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Rehabilitation of patients after transient ischaemic attack or minor stroke:

pilot feasibility randomised trial of a home-based prevention programme

Abstract

Background
Although the importance of secondary prevention after transient ischaemic attack (TIA) or minor stroke is recognised, research is sparse regarding novel, effective ways in which to intervene in a primary care context.

Aim
To pilot a randomised controlled trial (RCT) of a novel home-based prevention programme (*The Healthy Brain Rehabilitation Manual*) for patients with TIA or 'minor' stroke.

Design and setting
Pilot RCT, home-based, undertaken in Northern Ireland between May 2017 and March 2018.

Method
Patients within 4 weeks of a first TIA or 'minor' stroke received study information from clinicians in four hospitals. Participants were randomly allocated to one of three groups: standard care (control group) ($n = 12$); standard care with manual and GP follow-up ($n = 14$); or standard care with manual and stroke nurse follow-up ($n = 14$). Patients in all groups received telephone follow-up at 1, 4, and 9 weeks. Eligibility, recruitment, and retention were assessed; stroke/cardiovascular risk factors measured at baseline and 12 weeks; and participants' views were elicited about the study via focus groups.

Results
Over a 32-week period, 28.2% of clinic attendees (125/443) were eligible; 35.2% of whom (44/125) consented to research contact; 90.9% of these patients (40/44) participated, of whom 97.5% (39/40) completed the study. After 12 weeks, stroke risk factors [cardiovascular risk factors, including blood pressure and measures of physical activity] improved in both intervention groups. The research methods and the programme were acceptable to patients and health professionals, who commented that the programme 'filled a gap' in current post-TIA management.

Conclusion
Findings indicate that implementation of this novel cardiac rehabilitation programme, and of a trial to evaluate its effectiveness, is feasible, with potential for clinically important benefits and improved secondary prevention after TIA or 'minor' stroke.

Keywords
cardiac rehabilitation; pilot study; secondary prevention; stroke; transient ischaemic attack.

INTRODUCTION

The immediate period after a transient ischaemic attack (TIA) or 'minor' stroke is a crucial time to intervene to reduce risk of future cardiovascular events,[1,2] with GPs often managing this secondary prevention. Organisational interventions in general practice for secondary prevention of cardiovascular disease reduce mortality,[3] and participation in cardiac rehabilitation programmes after acute cardiac events are associated with reduced mortality and morbidity.[4,5] Home-based cardiac rehabilitation programmes may be as effective as those delivered in hospitals, with better compliance.[4] However, although cardiovascular and cerebrovascular disease share common pathological mechanisms and risk factors, the impact of cardiac rehabilitation and lifestyle interventions after stroke and TIA requires further research.[6–8] Furthermore, physical activity, a core element of cardiac rehabilitation, is supported by different behaviour change methods including goal setting, providing feedback, and monitoring, and by using pedometers,[9,10] but there are few studies of pedometer use by patients early after TIA or stroke.[11,12]

After systematically reviewing the underpinning evidence,[7,13,14] *The Healthy Brain Rehabilitation Manual*, an adaptation of *The Heart Manual*,[9] was developed by following Medical Research Council guidelines,[15] and the results of a feasibility study, with service user input.[7,14,16]

The aim of this study was to conduct a pilot trial of the effectiveness of a revised version of *The Healthy Brain Rehabilitation Manual* during the acute period following a first TIA or 'minor' stroke.

METHOD

This study follows CONSORT reporting guidelines for pilot and feasibility studies,[17] and the PREPARE trial guide.[18]

Study setting and participants

From May 2017 to December 2017, nurses working in 'drop-in' TIA clinics and scheduled outpatient clinics in four TIA/'minor' stroke assessment units in different Northern Ireland health and social care trusts identified eligible patients and gave them study information. Patients who consented to contact were telephoned by the researcher the next day and invited to participate in the study.

