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Proposing a Trial in Home Based Cardiac Rehabilitation Programmes – A way to effectively tackle modifiable vascular risk factors?

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ABSTRACT

Stroke is a major cause of mortality and morbidity that may be prevented by early intervention following a transient ischaemic attack (TIA). How to optimise such prevention, however, remains unknown. This paper therefore argues for a randomised controlled trial to assess the effectiveness of a home-based cardiac rehabilitation programme, based on the 'Heart Manual', begun within 2 weeks of a TIA, compared to usual care. Potential benefits for patients could include improved well-being and reduced risk of further vascular events, including stroke.

Key Words: Vascular disease; home-based cardiac rehabilitation programmes; Transient ischaemic attacks; the 'Heart Manual'; secondary prevention.

Introduction

With services overburdened by growing demand and restricted supply, there is an opportunity for health creation by providing an adapted home-based cardiac rehabilitation programme for patients who have recently suffered a transient ischaemic attack (TIA). This approach may improve the accessibility and sustainability of health services in the UK by using an already established treatment for this patient group as well as reducing their future risk of developing further vascular events.

Stroke prevalence, impact and risk

Stroke killed 5.7 million people worldwide in 2005 and is estimated to cause 6.5 million deaths in 2015[1], with stroke survivors often being left with considerable disability[2-3]. In 2006, approximately 1,700 TIAs and 4,000 strokes occurred in Northern Ireland alone[4]. TIA is defined as "a transient episode of neurological dysfunction caused by focal brain, spinal cord or retinal ischaemia, without acute infarction"[5-6]. The costs associated with both the acute hospitalisation and long-term follow-up care of patients with a past medical history of stroke is huge. Importantly, many strokes are preceded by TIAs, particularly within the first 90 days[3]. Therefore the immediate period after a TIA is a crucial time to intervene to reduce the

risk of stroke and interventions (drug and non-drug) in this period have been the focus of much clinical research.

Stroke risk following a first TIA

The 90-day risk of vascular events following a TIA, excluding events within the first week after diagnosis when the risk is highest, is 18% [5]. The ABCD^2 score in TIA patients is used to identify the future risk of stroke[3]. The ABCD^2 score consists of the following:

Elements of ABCD^2 score	**Points**
Age 60 years or above	1
Blood pressure 140/90mmHg or above on first evaluation	1
Clinical symptoms of focal weakness with spell Or, speech impairment without weakness	2, OR 1
Duration of 60 minutes or more or 10-59 minutes	2, OR 1
And **D**iabetes	1

The presence of a new infarct on brain imaging, indicating that the patient has actually had a stroke, places the patient at higher risk of a further stroke within the first 90 days[6]. Therefore, intense medical input is useful to help triage those patients most at risk of a stroke and subsequently direct patients towards appropriate secondary prevention.

Secondary prevention reduces risk of second stroke

Immediate assessment of TIA patients following the initial event, with initiation of secondary prevention, focusing on pharmacological interventions, can reduce the 90 day risk of stroke to 2% within the research setting[7]. These results have however not been replicated within routine practice[8]. Typical drug therapy initiated post-TIA event includes anti-platelets (aspirin, dipyridamole, and/or clopidogrel), statins and anti-hypertensives, if required.

Despite the benefits of drug therapy, non-drug approaches are of vital importance and, alongside reducing stroke risk post-TIA, may promote patient independence and engagement with their own health. Indeed, evidence is growing regarding the contribution of change in modifiable risk factors to reductions in cardiovascular deaths and there is a need to consider how to promote non-pharmacological measures within secondary prevention.

VO_2max links with stroke risk and exercise

Cardiorespiratory fitness, measured by VO_2max, is inversely correlated with mortality[9-12], the progression of carotid atherosclerosis[13] and the risk of stroke. An increase in VO_2max of 3.5 ml/kg/min was associated with a 17% decrease in stroke risk[14], with similar findings noted in a meta-analysis[15]. Aerobic exercise can increase VO_2max by up to 30% in sedentary persons[16] and sub-acute stroke survivors who participated in a twelve week supervised exercise programme demonstrated an increase in VO_2max of over 1ml/kg/min from baseline[17].

However there is an absence of published data linking post-TIA exercise to change in subsequent stroke risk.

Pedometers promote exercise

One method of promoting exercise and potentially improving VO2max is through the use of pedometers[18]. Pedometers are small waist-borne instruments that count the number of steps taken by the subject. Pedometers have been shown to be accurate and reliable in measuring ambulatory activity and their use has been suggested to increase patient engagement in exercise[19-22]. Pedometers appear feasible for use by patients with stroke although their accuracy at slow walking speeds has been questioned[23-24]. No reports have been identified regarding the use of pedometers as a physical activity promotion tool by patients with TIA or within the acute stroke setting and indeed a recent systematic review on the role of exercise post-stroke, has highlighted the lack of studies in the acute and sub-acute periods[25].

Increasing steps per day by between 2,500-3,000 leads to weight loss and some reductions in blood pressure[20, 26-27]. Physical activity public health recommendations have been translated into pedometer targets[26], with 100 steps per minute congruent with moderate-intensity activity 20 and 130 steps per minute considered vigorous intensity activity[26]. Pedometers can be used to give visual feedback to patients on their physical activity intensity as well as the total number of steps taken and the duration of activity.

