Indoor air quality and health – the K-HEALTHinAIR project

Submission date	Recruitment status	[X] Prospectively registered
05/09/2023	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
15/09/2023	Ongoing	Results
Last Edited	Condition category	Individual participant data
04/07/2025	Respiratory	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

The negative impact of outdoor air pollution and indoor air quality on health is well-accepted. However, the current knowledge on the health effects of impaired indoor air quality shows numerous gaps (e.g. previous studies cover limited parameters, limited scenarios or are limited in time). Therefore the Knowledge for improving indoor AIR quality and HEALTH (K-HEALTHINAIR) project aims to address these gaps by studying determinants of the effect of indoor air quality on health covering multiple parameters in nine relevant scenarios in six European countries with a project duration of 3 years.

The overall K-HEALTHinAIR project objectives are:

- 1. Identifying the determinants of indoor air quality and health, and the association between indoor air quality and health, by monitoring indoor air quality and performing big data analyses
- 2. Confirming the identified determinants and search for their sources by monitoring indoor air quality, performing big data analysis and using supporting studies
- 3. Testing preventive interventions using continued monitoring of indoor air quality and using reference spaces and theoretical analysis to evaluate interventions.

This registration is for the K-HEALTHinAIR Rotterdam pilot study. The primary objective of the Rotterdam pilot is to study the determinants of indoor air quality and its associations with health and well-being among older adults.

Who can participate?

Older adults (aged 60+ years) living at home. The participants will be recruited in Erasmus Medical Centre (EMC) outpatient clinics (e.g. department of geriatrics, internal medicine, and pulmonary medicine) and in collaboration with senior housing cooperations.

What does the study involve?

Using self-report questionnaires older adults will report on their (general) health and wellbeing and indoor air quality related behavior at the start of the study and at 6 and 12 months of follow-up. A two-page questionnaire on health symptoms related to indoor air quality is completed every 2 months.

What are the possible benefits and risks of participating?
This is a non-invasive study and there are low risks associated with participation. The study

involves non-invasive measurements that do not affect the physical and/or psychological integrity of the participants. Participants can withdraw from participation at any time during the study without having to explain why to the research team.

Where is the study run from? Erasmus Medical Center (Netherlands)

When is the study starting and how long is it expected to run for? September 2022 to September 2026

Who is funding the study? European Union - the European Health and Digital Executive Agency (HADEA) as part of HORIZON HEALTH 2021

Who is the main contact?

The main contact of the overall K-HEALTHinAIR project is josdom@cartif.es
The two contacts for the K-HEALTHinAIR Rotterdam pilot study are Amy van Grieken (a. vangrieken@erasmusmc.nl) and Simon de Leede (s.c.deleede@erasmusmc.nl)

Study website

https://k-healthinair.eu/

Contact information

Type(s)

Principal Investigator

Contact name

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Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

101057693

Study information

Scientific Title

Knowledge for improving indoor air quality and health - Rotterdam study

Acronym

K-HEALTHinAIR-Rotterdam

Study objectives

The primary objective of the K-HEALTHinAIR Rotterdam pilot is to study the determinants of indoor air quality and its associations with health and well-being among older adults.

The Rotterdam study is part of the larger K-HEALTHinAIR project funded by grant nr. 101057693. The information below all refers to the Rotterdam pilot study as part of the larger K-HEALTHinAIR project.

Ethics approval required

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Ethics approval(s)

Approved 17/05/2023, Non-WMO Review Committee (Niet WMO Toetsingscommissie) (Dr. Molewaterplein 40, Rotterdam, 3000CA, Netherlands; +31 (0)107033625; metc@erasmusmc.nl), ref: MEC-2023-0293

Study design

The Rotterdam pilot study uses mixed methods in a small size prospective cohort study, namely self-report questionnaires, a non-intrusive household indoor air quality monitoring device and an observational checklist.