Eligibility criteria

Patients were included if they were aged ≥18 years, within 4 weeks of their first TIA or 'mild' stroke symptoms, with diagnoses attributed to atherosclerosis or small vessel

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How this fits in

Cardiac rehabilitation after myocardial infarction reduces the risk of re-infarction, cardiac mortality, and all-cause mortality. However, the value of cardiac rehabilitation after a transient ischaemic attack (TIA) or 'minor' stroke is untested despite these conditions sharing similar pathology with coronary heart disease. Patients who have experienced a TIA are at high risk of future cardiovascular events but early intervention after a TIA or 'minor' stroke may prevent further stroke and disability. As awareness of the importance of lifestyle factors rises, the best approach to implementing secondary prevention remains unknown. The authors therefore developed a novel home-based intervention, *The Healthy Brain Rehabilitation*, for use in primary care, using core components of cardiac rehabilitation to promote secondary prevention for TIA and patients who have had a 'minor' stroke. The results of this pilot study indicate that this home-based intervention has potential for clinically important benefits and improved secondary prevention after TIA or 'minor' stroke.

occlusion.[19,20] Patients with unstable cardiac conditions, contraindications for exercise training,[21] or a previous cerebrovascular event were excluded. A stroke research nurse recorded their diagnosis and patients with a TIA and/or 'minor' stroke diagnosis who were eligible to participate agreed to be contacted, and consented to participate.

Data collection

At baseline and after 12 weeks, participants attended the NI Clinical Research Facility, Belfast City Hospital, for assessment; a minor protocol amendment, after 5 months' recruitment, allowed the option of home assessments.

Measurements were taken of height and weight, waist circumference, resting blood pressure, and heart rate (using an automatic blood pressure monitor).[22] The heart rhythm was checked for dysrhythmias (radial pulse; 1 minute) and sociodemographic variables, smoking status, alcohol intake (units in typical week before assessment), time from event, educational status, and current employment were recorded. A measure of deprivation (multiple deprivation measure) was derived from home address postcodes (nisra.gov.uk/mapxtreme_deprivation2010/default.asp), a family history was taken, physical activity was assessed (validated international physical activity questionnaire [IPAQ]),[23] and a Mediterranean diet score was calculated using a validated questionnaire.[24]

A 2-minute walk test was performed twice, separated by a rest period of at least 30 minutes.[25] Anxiety and depression (Hospital Anxiety and Depression Scale [HADS]),[26] disability (modified Rankin scale),[27] 'readiness to change',[28] and quality of life (EQ-5D-5L)[29] were assessed, and a timed 'Up and Go' test was administered.[30] All participants were invited to wear a wrist-worn, tri-axial accelerometer, for 1 week on their dominant wrist for objective measurement of physical activity,[31] and to return this in a prepaid envelope.

The intervention

The Healthy Brain Rehabilitation Manual has been described previously.[15] Briefly, it includes information about TIA and stroke, advice about healthy lifestyle, and a stroke risk reduction plan that focuses on a different risk factor each week for 6 successive weeks; and it promotes physical activity by setting and reviewing weekly pedometer step count targets. Telephone follow-up calls at 1, 4, and 9 weeks by a GP (Group 2) or stroke nurse (Group 3) supported its use.

Randomisation and blinding

An independent statistician generated random permuted blocks of 3 and placed the allocations in sealed, opaque envelopes, opened only after completion of baseline assessments. A research nurse, blinded to intervention allocation, undertook post-intervention assessments.

Study design

This pilot feasibility randomised trial comprised three study arms: Group 1 (control) received standard post-TIA/minor stroke care.[13,32] In addition, at the end of their baseline assessment, Groups 2 and 3 received *The Healthy Brain Rehabilitation Manual* and a wrist-worn pedometer, with a daily step count and physical activity diary. Groups 2 and 3 were informed about UK physical activity guidelines and how to achieve moderate and vigorous physical activity intensity,[33] reduce sedentary time, and set and monitor physical activity goals using the pedometer. All participants were telephoned at 1, 4, and 9 weeks, to address any concerns regarding their care.

