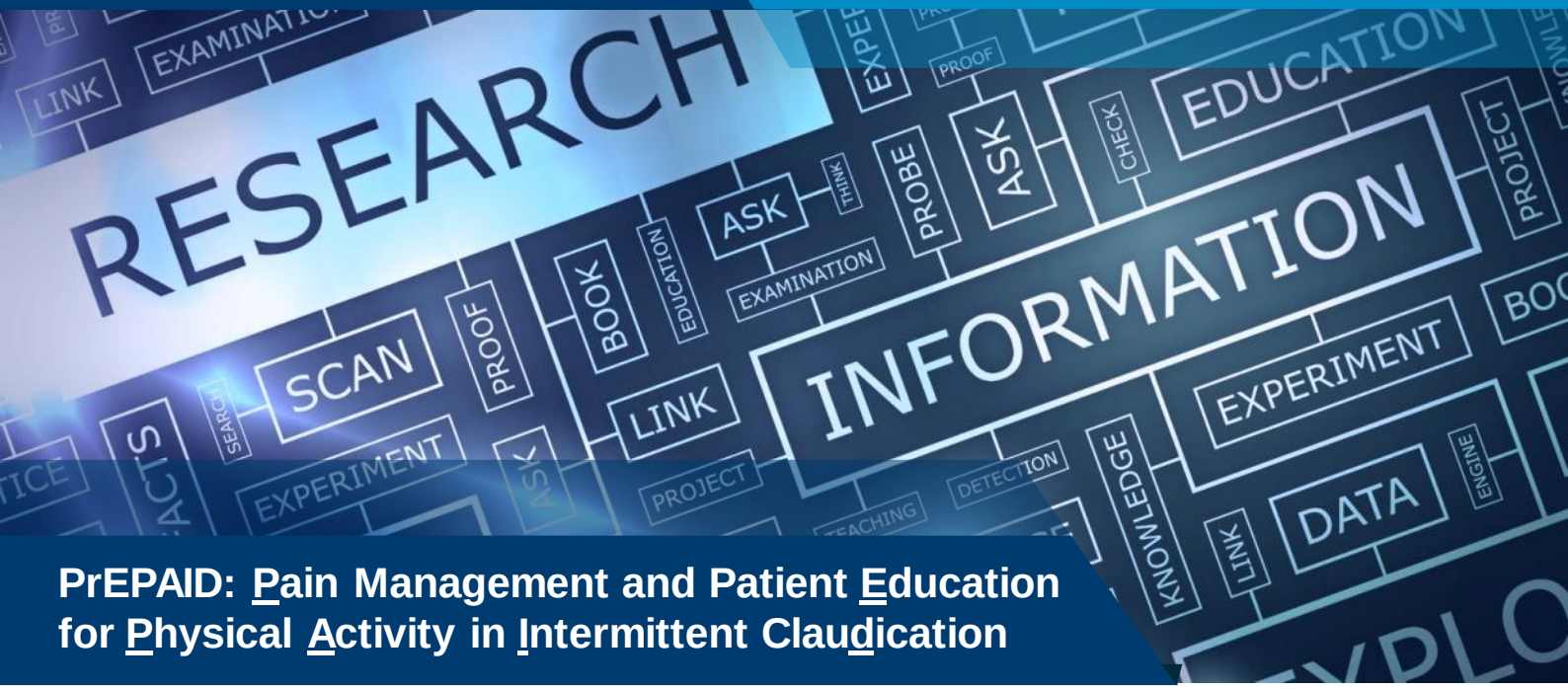
CHIEF SCIENTIST OFFICE

CODE: TCS/16/55

RESEARCH PROJECT BRIEFING



PrEPAID: Pain Management and Patient Education for Physical Activity in Intermittent Claudication

AIMS

Before testing whether treatments work it is essential to ensure they are acceptable for the people who are intended to use them. It is also important to check that the type of research study is feasible i.e. people are willing to participate and complete the requirements of the study.
As the treatments we were interested in have not been shown to work before, this study was designed to addressed these questions and aimed to:

1. To determine the feasibility of conducting a definitive trial that would assess the effects of a Transcutaneous Electrical Nerve Stimulation (TENS) intervention with/or without patient-centred education on physical activity (PA) in people with peripheral artery disease (PAD; furring of the arteries) and intermittent claudication (IC; pain when walking due to poor blood flow in the legs, which is relieved by rest).
2. To collect preliminary data on the acceptability of TENS and patient education, both as separate and combined interventions in people with IC.

