Stroke Prevention Rehabilitation Intervention Trial of Exercise (SPRITE)

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Stroke Prevention Rehabilitation Intervention Trial of Exercise (SPRITE) - A Randomised Feasibility Study

Keywords: TIA, minor stroke, secondary cardiovascular prevention, cardiac rehabilitation, SPRITE, 'The Healthy Brain Rehabilitation Manual', 'The Heart Manual'.

Background

The value of cardiac rehabilitation (CR) after a transient ischaemic attack (TIA) or minor stroke is untested despite these conditions sharing similar pathology and risk factors to coronary heart disease. We aimed to evaluate the feasibility of conducting a trial of an adapted home-based CR programme, 'The Healthy Brain Rehabilitation Manual', for patients following a TIA/minor stroke, participants' views on the intervention and, to identify the behaviour change techniques (BCTs) used.

Methods

Clinicians were asked to identify patients attending the Ulster Hospital, Belfast within 4 weeks of a first TIA or minor stroke. Those who agreed to participate underwent assessments of physical fitness, cardiovascular risk, quality of life and mental health, before random allocation to: Group (1) standard/usual care; (2) rehabilitation manual or (3) manual plus pedometer. All participants received telephone support at 1 and 4 weeks, reassessment at 6 weeks and an invitation to a focus group exploring views regarding the study. Two trained review authors independently assessed the manual to identify the BCTs used.

Results

Twenty-eight patients were invited to participate, with 15 (10 men, 5 women; 9 TIA, 6 minor stroke; mean age 69 years) consenting and completing the study. Mean time to enrolment from the TIA/stroke was 20.5 days. Participants completed all assessment measures except VO_{2max} testing, which all declined. The manual and telephone contact were viewed positively, as credible sources of advice. Pedometers were valued highly, particularly for goal-setting. Overall, 36 individual BCTs were used, the commonest being centred around setting goals and planning as well as social support.

Conclusion

Recruitment and retention rates suggest that a trial to evaluate the effectiveness of a novel home-based CR programme, implemented within 4 weeks of a first TIA/minor stroke is feasible. The commonest BCTs used within the manual revolve around goals, planning and social support, in keeping with UK national guidelines. The findings from this feasibility work have been used to further refine the next stage of the intervention's development, a pilot study.

Word count – 326.

Trial registration - ClinicalTrials.gov Identifier: NCT02712385.

Background

Strokes and transient ischaemic attacks (TIAs) are highly prevalent conditions (1)(2) and the 90 day risk of vascular events following a TIA or 'minor' stroke can be as high as 18% (3). Therefore, the immediate period after a TIA and 'minor' stroke is a crucial time to intervene to reduce the risk of future strokes and the impact that these conditions have on society.

Evidence is growing regarding the contribution of change in modifiable risk factors to reductions in cardiovascular deaths (4) and there is a need to consider how to promote non-pharmacological measures within secondary prevention (5). Despite the knowledge surrounding vascular risk factors and the recognition that TIA/'minor' strokes carry a significant morbidity and are often the precursors of disabling strokes, stroke remains the leading cause of adult disability (6).

Cardio- and cerebro-vascular disease share common underlying pathological mechanisms and risk factors, but cardiac rehabilitation for secondary prevention is only offered to patients in the UK with cardiovascular disease (7) and further research has been highlighted as required in assessing the impact of lifestyle interventions post-stroke and TIA (8). The benefit of cardiac rehabilitation for secondary cardiovascular prevention is well-evidenced. Indeed a systematic review of exercise-based cardiac rehabilitation after a myocardial infarction (MI) found statistically significant reductions in re-infarction (odds ratio 0.53), cardiac mortality (odds ratio 0.64), and all-cause mortality (odds ratio 0.74) (9). More recently, Rauch et al's review (10) has confirmed the benefits of cardiac rehabilitation for mortality despite recent advances in medical and surgical treatments.

Lennon et al (11) and McKay-Lyons et al (12) have described randomised trials of community-based cardiac rehabilitation programmes in both TIA and stroke patients. These studies did not review the use of home-based programmes, which we know are at least as effective as community-based options whilst being more cost-effective (13), and did not include a pedometer arm. These studies finished early, with no results available in their clinical trials registry entries or published. Both described a relatively long-period from the event to entry into the trial (up to 90 days for both studies). However other research has shown that vascular risk factors should be addressed as quickly as possible following the initial vascular event (14).

Prior et al (15) have described a pilot study of a community-based cardiac rehabilitation in 100 post-TIA and 'mild' stroke subjects and showed important reductions in biological markers linked to cardiovascular and cerebrovascular mortality. Thus community-based cardiac rehabilitation programmes appear feasible in this patient group. However the study did not include a control group, patients were eligible for inclusion up to one year post-event, the researchers did not offer home-based rehabilitation and did not include pedometers in the rehabilitation programme. Other authors have also piloted community-based cardiac rehabilitation programmes in the TIA and minor stroke population, with patients eligible for inclusion up to one year post-event (16)(17) but no authors have previously assessed the feasibility of adapting a home-based cardiac rehabilitation programme, with or without an added pedometer intervention, for use within this patient population in the sub-acute period following diagnosis.

Physical inactivity is one of the most important recognised risk factors for cerebrovascular disease (18) and pedometers have been shown to be effective in promoting physical activity (19) through different behaviour change methods, including goal setting, providing feedback, and monitoring of activity levels (20)(21). Pedometers appear feasible for use by patients with stroke (22)(23) although a systematic review on the role of exercise post-stroke, has highlighted the lack of studies of pedometers in the acute and sub-acute periods of TIA or stroke (24).

Comprehensive programmes, which try to alter participants' behaviours, are complex: information about their 'active' ingredients, such as specific BCTs (25), would facilitate their replication and the implementation of guidelines for good clinical practice (26)(27). Identifying behaviour change techniques (BCTs) used in different behaviour change programmes has also been identified as a national research priority (27). Thus 'The Healthy Brain Rehabilitation Manual', adapted from the 'Heart Manual', the only validated home-based cardiac rehabilitation programme supported by the UK National Institute for Health and Clinical Excellence (NICE) for patients who have had a myocardial infarction (MI) (28), is being developed following the MRC guidelines for developing complex health service interventions (29), to maximise secondary prevention post-TIA and minor stroke.

Research aims

The aim of this study is to assess the feasibility of evaluating the effectiveness of a novel adapted home-based cardiac rehabilitation programme, 'The Healthy Brain Rehabilitation Manual', with or without a pedometer intervention, initiated within 4 weeks of a first TIA or minor stroke of atherosclerotic origin. We aimed to assess rates of recruitment, completion of

outcome measures and follow-up, to explore participants' views of the programme and research methods, and to identify the BCTs used within the programme.

METHODS

Trial registration and Ethics Approval

The study was approved by the Office for Research Ethics Committees, Northern Ireland (REC reference 15/NI/0001, 21/09/2015) and registered (ClinicalTrials.gov, NCT02712385). We have followed CONSORT guidelines for reporting randomised feasibility trials (30) as well as National Institute of Health Research (NIHR) guidance for feasibility studies (31).

Study Setting and participants

Patients attending TIA/ 'minor' stroke assessment hospital clinics in Belfast (UK) were given information about the study by a nurse and asked for their consent to be telephoned by the lead researcher (NH) the following day to invite their participation. Those who agreed attended the Northern Ireland Clinical Research Facility (NICRF), Belfast City Hospital, for an initial meeting where, with consent, baseline data were collected.

Patients were eligible for inclusion if they were aged 18 years or older and within 4 weeks of their first symptoms of a TIA or 'mild' stroke. The diagnosis was made by the consultant at the clinic, based on history, neurological examination and neuroimaging (32). Using the TOAST classification system (33)(34) only TIAs and 'minor' strokes attributed to atherosclerosis or small vessel occlusion were included. We excluded patients who had unstable cardiac conditions or contra-indications for exercise training (35) by screening patients using the Physical Activity Readiness Questionnaire (PAR-Q) (36). We also

excluded patients who were unable to give informed consent or had a previous cerebrovascular event.

Data collection

At their initial meeting, lasting approximately one hour, the researcher measured height and weight (in light clothing, using a Seca scale, model 799), waist circumference (as per (37)), resting blood pressure and heart rate (using BpTRU, model BPM-200 (38), checked the heart rhythm manually to exclude any dysrhythmias (radial pulse for 1 minute) and recorded other variables including sex, age, marital status, smoking status, alcohol intake (units in a typical week before diagnosis), time from initial event to study enrolment, level of education (high school, apprenticeship, further education college or University) and current employment. A measure of deprivation (multiple deprivation measure (MDM)) was derived from their postcode (39). We enquired about family history of cardiovascular disease (CVD), assessed physical activity levels (validated International Physical Activity Questionnaire (IPAQ) questionnaire(40)(41)) and calculated a Mediterranean Diet Score using a validated questionnaire (42). A two-minute walk test was performed twice, separated by a rest period of at least 30 minutes, and the average distance walked in metres was calculated (43). A Hospital Anxiety and Depression (HADs) questionnaire (44) was used to assess anxiety and depression, a EQ5D-5L questionnaire (http://www.euroqol.org/eq-5d-products/eq-5d-5l.html) to assess quality of life, a Modified Rankin scale (45) to assess level of disability and a Prochaska stages of change questionnaire relating to physical activity was administered (46). All participants were offered VO_{2max} exercise testing via either a treadmill or bike.

