Effects of a ventilation intervention in classrooms upon cognitive performance and respiratory health of primary school pupils.

Published: 23-02-2010
Last updated: 04-05-2024

Main objective of this study is to investigate whether a high air exchange rate improves cognitive and/or respiratory functions in elementary school pupils in classrooms. Furthermore: to identify environment determinants of effects of ventilation to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32717

Source
ToetsingOnline

Brief title
FRESH: Forced-ventilation Related Environmental School Health

Condition

- Other condition
- Respiratory disorders NEC

Synonym
astma airway heath

Health condition

cognitief functioneren

Research involving
Human

Sponsors and support

Primary sponsor: GGD Groningen
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: cognitive functioning, indoor air, primary school, respiratory health

Outcome measures

Primary outcome

Differences in lung function (FEV1 and FEVC), exhaled NO and speed and accuracy

on simple math and reading tests for the different levels of ventilation.

Secondary outcome

none

Study description

Background summary

In schools children have a high exposure to CO2, odour and other bio-effluents emanating from classmates, and to particulate matter dispersed from classmates and their clothes, and resuspended from floors. This exposure may influence the cognitive function and respiratory health of children. However, the available evidence is not sufficient to infer a dose response relationship between ventilation levels and parameters of cognitive functioning and health. This hampers the introduction of health-based guidelines.

Study objective

Main objective of this study is to investigate whether a high air exchange rate improves cognitive and/or respiratory functions in elementary school pupils in classrooms. Furthermore: to identify environment determinants of effects of ventilation to performance of pupils, to elucidate an optimal level of outdoor air supply and to adjust or strengthen evidence based ventilation guidelines

and uses, and school building policies.

Study design

The study is an intervention study with a cross-over design, control condition and baseline measurements, data collection is longitudinal with the participants acting as their own control.

Intervention

In the twelve schools where the intervention will take place, a system for mechanical ventilation will be installed. During the study (in the heating season of 2010-2011 and 2011-2012), the concentrations of CO2 will be maintained at preset levels, established with the mechanical ventilation. In all cases, the set limits of CO2 will not exceed 1400 ppm which is below the levels that usually occur in Dutch classrooms. In the 6 classrooms that will act as controls, no mechanical ventilation is installed and therefore no intervention takes place. At the end of each week, cognitive and respiratory functioning test will be performed.

Study burden and risks

As this study is specifically aimed at the primary school population, children are involved in this study. As a benefit of this study, parents, teachers and school will gain more insight in the effects of ventilation upon health and cognitive functioning.
Although this study contains exposure to different levels of ventilation, it is not considered to be an invasive exposure. Furthermore, the set limits of CO2 will not exceed 1400 ppm which is below the levels that usually occur in Dutch classrooms.
The health risks of lung function testing and measuring exhaled NO are negligible, there are no health risk for measuring cognitive functioning.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

primary school children level 7

Exclusion criteria

none: all children of the included classes may participate

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2010
Enrollment:	540
Type:	Actual

Ethics review

Approved WMO Date:	23-02-2010
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-11-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL30313.000.09