Effect of woodsmoke on the respiratory health of adults with and without chronic respiratory diseases

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON49800

Source
ToetsingOnline

Brief title
Panel study woodsmoke and health

Condition

- Other condition
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
acute stress, asthma, COPD

Health condition

Stress ten gevolge van houtrook

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: European Union Horizon 2020 research and innovation programme

Intervention

Keyword: Citizien science, Respiratory health, Stress, Woodsmoke

Outcome measures

Primary outcome

The main study endpoints are lung function (FEV1 and PEF), daily respiratory

symptoms, use of bronchodilator medication, and cortisol.

Secondary outcome

Secondary parameters include inflammatory markers Interleukin (IL) 1b, IL-6,

IL-8, IL-10, and tumour necrosis factor (TNF)*.

Study description

Background summary

The Netherlands has about one million active woodstoves and fireplaces emitting a substantial amount of woodsmoke. Woodsmoke has become a regular nuisance for about 10% of the general Dutch population and 64% for the Dutch asthma and COPD patient population. There are still considerable knowledge gaps in the scientific literature about the level of woodsmoke exposure and related health effects in the Netherlands. This project will investigate the health effects of short-term exposure to woodsmoke in different areas in the Netherlands. This research question was chosen after consulting with citizens, organized stakeholders, experts and previous academic literature. This project will take on a co-created citizen science approach.

Study objective

The primary objectives are to study short-term changes in lung function, respiratory symptoms, bronchodilator medication use, and stress in association with short-term changes in woodsmoke exposures in adults suffering from

asthma/COPD and healthy adults. As a secondary objective we will also study the short-term changes in inflammatory markers in association with short-term changes in woodsmoke in the panel groups.

Study design

Panel study with repeated observations of respiratory health, cortisol and inflammatory markers in two panels of adults diagnosed with asthma/COPD and healthy adults over a three month period. Participants from both panels will complete daily symptom reporting and home spirometry, provide weekly cortisol samples and three inflammatory marker samples.

Study burden and risks

Total participation time for a participant in the study is three months. Each participant will fill in a daily diary which takes 3 minutes at most. Twice daily participants will conduct a simple lung function measurement of about 2 minutes. Participants will collect saliva samples once a week for cortisol determination which takes about 15 minutes. Furthermore, participants will also collect 3 nasal mucosal lining fluid samples which takes about 5 minutes per sample. There is no risk involved in participating. Participants don*t directly benefit from participating, unless significant associations are found causing new policy measures to be taken to reduce woodsmoke emissions in their living environment. If no associations are found this may reduce societal concern. In our experience with past panel studies, participating for 3 months is reasonable, people who start participating will almost always complete the requested period. Each participant will be given a 25 euro gift card as a token of our appreciation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Participant is 30 years or older
Participant lives in the participating study area
Participants for the asthma/COPD panel need to comply with the following criteria:
o Self-reported doctors diagnosis of asthma/COPD.
o Report of wheezing, shortness of breath And/or use of asthma/COPD medication in the past 12 months.
Participants for the healthy adult panel need to comply with the following criteria:
o No self-report of a doctor diagnosis of asthma/COPD ever
o No report of wheezing, shortness of breath, chronic cough, phlegm in the past 12 months
o No use of asthma/COPD medication in the past 12 months

Exclusion criteria

Active smokers
Subjects with a wood stove or fireplace
People with absolute contra-indications for spirometry:
o Heart attack in the last three months
o Chest or abdominal surgery in the past 3 months
o A brain, ear or eye surgery in the past 1 month

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2021
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	05-11-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	04-02-2021
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL75223.041.20