The Intervention – 'The Healthy Brain Rehabilitation Manual'

The development of a novel home-based rehabilitation programme for a TIA/'minor' stroke population followed the Medical Research Council (MRC) guidelines for developing complex health service interventions (47)(29). In terms of programme content, 'The Healthy Brain Rehabilitation Manual' contained an introduction, telling the user how to use the manual, medical and social information about TIAs/'minor' strokes and how to set goals and action plans for changing certain aspects of their lives. There was then sections focusing on topics relevant to cardiovascular risk (smoking, physical and sexual activity, mental health issues (primarily anxiety and depression), community resources (e.g. smoking cessation support; exercise classes), diet and secondary prevention medication). The manual was supported with telephone follow-up by a health professional, a General Practitioner (GP).

Two trained review authors (NH, MAT) independently assessed the manual to identify BCTs included, using Michie's BCT taxonomy (25) of 93 hierarchically clustered techniques and a narrative approach was used to describe the use of BCTs within the rehabilitation programme. They met to discuss the BCTs which they had identified and resolve any discrepancies. A third reviewer (FK) was available to arbitrate in case consensus could not be reached, but was not required.

Randomisation and blinding

Computer generated randomisation was carried out prior to recruitment and the allocations were concealed in sealed, opaque envelopes until baseline assessments were completed. Post-intervention assessments were undertaken by NH, who was not blinded to intervention allocation.

Study design

There were 3 study arms: the control group, Group 1, received current standard post-TIA/minor stroke care as per current UK guidelines (28)(48). In addition to standard care, Groups 2 and 3 received the intervention programme ('The Healthy Brain Rehabilitation Manual'). Group 3 also received a pedometer or a Fitbit Charge, with each participant choosing which they wanted to use, and being encouraged to keep a daily step-count diary. NH advised Groups 2 and 3 regarding the use of the manual and pedometer/diary at the end of their initial meeting and assessment. Participants in Groups 2 and 3 were informed about the national UK physical activity guidelines as well as how to achieve moderate and vigorous physical activity intensity (49). The pedometer was used to allow participants to set and monitor goals to increase their physical activity levels.

All participants, including Group 1, were telephoned at 1 and 4 weeks to answer any questions regarding their care or use of the manual and, for Group 3, NH encouraged participants to self-set step count targets after reviewing the previous week's daily step counts (19). Step counts were recorded, as reported by participants at the end of week 1 and diary records were reviewed by NH at the 6-week follow-up. Average step-counts for weeks 1 and 6 were calculated by adding the daily totals and dividing by the number of days/ week worn by the participant. During the initial meeting and telephone contacts NH used motivational interviewing techniques (50), guided by the theory of planned behaviour (51) and adopting the '5 As' approach to behaviour change (50), which have all been utilised within different healthcare settings (52), including primary care and the community.

Data treatment and statistical analysis

No formal power calculation was undertaken as this was a feasibility study but 5 patients in each of 3 treatment groups was considered sufficient to allow assessment of the feasibility of recruitment, conduct of proposed assessments and retention. It was also considered that 15 patients' views could provide useful information regarding our research methods and the acceptability of the intervention programme and its refinement for potential use in a pilot trial. Descriptive statistics were reported for baseline and post-intervention measurements, using Statistical Package for Social Sciences (SPSS, version 23) but the main outcomes were rates of recruitment, retention and completion of measures and the acceptability of the intervention.

Qualitative work

All participants were invited to attend a focus group which took place at least two months after their completion of the study and they were encouraged to bring their partner or a family member to the focus group. The primary questions of the topic guide (**Appendix I**) related to research participation and the acceptability of the different stages of the research study (53). The focus group discussion was led by NH, audio-recorded with the consent of participants, lasted approximately one hour and was transcribed by NH. Content analysis was undertaken with the practical purpose of eliciting views about the acceptability and usability of the intervention and research methods and how these could be refined. NH, a male GP, and MD, a male health services researcher/health psychologist, read and reread the transcripts and coded the content independently. NH and MD met to discuss the main areas covered within the transcripts. MC, a female professor of GP, acted as a referee as required as well as appraising critically the categories and the degree to which the transcript extracts and quotations supported the themes. The transcripts were not returned to participants for comment and/or correction and participants were not asked to provide feedback on the

qualitative results. NH has basic training in qualitative research methods whilst MD and MC are experienced qualitative researchers. The independent results of the qualitative analysis and data interpretation were discussed with the entire research team, to ensure clear definition of themes and that appropriate supporting evidence was identified for each. The reporting of the qualitative study and findings followed the guidance set out in the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist (54).

Results

Recruitment, retention and completion of assessment measures

During an 18-week recruitment period (March to July, 2016) 107 patients with confirmed TIA/minor stroke attended the hospital TIA clinic. From the hospital data recorded, we were unable to determine how many of these were eligible for the study but 28 eligible patients (15 male; 13 female) agreed to telephone contact from NH. Of these, 15 (10 male; 5 female; 53.6%) consented to participate. All of these completed the study and attended for 6-week follow up assessment. Participants completed all the outcome measures apart from the maximal exercise tests for VO_{2max} assessment, which was declined by all participants at baseline and follow-up. Four participants in Group 3chose to use a Fitbit Charge initially as their pedometer; 2 reported positive experiences using this device, particularly in goal setting and competition with other users but 2 others were unable to use it and transferred to use a pedometer, Yamax Digi-Walker CW-701, with which no patients reported any problems.

Baseline characteristics

The participants' mean age was 69 years; 9 were diagnosed with a TIA and 6 a minor stroke (**Table 1**). Mean time from event to enrolment was 20.5 days. Only one had attained University level education; most had retired. The majority (10) lived in the 50% least

disadvantaged areas of Northern Ireland. Although 7 were ex-smokers, only one participant currently smoked; mean alcohol intake was <14 units/week. Ten participants had a first degree relative with CVD and most participants were married (13/15). Baseline IPAQ scores indicated that 10 were either inactive or minimally active and many (9/15) reported sitting for over 5 hours daily. In their first week, Group 3 participants averaged over 8,000 steps/day. Baseline mean systolic and diastolic blood pressure (SBP and DBP) were <140/90mmHg in all groups. The total HADs score was elevated in all 3 groups, particularly for anxiety symptoms. Most participants within the study were classed as 'overweight' as per their BMI.

Post-intervention assessment

Groups 3's mean daily step counts increased over the 6 weeks of the intervention by 1407, with a concomitant fall in the numbers in the IPAQ categories of 'inactive' and 'minimally active' (**Table 2**). Participants reported good compliance with the pedometer, wearing it on most days, as recorded in the step-count diary. IPAQ data for Group 2 also showed an increase in physical activity and a reduction in hours sitting per day. The two-minute walk distance increased in all groups, with the greatest increase in Group 3. HADs scores, particularly for anxiety, improved in Groups 2 and 3. There was a wide variation in the rest of the measurements and overall they showed only small changes.

Qualitative findings

Seven research participants (3 male; 4 female) and one partner (female) attended the focus group. Their ages ranged from 55 to 82 years. Four participants were from Group 3, 2 from Group 1 and 1 from Group 2. Qualitative findings were analysed in order to determine participants' views of the manual, the study design and changes needed for a pilot study of the effectiveness of a novel home-based programme for rehabilitation for patients with TIA

or minor stroke. The analysis, supported by anonymised quotes (coded by age (years) and sex (M/F)), is reported within three themes relating to the content of the data.

1. Use of the manual

All participants had positive views about the manual. Its content provided reassurance and support, particularly in differentiating between symptoms for which they should seek medical help and those that were not of such significance. Some reported how they referred to it after having received varying information about their condition and risk factors from different healthcare professionals.

> "…there was some days when I was panicking a bit and I got the book out and I was like, no, that symptom is ok, that's normal…." (55 yrs, F)

> "I think this (the manual) should be at doctor (GP) surgeries as well because when you go to speak to the doctor you get conflicting advice at times." (55 yrs, F)

Participants' comments reflected their fear and uncertainty about their future health, attributed to their experience of sudden onset symptoms of their TIA or minor stroke. Some appeared to be in denial of their diagnosis, based on a rationale that their symptoms had been mild (predominantly affecting vision and speech; one had right-sided weakness) and transient but their comments also reflected a sense of uncertainty. However, the manual was welcomed by all as a reference source for credible information that helped them to understand their diagnosis.

