapore Sport Institute is at fault. There are however, conditions and limitations to the extent of compensation and treatment provided. You may wish to discuss this with your Principal Investigator. The SSI research team will follow standard first aid protocol and emergency evacuation to the nearest hospital, following the SSI and SAFRA Code Blue guidelines when necessary.

13. Withdrawals

Participation in this research study is purely voluntary, and you are free to withdraw from the study at any time, without penalty, prejudice, negative consequence, repercussion, or disadvantage. Your decision to withdraw from this study will be kept confidential. If you are not comfortable for the research team to keep all data obtained from you and associated with you, you have to inform the research team to erase and destroy all data within the 7 days after the withdrawal from the study.

14. Whom to Contact if you have questions?

If you have any questions, complaints, or feedback about this research study and in case of any injuries during the course of the study, you may contact

A. Principal Investigator:

Parimala Sivaperuman
Sport Dietitian
Singapore Sport Institute (SSI)
Sport Singapore
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B. Co-investigator researcher:

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The study has been reviewed by SSI Institutional Review Board (the central ethics committee) and SETU Institutional Review Board for ethics approval. If you want an independent opinion to discuss problems and questions (complaints/ feedback), obtain information and offer inputs on your rights as a research participant, please contact:

Singapore Sport Institute	**Institutional Review Board**
Intuitional Review Board	Research Ethics Committee
Singapore Sport Institute, Sport Singapore	South East Technological University (SETU)
3 Stadium Drive, Singapore 397630	Cork Road, Waterford City, Ireland
Tel: 65005215	Tele: +353-51-302000
Email: sport_ssi_research@sport.gov.sg	ethics@wit.ie

Thank you for the time to read this Invitation Sheet.