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Nutrition and physical activity intervention for families with familial hypercholesterolaemia

Submission date
04/06/2018

Recruitment status
No longer recruiting

Registration date
07/06/2018

Overall study status
Completed

Last Edited
14/07/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Familial hypercholesterolaemia (FH) is a common genetic disorder, characterised by raised levels of low density lipoprotein cholesterol (LDL-C) from birth. The lifelong exposure to these high LDL-C levels puts individuals at an increased risk of premature cardiovascular disease (CVD) and associated mortality (death). Lifelong treatment with medication is recommended for all patients. This has reduced the incidence of CVD in people with FH, but they still remain at higher risk than the general population. Lifestyle factors can also influence LDL-C levels and other CVD risk factors and therefore lifestyle advice is considered important for people with FH. However, there is limited evidence to support the effectiveness of the current nutritional and physical activity (PA) guidelines upon LDL-C levels in people with FH. The need for trials to investigate the effectiveness of nutrition and PA interventions in the FH population has been widely recognised and recommended. This study is designed to investigate if a family-based intervention based upon the current NICE nutrition and PA recommendations for people with FH can be implemented and accepted by young people and their affected parent.

Who can participate?
Patients aged 10-18 with FH and their parents

What does the study involve?
Families are randomly allocated to receive a 12-week nutrition and PA intervention or to a control group who receive usual care, which is medication only. Nutrition intake, PA levels and blood cholesterol levels are measured at the start of the study and at 12-week follow up. The feasibility of the intervention and research methods are assessed through measurement of recruitment to the study, attendance at study visits and acceptability of the intervention determined through interviews. Blood cholesterol levels, dietary intakes and PA levels are measured before the intervention and at 12-week follow up and any changes are compared between the control and intervention groups.

What are the possible benefits and risks of participating?
The results will inform the development of a full-scale study. There are no significant benefits or risks expected as a result of participation in this study.

Where is the study run from?
1. University Hospitals Bristol NHS Foundation Trust (UK)
2. Royal United Hospitals Bath NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2018 to April 2020

Who is funding the study?
NIHR Bristol Biomedical Research Centre (UK)

Who is the main contact?
Ms Fiona Kinnear

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
239039

Protocol serial number
38422, IRAS 239039

Study information

Scientific Title
Feasibility of a family-based nutrition and physical activity intervention in young people with familial hypercholesterolaemia: a mixed methods study

Study objectives
Familial hypercholesterolaemia (FH) is a common genetic disorder, characterised by raised levels of low density lipoprotein cholesterol (LDL-C) from birth. The lifelong exposure to these high LDL-C levels puts individuals at an increased risk of premature cardiovascular disease (CVD) and

associated mortality.
Lifelong treatment with medication is recommended for all patients. This has reduced the incidence of CVD in people with FH, however they still remain at higher risk than the general population. Lifestyle factors can also influence LDL-C levels and other CVD risk factors and therefore lifestyle advice is considered importance for people with FH. However, there is limited evidence to support the effectiveness of the current nutritional and physical activity (PA) guidelines upon LDL-C levels in people with FH. The need for trials to investigate the effectiveness of nutrition and PA interventions in the FH population has been widely recognised and recommended.

This study is designed to investigate if a family-based intervention based upon the current NICE nutrition and PA recommendations for people with FH can be implemented and accepted by young people and their affected parent.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/06/2018, South West - Cornwall & Plymouth Research Ethics Committee (Level 3 Block B Whitefriars Lewins Mead Bristol BS1 2NT; +44(0)20 7104 8049; nrescommittee.southwest-cornwall-plymouth@nhs.net), ref: 18/SW/0121

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Dietary, Physical

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Familial hypercholesterolaemia

Interventions
Family units will be randomly assigned to one of two groups to receive either usual care (control group) or the 12-week nutrition and PA intervention (intervention group). 1:1 randomisation of family units to intervention or control will be carried out according to prepared randomised lists, stratified by study site (University Hospitals Bristol or Royal United Hospitals Bath), anticipating a 50:50 split.