> "It (the TIA) just frightened me and knocked my confidence… because you get no warning." (72 year old female)

"You know, for just 10 minutes' worth of symptoms, surely nothing serious could have happened?" (79 year old female)

"I thought it was excellent…….. like a bible" (70 yrs, M)

Family members also used the manual in supporting decision-making about seeking medical help. Some did so effectively but others were less helpful: one participant's comments indicated how her family members wished they could deny the significance of her symptoms.

"…I was just going to go to my bed but my daughter phoned and I said to her the symptoms I was having and she took me straight to Accident and Emergency (A&E) department." (79 year old female)

"My daughters didn't want to read it because if you read it, then it's true…" (55 yrs, F)

Other information in the manual provided reassurance for those who felt guilty about not being able to fulfil their previous work-life commitments, particularly as they had no visible physical manifestations of illness. Information regarding the relevance of healthy lifestyle behaviours in helping to reduce risk of further events was valued and participants reported having continued to access it after the study programme had ended: some reported that they put the manual in a prominent place to remind them to sustain preventive behaviours. Other comments indicated how family members used the manual to encourage maintenance of healthy behaviours. Those who had received positive feedback about progress in reducing their risk factors attributed this to having followed guidance in the manual.

"I felt an awful fraud cause I was off work but there was nothing physically wrong with me…nothing to show " (55 yrs, F)

"I lift it every morning, read a wee bit, remind myself why I'm not smoking, why I'm not eating a whole load of pastries and why I'm avoiding salt….I might just read a line but it's the very fact that it's sitting there, reminding me of what to do right….I find that very important…" (70 yrs, M)

"my grand-daughter has read it from page to page and every time she comes up to see me, she's like, 'grandad, have you done that? Are you keeping to that?" (70 yrs, M)

"The fact that my blood pressure is a lot lower is also very encouraging for me to stay with the programme as I feel the things which I have done have definitely helped me…" (79 yrs, F).

2. The study design

Recruitment and randomisation

None of the participants considered that any change was needed to the process of recruitment or method of being allocated to study groups.

Intervention components – telephone follow-up

The structure and timing of telephone follow-up calls were well received by all participants who considered that they reduced their need to seek other medical advice. Comments revealed how participants valued the opportunity to share concerns with a professional and ask questions. For example, many participants expressed how they had fears for the implications of their diagnosis on future travel plans and being able to obtain travel insurance

"……they made me feel that there was someone out there interested in me and who cares for me." (70 yrs, M)

"...it put your mind at rest because you were thinking, NH is phoning me soon, so I don't need to go to see the GP. I enjoyed the explanations." (55 yrs, F)

"…..are we going to get to go on holiday and will I be able to fly?" (58 yrs, F)

Intervention components - pedometers

All Group 3 participants enjoyed using their pedometers, setting step-count targets and competing with others regarding their achievement of these. One participant reported her appreciation of the Fitbit with its provision of weekly email feedback on her performance. However, two participants discontinued using the Fitbit despite research team support, one because of battery problems and one lacked confidence in its accuracy: both used the Yamax pedometer without difficulty.

"…it's a competition between me and the wife who walks the furthest" (70 yrs, M)

" It was just so addictive …. I had that visual target to aim for…It would also send me an email at the end of the week, telling me how much activity I had done and I just thought it was brilliant." (55 yrs, F)

"…and the pedometer would always be less (in step-count measurement compared to Fitbit)…." (58 year old, female)

Outcome assessments

All participants were also content with the number and duration of assessments and with all outcome measures except treadmill exercise testing. They were apprehensive that they would

be unable to complete it, given their recent diagnosis. However, 4 participants expressed a readiness to consider undertaking it at the time of the focus group, approximately 2 months after having completed the rehabilitation programme.

> "I doubt that I would have been able to do the treadmill exercise test within 4 weeks of having the TIA…." (70 yrs, M)

> "I would be interested in doing it now…" (58 yrs, F and 79 yrs F)

3. Suggested changes

The only changes suggested by study participants related to the manual. One suggestion was to move the explanations about TIA and minor stroke to the beginning of the manual and another was to include a patient's story.

> "…. the explanation for the TIA (and minor stroke) is at the back of the manual. I think it should be at the start?"" (58 yrs, F)

> "people are interesting and it's good to hear their experiences…" (79 yrs, F)

BCTs used within the manual

Overall, 36 individual BCTs, from 14 different BCT groups were utilised. Examples of how the BCTs were used in each section of the manual are included in Supplementary Files 1 to 8. Within Section 1 (Smoking) 16 individual BCTs were used and in section 2, dealing with physical/sexual activity, with 11 being used in total. The commonest BCTs used were "1.1 Goal setting (behaviour)", "3.1 Social Support (unspecified)" and "3.3 Social support (emotional)" – all being used within 5 of the 8 manual sections. The commonest groups of BCTs used within the manual were "1 (Goals and Planning)", being detected 18 times and

Social Support (12 times). Two groups of BCTs were not used within the manual, "14 (Scheduled consequences)" and "16 (Covert learning)".

Discussion

These findings indicate that the evaluation of a novel home-based rehabilitation programme, 'The Healthy Brain Rehabilitation Manual', implemented within 4 weeks of a first TIA or 'minor' stroke is feasible. There was 100% retention of participants and more than 50% of patients who were invited by the researcher agreed to participate, although we could not be certain that all eligible patients consented to allow contact by the researcher. All but one of the proposed assessments, the VO_{2max} testing, were fully completed at baseline and follow-up. This study also illustrates the acceptability of pedometers as an appropriate method of promoting physical activity to generally inactive TIA and minor stroke patients. The rehabilitation programme was centred on the use of 'goals and planning' and social support as BCTs as well as the manual being a credible source of information to promote behaviour change. A Logic Model has been developed for this feasibility study and is included in Figure 1 (55) (56).

Comparison with previous literature

In comparison with previous studies of community-based cardiac rehabilitation for patients with TIA or 'mild' stroke, we have achieved higher rates of recruitment (50% of those invited) and retention (100%). A feasibility study (17) reported 62% retention of 85 patients enrolled and, in a pilot study (15), approximately 50% of 100 invited patients consented to participate and roughly 80% completed the study. Of note, home-based cardiac rehabilitation

programmes are reported to improve programme adherence (57) and to show longer-term sustainability of health benefits compared with hospital-based programmes (58).

An interesting finding was that all participants declined to undertake a maximal VO_2 test, both pre- and post-intervention, whereas all other assessments were well received. Exercise testing is safe to undertake among patients with TIA and stroke (59) as well as generally within the elderly population (60) but our participants felt unable to complete it. Thus, for further work, we have omitted the maximal exercise test, adding the Timed Up and Go test (61) and accelerometer assessments of physical activity pre- and post-intervention, which are reliable objective measures of physical activity in stroke survivors (62) and amongst the elderly population (63). Our Group 3 participants increased their physical activity by 1,400 steps/day over the study period of 6 weeks. However, previous work has shown that there is potential for larger increases to be achieved with pedometer interventions, with potential to reduce cardiovascular risk factors (64)(65)(66)(21), particularly among those who are least active. Pedometers are accurate and reliable in measuring ambulatory activity (67)(66)(68)(69) whilst also being relatively inexpensive. Yamax pedometers have been shown to be the most accurate waist-borne instrument (67)(67)(66).

The intervention appeared to improve quality of life as measured by the EQ-5D-5L VAS scale and mental health, as measured by the HADs questionnaire (44), although numbers were small and no significance testing was carried out. In keeping with previous work (70) which found a prevalence within TIA survivors of anxiety symptoms of up to 30% and depression symptoms of up to 21%, our focus group participants were anxious and fearful

about having future events. Patients appreciated the explanations and reassurance provided by the manual.

It is important for complex health service interventions to be evidence-based and to know that they are not only effective but how and why they are effective (71). Specifying and describing how a programme of behaviour change actually works is also advocated by UK national guidelines (27), with journal editors requesting detailed descriptions of the active intervention within their reporting guidelines (72). Thus, the active ingredients within a programme should be identified (73). NICE (27) have advocated the use of BCTs which have been proven to be effective in promoting behaviour change, particularly 'goals and planning'; 'feedback and monitoring'; and, 'social support'. 'The Healthy Brain Rehabilitation Manual' includes goal-setting for behaviour change, with agreed action plans and relapse prevention ('if-then') plans for each behavioural cardiovascular risk factor. These goals and plans are reviewed and refined in follow-up contacts with the health professional/facilitator. The manual includes feedback and monitoring as a BCT, for example, based on review of pedometer step counts. Social support is promoted through contact with health professionals and encouraging the person to share the manual with their family and friends and get them to join in the behaviour change.