Participants in Groups 2 and 3 were also asked to report weekly average step counts and encouraged to self-set step count targets,[9] using the '5 As' approach,[34] motivational interviewing techniques,[35] and a standardised format. Groups 1 and 2 received GP telephone follow-up; Group 3

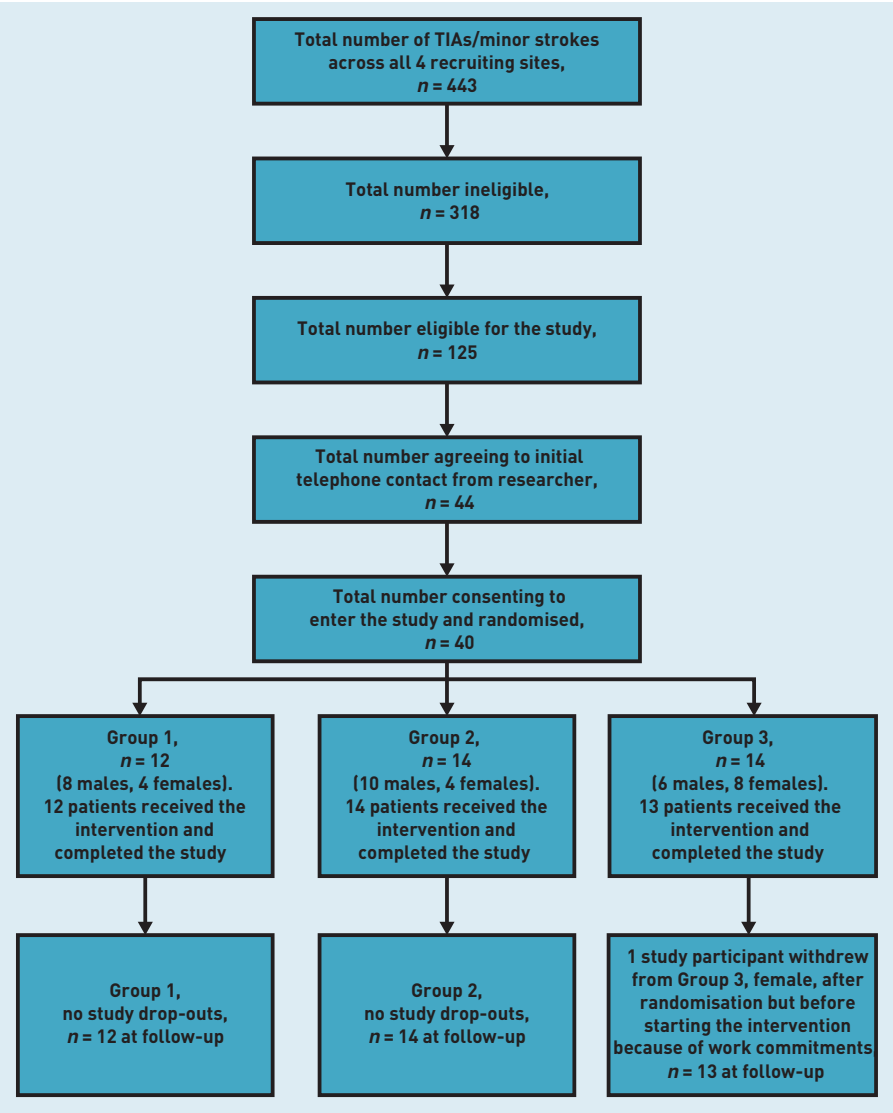

Figure 1. CONSORT flow diagram for pilot study of a novel home-based prevention programme after TIA or minor stroke.

received stroke nurse telephone follow-up. Diary records were reviewed at 12-week follow-up.

