Improving indoor air quality for a healthier home and Europe

Submission date	Recruitment status	[X] Prospectively registered
27/02/2023	No longer recruiting	[] Protocol
Registration date	Overall study status	[] Statistical analysis plan
21/03/2023	Ongoing	[_] Results
Last Edited	Condition category	Individual participant data
31/05/2024	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Most research into pollution and health has focused on outdoor air pollution. Although about 90% of our time is spent in indoor environments such as our homes, we know very little about indoor air pollution and how it affects our health. We don't know what factors cause indoor air pollution to be higher, or how best to reduce indoor pollution levels. The main goal of this study is the protection of citizen health by providing knowledge and tools to substantially improve indoor air quality. The researchers will conduct research and evaluate actions to reduce harmful exposures in homes and positively impact the health of residents. The study aims to look at patterns of indoor air pollution in homes and identify the main factors that drive indoor air pollution. Based on this assessment, the researchers will develop and test strategies to improve indoor air quality and lower the burden of chemical exposures that children and adults receive inside the home. This study will provide information to policymakers and regulators to allow informed and effective decisions towards the protection of citizens' health.

Who can participate?

Families across eight countries (Czechia, Estonia, Italy, Netherlands, Portugal, Slovenia, Sweden and the United Kingdom) with at least one child under 5 years of age

What does the study involve?

The study involves allowing research team members to install small, non-disruptive samplers of indoor air and dust in the living room of a home, and providing a urine sample to determine exposures to chemicals frequently found in household products and materials, indoor air and dust.

What are the possible benefits and risks of participating?

There is no risk to participating. Participants can benefit by opting to receive information about the indoor air quality in their homes and suggested actions to improve indoor air quality and reduce the burden of chemical exposure.

Where is the study run from? NILU - Norwegian Institute for Air Research (Norway) When is the study starting and how long is it expected to run for? September 2022 to August 2027

Who is funding the study? 1. Horizon Europe (UK) 2. UK Research and Innovation (UK)

Who is the main contact? NILU - Norwegian Institute for Air Research, inquire@nilu.no

Study website https://inquire-he.eu/

Contact information

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers 101057499

Study information

Scientific Title

INQUIRE: Identification of chemical and biological determinants, their sources, and strategies to promote healthier homes in Europe

Acronym

INQUIRE

Study objectives

Guidelines on indoor air quality (IAQ) are intended to prevent health risks from indoor exposure. WHO's guidelines on biological and chemical pollution include dampness, mould, benzene, carbon monoxide (CO), formaldehyde, nitrogen dioxide (NO2), naphthalene, polycyclic aromatic hydrocarbons (PAHs), radon and tetra- and tri-chloroethylene. However, there is an evidencebased consensus that the determinants of IAO are more numerous and complex than these few single-exposure IAQ parameters. More than 350,000 chemicals are in global commerce today (>100,000 in the EU), many with a complex array of degradation products, which must also be considered when assessing exposure and risk. Many other unknown or poorly characterized chemicals enter the European market unchecked in imported commercial products and household materials (despite the current chemical management regulation). It is evident that humans are ubiguitously and increasingly exposed to such man-made chemicals, especially indoors where materials such as building materials, furniture, electronics, personal care products, cleaning products, and toys contain man-made chemicals, often not chemically bound to the solid matrix, that can be released to indoor air and particles. There is however, in the EU, as elsewhere, a poor understanding of chemicals in indoor-related products, including building materials and consumer products. In addition to chemicals, also microbial communities in the built environments may affect human health. Some studies suggest that the indoor microbiome may elicit negative health effects, but recent findings provide strong evidence that the indoor microbiome may also reduce the risk of asthma and allergies, possibly by promoting the development of immune tolerance. There is a consensus that the identity and risk posed by this multitude of (mostly unknown) substances released into indoor air is the tip of the iceberg of

indoor environmental quality. INQUIRE's ambition is to enable the effective protection of citizens of Europe (and in particular children) from both currently prioritized chemical and biological hazards present in household air, as well as from yet undetected and/or overlooked pollutants. INQUIRE will achieve this by extending inventories of these pollutants, advancing knowledge on their sources, a better understanding of their importance for human health, providing new assessment techniques for exposure and health risk and proposing a series of interventions to improve IAQ and reduce exposure to hazards in the home.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval are distributed across eight sampling regions through local ethics boards: 1. Czechia (Responsible partner: Masaryk University) - CELSPAC ethics committee (Masaryk University, Kamenice 753/5, pavilion D29, 625 00 Brno, Czech Republic; +420 (0)549493079; andryskova@recetox.muni.cz), ref: (C)ELSPAC/EK/3/2023

