

Healthy diet to prevent migraine

Submission date 26/01/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/02/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 03/09/2020	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A migraine is usually a moderate or severe headache felt as a throbbing pain on 1 side of the head. Many people also have symptoms such as feeling sick, being sick and increased sensitivity to light or sound. Migraine is a chronic neurological disorder with a high social impact. Several diets have been proposed to help managing migraine, with different outcomes. We aimed at evaluating the effect of education on the Healthy Eating Plate on migraine frequency and disability.

Who can participate?

Patients aged 18 years or above with diagnosis of migraine with aura or migraine without aura.

What does the study involve?

The study will involve clinical evaluation (questionnaire) of diet habit and migraine disability, and anthropometric measure, followed by education on healthy eating from a nutritional biologist. After three months, the evaluation will be repeated.

What are the possible benefits and risks of participating?

No risk are expected. The patients will be educated on healthy eating with possible general benefits (beyond migraine).

Where is the study run from?

Campus Bio Medico University Hospital, Italy.

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

March 2018 to September 2019.

Who is funding the study?

Università Campus Bio-Medico di Roma, Italy.

Who is the main contact?

Dr Claudia Altamura
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

prot 6.18TS

Study information

Scientific Title

The healthy eating plate advice for migraine prevention

Acronym

CEFOOD

Study objectives

Healthy Eating Plate (HEP) advice can be of help in the management of migraine also as a strategy in add-on to pharmaceutical therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/03/2018, Campus Bio-Medico University Ethical Board (Comitato Etico Università Campus Bio-Medico di Roma, Via Alvaro del Portillo, 200, 00128 ROMA, Italy; +39 06.22541.8809; comitato.etico@unicampus.it), ref: prot 6.18TS ComET CBM

Study design

Unblinded longitudinal interventional study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Prevention

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

Migraine

Interventions

This longitudinal study consists of three visits: a screening visit (T-12), a baseline visit after 12 weeks (T0) and a follow-up visit (T12).

At T-12, the eligible people sign the informed consent and fill a Frequency Food Questionnaire (FFQ) to assess their dietary habits and migraine disability clinical scales concerning the previous three months. All people will receive prophylactic treatment indications as appropriate.

At T0, the eligible people undergo the assessments again (FFQ, migraine disability scales, BMI). They are all educated about the indications of the healthy heating plate by a nutritional biologist.

At the follow-up visit patients fill in a Frequency Food Questionnaire (FFQ) to assess their dietary habits and migraine disability clinical scales concerning the previous three months.

Intervention Type

Behavioural

Primary outcome measure

1. Monthly migraine days measured using patient self-report
2. Monthly drug intake measured using patient self-report
3. Migraine disability assessment score (MIDAS) measured at 12 weeks before the intervention, baseline, and 12 weeks after the start of the intervention

Secondary outcome measures

none

Overall study start date

10/03/2018

Completion date

30/09/2019

Eligibility

Key inclusion criteria

Diagnosis of migraine with aura or migraine without aura

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

95 participants

Total final enrolment

97

Key exclusion criteria

1. BMI > 30
2. Cancer
3. Inflammatory bowel disease
4. Celiac disease
5. Type 1 diabetes
6. Chronic renal insufficiency
7. Other neurological disorders

Date of first enrolment

15/03/2018

Date of final enrolment

30/09/2019

Locations

Countries of recruitment

Italy

Study participating centre

Università Campus Bio-Medico di Roma

Via Alvaro del Portillo, 200

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Sponsor information

Organisation

Campus Bio Medico University Hospital

Sponsor details

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f.vernieri@unicampus.it

Sponsor type

Hospital/treatment centre

Website

<http://www.campusbiomedicohospital.com/>

ROR

<https://ror.org/04gqbd180>

Funder(s)

Funder type

University/education

Funder Name

Università Campus Bio-Medico di Roma

Alternative Name(s)

Campus Bio-Medico University

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Italy

Results and Publications

Publication and dissemination plan

To publish in a journal dedicated to nutrition or headache.

Intention to publish date

01/03/2020

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/05/2020	03/09/2020	Yes	No