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Assessment of the mediterranean diet in heart and lung transplantation

Submission date
25/07/2016

Recruitment status
No longer recruiting

Registration date
27/07/2016

Overall study status
Completed

Last Edited
24/01/2020

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Heart and lung transplants are the only real treatment option for patients with end-stage heart or lung diseases that are resistant to treatment. However, despite significant advances in drug treatment and patient monitoring, death and severe disease still remain high. Complications brought about by disorders relating to nutrition such as obesity, type-2 diabetes and cardiovascular (heart and blood vessel) disease are higher in these patient groups that the general population, yet given the large amount of daily drugs needed to maintain a transplant patient, further treatments are probably not the ideal course. However, there is a large amount of evidence that modification diet can lead to wide-scale health changes, and improve health in a range of patient groups including several that eventually require heart or lung transplants. Currently, patients who have had a heart or lung transplant are given advice about following a low-fat diet after surgery. The aim of this study is to investigate the feasibility of a training programme based on the Mediterranean diet and modified low-fat eating pattern, and how well patients are able to stick to the diets. The investigators also aim to determine whether the diets lead to any health benefits.

Who can participate?
Heart and lung transplant recipients visiting the University Hospital of South Manchester (UHSM) Transplant Outpatient Centre

What does the study involve?
Patients are screened before enrolling in the study for current infections, rejection (where the body's immune system attacks the transplanted organ) and cancer episodes, and diabetes, food allergy and severe kidney disease. Participants who are eligible to take part are then split into two groups of mixed transplant-type and then are randomly assigned to each diet group. Participants are required to attend a group-specific training session providing information about the reasons the study is taking place and a combined practical cooking session. To help support behavioural change, a member of the same household is encouraged to accompany each patient. Each respective group receives printed information and a 5 litre extra-virgin olive oil gift, or a low-fat cook book. General and group-specific questionnaires are completed at the start of the study and then 25, 52 and 58 weeks later to see whether participants remain in the study until the end. At the start of the study and then again after 25 and 52 week, physical (such as weight)

and biochemical (such as blood sugar) changes in participants are measured. Further educational support is provided on an outpatient basis and through periodic telephone contact spaced over 52-weeks.

What are the possible benefits and risks of participating?
Changing to a healthier, low fat diet could help to reduce the risk of participants developing nutrition related complications, such as obesity and diabetes. There are no notable risks involved with participating.

Where is the study conducted?
University Hospital of South Manchester (UHSM) Transplant Outpatient Centre (UK)

When is the study starting and how long is it expected to run for?
June 2013 to June 2016

Who is funding the study?
NewStart Transplant Charity, Manchester (UK)

Who is the main contact?
Dr Timothy Entwistle

Contact information

Type(s)
Scientific

Contact name
Dr Timothy Entwistle

Contact details
The Transplant Centre
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Assessment of the Mediterranean Diet in Heart and Lung Transplantation: A Feasibility Study

Acronym
AMEND-IT Study

Study objectives
1. Implementation of Mediterranean and low-fat dietary training programmes is feasible and acceptable in a group of clinically stable heart and lung transplant recipients
2. Anthropometric and clinico-biochemical measurements can be used to assess key clinical outcomes after implementation of a Mediterranean and modified low-fat dietary training in this patient cohort

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service, NRES Committee North West - Greater Manchester West, 06/06/2013, ref: 13/NW/0310

Study design
Single-centre longitudinal randomised controlled feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Heart and lung transplant

Interventions
Heart and lung transplant recipients meeting the inclusion criteria will be randomly assigned to either a Mediterranean diet or Low-fat intervention group using a computer-generated allocation sequence with random block sizes and an equal 1:1 allocation ratio. Randomised codes will be sent to a fellow researcher to blind the investigator from recruitment bias. Recruitment will commence in two separate arms spaced 6 months apart; each intervention lasting 12 months, with an additional adherence questionnaire conducted at 6-weeks to determine short-term post-study adherence.

Both interventions will receive a baseline education and training session designed to represent each diet. As a support strategy, each participant is encouraged to attend with a member of the same household. Training sessions will comprise of the background and scientific rationale for the respective interventions, and a practical food preparation and cooking component with a trained chef. Participants will receive group-specific printed information, and each intervention will be offered the same foundational dietary advice based on plant-based wholefoods.