2. Estonia (Responsible partner: Health Board Terviseamet) - Research Ethics Committee of the National Institute for Health Development (Hiiu 42, Tallinn 11619, Estonia; +372 (0)659 3924; eetikakomitee@tai.ee), ref: 380/T-1

3. Italy. Approved 02/05/2023, (Responsible partner: Istituto Superiore di Sanità (ISS)) - National Ethics Committee for Clinical Trials of Public Research Bodies and Other National Public Institutions (CEN) (299, Viale Regina Elena, 00161, Roma, Italy; +39 (0)6 4990 4288; segreteria. comitatoetico@iss.it), ref: 0020314

4. Netherlands (Responsible partner: Vrije Universiteit Amsterdam) - BETHCIE, Research Ethics Review Committee, Faculty of Science (bethcie.beta@vu.nl), ref: 28-008

5. Portugal (Responsible partner: Institute of Science and Innovation in Mechanical and Industrial Engineering (INEGI)) - Ethics Committee of the University of Porto (CEUP, Praça Gomes Teixeira Porto, Portugal; +351 (0)4099 002), ref: No. 135/CEUP/2023

6. Slovenia (Responsible partner: Jožef Stefan Institute) - The Republic of Slovenia National Medical Ethics Committee (Štefanova ulica 5, 1000 Ljubljana, Slovenia; +38 (0)1 478 69 06; kme. mz@gov.si), ref: 0120-398/2023/3

7. Sweden (Responsible partner: Karlstad University) - Swedish Ethical Review Authority, Etikprövningsmyndigheten (Box 2110, 750 02 Uppsala, Sweden; +46 (0)10 475 08 00; registrator@etikprovning.se), ref: 2024-01249-01-581358

8. UK (Responsible partner: University of Cambridge) - Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (Jarrow Business Centre, Rolling Mill Road, Jarrow, E32 3DT, UK; +44 (0)207 104 8210; bradfordleeds.rec@hra.nhs.uk), ref: 322462

Study design

Phase 1: observational cross-sectional study; Phase 2: observational case-crossover study

Primary study design

Observational

Secondary study design

Case crossover study

Study setting(s) Home

Study type(s)

Other

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

Indoor air quality

Interventions

The first part of the project (Phase 1) is a study involving a cross-sectional design across eight locations (200 homes and their inhabitants) without intervention. A subsequent smaller study (Phase 2, 100 homes and their inhabitants) aiming at testing strategies to improve IAQ has a case-crossover design, with a moderate sample size, resulting in outcome-based evidence of moderate confidence. The intervention strategies in this second phase aiming at improving IAQ will be selected based on the outcome of the first screenings in Phase 1. Strategies will likely be different across dwellings and will be chosen case by case to maximise the improvement of IAQ.

Technological (air purifier) and behavioural interventions will be selected for Phase 2 households, and non-randomly assigned based on Phase 1 outcomes.

The interventions and timings are:

- 1. Air purifier and smart ventilation systems (measured at >1 month after installation)
- 2. Ventilation behavior (measured at >1 month after implementation)
- 3. Cleaning behavior (measured at >1 month after implementation)
- 4. Green buildings (existing buildings, no specific timing)
- 5. Renovation and refurnishing (measured at >1 month after installation)
- 6. Consumer product introduction/removal (measured at >1 month after implementation)

Intervention Type

Mixed

Primary outcome measure

1. Indoor air quality measured using low-cost air quality sensors over a 28-day period at baseline conditions (time=0) and 1-month post-intervention

2. Indoor levels of semi-volatile organic compounds measured using passive PDMS sorbent over a 28-day period at baseline conditions (time=0) and 1-month post-intervention

3. Outdoor, home-adjacent levels of semi-volatile organic compounds measured using passive PDMS sorbent over a 28-day period at baseline conditions (time=0) and 1-month post-intervention

4. Levels of semi- and non-volatile organic compounds measured in settled house dust by chemical extraction and instrumental analysis (composite, Day 1 and Day 28 of baseline period, and 1-month post-intervention)

5. Biological profiling of settled house dust, by gel clot LAL test and Amplicon sequencing (composite, Day 1 and Day 28, and 1-month post-intervention)