KEY FINDINGS

- Participants were willing to participate in the study and we were able to collect good quality data for most outcomes with minimal drop-outs or withdrawals from the trial.
- The patient education intervention was acceptable and practicable for people with PAD and IC
- Some participants really liked the TENS intervention, but some had issues with the usability of the device and were less willing to use the device if they thought it wasn't working well.
- One of the inclusion/exclusion criteria is not feasible for a future trial, specifically the requirement for less than 20% variation in maximal treadmill walking distance.

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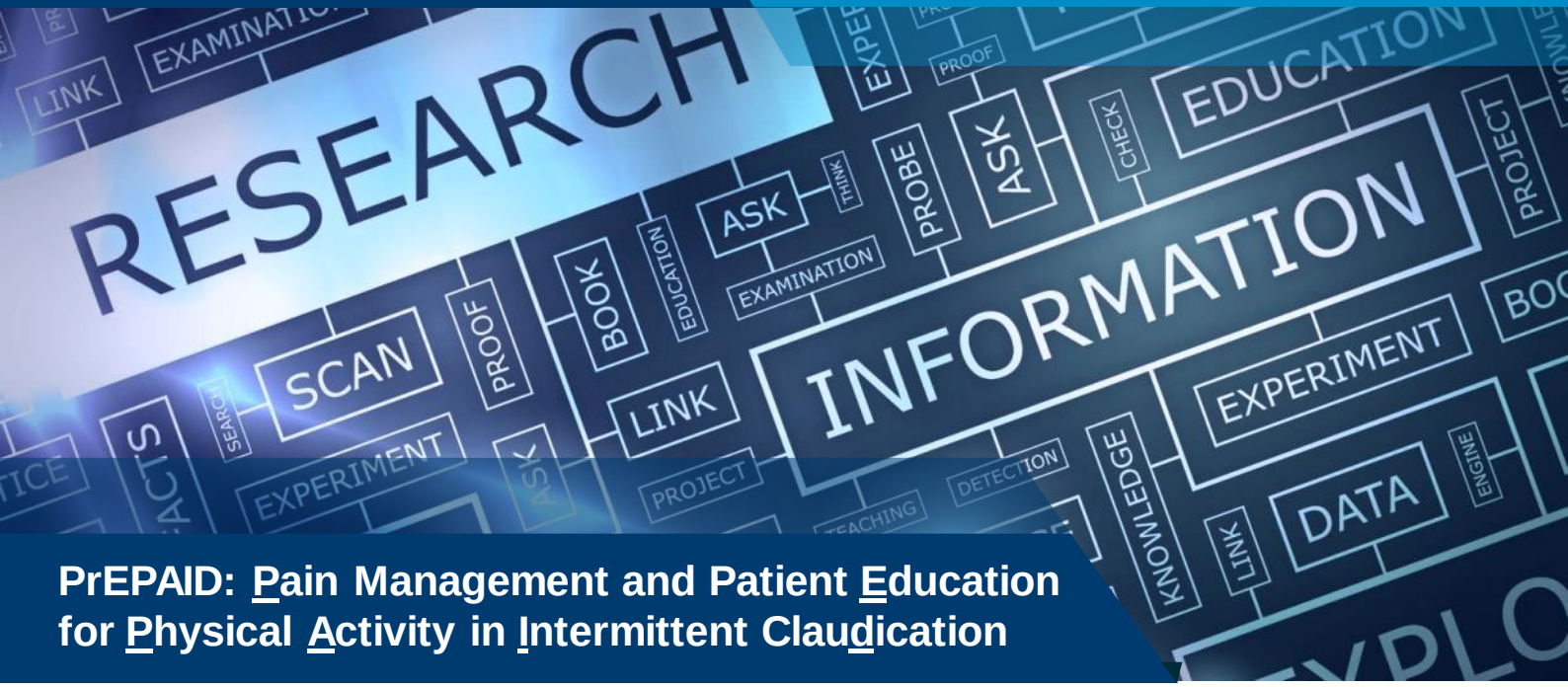

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WHAT DID THE STUDY INVOLVE?

