FAB-V Study

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Summary

We all get tired, but fatigue associated with ANCA-vasculitis is more than just tiredness. It's a feeling of utter weariness causing exhaustion and affecting concentration and motivation. Patients describe fatigue as causing poor quality of life. Little research has been conducted on how best to manage fatigue.

This study aims to undertake a large trial to investigate whether fatigue can be improved by increasing physical activity. The trial will recruit approximately 150 patients with ANCA-vasculitis from 7 hospitals. Participants will be allocated by chance to usual care or a physical activity programme, including support by an activity facilitator using both face-face and telephone contact conducted in the community. The physical activity programme will be tailored to participants' abilities and a Fitbit provided to help motivation. Fatigue levels will be measured at 0, 3, 6 and 12 months. Patient experience, health costs and barriers to the NHS providing this programme will be studied.

We have performed a small study to test whether we could recruit patients to such a trial which was successful in terms of assessing feasibility, that is could we run such a trial. We now need to undertake a large study to see if physical activity and support is successful in helping improve fatigue. We are interested in your views as to the value or such a study and whether you would participate in this study if you suffer from fatigue

Background to the problem

Anti-neutrophil associated vasculitis (AAV) is a rare inflammatory disease, which is controlled by immune suppressing treatments. However patients often suffer from severe fatigue following control of the disease. Many patients describe this fatigue as their worst system which reduces the quality of their lives. Fatigue is identified by patients as a high priority for research.

Currently there are no proven treatments but increasing physical activity helps reduce fatigue in other conditions. However patients with AAV are reluctant to exercise due to fear of their fatigue worsening. A large study is required to assess whether increasing physical activity may improve fatigue levels in patients with AAV.

We have recently completed a small feasibility trial to assess whether a large study of a physical activity programme plus usual care or usual care alone would be possible to conduct and of interest to AAV patients with severe fatigue. We set stop-go targets to determine whether we should progress to a definitive large trial. Forty three patients were recruited (32% of eligible patients) and allocated by chance to usual care or the activity programme with usual care. 50% of participants completed the programme as specified, only 5% of patients discontinued the intervention. Feedback was highly positive; participants allocated to

the activity programme reported significant benefits to their well-being. The programme was safe and fatigue was not made worse. All the targets set were met at green-go or amber (needs slight change) suggesting we could successfully undertake a definitive trial.

What are questions we want to address and why

We wish to investigate whether a large multi-centre trial of a supported 12 week physical activity programme, along with help to change habits, plus usual care or usual care alone is beneficial for patients with ANCA-associated vasculitis (AAV) and severe fatigue.

The questions the study will answer

1. Does increasing physical activity improve fatigue levels and quality of life in patients with AAV and fatigue and is increasing physical activity in patients with AAV safe?

2. How long does the benefits of increasing physical activity, if this is achieved, last after completion of the programme?

3. What impact the activity programme has on patients and what is their experience in participating in this activity programme?

4. What are the likely costs of implementing such a programme if it were to be transferred to the NHS?

5. What are the challenges and barriers to implementing such a programme within the NHS?

By conducting a large trial we will understand how increasing activity benefits patients and the duration of that benefit, and how well activity is tolerated by patients compared to those who have no support beyond advice to increase activity at a clinic visit. The answers to the subsequent questions will tell us whether a programme of supported physical activity can be implemented as part of NHS care by understanding costs, patient experience and the likely challenges to development of such a service.

Project plan

A large trial of a supported 12 week physical activity programme, along with help to change habits, plus usual care or usual care alone will be carried out in 7 centres across the UK. The trial will recruit 150 patients with ANCA vasculitis, who's disease is well controlled and have no conditions that would stop them undertaking physical activity. Participants will be allocated by chance (1:1) to usual care or a 12 week physical activity programme, including support by a physical activity facilitator using both face-face and telephone contact to help increase physical activity delivered in the community. The physical activity programme will be adapted to fit the participants' ability and a Fitbit provided to help motivation. Face to face contact will occur once weekly for 8 weeks to help participants develop their activity programme and provide education on the benefits of activity and coping with fatigue. A telephone call weekly for 12 weeks will help motivation and support progress. The most important measurement of the study will be change in fatigue levels. We will also measure change in sleep, anxiety and depression, and quality of life. We will measure these things

using questionnaires completed by participants. In addition we will measure change in activity levels measured by a wrist worn machine called an accelerometer, this will be a little black box watch that does not tell you how much activity you do but records this information for investigators. This is to allow objective measure of activity without influencing the likelihood of doing activity Assessments will be measured at 0, 3, 6 and 12 months.

Patient experience of the study will be measured by encouraging individuals to submit postcards with feedback about the study and focus groups will be conducted to gain more in depth information about their experience.

We will collect detail on health costs and conduct interviews and questionnaires with all staff who would be involved if the programme was implemented in the NHS to understand the challenges of developing such a programme as standard care.

Patient involvement

This study was initially conceived in response to patients' views collated following presentations on causes of fatigue at patient support meetings. Patients reported that fatigue was an important area requiring treatment. The feasibility study was co-designed by patients and comments collected from support groups (Vasculitis UK,West Midlands Vasculitis Society) that were incorporated into the protocol . An essential part of the feasibility study was the qualitative research aimed at understanding patients' attitudes towards the study. The views of patients have informed how the definitive trial will be conducted. Specific changes to the feasibility study include increasing the flexibility of the programme delivery - changing from delivery in the hospital to the community. Patients thought they would be more likely to participate if they did not have to travel far to participate and the programme was available outside of working hours. We will also increase the flexibility of our definition for sticking to the programme as patients wished to complete the programme but were not always able to commit to the tight timetable due to issues such as holiday or hospital appointments. Overall patients liked participating in the programme, they did not feel that the programme was a burden and they reported noticeable health benefits. They liked the diaries, the fitbits and telephone calls, all of which helped with motivation. Patients reported enthusiasm for a large study to be conducted, with many not participating reporting that they would take part if the study was more flexible.

We are now keen to hear the views of individuals who did not participate in the feasibility study as we will need to recruit many more patients.

Please send your feedback – by 27 June 2019, please – to john.mills@vasculitis.org.uk