Data analysis

It was estimated that data for 40 participants were required to inform planning of a randomised controlled trial (RCT). An independent statistician, blinded to group allocation, used SPSS (version 23) to report descriptive statistics. Accelerometer data were compared with diary records, using a minimum of 72 hours' wear time to define valid data,[31] removing non-wear time (consecutive stationary periods lasting 60 minutes or longer) prior to analysis using the Esliger formula.[36]

Output data were categorised as sedentary time and light, moderate, and vigorous physical activity, adding the latter categories to calculate mean group moderate and vigorous physical activity.

Qualitative study

Participants, selected purposively by sex, age, clinical condition, and group allocation, were invited to a focus group discussion. Both stroke nurses who delivered Group 3 follow-up were interviewed jointly. The focus group lasted approximately 1 hour and interviews lasted approximately 20 minutes; all were audiorecorded with participants' consent, and were transcribed verbatim. Primary questions related to research procedures, methods, and the intervention's acceptability (full details are available from the authors on request). Two researchers coded the transcript content independently, using a deductive approach to content analysis; a third researcher helped resolve any differences in coding and to agree the categories and themes identified before discussion with the research team.

RESULTS

Recruitment, retention, and completion of assessment measures

During the 32 weeks of recruitment between 8 May 2017 and 22 December 2017, 28.2% (125/443) of clinic attendees who were diagnosed with a TIA and/or 'minor stroke' were eligible for inclusion (Figure 1). Of these patients, 35.2% (44/125) agreed to research contact, 90.9% of whom (40/44) consented to participate; 60.0% (24/40) were male and all were white British and/or Irish citizens. Previous cerebrovascular events or non-atherosclerotic diagnoses were the main reasons for ineligibility.

One participant (Group 3) dropped out before beginning the intervention because of work commitments; 97.5% of participants (39/40) completed the study and 12-week follow-up. Two participants completed baseline home assessments and both attended the NI Clinical Research Facility for 12-week follow-up.

Baseline characteristics

Participants included 24 males (60%); 26 participants (65.0%) had a TIA and 14 (35.0%) had a minor stroke diagnosis. Mean time from event onset to enrolment ranged from 15 days (Group 2) to 19 days (Group 1). Participants were aged 38–88 years; 67.5% (27/40) attained only high school level education; 57.5% (23/40) lived in the 50% most disadvantaged areas of Northern Ireland. Nine participants were ex-smokers; 11 currently smoked; and mean alcohol intake was <14 units/week.

Table 1. Comparison of baseline and post-intervention assessments for pilot study of a novel home-based prevention programme for patients after a TIA or minor stroke

