

# Healthy diet to prevent migraine

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<b>Registration date</b> 14/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/09/2020	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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**

Dr Claudia Altamura

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**Additional identifiers****Protocol serial number**

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

**Study type(s)**

Prevention

## **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(s)**

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

## **Key secondary outcome(s)**

none

## **Completion date**

30/09/2019

# **Eligibility**

## **Key inclusion criteria**

Diagnosis of migraine with aura or migraine without aura

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Adult

## **Sex**

All

**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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Italy

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**Sponsor information****Organisation**

Campus Bio Medico University Hospital

**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

**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?
<a href="#">Results article</a>	results	28/05/2020	03/09/2020	Yes	No