Underlying pathological mechanism and risk factors for TIA

TIAs and strokes are most commonly caused by the embolic or thrombotic consequences of atherothrombotic disease[28-29], which is similar to the underlying pathological mechanism for cardiovascular disease[30-32]. As well as sharing a similar underlying pathological mechanism, cerebrovascular and cardiovascular disease share common underlying risk factors[31,33] and there is a high prevalence of asymptomatic coronary artery disease post-TIA [5, 32-35]. Atrial fibrilliation (AF) is also a common cause of stroke, with AF being more common in those with ischaemic heart disease.

The modifiable risk factors for all vascular diseases include smoking, excessive alcohol intake, physical inactivity, dietary factors, hypertension, dyslipidaemia, diabetes, and obesity[36] as well as low VO2max [9, 10-12, 37]. Thus there are several lifestyle interventions that might contribute to a substantial reduction in the risk of vascular events post-TIA and there is evidence that the earlier these interventions can be introduced, the better the outcome [7-8, 38-39]. National guidelines also state that TIA patients should be reviewed in a specific clinic within one week of the diagnosis [8].

Tackling modifiable vascular risk factors with cardiac rehabilitation

Although cardiovascular and cerebrovascular disease share common underlying pathological mechanisms and risk factors, cardiac rehabilitation for secondary prevention is only offered to patients in the UK who have suffered specific cardiovascular events, e.g. myocardial infarction[40]. NICE (National Institute for Health and Clinical Excellence) have recommended that the components of cardiac rehabilitation should include exercise, health education and

stress management[40]. Health education would include addressing the known modifiable vascular risk factors as well as advice regarding work, mental health and sexual activity[40-41]. These components are all addressed in the "Heart Manual", a home-based cardiac rehabilitation programme.[9]

The "Heart Manual" is the only validated home-based cardiac rehabilitation programme supported by NICE for patients who have had a myocardial infarction (MI)[42]. It is based on the Health Belief Model of behaviour change theory and uses cognitive behavioural techniques, including goal setting and its use has been associated with reductions in depression, anxiety and cholesterol levels and improved quality of life[43]. The "Heart Manual" has also been associated with reductions in blood pressure, improved exercise capacity and smoking cessation rates which are comparable to those achieved with hospital-based cardiac rehabilitation programmes[44]. The "Heart Manual" has been shown to strengthen illness control beliefs[45] and increase confidence in recovery and self-perceived progress[46].

Cardiac rehabilitation after a MI results in a statistically significant reduction in re-infarction, cardiac mortality, and all-cause mortality[47] and these conclusions were similar to a recent Cochrane Review[48]. Furthermore, a five-week cardiac rehabilitation programme improves VO_2max by 3-4 ml/kg/min in low risk post-MI patients[49], which is supported by an earlier study[50], which would have a positive impact on stroke risk following a TIA and improve the patient's quality of life.

A Cochrane Review demonstrated hospital-based and home-based cardiac rehabilitation programmes, most of which used the "Heart Manual", can result in similar health gains [51], with home-based programmes improving adherence to the programme [52]. Moreover, home-based cardiac programmes have shown longer-term sustainability of health benefits compared with hospital-based programmes [53]. Thus there is strong evidence to support the use of a home-based programme in a patient population with cerebrovascular disease, which shares underlying pathological mechanisms and risk factors.

The 'Heart Manual' addresses each of the modifiable vascular risk factors, managing one risk factor each week, whilst encouraging the patient to slowly increase their activity over the six week programme in the setting of their home and addressing the issues of anxiety and depression following the diagnosis of TIA. The manual therefore involves education and motivation of the patient to address these risk factors. The manual is aided by a facilitator who contacts the user at approximately 1 and 4 weeks and helps the user to identify local support resources, for example smoking cessation services, as well as tackling any issues which they may have. The 'Heart Manual' utilises the behaviour change techniques of goal setting, barrier identification, setting graded tasks, self monitoring, feedback, relapse prevention and stress management.

Innovation

The author therefore proposes a trial, based in primary care, to assess the effect of a home-based vascular rehabilitation programme with the addition of a pedometer on VO_2max, which is a marker of future risk of vascular events as well as death. The intervention is based

on a home-based cardiac rehabilitation programme, the 'Heart Manual', that has been shown to be effective for patients following myocardial infarction and other cardiac events. This proposal also incorporates the use of a pedometer, as a tool to prompt physical activity and promote longer-term behaviour change, providing a means of objective personal feedback regarding achievement of goals. The proposal also emphasises self-management and patient dignity as the rehabilitation programme will be home-based as well as an early intervention, aiming to initiate this within two weeks of the TIA (after being reviewed in a specialist clinic) to maximise the benefits to patients. This research project therefore has the potential for significant economic impact in the NHS and for impact on patients' quality of life and disability and proves that the UK health systems, as well as the people that work within the NHS, still care about their patients.

Concluding Remarks

Patients who have just suffered a TIA, are at high risk of suffering further vascular events and therefore at high risk of disability and death. From previous research, we know that if we target these patients with immediate secondary prevention, the future risk of vascular events can be reduced although this risk reduction has not been replicated within routine practice. Using the recognised cardiac rehabilitation model within TIA holds much promise, particularly with a home-based approach. If this study of the 'Heart Manual' within the cerebrovascular patient population proves successful, the next stage in knowledge translation will be to refine the intervention design, based on the pilot study findings and to develop an international, multi-centred, randomised controlled trial, of a home-based vascular rehabilitation programme to reduce the subsequent risk of vascular events after suffering a first TIA. This research project therefore has the potential for significant economic impact in the NHS and for impact on patients' quality of life and disability.

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