Strengths and Limitations

This is a feasibility study and therefore no statistical analysis was undertaken on the outcomes. Baseline assessments were completed before participants were allocated to different groups, to avoid allocation bias. The qualitative work undertaken included participants from each treatment group, of varying age and both sexes, with a range of

different symptoms and experiences and they identified valued components of the rehabilitation programme. The educational attainment of our participants was less than third level (post secondary school education), with only one having a University degree and no one reported any difficulty in following guidance or understanding information within the manual. This was reassuring since, in developing it, we had performed a readability check (http://www.webpagefx.com/tools/read-able/check.php), showing it to be readily understandable to 13 to 14 year olds.

The pragmatic approach, whereby TIA and 'minor' stroke diagnosis was made by the lead clinician at each clinic, may have led to variation in the case mix due to differing interpretation of clinical data but this was accepted as a reflection of 'real-world' practice. There was no post-intervention blinding of assessments so that it is possible that some measurement bias may have occurred. Also, Group 3 participants were not blinded to their step counts in the first week of the study, so that the baseline measure may be inflated and not a true reflection of levels of physical activity at this time in TIA and minor stroke patients.

Whilst initial discussions with clinical staff regarding the process of identification and invitation of eligible patients had included a plan to record anonymously the numbers of all eligible patients, this information was not recorded. Thus, although data suggested that 79 of the 107 clinic attendees during the recruitment period were ineligible, this could not be confirmed and limits our interpretation of the feasibility and acceptability of the research.

A strength of our study is the careful approach we have taken to identifying the 'active

ingredients' of the intervention. However, we recognise that our focus was on the manual content and that other BCTs were also involved in the delivery of the programme, during telephone contacts. No monitoring of the fidelity of these contacts was undertaken but this could be achieved in further study.

Implications for future work

In planning further development and evaluation of the intervention, 'The Healthy Brain Rehabilitation Manual' we will conduct a pilot study, involving other hospital clinics and ensuring that information is recorded regarding all eligible patients. In setting step-count goals for physical activity, only Yamax Digi-Walker CW-701 pedometers will be used. We will discard the maximal VO_{2max} exercise test and instead use the Timed Up and Go test (61) pre- and post-intervention, with accelerometer assessments, which provide reliable objective measures of physical activity in stroke survivors (62) and older people (63). We will also include a 'patient story' in the 'The Healthy Brain Rehabilitation Manual', in-keeping with previous authors' work (74), and will place information about TIAs and strokes at the start of the manual.

Conclusion

Our findings show the feasibility, acceptability and potential significance of implementing, early after TIA or 'minor' stroke, a novel home-based programme, 'The Healthy Brain Rehabilitation Manual', with or without an added pedometer. The main BCTs utilised within the manual included use of a credible source, social support and goal setting, in keeping with current UK national guidance for behaviour change. This preliminary work has informed the design of a pilot study which is in progress, with longer follow-up, recruitment from a range of settings and refined methodology (clinicaltrials.gov (NCT02712385)). This future work

should provide evidence of the value of early intervention that is focused on behaviour change for patients following TIA or minor stroke.

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Consent for publication

All authors give their consent for publication.

Availability of data and supporting materials section

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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Competing interests

The authors declare that they have no competing interests.

Conflicts of Interest/Disclosures

None.

Ethical Approval

Ethical approval granted for SPRITE - Stroke Prevention Rehabilitation Intervention Trial of Exercise - A Feasibility and Pilot Study through OREC-NI, REC reference: 15/NI/0001,

21/09/2015.

Authors' contributions

NH led the conception and design of study, collected the research data and prepared the first draft of the manuscript. MEC was involved in the conception and design of study, reviewing drafts, inputting on methodology and intellectual content. MD was involved in the qualitative analysis of results and MAT was involved in screening the intervention manual for BCTs. MD, FK, PMR, MAT and JM were all involved in critical revisions and reviewing methodology. All authors critically reviewed the manuscript and approved the final version submitted for publication.

Abbreviations

A&E – Accident and Emergency

COREQ - Consolidated Criteria for Reporting Qualitative Research checklist

CR – cardiac rehabilitation

DBP – diastolic blood pressure

HADS – Hospital Anxiety and Depression score

IPAQ – International Physical Activity Questionnaire

MI – myocardial infarction

MRC – Medical Research Council

NICE - National Institute of Health and Care Excellence

NICRF - Northern Ireland Clinical Research Facility

PPI – Patient and public involvement

SBP – systolic blood pressure

SD – standard deviation

SPRITE – Stroke Prevention Rehabilitation Intervention Trial of Exercise

TIA – transient ischaemic attack

WHO – World Health Organisation

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Table 1 – Baseline Characteristics of Participants

	Group 1 (Control)	Group 2 (Manual)	Group 3 (Manual + pedometer)
Number of patients	5	5	5
Sex (M – male, F – female)	4 M 1F	4M 1F	2M 3F
Diagnosis	1 TIA 4 Minor stroke	4 TIA 1 Minor stroke	4 TIA 1 Minor stroke
Mean age (years)	76.2	67.8	63
Mean time (days) event to enrolment (Standard Deviation (SD))	19.8 (SD 7.09)	22.2 (SD 9.18)	19.6 (3.58)
Level of education	3 High school 2 Further Education College	3 High school 2 Further Education College	1 High school 3 Further Education College 1 University
Employment	1 Employed 4 Retired	2 Employed 1 Unemployed 2 Retired	1 Employed 4 Retired
***Multiple deprivation measure (MDM) median (range)**	784 (51 – 863)	413 (250 – 726)	681 (333 – 825)
Family history of cardiovascular disease (<55 years for males, <65 years old for females)	4	3	3
Marital status	1 Single 4 Married	5 Married	4 Married 1 Divorced
Smoking status	2 non-smokers 3 ex-smokers	2 non-smokers 2 ex-smokers 1 current smoker	3 non-smokers 2 ex-smokers
Modified Rankin scale **0** **1** **2** **3** **4**	 2 1 1 0 1	 2 1 1 1 0	 4 1 0 0 0

***Multiple deprivation measure (MDM) is calculated from the subject's postcode and is a marker of spatial deprivation.**

Table 2 – Study Group Baseline and Post-Intervention Measurements (Mean (Standard Deviation (SD)) and categorical values)

	Group 1 (Control) – baseline	Group 1 – post-intervention	Group 2 (Manual) – baseline	Group 2 – post-intervention	Group 3 (Manual + pedometer) – baseline	Group 3 – post-intervention
IPAQ category **Inactive** **Minimally active** **Health-enhancing physical activity levels**	 2 1 2	 1 4 0	 3 1 1	 1 0 4	 1 2 2	 0 1 4
IPAQ continuous score (Mean (SD))	1514.6 (SD 1470.1)	1093.8 (SD 851.1)	870.4 (SD 948.2)	4366.2 (SD 3140.8)	1531.2 (SD 902.5)	5335.8 (SD 3133.6)
IPAQ number of hours sitting/day	6.20 (SD 4.10)	6.3 (SD 4.0)	4.80 (SD 1.5)	3.2 (SD 1.3)	5.00 (SD 1.0)	3.8 (SD 1.3)
Steps/day					8356	9762.8 (SD 3473.5)
Stages of change for physical activity **1** **2** **3** **4** **5**	 1 0 2 0 2	 1 0 2 0 2	 1 3 0 0 1	 0 0 1 3 1	 0 1 1 2 1	 0 0 0 4 1
Mediterranean diet total score	5.6 (SD 3.1)	5.8 (SD 2.5)	6.2 (SD 3.3)	8.4 (SD 2.3)	6.0 (SD 2.2)	8.0 (SD 1.4)
Number of pieces of vegetables/day	1.6 (SD 1.1)	1.8 (SD 1.5)	2.2 (SD 1.8)	2.4 (SD 0.6)	2.0 (SD 1.2)	2.8 (SD 0.8)
Number of pieces of fruit/day	2.2 (SD 1.9)	2.6 (SD 1.5)	2.2 (SD 1.3)	2.8 (SD 1.3)	3.4 (SD 0.9)	4.0 (SD 1.4)
Systolic blood pressure (mmHg)	135.8 (SD 8.4)	135.8 (SD 24.8)	136.2 (SD 15.2)	128 (SD 2.0)	129.4 (SD 15.2)	131.0 (SD 12.9)
Diastolic blood pressure (mmHg)	76.4 (SD 10.8)	76.8 (SD 10.0)	82.8 (SD 13.9)	74.8 (SD 4.0)	77.2 (SD 8.1)	80.4 (11.2)
Resting heart rate (beats per minute)	66.2 (SD 3.0)	71.6 (SD 8.4)	65.6 (SD 0.9)	74.8 (SD 4.0)	75.0 (SD 9.4)	73.8 (SD 10.8)
2 minute walk test performance (metres walked)	109.5 (SD 46.3)	118.2 (SD 28.2)	128.8 (SD 29.1)	149.8 (SD 28.7)	136.5 (SD 41.5)	163.4 (SD 23.4)
Weekly alcohol intake (units/week)	6.4 (SD 12.1)	5.6 (SD 8.4)	5.6 (SD 10.4)	1.6 (SD 2.6)	2.8 (SD 3.0)	2.4 (SD 2.6)
HADs total score	10.6 (SD 6.5)	11.0 (SD 5.2)	10.4 (SD 4.7)	7.4 (SD 5.5)	7.00 (SD 4.2)	3.8 (SD 2.7)
HADs Anxiety score	6.0 (SD 4.1)	6.2 (SD 3.6)	6.0 (SD 2.1)	4.2 (SD 3.5)	5.2 (SD 2.8)	3.0 (SD 2.0)
HADs Depression score	4.6 (SD 3.2)	4.8 (SD 2.4)	4.4 (SD 3.1)	3.2 (SD 2.4)	1.8 (SD 1.9)	0.8 (SD 0.1)
EQ5D5L overall score	0.7 (SD 0.4)	0.7 (SD 0.4)	0.9 (SD 0.1)	1.0 (SD 0.1)	1.0 (SD 0.0)	1.0 (SD 0.1)
EQ5D5L VAS score	66.0 (SD 32.1)	53 (SD 29.7)	72.0 (SD 17.5)	86 (SD 6.5)	83.0 (SD 18.2)	85.8 (SD 17.6)
Weight (kg)	80.6 (SD 10.9)	80.3 (SD10.9)	80.7 (SD 8.1)	80.1 (SD 8.2)	79.6 (SD 15.6)	79.4 (SD 16.5)
BMI (kg/m^2)	27.3 (SD 2.5)	27.2 (SD 2.5)	29.7 (SD 3.2)	29.5 (SD 3.4)	28.2 (SD 2.2)	28.1 (SD 2.2)
Waist circumference (cm)	97.7 (SD 5.7)	97.7 (SD 5.7)	99.9 (SD 6.1)	98.7 (SD 6.5)	101.2 (SD 11.3)	100.4 (SD 11.1)

