

# Trial to encourage adoption and maintenance of mediterranean diet

<b>Submission date</b> 16/12/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/02/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/01/2022	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A Mediterranean-style diet has been shown to reduce the risk of developing heart disease, stroke and diabetes. This study aims to determine whether people will change their diet to make it more like a Mediterranean diet, and to determine whether different ways of supporting people will make people adopt the Mediterranean diet.

### Who can participate?

Aged over 40 years, overweight and at increased risk of heart disease (i.e. with high blood pressure and/or cholesterol levels) but with no previous medical history of heart disease, stroke or diabetes, who do not currently follow a Mediterranean diet and are willing to make changes to their current diet towards a Mediterranean-style diet.

### What does the study involve?

Participants will be randomly allocated to one of three groups:

First group: brief written advice about the Mediterranean diet. This involves one 30-minute visit with the researcher at the beginning of the study. If you are in this group, you will be offered a further appointment for personalised dietary advice at the end of the study.

Second group: intensive advice to adopt the Mediterranean diet. If you are in this group you will receive an appointment with the study dietitian for individual dietary advice. This visit will last for up to 90 minutes. You will then be asked to attend a group education session once every three months over the 12-month study period (i.e., five group sessions in total), run by the dietitian. Each group session is expected to last no longer than 2 hours and will be scheduled at a convenient time. In addition, we will deliver some key Mediterranean foods to your home throughout the 12-month study period.

Third group: peer support to encourage adoption of the Mediterranean diet. If you are in this group you will attend 11 group support sessions over 12 months with up to six other people who are similar to you, along with two dedicated peer supporters. Each group session is expected to last no longer than 2 hours and will be held in a convenient location at a flexible time.

The study will last one year. At the beginning of the study and after 3 months, 6 months and 12 months (therefore four times over the study period) you will be asked to meet with the

researcher to provide a blood and urine sample, complete study measurements (including weight measurements and an oral glucose tolerance test to see how well your body deals with sugar) and complete study questionnaires.

What are the possible benefits and risks of participating?

This study is designed to determine whether different methods of giving dietary advice have an impact on how much change people will make to their diet. A further study is planned to determine whether that dietary change (i.e., towards a Mediterranean diet) could reduce the risk of diabetes or heart disease, and these studies together could therefore have important public health benefits. There is a small risk of developing bruising after the blood sampling, but a fully trained phlebotomist will take the blood samples to ensure that any discomfort is kept to a minimum.

Where is the study run from?

The study is recruiting people in Northern Ireland and all study assessments will take place in the Centre for Public Health at Queen's University Belfast.

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

October 2012 to December 2020

Who is funding the study?

The Medical Research Council (UK)

Who is the main contact?

Prof. Jayne Woodside

j.woodside@qub.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Jayne Woodside

**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

MR/J000388/1

## **Study information**

### **Scientific Title**

Trial to Encourage Adoption and Maintenance of a Mediterranean Diet (TEAM-MED): a pilot randomised controlled trial

### **Acronym**

TEAM-MED

### **Study objectives**

This pilot study will test the hypothesis that a peer support approach is as effective as a proven intensive intervention to encourage adoption of a Mediterranean diet in a population at high cardiovascular disease risk.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Office for Research Ethics Committees Northern Ireland (ORECNI), 29/10/2013, ref: HSC REC 13 /NI/0152

### **Study design**

Single-centre pilot randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Prevention

### **Participant information sheet**

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

### **Health condition(s) or problem(s) studied**

Cardiovascular disease and type 2 diabetes disease prevention

### **Interventions**

Participants will be randomly allocated to one of three groups:

1. Minimal Mediterranean diet intervention (Control) group will receive written advice on one occasion about the components of a Mediterranean diet and given suitable recipes (n=25). All participants in this group will be offered an individual appointment with the researcher for personal dietary advice, at the end of the intervention period
2. Proven intensive Mediterranean diet (MD) intervention group will receive tailored written advice and attend quarterly individual and group education sessions with a dietitian, along with provision of key Mediterranean foods (olive oil and/or nuts) (n=25)
3. Peer support MD intervention group will receive a targeted group-based peer support intervention delivered over 11 sessions by 2 trained peer supporters (n=7 max per group; total n=25)

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Change in the habitual Mediterranean Diet Score (MDS) at 6 months from baseline (i.e. adoption of dietary change)

## **Secondary outcome measures**

1. Change at 6 months from baseline in biochemical markers of nutritional status related to Mediterranean diet (adoption of Mediterranean diet) (including HDL cholesterol, carotenoids, Vitamin C, Vitamin E and fatty acids)
2. Change in Mediterranean Diet Score at 12 months (end of intervention) from 6 months i.e. maintenance of Mediterranean diet
3. Change at 12 months from 6 months in Mediterranean Diet Score and biochemical markers of nutritional status (maintenance of dietary change)
4. Change in markers of overall nutritional status, CVD risk and type 2 diabetes mellitus (T2DM) risk
5. Change in psychosocial status including health and dietary related quality of life
6. Evaluation of factors related to feasibility and fidelity of the pilot study including intervention delivery, participant engagement and participation, attrition and reasons for withdrawal from the study

## **Overall study start date**

01/10/2012

## **Completion date**

31/12/2020

# **Eligibility**

## **Key inclusion criteria**

1. Cardiovascular disease (CVD) risk of  $\geq 20\%$  over 10 years as defined by Joint British Societies Guidelines on prevention of cardiovascular disease in clinical practice. The new Joint British Societies CVD risk prediction charts, which can be used to estimate total risk of developing CVD over 10 years, are based on age, sex, smoking habit, systolic blood pressure and the ratio of total

- cholesterol to HDL cholesterol
2. Aged 40 years or over
  3. Mediterranean Diet Score (MDS)  $\leq 3$
  4. Body Mass Index (BMI)  $> 27$  and  $< 40$

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

75 participants and 12 peer supporters

**Total final enrolment**

75

**Key exclusion criteria**

1. Diabetes mellitus
2. Established cardiovascular disease of any kind
3. Surgery within previous three months
4. Psychiatric problems
5. Pregnant or lactating
6. Excessive alcohol consumption
7. Taking high-dose nutritional supplements
8. Medical conditions or dietary restrictions/allergies that would substantially limit ability to complete the study requirements
9. Low predicted likelihood to change dietary habits
10. Inability to provide informed consent

**Date of first enrolment**

01/10/2014

**Date of final enrolment**

30/04/2016

**Locations****Countries of recruitment**

Northern Ireland

United Kingdom

**Study participating centre**

Centre for Public Health

Belfast

United Kingdom  
BT12 6BJ

## Sponsor information

### Organisation

Queen's University Belfast (UK)

### Sponsor details

Research and Enterprise  
63 University Road  
Belfast  
Northern Ireland  
United Kingdom  
BT7 1NN

### Sponsor type

University/education

### ROR

<https://ror.org/00hswnk62>

## Funder(s)

### Funder type

Research council

### Funder Name

Medical Research Council (UK) - National Prevention Research Initiative (NPRI); Funding ref: MR/J000388/1

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

### Intention to publish date

31/12/2021

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Jayne Woodside ([j.woodside@qub.ac.uk](mailto:j.woodside@qub.ac.uk)).

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		04/10/2021	20/01/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No