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Built environment/local authority, Community, Home, Hospital

Study type(s)

Prevention, Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

General health and well-being in older adults (aged 60+ years) and older adults with pulmonary complaints

Interventions

Observational methodology and assessments:

- 1. Indoor air quality (e.g. particle matter, volatile organic compounds) continuously monitored with air quality sensors
- 2. Health and well-being (e.g. health complaints, mental health, quality of life, falls) assessed by self-report questionnaire
- 3. Indoor environment (e.g. cooking type, windows present etc) assessed by observational checklist
- 4. Indoor air quality related behavior (e.g. opening windows) assessed by self-report questionnaire

For the first year, the observations are as follows:

Month 0: installation of MICA device, administering of observational checklist and larger questionnaire

Month 2: diary questions, 5 days in a row

Month 4: diary questions, 5 days in a row

Month 6: larger questionnaire

Month 8: diary questions, 5 days in a row

Month 10: diary questions, 5 days in a row

Month 12: larger questionnaire

Intervention Type

Mixed

Primary outcome measure

- 1. Quality of life measured using EQ-5D-5L at baseline, 6-month and 12-month follow-up.
- 2. Mental health measured using PHQ-9 at baseline, 6-month and 12-month follow-up.
- 3. Indoor air quality (IAQ)-related health symptoms measured using a diary at months 2, 4, 8 and 10

After the 12-month follow-up, the researchers will assess which measurements will be administered and at what frequency for years 2 and 3 of the study. They will update the registration once they have this information.

Secondary outcome measures

- 1. Indoor air quality measured with MICA devices that measure IAQ continuously for 36 months
- 2. Indoor air quality related behavior (e.g. opening windows) assessed using a questionnaire every 6 months
- 3. Measured using International Consortium for Health Outcomes Measurement (ICHOM) adult and older set (combination) at baseline, 6-month and 12-month follow-up:
- 3.1. Medication and care use
- 3.2. Falls
- 3.3. Lifestyle
- 4. Living situation (perceived IAQ and outdoor air quality [OAQ], window opening, time spent in scenario) measured at baseline, 6-month and 12-month follow-up
- 5. Time spent at home measured using a diary at months 2, 4, 8 and 10 After the 12-month follow-up, the researchers will assess which measurements will be administered and at what frequency for years 2 and 3 of the study. They will update the registration once they have this information.

Overall study start date

01/09/2022

Completion date

01/09/2026

Eligibility

Key inclusion criteria

- 1. 60+ vears old
- 2. Cognitively capable of providing informed consent
- 3. Understand the Dutch language

Participant type(s)

Healthy volunteer

Age group

Senior

Lower age limit

60 Years

Upper age limit

110 Years

Sex

Both

Target number of participants

110

Total final enrolment

109

Key exclusion criteria

- 1. Not able to comprehend the information provided in Dutch
- 2. Unable or unwilling to give informed consent
- 3. Unable to cognitively evaluate the risks and benefits of participation

Date of first enrolment

07/01/2024

Date of final enrolment

20/09/2025

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus MC

Dr. Molewaterplein 40 Rotterdam Netherlands 3000CA

Sponsor information

Organisation

Cartif

Sponsor details

47151 Boecillo Valladolid Spain Av. Francisco Vallés, 4 +34 (0)983 54 65 04 josdom@cartif.es

Sponsor type

Research organisation

Website

http://www.cartif.com/en/

ROR

https://ror.org/036krsg33

Organisation

Erasmus MC

Sponsor details

Dr. Molewaterplein 40 Rotterdam Netherlands 3000CA +31 (0)10 704 0 704 secretariaat.mgz@erasmusmc.nl

Sponsor type

Hospital/treatment centre

Website

http://www.erasmusmc.nl/

ROR

https://ror.org/018906e22

Funder(s)

Funder type

Other

Funder Name

European Health and Digital Executive Agency

Alternative Name(s)

Health and Digital Executive Agency, HaDEA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/09/2027

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date