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Fatigue in vasculitis

Submission date 03/10/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/10/2016	**Overall study status** Completed	
Last Edited 29/12/2020	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Vasculitis is a condition in which the immune system attacks blood vessels by mistake, leading them to lead fluid into tissues causing inflammation (swelling). Fatigue (extreme tiredness) is a common problem in people with a wide range of diseases, including vasculitis, and can impact on quality of life. Research has shown that physical activity can help to reduce fatigue in people with a variety of conditions, but is rarely discussed with people suffering with vasculitis. It is therefore important to design a large study that will find out if increasing activity (by providing people with an activity programme and support to enable them to carry out the exercise) leads to an improvement in fatigue symptoms in people with vasculitis. However, before this can be done, a smaller study needs to be carried out to find out how best to carry out this large study. The aim of this study is to understand what problems may be found when carrying out a large study of exercise with support, and to find out whether undertaking a large study in this area is possible or feasible.

Who can participate?
Adults with vasculitis who are experiencing fatigue.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group continue as usual for the duration of the study. Participants in the second group take part in a 12 week physical activity and behavioural change support programme in addition to the usual care and treatment. The activity programme consists of 8 exercise appointments held at the University Hospital where they take part in supervised exercise sessions in a group of 4-7 people, and 12 individual health coaching sessions by telephone. These sessions replace usual contact with a therapist. During the first support session participants are provided with a FitBit, and shown what it does and how to use it, so that physical activity levels can be recorded. At the start of the study and then after 12 and 24 weeks, participants in both groups complete a number of questionnaires at follow up appointments and by post at 52 weeks to assess their quality of life and fatigue levels. Throughout the study, information is collected about how many participants take part in order to see if a larger study would be possible.

What are the possible benefits and risks of participating?
Participants benefit from receiving medical reviews and information about how fatigue is affecting their lives. There is a small risk that when participants fist start exercising their fatigue

may get worse but this should only last for a couple of weeks. There is also a slight chance that participants may be injured during exercise, however as participants are supported throughout the study this risk is very small.

Where is the study run from?
NIHR / Wellcome Trust Clinical Research Facility (UK)

When is the study starting and how long is it expected to run for?
December 2015 to October 2018

Who is funding the study?
Arthritis Research UK (UK)

Who is the main contact?
Professor Lorraine Harper, L.harper@bham.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
31622

Study information

Scientific Title
FAB-V: Treatment of Fatigue with physical Activity and Behavioural change support in Vasculitis – feasibility study

Acronym
FAB-V

Study objectives
The aim of this study is to investigate the feasibility of undertaking a large RCT of physical activity with behaviour change support, including device assisted self-monitoring and telephone support with cognitive behavioural strategies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Black Country Research Ethics Committee, 28/09/2016, ref: 16/WM/0374

Study design
Randomised; Interventional; Design type: Treatment, Screening, Psychological & Behavioural, Immunotherapy, Active Monitoring

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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
Specialty: Renal disorders, Primary sub-specialty: Renal disorders; UKCRC code/ Disease: Renal and Urogenital/ Other disorders of kidney and ureter

Interventions
Patients meeting all eligibility criteria and providing written informed consent will be randomised after the patient has worn the Accelerometer for 5-7 days and attended a baseline visit. Patients will be randomised on a 1:1 basis, with 25 patients randomised to intervention and 25 to standard care. Randomisation will be provided by a computer-generated program at the Birmingham Clinical Trials Units (BCTU). A minimisation algorithm will be used to ensure balance

in the allocation over age (<65, >=65). Full details of the algorithm used will be stored in a confidential document at BCTU.

Intervention group: Following completion of the baseline assessments participants who have been randomised to the intervention will be given information about physical activity. The intervention will be staged-adapted and participants will be encouraged to increase physical activity within their capabilities. Participants will be provided with personal activity self-monitoring devices, which are wrist worn accelerometers (FitBit). They will then receive weekly supervised exercise sessions for 12 weeks that will incorporate cognitive-behavioural strategies (e.g. goal setting, finding social support, understanding the costs/benefits of exercise, etc.) to promote long-term participation in physical activity. Direct contact with a therapist will be supplemented by telephone health coaching one a week for 4 weeks. The intervention includes education, monitoring and assessment of progress and teaches skills with the aim of increasing self-efficacy. Participants will be encouraged to wear the Fitbit monitor during the physical activity intervention (12 weeks). Data collected by participant will be shared with the therapist to facilitate the setting of SMART goals. The Fitbit monitors will be left with the patients to use as they wish at the end of the intervention, and collected at the end of the study. Physical activity intervention support will be provided for 12 weeks, weeks 1-8 will have weekly direct contact in groups of 4-7 patients and additional individual telephone health coaching once weekly, weeks 8-12 telephone health coaching only will be provided. During the telephone discussion participants will be encouraged to use their activity profiles, generated from their Fitbit device, with data collected and stored using the online dashboard or paper diaries, , to promote self-determination and self-regulation to achieve personal goals and maintain activity. The therapist will review fatigue, the impact of physical activity on fatigue and the management of fatigue with the participant. The therapist will review activity plans, physical activity education and understanding, and maintenance plans with the patient and help set new goals.

Control group: Participants continue to receive standard care for the duration of the study.