Variables	Group 1 (control) (*n* = 12) Baseline, mean (SD)	Group 1 (*n* = 12) Post-intervention, mean (SD)	Group 2 (GP follow-up) (*n* = 14) Baseline, mean (SD)	Group 2 (*n* = 14) Post-intervention, mean (SD)	Group 3 (stroke nurse follow-up) (*n* = 14) Baseline, mean (SD)	Group 3 (*n* = 13) Post-intervention, mean (SD)
Mean age, years	69.7 (14.7)	–	65.7 (13.0)	–	63.3 (9.6)	–
Diagnosis	6 TIA 6 Minor stroke	–	12 TIA 2 Minor stroke	–	9 TIA 5 Minor stroke	–
$ABCD^2$ score	3.3 (1.0)	–	3.7 (1.3)	–	3.6 (1.1)	–
Number with $ABCD^2$ score ≥4	3	–	8	–	6	–
Sex (M = male, F = female)	8M, 4F	8M, 4F	9M, 5F	9M, 5F	7M, 7F	7M, 6F
Systolic BP, mmHg	140.4 (23.7)	140.8 (8.0)	137.9 (16.4)	127.6 (10.0)	129.4 (19.8)	130.7 (15.8)
Diastolic BP, mmHg	84.2 (12.3)	83.6 (16.6)	88.9 (11.8)	80.5 (8.2)	81.0 (14.5)	82.3 (7.5)
Waist circumference, cm	99.83 (10.6)	102.8 (11.4)	104.3 (15.4)	102.8 (14.0)	93.9 (10.2)	93.6 (10.5)
BMI[a]	29.0 (3.9)	29.2 (4.4)	29.8 (6.7)	29.2 (6.3)	28.0 (3.0)[a]	27.7 (3.3)[a]
Mediterranean diet score	3.1 (1.6)	3.5 (1.7)	4.5 (1.8)	7.7 (2.1)	3.6 (2.6)	6.9 (2.8)
HADS total score	7.5 (3.1)	6.7 (5.3)	9.4 (6.8)	5.6 (5.9)	13.2 (10.9)	8.8 (9.5)
EQ-5D-5L index score	0.8 (0.1)	0.8 (0.2)	0.8 (0.2)	0.9 (0.2)	0.7 (0.3)	0.9 (0.2)
VAS score, EQ-5D-5L	65.8 (13.3)	66.3 (11.7)	62.9 (21.9)	71.8 (14.8)	69.6 (16.0)	76.9 (17.5)
[a]2-minute walk test, metres	127.5 (33.1)	126.6 (45.8)	143.5 (53.8)	159.0 (50.3)	142.2 (38.6)[a]	160.4 (37.8)[a]
[a]TUGT, seconds	13.3 (6.5)	12.2 (7.6)	12.9 (7.0)	9.3 (5.8)	10.5 (6.0)[a]	8.2 (2.8)[a]
IPAQ, MET/minutes/week	1287 (1738)	2534 (4055)	1104 (1883)	4060 (4865)	1276 (1397)	6787 (13047)
IPAQ sitting, minutes/day	452.5 (229.4)	390.0 (223.8)	533.6 (247.0)	312.9 (156.4)	520.0 (351.5)	378.5 (347.6)
Number sitting ≥5 hours	8	8	11	8	10	7
Steps/day[b]	–	–	5546 (4127)	6710 (4585)	6538 (3993)	8423 (4686)
Accelerometer (minutes/day)[c]						
Sedentary time	1266 (72.2)	1266 (90.0)	1240 (73.8)	1210 (110.6)	1230 (108.1)	1236 (98.5)
MVPA	137.6 (66.2)	137.1 (79.1)	163.6 (68.8)	190.2 (103.9)	176.9 (100.8)	170.5 (93.3)
Event to study entry, days, mean (SD)	19.25 (8.9)		15.23 (7.8)		16.87 (7.3)	

*[a]Group 3: baseline (*n *= 13); post-intervention (*n *= 12). [b]Baseline: Group 2 (*n *= 14), Group 3 (*n *= 13). Post-intervention: Group 2 (*n *= 10), Group 3 (*n *= 10). [c]Baseline: Group 3 (*n *= 13); Post-intervention: Group 1 (*n *= 12), Group 2 (*n *= 13), Group 3 (*n *= 12). $ABCD^2$ = age, blood pressure, clinical presentation/features, duration of episode and diabetes. BMI = body mass index. BP = blood pressure. EQ-5D-5L = quality of life score. HADS = Hospital Anxiety and Depression Scale. IPAQ = International Physical Activity Questionnaire. MET = metabolic equivalent of task. MVPA = moderate and vigorous physical activity. TIA = transient ischaemic attack. TUGT = timed 'Up and Go' test. VAS = visual analogue scale.*

Baseline distributions were similar across all groups for mean systolic blood pressure and diastolic blood pressure, waist circumference, and body mass index (BMI) (Table 1). For all groups, mean blood pressure was ≤140/90 mmHg; mean waist circumference and BMI reflected that most participants were overweight. Mediterranean diet scores were poor and mean total HADS were elevated, particularly for anxiety. Baseline IPAQ scores indicated that 21 participants (52.5%) were physically inactive, with 72.5% (29/40) reporting sitting for ≥5 hours daily. Accelerometer data were returned by all participants, but one dataset was excluded from analysis (<72 hours' wear time). All groups showed similar sedentary time (approximately 20.5 hours/day).

