

Precision nutrition approach based on lipid and microbiota profile to promote health and performance in football players

Submission date 04/10/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/10/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/10/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In high-performance athletes, high physical activity produces stress at the cardiac, muscular and metabolic levels in general. At the cellular level, the ruptures caused by exercise must be repaired quickly and this depends on diverse factors, which may vary between individuals, some of which are controllable. Different studies indicate that physical activity promotes an inflammatory state and increases oxidative stress. To reverse these situations, supplements such as antioxidants, vitamins and fatty acids are increasingly used in sports practice, based on the idea that they are natural substances and they are not harmful. However, there are different aspects to be taken into account when using this type of product. A high dose may be harmful to the body, or a general recommendation may not be suitable for a given person. Therefore, the intake of these supplements should be considered according to the specific needs of the individual athlete. The use of new precision nutrition tools is making it possible to advance the personalisation and individualisation of nutritional interventions.

The main aim of this study is to design a personalised nutritional intervention. To this end, the lipid profile of mature erythrocyte membrane (LPMEM), the taxonomy profile of the gut microbiota (bacteria) and the quantification of metabolites and other variables, such as performance, endurance, recovery, injuries and diet, will be characterised. To this end, a study was carried out to determine the LPMEM, lifestyle and dietary pattern in football players from the Real Sociedad team (men's first and second teams and women's first team).

Who can participate?

Female and male football players aged 18 to 45 years from the Real Sociedad team

What does the study involve?

The study duration was the football seasons 2022-2023 and 2023-2024. Blood and stool samples, nutritional information and physical activity data were collected three times at the beginning of the season, mid-season and end of the season.

The nutritional intervention had three phases:

Pre-season: during the pre-season, the parameters above were analysed to define the nutritional intervention for each player. The athletes started the intervention at this time.

Mid-season: after 4 months, the same parameters were measured again for a new cycle of intervention.

End of season: the parameters obtained in the pre-season and mid-season were determined again and the relevant conclusions were drawn.

What are the possible benefits and risks of participating?

There are no risks of participating. The possible benefits are to enhance sports performance, inflammation state and gut health.

Where is the study run from?

Fundación AZTI (Spain)

When is the study starting and how long is it expected to run for?

March 2022 to September 2024

Who is funding the study?

1. Fundación AZTI (Spain)
2. Real Sociedad football team (Spain)

Who is the main contact?

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

TUE-RS-2022-01

Study information

Scientific Title

Gut microbiota modulation is associated with personalised fatty acids supplementation in professional football players assayed across the competitive season

Study objectives

This project is based on the hypothesis that mature erythrocytes and the taxonomic profile of the gut microbiota provide key information about the metabolism of each individual and their relationship with nutritional intake and lifestyle. Therefore, characterisation through these techniques is very useful for tailoring optimal nutritional recommendations from a precision nutrition approach.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 02/05/2022, Research Ethics Committee of the Gipuzkoa Healthcare Area (Begiristain Doktoarea Pasealekua, San Sebastian, 20014, Spain; +34 (0)943007402; mjose.velazquezzubicoa@oakidetza.net), ref: TUE-RS-2022-01

Study design

Interventional study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Fitness/sport facility

Study type(s)

Other, Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Lipid profile of mature erythrocyte membrane and the composition of the gut microbiota

Interventions

Intervention study to determine the lipid profile of mature erythrocyte membrane, and the composition of the gut microbiota associated with nutrition, lifestyle and dietary pattern in football players and to carry out a nutritional intervention based on the results obtained.

The study was conducted with adult female and male football players (>18 years old) from the Real Sociedad team, playing in the first and second divisions of the Spanish league over two seasons (2022-2023 and 2023-2024). Recruitment was conducted by the medical services of the Real Sociedad in Zubieta, Spain. The inclusion criteria were players who signed the informed consent to participate.

Other parameters were also studied, such as nutritional habits, by a validated Food Frequency Questionnaire (FFQ) PREDIMED for the Spanish population and physical activity. Additionally, other biochemical parameters were measured (plasma lipid profile, liver functions, inflammation), along with performance, endurance, recovery and injury history. This information was collected by medical and technical staff.

The nutritional intervention had three phases:

Pre-season: during the pre-season, the parameters mentioned above were analysed to define the nutritional intervention for each player. The athletes started the intervention at this time.

Mid-season: after 4 months, the same parameters were measured again for a new cycle of

intervention.

End of season: the parameters obtained in the pre-season and mid-season were determined again and the relevant conclusions were drawn.

Intervention Type

Supplement

Primary outcome measure

Inflammatory and nutritional status of the football players is measured through the analysis of the fatty acids in the membrane of the mature red blood cells (targeting omega-3, omega-6 and MUFA and SFA) at three points (T1: beginning of the season, T2: mid-season and T3: at the end of the season) during the seasons 2022-2023 and 2023-2024.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

14/03/2022

Completion date

27/09/2024

Eligibility

Key inclusion criteria

Players who signed the informed consent to participate

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Both

Target number of participants

100

Total final enrolment

77

Key exclusion criteria

1. Not playing due to health reasons
2. Not having signed the informed consent form

Date of first enrolment

01/07/2022

Date of final enrolment

30/07/2024

Locations

Countries of recruitment

Spain

Study participating centre**Real Sociedad Fútbol Club**

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Study participating centre**Fundación AZTI**

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Sponsor type

Research organisation

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Funder(s)

Funder type

Research organisation

Funder Name

Fundación AZTI

Funder Name

Real Sociedad Fútbol Club

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

10/10/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the challenges of anonymising qualitative data and the risk of identifying study participants

IPD sharing plan summary

Not expected to be made available