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A study of the effectiveness of the Air Quality Health Index (AQHI) in reducing harmful effects of air pollution on the heart and lungs in adults 55 and over

Submission date
05/05/2015

Recruitment status
No longer recruiting

Registration date
07/05/2015

Overall study status
Completed

Last Edited
13/12/2019

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Air pollution can seriously affect people's health; young children and older adults are particularly vulnerable to its effects. Air pollution, which mainly comes from traffic exhaust fumes, can cause breathing and heart problems and has been linked to disease and early death. Older adults are encouraged to be physically active and carry out daily activities such as walking, cycling and taking part in sports to maintain their health. However, many physical activities are performed outdoors. Normally, outdoor activities are a healthy way to keep fit, but when air pollution levels are high, outdoor exercise may have a negative effect on a person's health. The Air Quality Health Index (AQHI) is a health risk communication tool which provides information on current and forecast air quality conditions. The AQHI tool provides advice to guide outdoor activities and to reduce the risk of adverse health effects from exposure to high levels of air pollution. This study aims to test whether following AQHI advice is effective in reducing the risk of adverse health effects of air pollution in healthy older adults.

Who can participate?
Healthy adults 55 years and older.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are asked to exercise every day, but to exercise indoors rather than outdoors when the forecast AQHI value is 5 or greater. Those in group 2 (control group) are asked to exercise outdoors daily. All participants complete 10 weeks of daily health measures before and after exercise at home. Health measures are also carried out every week at a central site for the duration of the study.

What are the possible benefits and risks of participating?
Participants will not benefit directly from participating in this study; however there is financial compensation at the completion of data collection. This study will entail a moderate time

commitment of approximately 1 ½ hours per day and 4 hours once per week for 10 weeks. Clinical tests may cause some discomfort, however, any discomfort should be brief and transient. Some participants may experience some skin irritation at the electrode sites, but this reaction will disappear.

Where is the study run from?
University of Western Ontario (Canada)

When is the study starting and how long is it expected to run for?
Feb 2015 to August 2016

Who is funding the study?
Health Canada (Canada)

Who is the main contact?
Dr D Stieb
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
810438

Study information

Scientific Title
A randomised controlled trial of the effectiveness of the Air Quality Health Index (AQHI) in reducing cardiac and respiratory adverse effects of air pollution in adults 55 and over

Study objectives
Reducing outdoor physical activity in accordance with advice provided through the Air Quality Health Index will reduce adverse cardiac and respiratory effects of air pollution in adults 55 and over.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Canada/Public Health Agency of Canada, 23/04/2015, ref: 2012-0035.

Study design
Single-centre randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Cardiac and respiratory health

Interventions
1. The intervention group will be asked to exercise indoors rather than outdoors and avoid other outdoor activity prior to physiological testing when the maximum AQHI is forecast to be 5 or higher (on the remaining days they will exercise outdoors). The intervention group will receive instructions for a simple indoor exercise routine that can be completed on designated days.
2. The control group will exercise outdoors daily

Intervention Type
Behavioural

Primary outcome measure
Weekly measures before and after 30 minutes of mild activity:
1. Heart rate variability (Holter monitoring)
2. Endothelial function (Reactive Hyperemia Index - Peripheral artery tone)
3. Oxygen saturation (finger oximeter)
4. Blood pressure (automated sphygmomanometer)
5. Fraction of exhaled Nitric Oxide (exhaled NO sensor)

6. Spirometric measures (spirometer)
7. Urinary oxidative stress markers (vascular endothelial growth factor (VEGF), 8-isoprostane, malondialdehyde (MDA), 8-hydroxydeoxyguanosine (8-OHdG))

Secondary outcome measures
Respiratory symptoms.

Overall study start date
01/02/2015

Completion date
31/08/2016

Eligibility

Key inclusion criteria
1. Participants must be 55 years of age or older
2. Non-smokers
3. Not exposed to environmental tobacco smoke at home
4. No seasonal allergies

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
80

Total final enrolment
72

Key exclusion criteria
1. Unstable angina
2. Atrial flutter
3. Atrial fibrillation
4. Paced rhythm
5. Left bundle branch block
6. Implanted cardioverter-defibrillator (ICD)
7. Participants with allergies to latex or adhesives will be excluded

Date of first enrolment
18/05/2015

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Canada

Study participating centre
University of Western Ontario
1151 Richmond St
London
Canada
N6A 3K7

Sponsor information

Organisation
Health Canada

Sponsor details
50 Colombine Drwy
Tunney's Pasture
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Sponsor type
Government

ROR
https://ror.org/05p8nb362

Funder(s)

Funder type
Government

Funder Name
Health Canada

Alternative Name(s)
Santé Canada

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Papers will be submitted to peer reviewed journals regarding primary study findings and possibly secondary findings regarding effect modification by genotype. It is estimated that the first paper will be submitted by 31/12/2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to privacy restrictions.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/12/2019	13/12/2019	Yes	No