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Trial to encourage adoption and maintenance of mediterranean diet

Submission date
16/12/2013

Recruitment status
No longer recruiting

Registration date
04/02/2014

Overall study status
Completed

Last Edited
20/01/2022

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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 >=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) ≤ 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).

IPD sharing plan summary

Available on request

Study outputs

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