Post-intervention results

Groups 2 and 3 showed greater improvements than Group 1 in mean BMI and waist circumference; in Mediterranean diet, IPAQ (International Physical Activity Questionnaire) (MET [metabolic equivalent of task] minutes/week and sitting time), HADS (Hospital Anxiety and Depression Scale, and EQ-5D-5L (quality of life) scores; and in a 2-minute walk test and timed 'Up and Go' test (TUGT) performance (Table 1). Mean daily pedometer step counts increased in Groups 2 and 3 (pedometers were not given to Group 1 participants). Three participants, all aged >80 years and frail, believed the pedometer under-counted their steps; five lost their pedometer; and one discontinued using it because of skin irritation. At follow-

up, two accelerometers were lost in the post; and 37 returned valid data.

One participant who was a wheelchair user could not use a pedometer: their 2-minute walk test, timed 'Up and Go' test, and BMI were not measured. One stroke event occurred during follow-up in the control group. No adverse events were reported.

Qualitative results

Four participants (1 male, 3 female; 3 in Group 3; 1 in Group 2; age range 50–80 years) attended the focus group. Both stroke nurses (N) (female) were interviewed together.

Three main themes were uncovered as reported below with examples of anonymised supporting quotes.

Use of the manual. Participants and stroke nurses approved the manual, commending its physical dimensions and format:

'So the size was nice, it was nice to handle, and it was very clearly written. There was good feedback from patients about the manual.' (N1)

In particular, pictorial information was noted in terms of encouraging behaviour change:

'The easiest thing for me was, with regards eating, the picture of the plate with the proportions you should have on it. So, for example, half your plate should be vegetables.' (60-year-old male, group 2)

Some participants read it once; others re-read it after follow-up contacts:

'I just read it as a one-off and ... that was good enough for me ... got an idea about diet and exercise, so the message was there.' (60-year-old male, group 2)

'When the nurses rang, I was like, oh, I better get the manual out again and read over those sections again.' (83-year-old female, group 3)

Family members viewed it as a useful source for healthy living advice:

'It works well when you read it and then discuss it with someone. She [the stroke nurse] *could point out things ... to pick up on.'* (57-year-old female, group 3)

'Yes, my daughter too [read the manual] *... she tried to help me with easy to make healthy food.'* (60-year-old male, group 2)

Study design. Participants identified no problems with the recruitment process and noted positively that participation provided the benefit of follow-up, which was unavailable within routine NHS care:

'I thought that was a good thing ... to have some aftercare.' (60-year-old male, group 2)

'I was really glad that there was something there as a back-up because I wasn't sure about the medication.' (78-year-old female, group 3)

'I got quite a shock after my stroke ... I was glad to have someone follow me up and to know if there is something I can do to avoid having another one.' (83-year-old female, group 2)

The stroke nurses suggested that it would have been appropriate to include patients with cardioembolic and previous cerebrovascular events, as these were *'two things which restricted our recruitment'*.

Few patients were dissuaded by the logistics or challenges of travelling to the assessment centre (travel expenses were covered):

'It maybe put off some of the more elderly participants, who didn't have any transport.' (N1)

'The last time, it was bucketing [raining] *... by the time I got home, I was drenched. So today I thought, I'll take a taxi.'* (83-year-old female, group 2)

Conducting assessments in local hospitals was not considered a better option. Baseline assessment and individually tailored goals were regarded as key intervention components:

'I think the actual meeting is more powerful than reading the manual. The other thing was, you know you're coming back, so you have that accountability.' (60-year-old male, group 2)

Participants recognised the standardised format of follow-up calls and perceived no differences between stroke nurse or GP delivery; follow-up facilitated compliance with the programme and, on average, lasted 5 minutes:

'I don't think it makes a difference if you're followed up by a GP or stroke nurse

because it's all about the conversation and the questions you were asked.' (57-year-old female, group 3)

'It was motivating ... someone was showing an interest in you.' (60-year-old male, group 2)

Three telephone calls provided sufficient support and participants did not suggest any other format of follow-up.