Supplementary File 1 – BCTs utilised within the Manual Preface

BCT Label	BCT group	Example of how the BCT was used
2.4 Self-monitoring of outcome(s) of behaviour	2. Feedback and monitoring	"Please remember to visit them (GP/practice nurses) regularly for health advice, e.g. to monitor your BP…"
3.1 Social support (unspecified)	3. Social support	"This manual can also be shared with your family and friends…as well as with your General Practitioner (GP) and practice nurse"
3.2 Social support (practical)	3. Social support	"The facilitator, who will contact you by telephone, will help you go through the book."
5.3 Information about social and environmental consequences	5. Natural consequences	"….giving you information about TIAs, minor strokes, your brain and the impact which your diagnosis can have on your life."
9.1 Credible source	9. Comparison of outcomes	"Your facilitator, GP and practice nurse are good sources of health information."
13.2 Framing/Reframing	13. Identity	"This manual contains information about ways you can help yourself to feel good now and remain healthy in the future."

Supplementary File 2 – BCTs utilised within the Manual Introduction

BCT Label	BCT group	Example of how the BCT was used
1.1 Goal setting (behaviour)	1. Goals and planning	"Have realistic goals." Patient encouraged to keep a goal and action plans diary and write this down within the manual.
1.3 Goal setting (outcome)	1. Goals and planning	"Goal – stress (reduction). Plan – I will join a yoga class. I will find out about where there are yoga classes happening and I will sign up to attend a class once a week starting from next week."
1.4 Action planning	1. Goals and planning	"Make an action plan." Patient encouraged to keep a goal and action plans diary and write this down within the manual.
1.7 Review outcome goal(s)	1. Goals and planning	"Write a few goals and action plans down for you to try to achieve over the next few weeks. You can discuss how to achieve these with your facilitator or other health professional."
1.8 Behavioural contract	1. Goals and planning	The goals and action plans diary is agreed with the facilitator.
3.1 Social support (unspecified)	3. Social support	Advice provided about what to do if they suspect they are having another TIA or stroke.
3.2 Social support (practical)	3. Social support	"….try to contact someone who could come and be with you while you are waiting for the ambulance."
5.1 Information about health consequences	5. Natural consequences	"The fact that you have had a TIA or minor stroke doesn't mean that your brain is worn out or that you are 'finished' but should serve as a warning to you that you need to improve your health." "Changing the way you live, such as making small changes to your diet or getting more exercise, can reduce your risk of having another transient ischaemic attack (TIA) or stroke…."
5.6 Information about emotional consequences	5. Natural consequences	"These changes can also make you feel better and more energetic."
11.2 Reduce negative	11. Regulation	"After a TIA or stroke it is common to notice unusual feelings in your body much more than you did before. It is important not to get too worried about this. Worrying and thinking

emotions		about these sensations can often make them seem worse."
13.2 Framing/ reframing	13. Identity	"The good news is that it's well on the way to recovery already."
15.1 Verbal persuasion about capability	15. Self-belief	"Things to remember: - The brain has miraculous powers of recovery. - It is one of the strongest and most adaptable organs in your body. - It is also capable of doing much more work than most of us ever need." "People who have realistic goals and plan changes have greater success in changing the way they live."

Supplementary File 3 – BCTs utilised within Section 1 - Smoking

BCT Label	BCT group	Example of how the BCT was used
1.1 Goal setting (behaviour)	1. Goals and planning	"Weigh these up for yourself and decide whether you are ready to quit."
1.2 Problem solving	1. Goals and planning	"Identify situations that will be difficult and plan how you'll cope…"
1.4 Action planning	1. Goals and planning	"Try taking chewing gum or something healthy rather than a cigarette." "Some people say that smoking is good for them because it helps them to relax. If this is the case for you, think of other ways to relax. Perhaps going for a walk, instead of having a cigarette, might make you feel good?"
3.1 Social support (unspecified)	3. Social support	"Perhaps a friend or someone in your family wants to stop too?" "For those experiencing specific difficulties and challenges, there is specific help available in the community and your facilitator can help identify this."
4.1 Instruction on how to perform the behaviour	4. Shaping knowledge	"If you enjoy a cigarette after a meal, clean your teeth after eating if possible."
4.2 Information about Antecedents	4. Shaping knowledge	"Stick with it….. - even though you may have withdrawal symptoms once you stop smoking. These should disappear within a week or two. - Don't give in to cravings – these usually only last a few minutes and then pass."
5.1 Information about health consequences	5. Natural consequences	"It is never too late to stop smoking and the benefits begin as soon as you give up: - Within days, your blood is less likely to clot. - Within 5 years, the risk of a heart attack falls to half that of a smoker. Within 10 years, you will have about the same risk of heart and brain disease as someone who has never smoked."
8.2 Behaviour substitution	8. Repetition and substitution	"If you normally have a cigarette first thing in the morning, get up and have a shower instead."
8.4 Habit reversal	8. Repetition and substitution	"If you like a cigarette with tea or coffee, try changing your drink to water or a fruit juice."
9.2 Pros and cons	9. Comparison of outcomes	"First, think about the reasons you like smoking and the reasons you would like to quit smoking."
10.3 Non-specific	10. Reward and threat	"Be nice to yourself: - Reward yourself for staying off cigarettes, even for one day.

reward 10.6 Non-specific incentive 10.7 Self-incentive 10.9 Self-reward		- Save the money you are not spending on cigarettes to buy yourself something nice."
11.1 Pharmacologic-al support	11. Regulation	"There are treatments available that can at least double your chances of quitting…"
12.1 Restructuring the physical environment	12. Antecedents	"If you like to smoke when chatting on the phone, move the ashtray."

Supplementary File 4 – BCTs utilised within Section 2 – Physical Activity

BCT Label	BCT group	Example of how the BCT was used
1.1 Goal setting (behaviour)	1. Goals and planning	"Your aim is to build up to 30 minutes of moderate activity every day and reduce the amount of time you spend being inactive." "To help guide the intensity of your physical activity/exercise: moderate intensity activity is when you're working hard enough to raise your heart rate and break into a sweat."
1.2 Problem solving	1. Goals and planning	"Finding a way of being active can sometimes be hard, so here are some tips on how to make it easier for yourself: - Choose an activity you enjoy! - Listen to music whilst you exercise. - Try and find activities that fit in with your lifestyle and that you can do on most days of the week." "Give the car a rest – walk or cycle to the shops, church or work."
2.3 Self-monitoring of behaviour	2. Feedback and monitoring	"A general target to aim for is about 7,500 steps/day although some people will manage more than this…" "You will be able to talk but unable to sing the words to a song (the 'talk-sing' test)." "Physical activity and exercise record". "Please continue writing at the end of the manual, use a separate diary or an app on your phone to record your activity levels."
3.1 Social support (unspecified)	3. Social support	"….set your own personal target after talking to the facilitator." "Sexual counselling".
3.2 Social support (practical)	3. Social support	"Chest Heart and Stroke (NI) organise exercise classes (called Post Rehab Exercise Programme – PREP) for patients and can be accessed directly through the Association."
3.3 Social support (emotional)	3. Social support	"Having company can make exercising more enjoyable." "Discuss the problem with your partner so that they know that they aren't putting you off."
4.1 Instruction on how to perform	4. Shaping knowledge	Written explanation of 5 exercises to try at home.

the behaviour		
6.1 Demonstration of the behaviour	6. Comparison of behaviour	The home exercise programme is illustrated to the reader through appropriate diagrams.
7.1 Prompts/cues	7. Associations	For being physically active: "- Keep your walking shoes near the door. - Keep your golf clubs or swim suit in the boot of the car."
8.1 Behavioural practice/ rehearsal	8. Repetition and substitution	"Add activity to your daily routine – begin with three 10-minute walks spread throughout your day, for example."
9.1 Credible source	9. Comparison of outcomes	"Some GPs can also refer you to your local council gyms through local initiatives, e.g. Healthwise scheme."
11.2 Reduce negative emotions	11. Regulation	"This often leads to avoiding sex or not enjoying it when it does happen. In fact, it seems to be very rare for a person to have a TIA or stroke after having sex."
12.5 Adding objects to the environment	12. Antecedents	"A pedometer…"
13.2 Framing/ reframing	13. Identity	"It is important to realise that sex is no different from any other kind of exercise. It does not put a special kind of strain on your brain."