Mediterranean diet group: MedDiet participants will receive educational support to follow an eating pattern representative of a traditional Mediterranean diet. The key dietary guidelines advocated in the MedDiet group are: daily consumption of a range of mixed vegetables, fruit, whole-grains, fish and seafood, raw nuts and legumes; abundant use of extra-virgin olive oil (5ltrs of high quality extra-virgin olive oil will be gifted to each participant); moderate consumption of dairy products and red wine; low intake of red and processed meats, sweets, sweet-baked pastries, desserts and sweetened beverages.

Low-fat diet group: The low-fat diet group will be advised to follow modified British Heart Foundation low-fat guidelines. Key low-fat diet information includes: minimise high fat foods such as processed meats, commercial baked pastries and desserts, vegetable oils and spreads; choose low-fat options - lean meat, poultry, white fish, and low-fat dairy. Provide a description of different dietary fat types and advice to minimise vegetable oil and spread intake. Explain the rationale for restricting dietary fat and refined carbohydrate intake. Each participant will be gifted a low-fat recipe book.

Intervention Type
Mixed

Primary outcome measure
Determine the feasibility and compliance of implementing a Mediterranean and low-fat dietary training programme in a group of clinically stable heart and lung transplant recipients using:
1. Recruitment and attrition rates of study participants will be recorded over the 12 month intervention
2. Measure changes in dietary pattern with a validated food frequency questionnaire at week 0 and 52
3. Monitor adherence to each diet with intervention-specific adherence screening questionnaires at week 0, 25, 52 and 58
4. Urinary polyphenol excretion at week 0, 25 and 52, detected with Folin-Ciocalteu total polyphenol test

Secondary outcome measures
Anthropometric and biochemical changes at baseline and week 25 and 52 using:
1. Weight measured in kilograms using calibrated Seca 877® mobile weighing scales
2. Waist circumference measured in millimeters at iliac crest and underside of 12th
3. BMI calculated as weight and height (kg/m2) ratio
4. Basal metabolic rate calculated with metric Harris-Benedict formula
5. Blood pressure and heart rate taken seated with calibrated Dinamap Pro100V2® device
6. Fasting insulin and glucose detected on Abbott Architect c16000 Immunoassay Analyser
7. Fasting HbA1c detected on Bio-Rad Variant™ II Turbo haemoglobin testing system
8. HOMA2 insulin resistance, sensitivity and beta-cell function calculated with University of Oxford HOMA2 calculator
9. IGF-1 (baseline and 12 months only) measured on Immunodiagnostics Systems IDS-iSYS™ automated system

10. Fasting total cholesterol, HDL, LDL and triglycerides measured on Abbott Architect c16000 Immunoassay Analyser
11. Fasting lipid ratios; total cholesterol/HDL, LDL/HDL and triglyceride/HDL
12. HsCRP detected on Immunodiagnostics Systems IDS-iSYS™ automated system

Overall study start date
06/06/2013

Completion date
06/06/2016

Eligibility

Key inclusion criteria
1. Male and female, aged 16 or over
2. Clinically stable, with a minimum post-transplant period of 6-months
3. Free from current rejection or infection, cancer or diabetes
4. Estimated glomerular filtration rate (eGFR) greater than 30 was the cut off. However, an eGFR >45 was the ideal lower limit
5. Not following any medically prescribed diet
6. No food allergies contra to study guidelines
7. Willing to make new dietary changes

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80 patients: 40-wave one (20/20 heart and lung recipient) and repeat wave-2 with the same criteria

Total final enrolment
41

Key exclusion criteria
1. <16 years of age
2. <6-months post-surgery
3. Rejection and Infection
4. Cancer and diabetes
5. eGFR <30
6. Food allergy
7. Unwilling to make dietary changes

Date of first enrolment
11/02/2014

Date of final enrolment
07/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital of South Manchester (UHSM) Transplant Outpatient Centre
The University Hospital of South Manchester NHS Foundation Trust
Southmoor Road
Wythenshawe
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Sponsor information

Organisation
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Sponsor type
Research organisation

ROR
https://ror.org/05vpsdj37

Funder(s)

Funder type

Charity

Funder Name
NewStart Heart and Lung Transplant Charity

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal, and dissemination of study results at scientific congresses.

Intention to publish date
27/07/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from:
Dr Timothy Entwistle: timothy.entwistle@manchester.ac.uk
Dr James Fildes: james.fildes@manchester.ac.uk
Professor Adele C Green: adele.green@qimrberghofer.edu.au

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/02/2018	24/01/2020	Yes	No
HRA research summary			28/06/2023	No	No