Stroke nurses said they felt confident about delivering follow-up but commented that access to a patient's electronic healthcare record would provide reassurance:

'The thing which I found difficult was that we were phoning people "cold" if you like, there was no background.' (N2)

Pedometers were valued for self-monitoring physical activity, although one participant considered that their measurement was unreliable.

Stroke nurses lacked confidence to address problems regarding pedometers but suggested this could be overcome with appropriate training:

'I'm not too good with technology plus I hadn't actually seen the pedometer' (N2)

No issues regarding any assessment measurements were identified:

'They were fine to do.' (57-year-old female, group 3)

Suggested changes. All participants and stroke nurses were positive about the intervention and the study:

'It was a very positive thing to be involved with, with lots of positive feedback from the patients.' (N1)

One suggestion was to provide an option of using an electronic or paper version:

'You would have to give people both options but, yes, it's [an electronic version] *a good idea.'* (N2)

Participants described persistent symptoms following their event, including increased anxiety and fatigue, shock following diagnosis, and worry about further events:

'Anxiety, it's definitely a factor after my stroke. Just worrying about stupid things, things which might never happen ... if I try to do as much as I used to, then the next day I'm very tired. Is that part of the stroke?' (83-year-old female, group 2)

Some reported difficulty with expressive language; others identified effects on memory or cognition:

'One thing I found after my stroke, is struggling over words ... I thought it would be better by now.' (60-year-old female, group 3)

Participants suggested that the manual should include information about these problems. One patient commented that outcome measures could include an assessment of cognitive impairment; others suggested giving accelerometer feedback. It was also suggested that more open questions would encourage dialogue in follow-up and that patients should construct questions for subsequent contacts:

'There were a few things that I would have liked to have been asked ... Perhaps, say, before the next time ... write down a few questions which you would like to ask me.' (60-year-old male, group 2)

Adding a food diary was suggested, perhaps using smartphone apps, to emphasise patients' ownership of their lifestyles:

'You don't know how bad your diet is until you write it down. I wouldn't have thought I would eat more than three bars of chocolate a month but when it is written down, it's more like 10 or 12.' (57-year-old female, group 3)

'I have an app ... it tells you the calories and so on. It's good for accountability.' (60-year-old male, group 2)

Also, it was suggested that a 6-month follow-up might support maintained behaviour change:

'As time goes on and you get the confidence that you're not going to have another one, there is a danger that you can just drift back into bad habits ... 6-month review might motivate you further to get into a real life change habit.' (60-year-old male, group 2)

DISCUSSION

Summary

This study reports the use of an adapted home-based cardiac rehabilitation programme in patients within 4 weeks of their first TIA and/or 'minor' stroke of

atherosclerotic origin. More than one-third of eligible patients consented to research contact; 90.9% (40/44) of these consented to participate and 97.5% (39/40) completed the study. All outcome assessments were positively received and fully completed. These recruitment and retention rates provide evidence of the acceptability of the intervention and research protocol. Baseline assessments indicated participants' potential for improvement in stroke risk factors. Changes observed in intervention groups (improvement in cardiovascular risk factors, including reduction in blood pressure and improvement in levels of physical activity) suggested that the programme may impact positively on stroke risk reduction. Focus group findings indicated that the intervention was acceptable to, and welcomed by, patients, and that the programme addressed a perceived gap in their healthcare provision. Participants suggested that some additional information, particularly regarding symptoms after a TIA, and outcome measures such as cognitive assessment, would contribute to the intervention's further development and appraisal.

