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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	[_] Prospectively registered [_] Protocol
Registration date 14/10/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/10/2024	**Condition category** Other	[_] Individual participant data [X] 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?
Dr Itziar Tueros, itueros@azti.es

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Public, Principal Investigator

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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 Doktorea 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
Intevention 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
Anoeta Pasalekua,1
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Study participating centre
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Sponsor type
Research organisation

Website
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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