Supplementary File 5 – BCTs utilised within Section 3 – Healthy Eating and Alcohol

BCT Label	BCT group	Example of how the BCT was used
1.1 Goal setting (behaviours)	1. Goals and planning	"Safe limits of alcohol intake: 1) 14 units per week for both men and women; 2) spread your alcohol intake evenly throughout the week; 3) maximum of 2-3 units per day." - " I will use only semi-skimmed milk. - I won't have second helping. - I will eat a healthy breakfast every morning like Weetabix or porridge…."
1.3 Goal setting (outcome)	1. Goals and planning	"Aim to lose weight slowly. Short-term or quick-fix diets are not good – you need to make changes you can keep to long-term."
1.4 Action planning	1. Goal and planning	"Recommendations to adopt a Mediterranean-style diet:…." "Make out a shopiing list with all the healthy foods you plan to buy, then take it with you to the shop."
1.5 Review behaviour goal(s)	1. Goal and planning	"Keep a Food Diary….You might be surprised to see what your Food Diary looks like after one week! Try writing this down and discussing it with the facilitator."
2.3 Self-monitoring of behaviour	2. Feedback and monitoring	"Set Targets for Yourself…"
4.1 Instruction on how to perform the behaviour	4. Shaping knowledge	"There are four main messages when eating for a healthy brain and heart: - Eat less fat – especially saturated fat. - Eat more fibre – fruits, vegetables, cereals. - Eat less salt. - Eat less sugar." "Here are some helpful tips to make it easier for you to switch to healthier eating choices – and to enjoy them!"
5.1 Information about health consequences	5. Natural consequences	"A healthy Mediterranean diet can help prevent further brain disease, as well as other diseases such as heart attacks, by: 1. Lowering cholesterol in the blood vessels around your heart. 2. Controlling your weight, which affects your blood pressure. Supplying you with vitamins and antioxidants, which help to keep your blood vessels in good shape."

5.6 Information about emotional consequences	5. Natural consequences	"After a few weeks you may find that you can enjoy yourself just as much on a lot less alcohol."
6.2 Social comparison	6. Comparison of behaviour	"A Patient's Story" A patient details their experience of suffering a TIA.
8.1 Behavioural practice/ rehearsal	8. Repetition and substitution	"Eat more fruit and vegetables – aim for minimum 5 portions/day….oily fish (2/3 times/week)."
8.2 Behaviour substitution	8. Repetition and substitution	"Switch to olive oil and rapeseed oil instead of lard or other vegetable oils - Switch to olive oil spreads instead of butter or margarine". "….try making every other drink a low-alcohol drink." "Try half-fat or low-fat dairy products…."
9.1 Credible source	9. Comparison of outcomes	"A Patient's Story" A patient details their experience of suffering a TIA.
10.3 Non-specific reward	10. Reward and threat	"Enjoy a treat once a week as a reward."

Supplementary File 6 – BCTs utilised within Section 4 – Stress and Fatigue

BCT Label	BCT group	Example of how the BCT was used
1.1 Goal setting (behaviour)	Goals and planning	"- Keep active – a healthy body helps keep a healthy mind." "…take adequate rest periods during the day…."
1.2 Problem solving	1. Goals and planning	"The way we think about a situation is part of what makes it stressful. It's not always the situation itself that matters most, but our response to it." "Practical Ways to Help you Control your Stress"
2.3 Self-monitoring of behaviour	2. Feedback and monitoring	"…keeping a diary of your activities can help with this."
3.1 Social support (unspecified)	3. Social support	"If you are finding it difficult to sleep, discuss this with your GP or another health professional."
3.2 Social support (practical)	3. Social support	"Speak with your GP or healthcare professional who can suggest some treatments, e.g. ….antidepressant medication"
3.3 Social support (emotional)	3. Social support	"Speak with your GP or healthcare professional who can suggest some treatments, e.g. counselling…"
4.2 Information about Antecedents	4. Shaping knowledge	"two people might experience the same stressful situation in two different ways: One might say it makes them feel helpless against an impossible barrier, as in a nightmare or a trap, with pressure from both sides – like being the meat in a sandwich. Another person might view the same situation as an obstacle which can be overcome – an exciting opportunity or a challenge, like a successful juggler."
5.1 Information about health consequences	5. Natural consequences	"Long periods of stress can lead to: - High blood pressure - Muscle tension and backache…"
5.3 Information about social and environmental	5. Natural consequences	"Without stress and adrenaline, we might never get anything done!"

consequences		
5.6 Information about emotional consequences	5. Natural consequences	"Long periods of stress can lead to: - Frustration, irritability and anxiety…"
9.1 Credible source	9. Comparison of outcomes	"..speak to your GP…"
11.2 Reduce negative emotions	11. Regulation	"Try not to be a perfectionist in everything."

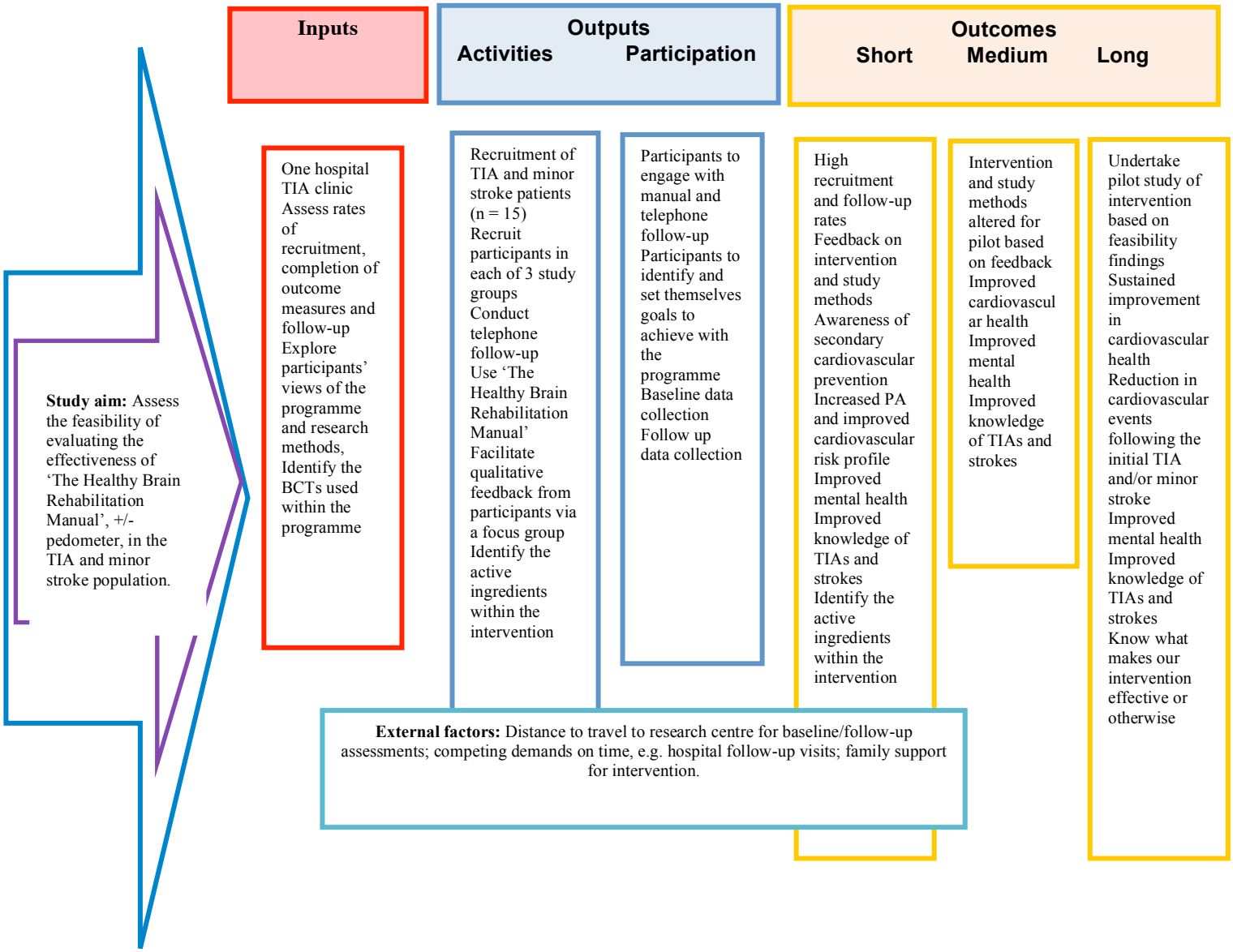
Supplementary File 7 – BCTs utilised within Section 5 - Medication

BCT Label	BCT group	Example of how the BCT was used
1.2 Problem solving	1. Goals and planning	"You may find it useful to make a list of all the medicine you have to take, at which time and connect it with something you usually do at that time – like your morning wash, eating lunch, getting changed after work or going to bed."
1.4 Action planning	1. Goals and planning	"You may find it useful to make a list of all the medicine you have to take, at which time and connect it with something you usually do at that time – like your morning wash, eating lunch, getting changed after work or going to bed."
7.1 Prompts/cues	7. Associations	"You may find it useful to make a list of all the medicine you have to take, at which time and connect it with something you usually do at that time – like your morning wash, eating lunch, getting changed after work or going to bed."
8.1 Behavioural practice/ rehearsal	8. Repetition and substitution	"If you always take them at these times it will soon become a habit and you are less likely to forget."
8.3 Habit formation	8. Repetition and substitution	"If you always take them at these times it will soon become a habit and you are less likely to forget."
9.1 Credible source	9. Comparison of outcomes	"…ask your doctor."
11.1 Pharmacologic-al support	11. Regulation	"Medication to Help your Brain".

Supplementary File 8 – BCTs utilised within Section 6 – Community Support

BCT Label	BCT group	Example of how the BCT was used
3.2 Social support (practical)	3. Social support	"A friend or family member may join you, for example, in starting an exercise programme or indeed you may quit smoking together."
9.1 Credible source	9. Comparison of outcomes	"Your facilitator, doctor or practice nurse will help you to identify organisations and services in your area that can help you in whatever positive lifestyle changes you choose to make."

Figure 1 Intervention Logic Model



Appendix I

Focus group topic guide:

Impact of the diagnosis/illness on the patient:

75) After the diagnosis, what was your biggest problem, e.g. fatigue?
76) How did the diagnosis affect your life?

Views on the manual:

77) What do you think of the manual?
78) What do you think about the general level of information included within the booklet – too much/too little?
79) What do you think of the length of the booklet? Is it too short? Is it too long?
80) What do you think of the layout of the booklet? Does it need more colour, pictures, different font size, etc?
81) Would you like a patient story within the book – detailing their thoughts/emotions after being diagnosed with a TIA/minor stroke?
82) Are there any risk factors which haven't been covered, which you would like included? Are there any risk factors on which you would like more information to be given – or less?
83) Did family members read the manual? What did they think? Anything which you particularly enjoyed about the manual?
84) Anything you would improve about the manual?

Exercise programme within the manual:

85) Is there anything in particular which would worry you about exercising or asking people to exercise after a TIA/stroke?
86) What do you think of the exercise programme? Would you be able to do this within your own home? Is it hard enough?

Study duration and future goals:

87) What goals/aims are important to you now that you have been diagnosed and are on the path to recovery?
88) What did you think about the duration of the study follow-up? Longer/shorter?

Review of FitBit v pedometer:

89) What are your views on the pedometer?
90) How did people find using the FitBit compared to the pedometer? What did you prefer/ why?
91) What made you stop using the FitBit?

Research assessments and exercise treadmill test:

92) What did people think about how they were invited and then recruited into the research study?
93) What did people think about the research assessments?
94) What did people think about the amount of time involved in the research assessments?
95) Why did people refuse to consent to the treadmill/bicycle exercise test?

Home-based rehabilitation after TIA or minor stroke: pilot feasibility randomised trial of 'The Healthy Brain Rehabilitation Manual'

Abstract

Background

Whilst 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 of a novel home-based prevention programme ('*The Healthy Brain Rehabilitation Manual*') for patients with TIA or 'minor' stroke.

Design and setting

Pilot randomised controlled trial, home-based.

Method

Patients within 4 weeks of a first TIA or 'minor' stroke received study information from clinicians in 4 hospitals. Participants were randomly allocated to: (1) standard care (control group) (n=12); (2) standard care, manual and GP follow-up (n=14); (3) standard care, manual and stroke nurse follow-up (n=14). All groups received telephone follow-up at 1, 4 and 9 weeks. We assessed eligibility, recruitment and retention; measured stroke/cardiovascular risk factors at baseline and 12 weeks; and elicited participants' views about the study via focus groups.

Results

Over a 32-week period, 28% of clinic attendees (125/443) were eligible; 35% (44/125) consented to research contact; 91% (40/44) participated: 98% (39/40) completed the study. After 12 weeks, stroke risk factors improved in both intervention groups. The research methods and programme were acceptable to patients and health professionals who commented that the programme 'filled a gap' in current post-TIA management.

Conclusions

Our findings indicate that implementation of this novel home-based CR programme, and of a trial to evaluate its effectiveness, is feasible, with potential for clinically important benefits and improved secondary prevention following TIA or 'minor' stroke.

Keywords: cardiac rehabilitation; stroke; transient ischaemic attack; home-based program; randomized controlled trial; pilot study; secondary prevention

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 General Practitioners (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 (CR) programmes following acute cardiac events are associated with reduced mortality and morbidity (4)(5). Home-based CR programmes may be as effective as those delivered in hospitals, with better compliance (4). However, whilst cardio- and cerebro-vascular disease share common pathological mechanisms and risk factors, the impact of CR and lifestyle interventions post-stroke and TIA requires further research (6)(7)(8). Furthermore, physical activity, a core element of CR, 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)(16), *'The Healthy Brain Rehabilitation Manual*', an adaptation of the 'Heart Manual' (13), was developed by following Medical Research Council (MRC) guidelines (14) and the results of a feasibility study, with service user input (7)(15)(16).

Aim

We conducted 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. We assessed rates of recruitment, retention and completion of outcome measures, explored participants' views about the intervention and research methods, and obtained an estimate of the intervention's potential effect on cardiovascular risk factors.

Methods

The Office for Research Ethics Committees, Northern Ireland (NI) approved the study (REC reference 15/NI/0001, 21/09/2015). Our report follows CONSORT reporting guidelines for pilot and feasibility studies (17) and the PREPARE trial guide (18).

Study Setting and participants

Nurses working in 'drop-in' TIA clinics and scheduled outpatient clinics in four TIA/'minor' stroke assessment units in different NI Health and Social Care Trusts identified eligible patients and gave them study information. Patients who consented to contact were telephoned by the researcher the following day and invited to participate.

Eligibility Criteria

Patients were included if they were aged 18 years or older, within 4 weeks of their first TIA or 'mild' stroke symptoms, with diagnoses attributed to atherosclerosis or small vessel occlusion (19)(20). Patients with unstable cardiac conditions, contraindications for exercise training (21) or a previous cerebrovascular event were excluded. A stroke research nurse (SN) recorded 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 (NICRF), Belfast City Hospital for assessment: a minor protocol amendment, after five

months' recruitment, allowed the option of home assessments. We measured height and weight (light clothing; Seca scale, model 799), waist circumference, resting blood pressure and heart rate (using BpTRU, model BPM-200 (22)), checked the heart rhythm for dysrhythmias (radial pulse; 1 minute) and recorded socio-demographic variables, smoking status, alcohol intake (units in typical week before assessment), time from event, educational status and current employment. We derived a measure of deprivation (multiple deprivation measure (MDM)) from home address postcodes (23), enquired about family history, assessed physical activity (validated International Physical Activity Questionnaire (IPAQ))(24)) and calculated a Mediterranean Diet Score using a validated questionnaire (25). A 2-minute walk test was performed twice, separated by a rest period of at least 30 minutes (26). We assessed anxiety and depression (Hospital Anxiety and Depression (HADs) questionnaire) (27), disability (Modified Rankin scale) (28), 'readiness to change' (29), quality of life (EQ5D-5L, http://www.euroqol.org/eq-5d-products/eq-5d-5l.html) (30) and administered a Timed Up and Go test (31). Participants were invited to wear a wrist-worn, tri-axial accelerometer, Axivity AX3, for one week on their dominant wrist for objective measurement of physical activity (32) and to return this in a pre-paid envelope.