6. Indoor profiles of volatile organic compounds measured using passive sorbent over a 7-day period at baseline conditions (time=0) and 1-month post-intervention

7. Outdoor, home-adjacent profiles of volatile organic compounds measured using passive sorbent over a 7-day period at baseline conditions (time=0) and 1-month post-intervention 8. Biomarkers of chemical exposure in human urine, measured by liquid chromatography with tandem mass spectrometry (LC-MS/MS) at Day 28 and 1-month post-intervention

Secondary outcome measures

 Toxicological profiling of settled house dust (composite, Day 1 and Day 28), measured by bioassays for oxidative stress, cytotoxicity, endocrine disruption and immunotoxicity
Toxicological profiling of indoor aerosols measured using active sampler collection over a 28day period at baseline conditions (time=0), measured by lung barrier integrity, inflammatory and oxidative stress response

3. Levels of chemical additives in household products measured using direct sampling or wiping and fast screening ambient mass spectrometry on Day 28

4. Self-perceived indoor air quality measured by questionnaire on Day 28

Overall study start date

01/09/2022

Completion date

31/08/2027

Eligibility

Key inclusion criteria

Recruitment is at a household level. Households must have:

1. At least one child under 5 years of age at the time of recruitment

2. Reside in one of the designated areas specified by each local sampling partner

Participant type(s) All

Age group Mixed

Sex Both

Both

Target number of participants

200 households, 400 participants (1 adult, 1 child per household)

Key exclusion criteria

- 1. Household does not have a child under 5 years of age
- 2. Child spends more than 10 nights per month away from home
- 3. Any resident smokes inside the home

Date of first enrolment

01/05/2023

Date of final enrolment 31/05/2024

Locations

Countries of recruitment

Czech Republic

England

Estonia

Italy

Netherlands

Portugal

Slovenia

Sweden

10617

United Kingdom

Study participating centre Masarykova Univerzita

Zerotinovo namesti 9 Brno Czech Republic 601 77

Study participating centre Terviseamet Paldski Mnt 81 Tallinn Estonia

Study participating centre Institut Jozef Stefan Jamova 39 Ljubljana Slovenia 1000

Study participating centre Karlstads Universitet Universitetsgatan 2

Karlstad Sweden 651 88

Study participating centre Stichting VU De Boelelaan 1105 Amsterdam Netherlands 1081 HV

Study participating centre Istituto Superiore Di Sanita Viale Regina Elena 299 Roma Italy 00161

Study participating centre INEGI - Instituto De Ciencia E Inovacao Em Engenharia Mecanica E Engenharia Industrial Rua Dr Roberto Frias 400 Porto Porto Portugal 4200 465

Study participating centre University of Cambridge The Old Schools Trinity Lane Cambridge United Kingdom CB2 1TN

Sponsor information

Organisation Norwegian Institute for Air Research

Sponsor details

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Sponsor type Research organisation

Website https://www.nilu.com/

ROR https://ror.org/00q7d9z06

Funder(s)

Funder type Government

Funder Name HORIZON EUROPE Framework Programme

Alternative Name(s) Horizon Europe, Horizon Europe Programme, Framework Programme, Horizon Europe, EU Framework Programme, Horizon

Funding Body Type Government organisation

Funding Body Subtype National government

Location

Funder Name UK Research and Innovation

Alternative Name(s) UKRI

Funding Body Type Government organisation

Funding Body Subtype

National government

Location United Kingdom

Results and Publications

Publication and dissemination plan

Planned publications in open access high-impact peer-reviewed journals.

Intention to publish date

31/08/2028

Individual participant data (IPD) sharing plan

Data from INQUIRE (raw and pre-processed data, data analysis and modelling results) will be transferred to external trusted FAIR repositories. No single repository will be able to offer detailed metadata formats and fine-grained search and query options for all types of generated data. Therefore, sub-datasets will be deposited in discipline-specific repositories. The INQUIRE MasterDataset, which will allow linking all distributed sub-datasets through linked persistent identifiers (PIDs), will be deposited at Zenodo, B2SHARE or similar. Part of the INQUIRE data (i. e., quantitative chemical data, biological data and possibly biomonitoring data) will be made available through IPCHEM. Other public repositories will be identified during the course of the study. Informed consent will be obtained from all participants explicitly covering data sharing in GDPR-compliant repositories.

IPD sharing plan summary

Stored in publicly available repository, Available on request