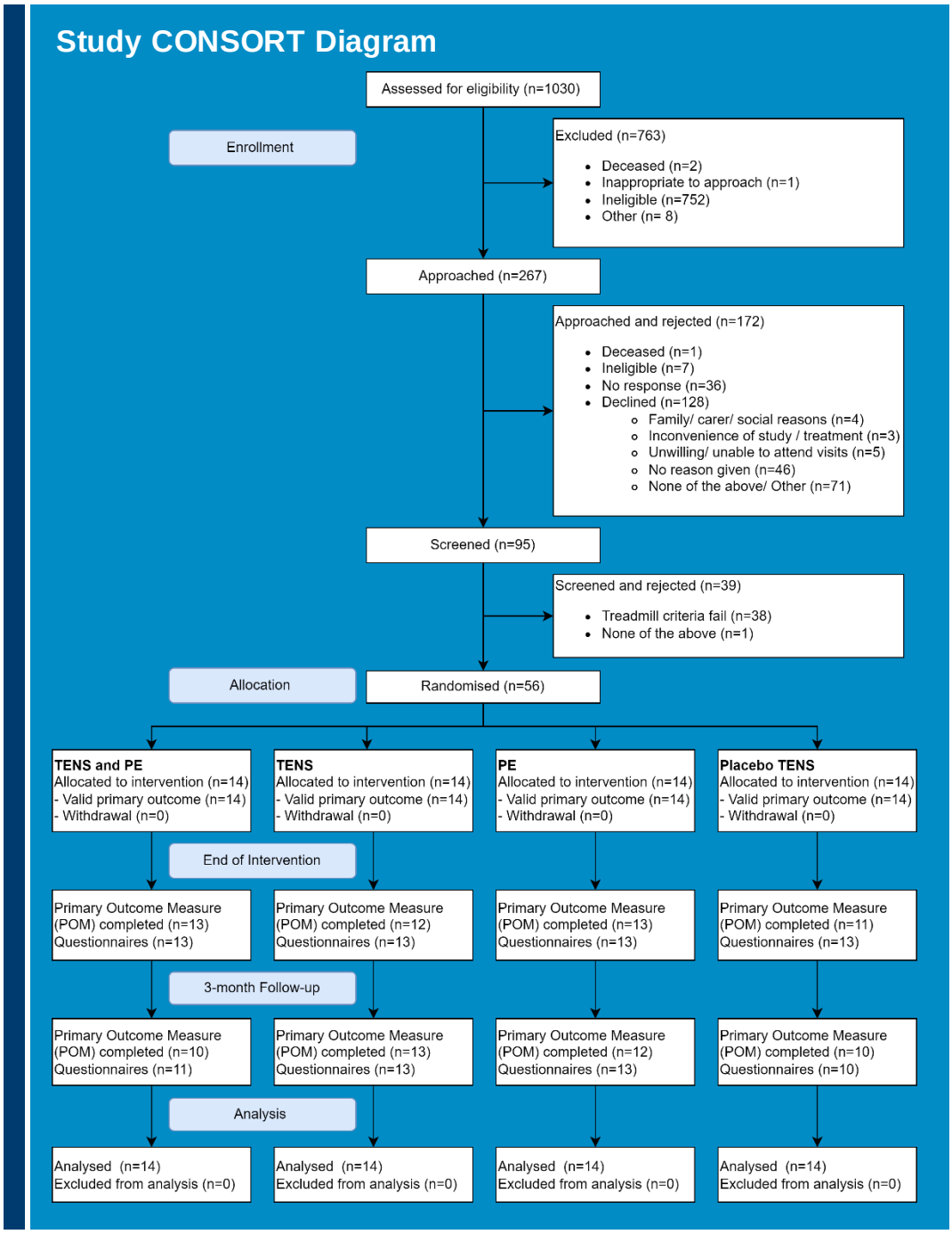
This was a randomised controlled feasibility trial of TENS versus placebo TENS with or without patient-centred education. We randomised people with PAD and IC to 6-week of TENS (wearing a TENS machine on the lower leg when walking), Placebo TENS (wearing a TENS machine while walking but where the stimulation can't be felt), Education (a 3-hour session exploring the condition, risk factors and behaviour change techniques to encourage daily walking with two follow-up phone calls to provide ongoing motivation)+TENS, Education + Placebo TENS. Participants were unaware of the type of TENS they received and measurement of the primary outcome was completed by someone who didn't know what intervention(s) the person had received. Outcomes were measured at baseline, end of intervention and 3-month follow-up. Participants were also invited to share their views on the study and interventions via a semi-structured telephone interview.

WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

Feasibility of recruiting participants, adherence and collecting outcome measures

The study team reviewed the medical records of 1030 people with PAD and IC, and the 267 people who met the inclusion criteria were invited to participate (see CONSORT flow chart on following page). Of those, 95 individuals with PAD and IC attended for eligibility screening, including treadmill walking assessment. Although we screened 95 people for eligibility, the study did not meet the target of 80 participants for randomisation. This was because many people (n=38) had a greater than 20% variability in maximal treadmill walking distance, the primary outcome measure and an exclusion criteria. The 56 participants who were randomised all received their allocated intervention (42 (75%) male, mean age 66 years).

