

PROMote weight loss in obese PAD patients to preVENT mobility Loss: The PROVE Trial

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- at least 18 years old - diagnosis of Peripheral Artery Disease (PAD) with leg symptoms - BMI 25kg/m² or more

Exclusion Criteria:

- above or below knee amputation, critical limb ischemia, or wheelchair confinement - walking is limited by a condition other than PAD - heart attack or stroke in the past 3 months - medical or mental health disease that will interfere with study participations (study staff will review) - currently walking regularly for exercise at a level comparable to the amount of exercise prescribed in the intervention - unwilling/unable to use a smart phone and unwilling to attend weekly study sessions - unable to speak English

Conditions & Interventions

Conditions:

Heart & Vascular

Keywords:

cocoa, intercede, pad, peripheral arterial disease, peripheral artery disease, prove

More Information

Description: More than 65% of people with lower extremity peripheral artery disease (PAD) are overweight or obese. Overweight or obese people with PAD have greater functional impairment and faster functional decline than normal weight people with PAD. Walking exercise is first line therapy to improve walking performance in PAD. However, our NHLBI-funded observational longitudinal study of functional decline in PAD showed that overweight and obese PAD participants who combined weight loss with walking exercise had significantly less functional decline than those who walked for exercise but did not lose weight. Therefore, we hypothesize that among people with PAD who are overweight or obese, a weight loss intervention combined with exercise will improve walking ability more than exercise alone. However, the effects of intentional weight loss in overweight or obese people with PAD are unknown and may not be beneficial if weight loss exacerbates PAD-related sarcopenia. Behavior change that achieves sustained weight loss is particularly challenging in older obese people with chronic disease. Therefore, among people with PAD and BMI>28 kg/m², we will conduct a randomized clinical trial to test the hypothesis that a weight loss intervention combined with walking exercise achieves greater improvement in functional performance than exercise alone at 12-month follow-up.

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Phase: NA

IRB Number: SITE00000513

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