Strengths and limitations

The intervention was developed within a theoretical and evidence-based framework. Physical activity was assessed objectively using an accelerometer and blood pressure was measured using an automatic blood pressure monitor, which is equivalent to 24-hour blood pressure monitoring,[22] a current standard for diagnosing hypertension.[37] Patients were recruited from various levels of socioeconomic deprivation and educational attainment, and from different healthcare trusts, including urban and rural settings. The sample size of 40 was appropriate for a pilot study. Some authors have argued that pilot studies should have at least 9% of the main study's sample size,[38] while others advocate having a minimum of 12 patients in each treatment arm,[39] giving a total potential sample size of 36 for this current study.

A GP led the study, including conducting the interview and focus groups, and it is possible that participants' responses were affected in terms of limiting adverse comments. Blinding of participants, GP, and stroke nurses was not possible because of the nature of the intervention. However, engaging independent statisticians in randomisation and analysis, and blinding of the review assessor, avoided bias in group allocation and outcome measurements. Consideration should be given to adjusting the intervention and research methods appropriately for participants with a disability and to collecting resource use data, to assess cost-effectiveness. Participants had an electrocardiogram carried out as a routine clinical investigation at their TIA clinic appointment to check for dysrhythmias as well as being referred for a 24-hour event recorder, although these investigations are outwith the current research project. There is evidence that a radial pulse check is an acceptable method of detecting atrial fibrillation,[40] although it does have limitations, so that it would be appropriate to use more novel methods of detecting arrhythmias in future research studies.

Comparison with existing literature

The results of this study may indicate that this intervention promotes physical activity, endurance, and balance, as reflected in the self-reported physical activity questionnaire, step count, timed 'Up and Go' test, and 2-minute walk test data in intervention groups. These findings concur with a 2016 Cochrane Systematic review,[41] which found that cardiorespiratory and mixed exercise training was effective in reducing disability in survivors of stroke and that promoting walking increased mobility. The findings of the current pilot study confirmed the importance of managing post-TIA/'minor' stroke symptoms, including fatigue, mental health, and focal neurological symptoms.[42] This intervention could be delivered by GPs to help maximise secondary prevention after a TIA or 'minor' stroke, particularly with the current emphasis on greater community management of these common conditions.[43,44]

Implications for research and practice

This pilot study of an innovative secondary prevention intervention, using core components of cardiac rehabilitation, for those experiencing a first TIA or minor stroke within the preceding month, has shown that an RCT to test its effectiveness is feasible, with minor changes to the intervention and outcome measures. *The Healthy Brain Rehabilitation Manual* is a patient-centred rehabilitation programme, suitable for use in primary care, with potential for important clinical benefit in a patient cohort with a high risk of stroke. This programme could be initiated by either primary or secondary care following the diagnosis of a TIA and/or 'minor' stroke. The patients could then be followed up and supported by the stroke nurse over the telephone, similar to the home-based cardiac rehabilitation model.

For the next stage in the evaluation of the intervention, the authors plan to undertake an RCT to compare the intervention with 'usual' post-TIA/'minor' stroke management. This trial will be powered to detect reductions in systolic blood pressure, which is one of the most important risk factors for stroke.[45] Based on ANCOVA (analysis of covariance),[46] and the current pilot study sample data, using a baseline standard deviation of 25.5 mmHg with correlation between baseline and follow-up measurements of 0.55, in order to detect a between-group difference in systolic blood pressure of ≥5 mmHg at 12 months, with 90% power and a 5% two-tailed significance level, 382 participants are required per group. To account for 15% loss to follow-up, 450 participants should be recruited per group (900 in total).

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Ethical approval

The study was approved by the Office for Research Ethics Committees, Northern Ireland (REC reference 15/NI/0001) and registered as a clinical trial (ClinicalTrials.gov, NCT02712385).

Provenance

Freely submitted; externally peer reviewed.

Competing interests

The authors have declared no competing interests.

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