Retention and outcome measure completion:
91% of participants (n=51) completed outcome measures at end of intervention and 80% at 3-month follow-up (n=45). The data collected was of good quality for all outcome measures. These data indicate that the trial procedures and design of the interventions are largely successful. Participants were willing to participate and kept returning for the assessment visits.



Adverse events:
Three participants reported 'Itching' as a defined adverse event related to use of TENS. No other adverse events were reported throughout the study indicating that the interventions and testing procedures are generally safe for this group of participants.

WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

Uptake of interventions:
Participant compliance with TENS use (30 mins per day 3 times per week for at least 3 weeks) was 70% according to participant completed logbooks but only 28% according to objective record of the TENS machines. Although the TENS machine internal log objectively measured use, problems with batteries and study procedures meant that there were fewer of these records. The discrepancy between participant-reported and objective rates of adherence with TENS may indicate social desirability bias in reporting but may also be an artefact of the issues with collecting objective data from the devices. Attendance at the group education session was 96% and overall compliance with intervention was 63% (attendance at the session, and answering to at least one of the 2-weekly phone calls). Education sessions were very well-attended and the drop-off in adherence to the follow-up phone calls could be addressed by agreeing the timing of the phone calls with the participants, rather than the ad hoc approach used in the study.

Acceptability of interventions:
Eighteen participants agreed to be interviewed about their experience of the study and interventions. Nine completed the interviews and were generally positive about the interventions and the trial procedures. The quotes below are representative examples of the participant responses.

Participant quotes from the semi-structured interviews

"Well, as I say, the TENS wasn't a great benefit for me personally. But the actual programme, it does make you think more about what you're doing and what you're not doing, and getting a wee bit more movement into your life"

"The usability was quite restricted on the length of the cable, the buttons on the actual TENS machine were sticking out that wee bit so if you knocked it at all, you'd either put the electricity up, the pulses up higher or it was knocking it off altogether"

"[Education] Definitely has helped because I realise now I need to walk more. Before I thought if the pain's there, if I sit, the pain will go away. Which it did, but that's not helping"

"with the TENS machine it helped. Instead of me walking maybe about a hundred yards before I'd stop, I could walk maybe three, four hundred yards but near the end I could walk quite a wee bit before I had to stop. Then the TENS machine got taken off me again and I'm away back as bad as ever"

WHAT IMPACT COULD THE FINDINGS HAVE?

The interventions were delivered successfully and the outcomes recorded effectively at the different timepoints, however the inclusion criteria employed meant that a large number of people with PAD and IC were excluded at the point of screening. This was due to the primary outcome measure used in the study and not due to participant interest. This shows the importance of conducting feasibility trials to test the study methods and this study has shown that our current inclusion and exclusion criteria are not feasible. Further research could explore different approaches to study inclusion and potentially identify an alternative primary outcome in an effort to enhance successful screening rate.

HOW WILL THE OUTCOMES BE DISSEMINATED?

We will use our existing connections, collaborators, and networks to maximise the impact of this research, in addition to the expected dissemination approaches (peer reviewed publications, local, national, and international scientific conferences). This Research Project Briefing has been developed with feedback from Patient Public Involvement group and will be distributed to all the clinical staff involved, all those who participated in the study and all other stakeholders who contributed to the development of the study and interventions. The study PPI representatives will also help to disseminate the findings within their local networks and online forums.

CONCLUSION

This is the first study to explore the use of TENS for pain relief and patient-centred education to enhance physical activity in people with PAD and IC. PAD represents a significant health threat which can go on to have serious implications for people/society more widely. There is an urgent need for services and interventions to help people increase their Physical Activity. PAD and IC is unique as a cardiovascular and pain condition because the pain is caused by walking, and individuals need to walk through to gain improvements. There is therefore great potential for interventions that address both pain and motivation to walk in the population. Based on this study, we now know that conducting a trial to explore TENS and education interventions is feasible. Participants were willing to be randomised, but we may need to revise our exclusion criteria and outcome measures to include individuals whose walking distance on a treadmill varies from week to week. We found that people with PAD and IC enjoyed participating in the trial and reported physical and psychological benefits from these interventions in the short term.

RESEARCH TEAM & CONTACT

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Additional Information

The project ran from August 2017- September 2021 | Total awarded: £244,085