Control group: families will receive usual care, which at these hospital sites is medication only
Intervention group: receive an individualised family-based nutrition and PA intervention with the research dietitian lasting approximately 1 hour. This will be followed up with regular phone call and email contact throughout the 12 weeks of the intervention.
The nutrition component of the intervention aims to help family units to achieve the following daily intake guidelines:
1. Total fat intake ≤30% of total energy intake (TEI)
2. Saturated fat intake of ≤10% TEI
3. Replacement of saturated fats with mono and poly-unsaturated fats

3. Dietary cholesterol intake ≤300mg
4. Consumption of ≥ 5 portions of fruit and vegetables
5. Age appropriate fibre intake (10 year olds= 20g/day; 11-16 year olds= 25g/day and 30g/day for ≥17 year olds)
6. 2g of stanol/sterols

The PA component of the intervention aims to help family units achieve the recommended population PA guidelines which are:
Adults and young people are to minimise time spent being sedentary
2. Adults (19-64 years old) are to achieve a minimum of 150 minutes a week of moderate intensity PA or 75 minutes of vigorous intensity PA, or a mixture of the two. Additionally activity focussing upon improving muscle strength should be undertaken twice a week.
3. Young people (5-18 years old) are to achieve a minimum of 60 minutes of at least moderate intensity PA each day, with 3 of these sessions each week being of vigorous activity and including activities that strengthen muscle and bone.
These guidelines are targets and will be used to guide the consultation and educate the family units. The dietitian will work with the family units to agree upon changes they will make to their nutrition and PA over the 12-week intervention to achieve intakes closer to the recommended targets than they were achieving at baseline. However, the advice delivered from the dietitian will take into consideration the individuals' baseline dietary and PA data alongside insights gained from qualitative interviews conducted with a sub-sample of the study participants. Individual circumstances such as work or school schedules, food preferences, religious beliefs, available space for cooking and financial situations will also be taken into consideration by the dietitian. Intervention booklets, one for participants aged 10-13 years and one for participants aged ≥ 14 years, have been created for use at research contact 2 to record the agreed changes and provide a summary of the information covered in the consultation for the family units to refer to at home during the 12-week intervention period. The agreed changes to PA or nutrition may be most appropriately recorded as targets for the family unit as one, or for individual members, or a mixture of the two. This will depend on individual circumstances such as age of the child, frequency of meals eaten together and differences in baseline nutritional and PA levels. In-depth dietary planning will be conducted, in addition to the provision of behaviour change advice and practical advice to address any challenges that implementing nutrition or PA change may provoke.

Nutrition intake, PA levels and blood cholesterol levels will be measured at baseline and at 12-week follow up.

Intervention Type
Behavioural

Primary outcome(s)
The feasibility of the intervention and research methods, assessed through measurement of:
1. Recruitment to the trial
2. Attendance at research visits
3. Retention rate
4. Adherence to research procedure methods including data collection
5. Acceptability of the dietary and PA intervention
These will all be measured at the end of the study. Data from adult and child participants will be analysed separately. Recruitment, attendance and retention rates will be descriptively described. Adherence to research procedures will be measured through the calculating the number of participants who completed each research procedure. Acceptability of the dietary

and PA intervention will be measured through analysis of the qualitative data collected through qualitative interviews conducted with a sub-sample of the participants at their final research visit.

Key secondary outcome(s))
1. Blood metabolomic (primarily lipidomic) markers , measured through analysis of blood samples collected pre and post intervention
2. Energy content and nutrient composition (macro- and micro-nutrient) of dietary intake, measured using online 24hr recall tool over 4 days at home by each participant pre and post intervention
3. PA levels (minutes of moderate and vigorous PA) and sedentary activity (minutes of sedentary time), measured by Actigraph and ActivPal monitors worn by participants over 7 days 1 week pre and post intervention
4. Health related quality of life (QOL), measured using an age-appropriate QOL questionnaire pre and post intervention
These will be measured at research contacts 2 and 3. Research contact 2 will be carried out at baseline and research contact 3 approximately 12 weeks after this

Completion date
01/04/2020

Eligibility

Key inclusion criteria
1. Patients aged 10-18 years and their parent (≥18 years)
2. Genetically confirmed clinical diagnosis of heterozygous FH
3. Receive their care from the paediatric or adult lipid clinics at Bristol University Hospitals or Royal United Hospitals Bath NHS Trust Foundations

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Pregnant female patients, or those planning pregnancy
2. Patients who are unable to give informed consent
3. Parents or carers of young people with FH who themselves do not have FH

4. Patients with a diagnosis of homozygous FH
5. Patients not established on statin therapy for at least 3 months prior to recruitment to the study

Date of first enrolment
01/09/2018

Date of final enrolment
06/01/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Bristol NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
St George's University Hospitals NHS Foundation Trust
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR Bristol Biomedical Research Centre; Grant Codes: BRC-1215-20011

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study 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		28/12/2020	14/07/2023	Yes	No
Protocol article	protocol	02/04/2020	09/04/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes