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**Patient recruitment and experiences in a randomised trial of supervised exercise training  
for individuals with small abdominal aortic aneurysm**

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## 1   **Abstract**

2   *Introduction:* This paper describes the effectiveness of recruitment strategies used in a  
3   randomised controlled pilot study of supervised exercise training in patients with small  
4   abdominal aortic aneurysm (AAA). We also conducted a qualitative evaluation of the  
5   acceptability of the exercise programme.

6   *Methods:* We aimed to recruit 60 patients with small AAA within 21 months. Participants were  
7   randomly allocated to a 12-week programme of exercise or standard care control. Patients were  
8   identified via aneurysm surveillance lists or consultants at vascular clinics. Postal invitations  
9   were sent and followed up by telephone contact unless a “no” response was received.  
10   Participants undertook health and fitness assessments at baseline (week 0) and intervention end-  
11   point (week 13). A focus group session was conducted ( $N=6$ ) where patients discussed their  
12   medical condition and experiences of study participation.

13   *Results:* The recruitment strategy identified 545 potentially eligible patients. The response rate to  
14   postal invitation was 81.7% (445/545), with 108 patients responding as “interested”. Only 28 of  
15   these patients were eligible and recruited (46.7% of recruitment target), yielding an overall  
16   recruitment rate of 5.1%. However, the estimated recruitment rate amongst eligible patients was  
17   23.7%. The attrition rate was low, with 25 patients (89.3%) completing the study, and  
18   compliance to the exercise programme was excellent (94%). Participants attending the focus  
19   group session indicated that the exercise programme was manageable, beneficial and enjoyable.

20   *Conclusions:* The feasibility of supervised exercise training in individuals with small AAA  
21   remains unclear. Our study revealed a poorer than expected recruitment rate but good  
22   compliance to, and feedback for, the exercise intervention. We present potential explanations for  
23   these findings and suggestions for future trials involving similar populations.

## 1 Introduction

2 Abdominal aortic aneurysm (AAA) is a frequently lethal age-related disease affecting 5% to 7.5%  
3 of men and 1.5% to 3% of women aged >65 years.<sup>1</sup> Mechanical intervention (open surgical or  
4 endovascular repair) is currently the only treatment shown to be effective in preventing AAA  
5 rupture and aneurysm-related death; it is reserved for AAA >55 mm in diameter for men and >50  
6 mm in women.<sup>2</sup> Unfortunately, there are currently few treatment options available for inhibiting  
7 AAA expansion in individuals with small AAA (30 to 49 mm);<sup>2,3</sup> most patients simply enter a  
8 surveillance programme to monitor the progression of their aneurysm. Recently, there has been a  
9 growing interest in the role of exercise training in reducing AAA progression and increasing  
10 fitness for surgery in individuals with small AAA;<sup>4-6</sup> however, no previous studies have provided  
11 detailed information about the effectiveness of recruitment strategies. Patient recruitment into  
12 randomised controlled trials is recognised as one of the most difficult aspects of the study  
13 process since it can be costly and time consuming.<sup>7</sup> It also has implications for the level of  
14 statistical power that can be demonstrated by trials and their subsequent value. Besides limited  
15 information on recruitment, it is also unclear how patients with AAA evaluate the experience of  
16 participating in a trial of exercise training. Understanding patient perspectives of primary and  
17 adjunctive treatment modalities is necessary to optimise patient care.

18  
19 We have recently completed a randomised controlled pilot study of supervised exercise training  
20 in patients with small AAA.<sup>6</sup> Recruitment to this study was difficult with uptake <50% of our  
21 original target. The purpose of this paper is twofold: (i) to provide a detailed report of our  
22 recruitment strategies and results with a view to informing recruitment in future trials in this area,

and; (ii) to highlight the findings of a focus group session that allowed participants to reflect on and share their experiences of the trial.

## **Methods**

### *Study design and participants*

This was a two-arm, parallel-group randomised controlled pilot study. Based on the pilot study guidelines of Lancaster et al.,<sup>8</sup> we aimed to recruit 60 patients with small AAA between January 2010 and September 2011. Participants were randomised to a 12-week programme of moderate-intensity endurance exercise training or standard care control (no exercise). Allocation to exercise or control was done using a randomisation sequence created by an independent researcher before study commencement. The research was carried out in accordance with the Declaration of Helsinki of the World Medical Association, and was approved by the South Yorkshire Research Ethics Committee. Inclusion criteria were men and women aged 50 to 85 years with an asymptomatic, infra-renal AAA 30 to 50 mm in diameter. Exclusion criteria were any contraindications to exercise testing and training (such as severe hypertension, unstable angina and uncontrolled cardiac arrhythmias), an inability or unwillingness to undertake the commitments of the study, and current participation in regular purposeful exercise (self-reported;  $\geq 30$  min,  $\geq 3$  times per week).

### *Recruitment strategies*

The main recruitment strategy was to identify potential participants from a large hospital trust in Sheffield, UK using the local aneurysm surveillance list, since it was predicted that there would be a large enough pool of patients to recruit 60 from. The list was accessed twice, once in

1 January 2010 and then in January 2011. Recruitment from a smaller nearby hospital's  
2 (Rotherham, UK) surveillance list was also carried out in March 2011, due to poor recruitment  
3 up until then. Alongside the surveillance lists, consultants also identified and referred potentially  
4 eligible patients from local vascular clinics. This was to identify patients who were not on the  
5 surveillance lists at the times they were accessed.

6  
7 Once patients had been identified, invitation letters were sent along with participant information  
8 sheets. The invitation letter, written by a Consultant Vascular Surgeon (SN), informed the patient  
9 about the reasons they had been contacted to participate in the research study and its aims. It also  
10 indicated that a member of the research team would be phoning them to see if they would be  
11 interested in participating. In addition, there was a reply slip at the bottom which allowed the  
12 patient to check a box identifying whether they were interested or not, the latter of which  
13 resulted in no further contact. Reply slips could be sent back in a prepaid envelope. If the  
14 interested box was ticked, the individual received a phone call from a researcher within a week.  
15 If there was no response within 10 to 14 days, the patient was contacted via telephone. A 4-page  
16 participant information sheet was included with the invitation letter, which described the study  
17 and contained contact details for the principal researchers (GT, SN).

18  
19 Once patients had shown interest via reply or telephone contact they were briefly screened for  
20 eligibility via telephone. Individuals were then invited to a familiarisation session where they  
21 underwent a basic medical and further screening by an experienced researcher. If the patient  
22 agreed to undertake the study they signed an informed consent form and were scheduled for a

session with the Consultant Vascular Surgeon for further medical examination. If the patient was still deemed eligible they undertook the baseline assessments.

#### *Recruitment incentives*

There were no recruitment incentives other than the opportunity to have a free medical examination with a vascular surgeon and the potential opportunity for one-to-one exercise training with an exercise physiologist. The control group were offered the option of receiving supervised exercise in the form of a 4-week intervention after all study commitments had been completed.

#### *Exercise training*

Participants randomised to exercise were invited to undertake training 3 times per week for 12 consecutive weeks at a dedicated exercise suite at Sheffield Hallam University. Each session involved a mixture of treadmill walking and stationary upright cycling for 35 to 45 minutes supervised by exercise physiologists (GT, JM). Perceived exertion was targeted to fall within the range of 12 to 14 on the Borg 6 to 20 scale (i.e. somewhat hard).<sup>9</sup> It was anticipated that patients would need to organise their time around household and family responsibilities and the working week. Session times were therefore flexible and available throughout the day between 0900 and 1800 Monday to Friday. Both groups had access to standard care, which consisted of a basic recommendation to be physically active, but to avoid strenuous lifting.

#### *Measures*

Personal details, medical history and medication information for all participants were ascertained via medical records and patient interview. The following outcomes were assessed at baseline and after 12 weeks of follow up: health-related quality of life using the SF-36v2 questionnaire, maximum AAA diameter via transabdominal ultrasound, and ventilatory threshold via cardiopulmonary exercise testing. Fasting venous blood samples were collected for analysis of lipid profiles, C reactive protein, matrix metalloproteinase-9, and glucose (all serum). The exercise testing procedures have been described previously.<sup>6</sup>

### *Focus Group*

A purposive sample of 6 participants (5 men, 1 women; age 61 to 79 years) who had completed the experimental arm of the study was invited to take part in a focus group session conducted by three researchers (GT, HC, JM). This occurred within 1 to 3 months of patients completing follow-up assessments. The focus group provided the opportunity for participants to personally reflect on and share their own experiences of the study. Furthermore, the group interaction stimulated discussion between participants and generated new insights. A topic guide was used flexibly to guide the discussion (Table I).

The focus group was audio recorded and the recording was transcribed verbatim. Transcripts were independently read by three investigators (RG, HC, GT). Framework analysis was used to analyse and interpret the data.<sup>10</sup> Despite a limited sample size, the authors feel the findings gleaned from the focus group will be useful for future trials in this area. The views expressed by participants are those from a post-diagnosis and post-12 week exercise trial perspective.

## Results

### *Recruitment*

Figure 1 outlines the flow of patients into and through this study. 466 AAA patients were identified from the Sheffield surveillance list, (380 from 2010, 86 from Jan-Sept 2011), 72 from the Rotherham list (all March-Sept 2011), and 7 via consultant-led vascular clinics (Sheffield and Rotherham combined). The rate of participant recruitment is expressed in Figure 2. The response rate from the invitation letter was 81.7% (445/545), with 75.7% of these (337/445) not interested. Therefore, 108 patients were interested and potentially eligible.

Of the 337 patients not interested in participating, the cited reasons in order of prevalence were: No reason 64.4% (217/337), Health problems 14.2% (48/337) Time commitment 5.3% (18/337), Too far 2.7% (9/337), AAA outside required range 2.4% (8/337), AAA intervention 2.4% (8/337), Disinterest 2.0% (7/337), Felt too old 2% (7/337), Not eligible 2.0% (7/337), Deceased 1.2% (4/337), Family ill health 0.6% (2/337), and Lack of transport 0.6% (2/337).

From the 108 interested participants a further 78 were excluded after screening. The reasons for ineligibility in order of prevalence were: Co-morbidities 32.1% (25/78), AAA >50 mm 16.7% (13/78), Time commitment 14.1% (12/78), Too far 11.5% (9/78), Disinterest 6.4% (5/78), Lack of transport 5.1% (4/78), Regular exerciser 5.1% (4/78), AAA intervention 2.6% (2/78), and AAA <30 mm 2.6% (2/78).

After screening, a total of 30 patients remained eligible and interested. Two patients withdrew before providing written informed consent, resulting in 28 being recruited to the study (46.7% of recruitment target) and an overall recruitment rate of 5.1%. Characteristics of recruited and non-recruited patients are shown in Table II. The mean age of participants was  $72 \pm 7$  years and 86% (24/28) were male. Three patients from the exercise group withdrew prior to completion for the following reasons: pacemaker insertion, diagnosed with cancer and chronic back pain. In total, 25 patients completed the study (89.3%; 11 exercise, 14 control). Compliance to the exercise programme was excellent, with 371 of 396 sessions attended (94%).

Of patients who responded with interest, 27.8% (30/108) were eligible to be randomised. Assuming a similar eligibility rate for non-responders ( $N=100$ ) and responders who were disinterested but provided no reason ( $N=217$ ), it is estimated that 28 and 60 of these patients, respectively, would have been eligible had they been interested in taking part in the study. Therefore a total of 118 patients were estimated to be eligible (28 non-responders and 60 responders estimated to be eligible plus 30 responders known to be eligible). On this basis, the estimated recruitment rate amongst eligible patients was 23.7% (28 recruited patients divided by a total of 118 eligible patients).

### *Focus group*

The key themes of experience of diagnosis, management of condition, trial recruitment and expectations and experiences of exercise trial were identified.

### *Experience of diagnosis*

There was a consensus amongst participants that the diagnosis of an AAA had come as a surprise, and usually without warning, as one participant noted it was like a "shot out of the blue". Participants commented that the shock of diagnosis was also accompanied by a sense of not knowing what to expect:

*"I was really in the dark and wondering what would happen next" (1)*

There was also a concern for the future and a sense of hopelessness in terms of being able to understand and know how to manage their condition:

*"I thought oh well that's that then, as it were, I expected to go anytime" (3)*

*"Since then I've just hoped for the best and hoped it doesn't start gathering momentum and growing again" (3)*

Discussion between the group participants revealed that there was considerable variation in the clinical presentation of the condition at diagnosis and its subsequent prognosis, which raised awareness amongst the group that each individual's case was unique.

#### *Management of condition and effect upon lifestyle*

In contrast to the sense of surprise that accompanied their diagnosis, participants' reflections of living with the condition were conveyed in a manner of acceptance; that they had to live with their condition. The condition presented considerable variability in terms of impact on participants' lifestyle. For some the imposed restriction on lifting heavy items was a mark of losing their independence and work-related functional capacity. One participant had not been given any specific advice regarding lifting so had continued to perform heavy lifting in the garden without any perceived risk. This thread of the discussion prompted participant's to ask about the risk of doing harm in the absence of any overt physical symptoms and this elicited

1 information seeking by the group, directing clinical questions toward the researchers. One  
2 participant had given up smoking and most participants had received very general advice to  
3 exercise more, keep a healthy weight and follow a healthy diet. However, the majority of the  
4 group felt the exercise advice they had been given had not then resulted in an increase in their  
5 physical activity beyond their usual daily routine. In contrast, one participant was really pleased  
6 with the walking advice he had been given by a primary care nurse and had put the advice into  
7 practice by walking up to two miles a day. Despite encouragement from his doctor to initiate an  
8 exercise programme within a local exercise referral scheme, one participant was disappointed to  
9 have been turned away from the programme due to having an AAA.

#### 11 *Reasons for taking part in the study*

12 Key themes emerged as to why the participants decided to join the study. Firstly participants  
13 were interested to see what the study involved and how it might benefit them. In particular, the  
14 group welcomed the chance to "learn something" about their condition from researchers.  
15 Participants were also interested to understand "how it was affecting everyone else" and "how  
16 other people were coping". Furthermore, there was a common reflection that their involvement in  
17 research may benefit future patients.

18  
19 There was a concern from the study researchers before starting the study that participants could  
20 be worried about exercising with an AAA. This notion was dispelled as the group commented  
21 that a research based trial created a sense of safety, this was summarised by one of the  
22 participant:

1       *"It couldn't do any harm; you people would not let us go too far, everything was going to*  
 2       *be checked out... I had faith in the research you were doing and you knew what you were*  
 3       *doing and it was for our benefit that if you could find something that could recognise it or*  
 4       *that the exercise did help" (2)*

#### 6   *Expectations and experiences of exercise trial*

7   Overall, the group participants reported positive experiences of the exercise trial. Tailored  
 8   supervision in a professional environment fostered reassurance and the opportunity to ask  
 9   questions and learn more about their condition was particularly welcomed. The group  
 10   commented that the social element of the programme was an additional attractive feature of the  
 11   programme, one participant commented:

12       *"It was different from the everyday run of the mill.... it was a change to do something*  
 13       *different " (1)*

14   Initially, however, there were apprehensions that participants might "make fools out of  
 15   themselves in front of strangers", but peer support and the opportunity for social interaction with  
 16   others became appreciated elements of the session. The 12-week exercise intervention was  
 17   perceived to be acceptable in terms of exercise intensity, frequency and duration of individual  
 18   sessions. Insights revealed that despite most participants being retired ( $N=5$ ), participants were  
 19   “busier than ever” with childcare responsibilities, personal commitments, hospital appointments  
 20   of their own and others, and thus felt unable to attend more than three supervised, facility-based  
 21   exercise sessions per week. Exercise intensity was reported to be pitched in accordance with  
 22   participants’ abilities and only one participant remarked the intensity “was not as easy I thought

it would be“. Further questioning regarding the length of the intervention revealed that at least half of the group would have liked the programme to be longer than 12 weeks.

An interesting discussion arose within the group around the expectation of benefit from exercise training. Participants stated that their ideal clinical scenario was to see a reduction in the size of their aneurysm. Across the group there was a general lack of understanding of the clinical benefit of exercise in relation to AAA:

*"I was expecting too much in term of results, I was expecting to see a slight drop in size of my aneurysm, it was my fault in interpreting what you told me, if you make that a little clearer to people, maybe tell us what the expected benefits of exercise are." (1)*

Current evidence (mostly indirect) from both human and animal studies suggests that it is unlikely that chronic exercise training will reduce the size of an aneurysm, but it might inhibit aneurysm development and reduce the rate of aneurysm progression.<sup>5,6,11-13</sup> The group's reflections suggest that this detailed type of knowledge and information is not being communicated to patients and thus there is a need for tailored exercise advice whereby likely benefit should be made explicit. This, however, might be difficult at present considering that the role of exercise training in the management of AAA disease and the optimal exercise prescription for this population are yet to be clearly defined.

It was mentioned that the value of exercise training was less attractive if there weren't any associated palpable outcomes such as losing weight or feeling fitter. Nevertheless, there was a common understanding that exercise could offer other health benefits, such as improving cardiovascular health. Tangible outcomes such as "walking better without loss of breath" and an

enhanced sense of well-being were valued benefits and deemed important for helping to sustain exercise motivation.

*"It was rewarding to me to think well I've got some good out of it... it was important to have the numbers there... it made it worth it". (4)*

A sub-theme that arose from the group discussion was the issue of whom should deliver exercise advice and the setting in which opportunities to try exercise should be given. All participants were keen to receive exercise advice or at least endorsement from clinicians and other medical professionals. Additionally, they commented that they would like to attend exercise sessions in a non-medical setting, preferring not to be based at the hospital, as they already attended numerous appointments at hospital. It was suggested that exercise instructors and/or researchers with expert knowledge would be best placed to deliver exercise sessions.

## **Discussion**

To our knowledge, no prior manuscripts have provided a detailed account of recruitment experiences in clinical trials of patients with AAA. Therefore, we are unable to compare the effectiveness of our recruitment strategies with those from other trials in this patient group. Nevertheless, our overall recruitment rate (5.1%) is lower than that reported in a recent exercise trial in small AAA from the USA; 14.6%.<sup>5</sup> In that study, the exercise intervention was home or centre based depending on participant preference, which was likely to have facilitated recruitment. Their higher recruitment rate might also be attributed to a more thorough screening of patient notes before initiating contact. Our recruitment rate also compares unfavourably with previous exercise trials from our Centre involving other clinical populations, which used similar recruitment strategies: breast cancer, 18.9%;<sup>14</sup> colon cancer, 10%;<sup>15</sup> peripheral arterial disease,

20.1%;<sup>16</sup> obstructive sleep apnoea, 12.5%.<sup>17</sup> This suggests that patients with small AAA are a particularly difficult group to recruit to exercise trials. Although the low recruitment rate could mean that only a small minority of highly motivated (perhaps atypical) patients volunteered for our study, the baseline characteristics were similar to those of patients in a large trial of surveillance versus aortic endografting for small AAA,<sup>18</sup> suggesting that this was unlikely to be the case. Furthermore, the recruited and non-recruited patients did not differ markedly in terms of age and sex (Table II).

The response rate to the invitation letter was high (81.7%) and established a good foundation for recruitment. Unfortunately, approximately only 1 in 4 (24.3%) responders were interested in participating, leaving only 108 patients to recruit 60 from. It is difficult to provide a clear explanation as to why so many patients were disinterested, because approximately two thirds did not provide a reason. From cited reasons, the most prevalent theme was a perceived inability to participate because of health problems and lack of time. There may be a number of other reasons why patients showed disinterest or did not respond. For example, it is possible that the physically demanding nature of the exercise programme made it unattractive compared to say other types of behavioural interventions.<sup>19</sup> An interesting point to consider here is that we were probably only ever going to recruit patients who were in equipoise about whether to exercise or not, a subgroup who likely make up a small proportion of the total AAA population. Indeed, given that a large proportion of older adults choose not to exercise regularly,<sup>20</sup> it is likely that most of the patients we contacted were not interested in exercise, and those who already exercised regularly were ineligible. Other potential reasons for many patients not responding or declining without reason include a perceived lack of time or benefit, an unwillingness to travel, or patients not

1 understanding or even reading the invitation letter and participant information sheet. Regarding  
2 the latter, studies have shown that non-responders in community surveys of the elderly appear to  
3 be disproportionately cognitively impaired.<sup>21</sup> A further barrier with recruiting from elderly  
4 populations is that significant proportions have co-morbidities related with normal aging and  
5 complications associated with chronic disease states. This study revealed that a large proportion  
6 of interested patients were ineligible to participate due to co-morbidities (32.1%). Regardless of  
7 the underpinning reasons, our findings suggest that patients with small AAA in the UK are  
8 generally disinterested in participating in institution-based exercise trials.

9  
10 In the UK, individuals with small AAA are mostly on a surveillance list or undiagnosed. Seeing  
11 as we had exhausted the local surveillance lists, the only way we could have identified more  
12 potential participants would have been screen the general public for AAA ourselves. This was  
13 clearly not feasible within the confines of a preliminary unfunded research study. An AAA  
14 screening programme in men aged >65 years has since been implemented throughout England  
15 ([www.aaa.screening.nhs.uk](http://www.aaa.screening.nhs.uk)). We envisage that recruitment would have been more successful if  
16 we could have recruited via this programme. Indeed, local screening would have increased the  
17 pool of patients to recruit from and it is possible that patients would be more receptive to  
18 participating at the point of diagnosis. Along this line, community surveys of the elderly indicate  
19 a distinct preference for in-person as opposed to written contact.<sup>21</sup> The possibility of placing a  
20 researcher in vascular clinics to recruit was not logistically possible due to limited funding, but  
21 may be in future studies if such activities are built in.

22

1 The results demonstrated that 54 individuals did not take part in the study due to transport, time  
2 and distance issues. Therefore, sessions at home or nearby gymnasias may have been preferred.  
3 Future trials could explore the efficacy of self-managed, remotely-monitored exercise training in  
4 these patients, and this appears to be an area of growing interest in cardiac rehabilitation.<sup>22</sup> We  
5 opted for a supervised approach in the current study due to uncertainty about the safety of  
6 exercise in aneurysm patients, but preliminary evidence from Myers et al.<sup>5</sup> suggests that  
7 unsupervised exercise training can be performed safely. Another key factor that may have  
8 facilitated recruitment but was not offered was providing financial incentives. Many researchers  
9 use financial incentives to improve recruitment into studies,<sup>23</sup> and Martinson demonstrated the  
10 effectiveness of such an approach in the context of a randomised controlled trial of an  
11 intervention to reduce smoking.<sup>24</sup> However, the ethics of such an approach needs to be  
12 considered, as argued by Tishler.<sup>25</sup> The two main concerns are undue inducement and taking  
13 advantage of economically vulnerable patients. As well as the ethical issues of undue inducement,  
14 financial incentives also have the potential to encourage false information from whomever the  
15 inducement is aimed. We encourage UK-based researchers to consult INVOLVE policy on  
16 payments and expenses when planning a trial involving human participants ([www.invo.org.uk](http://www.invo.org.uk)).

17  
18 The combination of a clear explanation, frequent contact and encouragement during exercise  
19 sessions likely contributed to the high exercise compliance and low dropout in our study. A clear  
20 explanation was delivered at multiple points throughout the recruitment process via the  
21 participant information sheet, telephone screening and familiarisation session. During the 12-  
22 week programme the individuals met with the same researchers who encouraged them  
23 throughout the exercise regime and built a rapport with them. The timetabling of exercise

1 sessions was very flexible and sessions were only scheduled a week in advance allowing the  
2 patient to keep any prior commitments. The participants undertook their exercise sessions in  
3 groups, which promoted camaraderie and enjoyment. Finally, offering a 4-week exercise  
4 intervention to those completing the control arm likely contributed to the low dropout rate.

## 6 **Conclusions**

7 Despite having a large pool of patients to recruit from, we did not recruit to target. This is likely  
8 explained by a combination of reasonably stringent eligibility criteria and issues surrounding the  
9 perceived burden of participating in the study and disinterest with exercise. Nevertheless, the  
10 exercise programme was deemed manageable and useful by those completing the study and,  
11 alongside encouraging preliminary evidence from recent studies,<sup>4-6</sup> this supports our belief that  
12 the role of exercise training in the management of AAA disease should be further explored. The  
13 data presented will help inform future studies in this area.

## 15 **Acknowledgements**

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18 throughout the study. This study was supported by Sheffield Hallam University and the Sheffield  
19 Vascular Institute.

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