Follow up for all participants takes place at the Wellcome Trust Clinical Research Facility (University Hospital Birmingham) and involves attending for two follow up appointments at 12 and 24 weeks. A final follow up will take place at 52 weeks where participants will be sent postal questionnares and asked to complete and return; no appointment will be held at this time point.

Participants are also invited to participate in focus groups. Focus groups will consist of 4-6 participants, and 4 focus groups will be carried out. Two groups will consist of people who participated and were in the intervention group of the study; one will consist of people in the control group; and the final group will be made up of people who did not participate in the trial. During the focus groups, participants are asked questions about how vasculitis affects their daily life, how they feel about the current approacheds to management of the condition, why they took part in the trial, and how they found participation in the trial (both from participating in research perspective, and from the acceptability and ease of taking part in the intervention arm of the trial). One focus group will also take place with people who did not wish to take part in the study to determine why they chose not to participate, and if/what could have been changed about the trial that may have changed their decision. The aim of this focus group is to ensure that the trial is not ‘putting people off’ participating because of amendable factors.

Intervention Type
Other

Primary outcome measure

Feasibility outcomes:
1. Eligibility rate is measured by calculating the % of people with AAV who are eligible for the study. List of all AAV sufferers at site is collected at study start and reviewed by clinician. Those who fulfil inclusion/exclusion criteria will be potentially eligible and invited to baseline clinic. Eligibility is confirmed on study CRFs at baseline clinics, and eligible patients will be offered trial entry. Rates will be calculated once recruitment completed.
2. Recruitment rate is measured by the % of eligible people who enter the study. The percentage of potentially eligible people who do not wish to attend baseline clinic appointments are calculated, as well as the rate of those who do attend clinics and do not wish to participate in the study. This will be calculated at recruitment end.
3. Retention rate is measured as the percentage of randomised patients who complete the trial at trial end
4. Drop-out rate is measured bas the percentage of people who entered the trial but who dropped out of the study before trial end at trial end
5. Acceptability of collecting outcome measures is measured by participation in focus groups which take place in months 9-12
6. Quality of completion of questionnaires is measured by the monitoring the missing data items within completed questionnaires and calculating whether they are completed accurately enough for meaningful analysis
7. Safety of the intervention is measured by collecting information regarding Adverse Events during follow up clinic appointments, at 12 and 24 weeks
8. Patient acceptability of the intervention is measured by participation in focus groups which take place in months 9-12.
9. Utility of operational manual is assessed through formal feedback from the physiotherapists using the manual on an ongoing basis throughout the study, and the manual adjusted as appropriate
10. Telephone support provision and associated resource requirements is assessed by recording all telephone calls, the grade of staff making the call their duration, and brief description of their purpose throughout the trial and analysed for Health Economic purposes at study end
11. Costs and processes relating to face to face support for the intervention is assessed by recording information about duration and frequency of meetings, and reviewing practicalities of organising the groups throughout the study. Analysis will be carried out for health economic purposes at study end.
12. Validity of assessing activity levels using the physical activity questionnaire is assessed by comparing with objective measures (accelerometers) at the end of the study

Secondary outcome measures
1. Quality of life and fatigue are measured using a number of QoL questionnaires (EQ5D, SF36, IPAQ, MFI-20, BRAF-MDQ, Pittsburgh Sleep Index, HADS, Brief Cope Questionnaire, AAV-PRO) at baseline and 12, 24 and 52 weeks.
2. Muscular or bony injury requiring medical attention is assessed on study CRFs during follow up appointments at 12 and 24 weeks
3. Disease relapse is assessed on study CRFs during follow up appointments at 12 and 24 weeks
4. Increase in fatigue is assessed using the MFI-20 and BRAF-MDQ during follow up appointments at 12 and 24 weeks, and in the postal questionnaires follow-up at 52 weeks

Overall study start date
01/12/2015

Completion date
11/03/2019

Eligibility

Key inclusion criteria
1. Age 18 and over
2. A diagnosis of AAV as classified by the European Medicines Agency Algorithm (EMEA)
3. Remission for at least six months on day of consent (defined by BVAS=0 on day of consent AND prednisolone dose <7.5mg for 6 months)
4. Significant fatigue levels (MFI-20 general fatigue score 14 or higher)
5. Ability to understand and complete questionnaires

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Total final enrolment
43

Key exclusion criteria
1. Inability to provide informed consent
2. Inability or unwillingness to undertake physical activity
3. Co-morbidities identified by clinician, considered to contra-indicate an increase in physical activity

Date of first enrolment
24/11/2016

Date of final enrolment
24/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

NIHR / Wellcome Trust Clinical Research Facility (CRF)
University Hospitals Birmingham NHS Foundation Trust
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
Hospital/treatment centre

Website
www.arthritisresearchuk.org

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan
Results of this trial will be submitted for publication in a peer reviewed journal. The manuscript will be prepared by the CI, with support from appropriate members of the research team, and authorship will be determined by mutual agreement.

Any secondary publications and presentations prepared by Investigators must be reviewed by the CI. Manuscripts must be submitted to Arthritis Research UK. Authors must acknowledge that the trial was performed with the support of the sponsor (University of Birmingham). Intellectual property rights will be addressed in the Clinical Trial Site Agreement between Sponsor and site.

Intention to publish date
11/03/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/10/2018	27/09/2019	Yes	No
Results article	results	28/12/2020	29/12/2020	Yes	No
HRA research summary			28/06/2023	No	No