ISRCTN23904851 https://doi.org/10.1186/ISRCTN23904851

The roles of decreasing sedentary behaviors on artery health and overall quality of life in individuals with peripheral arterial disease

Submission date
23/01/2018

Recruitment status
No longer recruiting

Registration date
29/01/2018

Overall study status
Completed

Last Edited
29/01/2018

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Peripheral arterial disease (PAD) affects 8 to 10 million Americans over the age of 50 years and is associated with greater risk for heart attack and stroke. People with this kind of artery disease tend to live a much more sedentary (inactive) lifestyle than others. Research is also showing a direct relationship between a sedentary lifestyle and heart attack or stroke. For those with PAD the risk is even higher and being sedentary may just add even more to the risk. The aim of this study is to assess whether simply reducing the amount of time a person with PAD sits throughout the day and increasing their daily physical activity affects the health of the blood vessels and overall quality of life.

Who can participate?
Patients aged 50 or over with PAD who either sit or lie for at least 8 hours per day during non-sleeping hours

What does the study involve?
Participants are randomly allocated to one of two groups. The first group receive six 10-minute videos on various aspects of cardiovascular (heart) health (nutrition, BMI, peripheral arterial disease, physical activity, diabetes) on a biweekly basis. In the second group participants are provided with an interactive waist worn activity monitor and a 12-week home based physical activity program targeting 2 ten-minute walks per day and methods to reduce prolonged sitting bouts. They are also provided with access to an interactive online software program in which their downloaded activity levels from the daily waist worn monitor (accelerometer) provide the ability for direct feedback of the amounts of sedentary, light, moderate, and high physical activity levels achieved each day during the 12-week intervention. The web-based program includes automated goal setting for physical activity levels based on previous daily physical activity data uploaded from the participants physical activity monitor. Participants also receive auto-generated online messages promoting physical activity.

What are the possible benefits and risks of participating?
Participation in this study can potentially provide improvement in participants' overall sense of

wellness and help their arteries to become healthier. Participants may also gain a greater understanding of what PAD is, its risks, and the various lifestyle changes that can improve their health. There have been few risks identified in this study. There are no needles, blood samples or radiation exposure in this study. There may be some mild discomfort with a test of the reactivity of the arteries as the arm may feel like it is falling asleep during the test but this will go away as soon as the test is completed. Participants are asked to walk as far as they can for 6 minutes and this will make their heart rate increase and they may feel fatigue and shortness of breath.

Where is the study run from?
University of St Augustine for Health Sciences (USA)

When is the study starting and how long is it expected to run for?
March 2014 to March 2018

Who is funding the study?
University of St Augustine for Health Sciences (USA)

Who is the main contact?
Prof. Steve Laslovich
SLaslovich@usa.edu

Contact information

Type(s)
Public

Contact name
Prof Steve Laslovich

Contact details
700 Windy Point Drive
San Marcos
United States of America
92069
+1 (0)760 994 3576
slaslovich@usa.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UR-1030-018

Study information

Scientific Title
Effects of reducing sedentary behaviors on total wellness, vascular reactivity, and vascular stiffness in adults with peripheral arterial disease: a 12-week randomised controlled trial

Study objectives
Decreased sedentary behavior couples with increased lifestyle physical activity will improve perceptions of total wellness, microvascular reactivity and arterial compliance in sedentary adults with PAD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of St Augustine for Health Sciences, 28/01/2015, ref: UR-1030-018
2. Rocky Mountain University for Health Professions, 09/04/2015, ref: 141061-03

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Peripheral arterial disease

Interventions
Subjects randomized to two groups using standardized procedures employing an online random number generator:
1. Control group: (attention control): subjects received six 10-minute videos on various aspects of cardiovascular health (nutrition, BMI, 2 topics in peripheral arterial disease, physical activity, diabetes) on a biweekly basis
2. Intervention group: subjects were provided with an interactive waist worn activity monitor (GRUVE technologies) and a 12-week home based physical activity program targeting 2 ten-minute walks per day and methods to reduce prolonged sitting bouts. Subjects were also provided access to an interactive online software program in which their downloaded activity levels from the daily waist worn monitor (accelerometer) provided the ability for direct feedback of the amounts of sedentary, light, moderate, and high physical activity levels achieved each day during the 12-week intervention. The web-based program included automated goal setting for

physical activity levels based on previous daily physical activity data uploaded from the participants physical activity monitor. Participants also received auto-generated online messages promoting physical activity

Intervention Type
Behavioural

Primary outcome measure
1. EndoPAT measurements at baseline and immediately following the conclusion of the 12-week intervention. EndoPat is a non-invasive instrument used to measure endothelial function and vascular compliance. EndoPAT quantifies the endothelium-mediated changes in vascular tone, produced by a 5-minute occlusion of the brachial artery (using a standard blood pressure cuff). When the cuff is released, the surge of blood flow causes an endothelium-dependent flow mediated dilatation. The dilatation, manifested as Reactive Hyperemia, is captured by EndoPAT as an increase in the PAT Signal amplitude. A post-occlusion to pre-occlusion ratio is auto calculated by the EndoPAT software, providing the EndoPAT index.
2. ActivPAL measurements for 7 continuous days at baseline and following the 12-week study intervention. ActivPAL is a thigh worn accelerometer that provides quantification of free-living sedentary, upright and ambulatory activities

Secondary outcome measures
Wellness Evaluation of Lifestyle (WEL) survey instrument (paper and pencil version with 123 self-scored statements in which the subject replies to each statement using a five-point Likert scale) taken at baseline and following the 12-week intervention

Overall study start date
27/03/2014

Completion date
01/03/2017

Eligibility

Key inclusion criteria
1. Age 50 years or older
2. Ankle Brachial Index of 0.90 or lower
3. Non-sleep daily sedentary time of 8 or more hours
4. Able to access and utilize a home personal computer

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
38

Key exclusion criteria
1. Unable to obtain an ABI
2. Lower limb amputation
3. Inability to ambulate 25 feet independently
4. Current foot ulceration
5. Presence of myocardial ischemia or NY Heart Association Class II heart failure
6. Uncontrolled hypertension
7. Uncontrolled diabetes
8. Undergone lower limb re-vascularization procedures

Date of first enrolment
01/05/2015

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
United States of America

Study participating centre
University of St. Augustine for Health Sciences
700 Windy Point Drive
San Marcos
United States of America
92069

Sponsor information

Organisation
University of St Augustine for Health Sciences

Sponsor details
700 Windy Point Drive
San Marcos
United States of America
92069

Sponsor type
University/education

Website
www.usa.edu

ROR
https://ror.org/02b108x81

Funder(s)

Funder type
University/education

Funder Name
University of St Augustine for Health Sciences

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Study protocol and statistical analyses plan are available upon request from primary investigator Prof. Steve Laslovich (slaslovich@usa.edu). Planned publication of the study results in a high-impact peer reviewed journal.

Intention to publish date
01/05/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the trialists did not include participant data sharing in the IRBs and the participants were not informed in their consent form that their data (de-identified or not) from this study could be shared.

IPD sharing plan summary
Not expected to be made available