The Intervention

'*The Healthy Brain Rehabilitation Manual*' has been described previously (15). Briefly, it included information about TIA and stroke, advice about healthy lifestyle and a stroke risk reduction plan that focused on a different risk factor each week for six successive weeks; it promoted physical activity by setting and reviewing weekly pedometer step-count targets. Telephone follow-up calls at 1, 4 and 9 weeks by a General Practitioner (GP) (Group 2) or SN (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

The RCT comprised three study arms: Group 1 (control) received standard post-TIA/minor stroke care (13)(33). In addition, at the end of their baseline assessment, Groups 2 and 3 received '*The Healthy Brain Rehabilitation Manual*' and a wrist-worn pedometer (Yamax Digi-Walker CW-701), 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 (MVPA) intensity (34), 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. 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 (35), motivational interviewing techniques (36) and a standardised format. Groups 1 and 2 received GP telephone follow-up; Group 3 received SN telephone follow-up. Diary records were reviewed at 12-week follow-up.

Data analysis

We estimated that data on 40 participants were required to inform planning of a randomised controlled trial. An independent statistician, blinded to group allocation, used SPSS, version

23 to report descriptive statistics. We compared accelerometer data with diary records, using a minimum of 72 hours wear time to define valid data (32), removing non-wear time (consecutive stationary periods lasting 60 minutes or longer (32)) prior to analysis using the Esliger formula (https://axivity.com). We categorised output data as sedentary time and light, moderate and vigorous physical activity, adding the latter categories to calculate mean Group MVPA.

Qualitative study

Participants, selected purposively by gender, age, clinical condition and Group allocation, were invited to a focus group discussion. Both SNs who delivered Group 3 follow-up were interviewed jointly. The focus group and interview were audio-recorded with consent, lasted approximately one hour and 20 minutes, respectively, and were transcribed verbatim. Primary questions related to research procedures, methods and the intervention's acceptability (**Supplement, File** 1). Two researchers (NH, MD) coded the transcript content independently, using a deductive approach to content analysis; a third researcher helped resolve any differences in coding and agree the categories and themes identified before discussion with the research team.

Results

Recruitment, retention and completion of assessment measures

During 32 weeks recruitment (08/05/2017 to 22/12/17), 28% (125/443) of clinic attendees, diagnosed with TIA and/or 'minor stroke' (**Figure 1**), were eligible for inclusion; 35.2% (44/125) agreed to research contact; 91% of these (40/44) consented to participate; 60% (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 due to work commitments; 97.5% (39/40) participants completed the study and 12-week follow-up. Two participants completed baseline home assessments; both attended the NICRF for 12-week follow-up.

Baseline characteristics

Participants included 24 males (24/40; 60%); 26 (65%) had a TIA and 14 a minor stroke diagnosis. Mean time from event onset to enrolment ranged from 15 days (Group 2) to 19 days (Group 1). They were aged 38-88 years old; 67.5% (27/40) attained only High school level education; 57.5% (23/40) lived in the 50% most disadvantaged areas of NI. Nine were ex-smokers; 11 currently smoked; mean alcohol intake was <14 units/week.

Baseline distributions were similar across all groups for mean systolic and diastolic blood pressure (SBP and DBP), waist circumference and body mass index (BMI) **(Table 1)**. For all Groups, mean SDP and DBP was ≤140/90mmHg; mean waist circumference and BMI reflected that most participants were overweight. Mediterranean diet scores were poor and mean total HADs scores were elevated, particularly for anxiety.

Baseline IPAQ scores indicated that 21 participants were physically inactive; 72.5% (29/40) reported sitting for 5 or more hours daily. Accelerometer data were returned by all participants; 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 (MET minutes/week and sitting time), HADs and EQ5D-5L scores; and in 2MWT and TUGT performance **(Table 1)**. Mean daily

pedometer step counts increased in Groups 2 and 3 (pedometers were not given to Group1). Three participants, all aged >80 years and frail, thought the pedometer under-counted their steps; 5 lost their pedometer; one discontinued using it due to skin irritation. At follow-up, 2 accelerometers were lost in the post; 37 returned valid data.

One participant, wheelchair-bound, could not use a pedometer: their 2MWT, TUGT, 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 Group 3; 1 Group 2; age range 50-80 years) attended the focus group. The SNs (female) were interviewed together. Three main themes were uncovered as reported below with examples of anonymised supporting quotes.

1. **Use of the manual**

Participants and SNs 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." (60yo, male)*

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." (60yo, male).*

"When the nurses rang, I was like, oh I better get the manual out again and read over those sections again…" (83yo, female)

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…" (57yo, female)

"Yes my daughter too [read the manual]….. she tried to help me with easy to make healthy food." (60yo, male)

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." (60yo, male).

"I was really glad that there was something there as a back-up because I wasn't sure about the medication…. ." (78yo, female)

"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…" (83yo, female

The SNs suggested that it would have been appropriate to include patients with cardio-embolic 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....." (83yo, female)

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." (60yo, male)

Participants recognised the standardised format of follow-up calls and perceived no differences between SN 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 SN because it's all about the conversation and the questions you were asked." (57yo, female)

" it was motivating.... someone was showing an interest in you." (60yo, male)

Three telephone calls provided sufficient support and no other format of follow-up was suggested by participants. SNs 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, though one participant considered that their measurement was unreliable. SNs 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." (57yo, female).

3. Suggested changes

All participants and SNs 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."

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?" (83yo, female)

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." (60yo, female)

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." (60yo, male)*

Adding a food diary was suggested, perhaps utilising smartphone apps, to emphasize 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 3 bars of chocolate a month but when it is written down, it's more like 10 or 12." (57yo, female)*
>
> *"I have an app, …. it tells you the calories and so on. It's good for accountability." (60yo, male)*

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." (60yo, male)*

Discussion

Summary

This study reports the use of an adapted home-based CR programme in patients within four weeks of their first TIA and/or 'minor' stroke of atherosclerotic origin. Over one third (44/125; 35%) 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 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 post-TIA symptoms, and outcome measures, such as cognitive assessment, would contribute to the intervention's further development and appraisal.

Strengths and Limitations

Our intervention was developed within a theoretical and evidence-based framework. Physical activity was assessed objectively using an accelerometer and blood pressure was measured using BpTru, which is equivalent to 24 hour blood pressure monitoring (22), a current standard for diagnosing hypertension (45). Patients were recruited from various levels of socio-economic deprivation and educational attainment, and from different healthcare Trusts, including urban and rural settings. Our sample size of 40 was appropriate

for a pilot study. Some authors (46) have argued that pilot studies should have at least 9% of the main study's sample size whilst others (47) advocate having a minimum of 12 patients in each treatment arm, giving a total potential sample size of 36 for this current study.

A GP (NH) 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 SNs was impossible due to 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 ECG done 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 our research project. There is evidence that a radial pulse check is an acceptable method of detecting AF (48) 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

Our results may indicate that this intervention promotes physical activity, endurance and balance, as reflected in the self-reported physical activity questionnaire, step-count, TUGT and 2MWT data in intervention groups. These findings concur with a recent Cochrane Systematic Review (43) which found that cardiorespiratory and mixed exercise training was effective in reducing disability in stroke survivors and promotion of walking increased mobility. Our findings confirmed the importance of managing post-TIA/'minor' stroke

symptoms, including fatigue, mental health, and focal neurological symptoms (44). This intervention could be delivered by GPs to help maximise secondary prevention following a TIA or 'minor' stroke, particularly with the emphasis now on greater community management of these common conditions (41)(42).

Implications for research and/or practice

This pilot study of an innovative secondary prevention intervention, utilising core components of CR, for those suffering a first TIA or minor stroke within the preceding month, has shown that a randomised controlled trial 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 high risk of stroke. For the next stage in the evaluation of the intervention, we plan to undertake a randomised controlled trial, comparing the intervention with 'usual' post-TIA/'minor' stroke management. This trial will be powered to detect reductions in systolic blood pressure (SBP) as SBP is one of the most important risk factors for stroke (49). Based on ANCOVA (50) and our pilot study sample data, using a baseline standard deviation of 25.5mmHg with correlation between baseline and follow-up measurements of 0.55, in order to detect a between-group difference in SDP of 5mmHg or greater 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, 21/09/2015) and registered (ClinicalTrials.gov, NCT02712385).

Competing Interests

None.

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How this fits in

Cardiac rehabilitation (CR) after myocardial infarction reduces risk of re-infarction, cardiac mortality and all-cause mortality but the value of CR after a TIA or 'minor' stroke is untested despite these conditions sharing similar pathology with coronary heart disease. Such patients are at high risk of future cardiovascular events but early intervention following 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. I therefore developed a novel home-based intervention, '*The Healthy Brain Rehabilitation*', for use in primary care, using core components of CR to promote secondary prevention for TIA and 'minor' stroke patients and this intervention's effectiveness should now be evaluated within a randomised controlled trial.

Figure 1

Figure 1 - CONSORT Flow diagram for Pilot Study