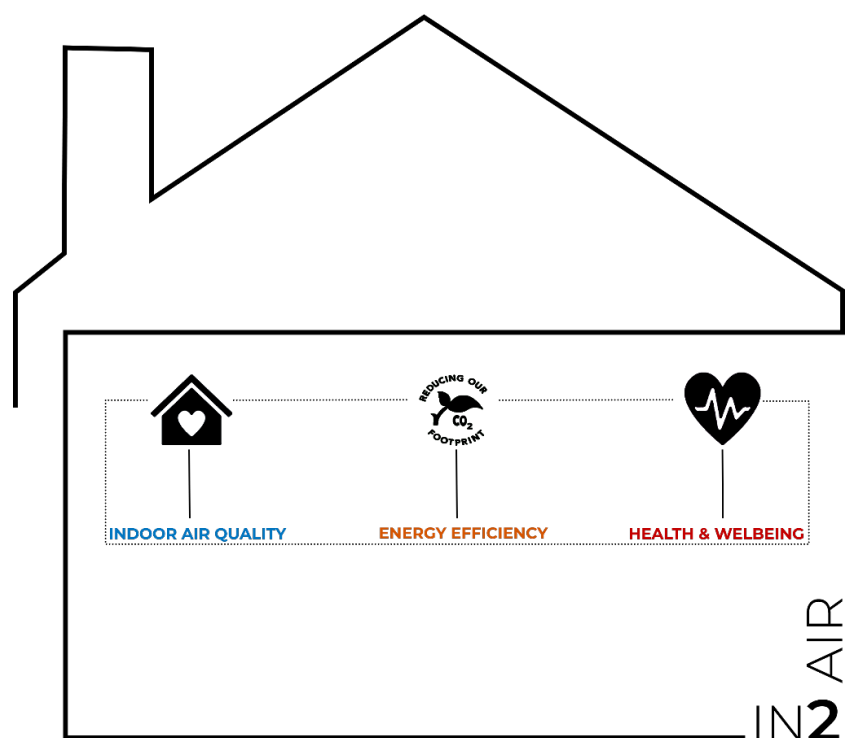


The impact of 'net-zero' household energy intervention on indoor air quality, occupant self-reported general health and wellbeing, and household energy use.

In2Air



This protocol has regard for the Health Research Authority guidance (Version 1.2 March 2016)

RESEARCH REFERENCE NUMBERS

PHR Project: NIHR153617

PROTOCOL VERSION NUMBER AND DATE

Version 1.0

Late updated 14_11_2022

OTHER RESEARCH REFERENCE NUMBERS

researchregistry8208

STUDY SPONSOR

Northumbria University

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the co_Principal Investigators agree to conduct the study in compliance with the approved protocol and any subsequent amendments.

We also confirm that we will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the research will be given; and that any discrepancies from the research as planned in this protocol will be explained.

Co-Principal Investigator:

Signature:

.....

Name: Jane A Entwistle

Date:

14/11/2022

Co-Principal Investigator:

Signature:

.....

Name: Richard McNally

Date:

14/11/2022

KEY RESEARCH CONTACTS

Co-Principal Investigator	<p>Prof. Jane A Entwistle Department of Geography and Environmental Sciences, Engineering and Environment, Sutherland Building, Northumbria University, Newcastle upon Tyne, NE1 8ST, United Kingdom E: Jane.entwistle@northumbria.ac.uk T: +44 (0)191 227 3017</p> <p>Dr Richard McNally Population health Sciences Institute, Faculty of Medical Sciences, Newcastle University, NE1 4LP, United Kingdom. E: Richard.mcnally@newcastle.ac.uk T: +44 (0) 191 282 4724</p>
Research Co-ordinator (Senior Researcher)	<p>Dr Lindsay Bramwell Department of Geography and Environmental Sciences Engineering and Environment, Ellison Building, Northumbria University, Newcastle upon Tyne, NE1 8ST, United Kingdom E: Lindsay.bramwell@northumbria.ac.uk T: +44 (0)191 227 3768</p>
Funder(s)	<p>National Institute for Health and Care Research (NIHR) Public Health Research (PHR) Programme</p> <p>Newcastle City Council Fairer Housing Unit Civic Centre Newcastle upon Tyne NE1 8QN E: colin.white@newcastle.gov.uk T: +44 (0)191 277 7839</p> <p>A range of support in kind is also provided by external members of the Study Steering Committee (for contact details see Appendix 1).</p>
Key Protocol Contributors	<p>Prof. Jane A Entwistle (Indoor Air Quality, PPI) [as above]</p> <p>Dr Richard McNally (Health statistician) [as above]</p> <p>Dr Lindsay Bramwell (PPI, Indoor Air Quality) [as above]</p> <p>Dr Tarek Ahmed (Architect, Building performance) Department of Architecture and Built Environment Engineering and Environment, Sutherland Building, Northumbria University, Newcastle upon Tyne, NE1 8ST, United Kingdom E: tarek2.ahmed@northumbria.ac.uk T: +44 (0)191 349 5278</p>

	<p>Mr Colin White (Housing Renewal Intervention lead) Senior Housing Renewal Officer Fairer Housing Unit Civic Centre Newcastle upon Tyne NE1 8QN E: colin.white@newcastle.gov.uk T: +44 (0)191 277 7839</p> <p>Dr Haibo Feng (Building performance) Department of Mechanical and Civil Engineering Engineering and Environment, Ellison Building, Northumbria University, Newcastle upon Tyne, NE1 8ST, United Kingdom E: haibo.feng@northumbria.ac.uk</p> <p>Prof Anil Namdeo (Air Quality Management) Department of Geography and Environmental Sciences Engineering and Environment, Ellison Building, Northumbria University, Newcastle upon Tyne, NE1 8ST, United Kingdom E: anil.namdeo@northumbria.ac.uk T: +44 (0)191 227 4155</p> <p>Dr Michael Deary (Air Quality Monitoring) Department of Geography and Environmental Sciences Engineering and Environment, Ellison Building, Northumbria University, Newcastle upon Tyne, NE1 8ST, United Kingdom E: michael.deary@northumbria.ac.uk T: +44 (0)191 227 3593</p> <p>Prof Luke Vale (Health economics) Population health Sciences Institute, Faculty of Medical Sciences, Newcastle University, NE1 4LP, United Kingdom. E: luke.vale@newcastle.ac.uk T: +44 (0) 191 208 5590</p>
Committees	<p>Study Steering Committee: Chair Prof Anil Namdeo See Appendix 1</p> <p>Community Steering Committee: Chair Dr Lindsay Bramwell See Appendix 1</p>

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ii. LIST OF ABBREVIATIONS

AQ	Air Quality
CSC	Community Steering Committee
DMP	Data Management Plan
ICF	Informed Consent Form
NCC	Newcastle City Council
NU	Northumbria University
NITV	Newcastle Independent Tenants Voice
PI	Principal Investigator
PIL	Participant Information Leaflet
PMB	Project Management Board
PM _{xx}	Particulate Matter <small>(size fraction)</small>
PPI	Patient Public Interaction
QA	Quality Assurance
QC	Quality Control
REC	Research Ethics Committee
SI	Supplementary Information
SOP	Standard Operating Procedure
SSI	Site Specific Information
SSC	Study Steering Committee

iii. RESEARCH SUMMARY

Internal ref. no. (or short title)	In2Air	
Study Design	non-randomized natural experiment	
Study Participants	Elderly human participants in social housing in Newcastle upon Tyne, Tyne and Wear, UK	
Planned Sample Size	30 bungalows	
Intervention	Informed by the Citywide Decarbonisation Delivery Plan, the optimal intervention has been designed to reduce by half the heating consumption in social housing focussing on fabric improvement measures. The planned interventions include a mix of: new windows, loft insulation (300mm thickness), new front doors (1.2w/m ² K), decentralised mechanical extract ventilation, solar panels.	
Follow up duration	Approx. 12 months after intervention (matching month/season of pre-intervention baseline monitoring) as part of a separate, follow-on, study.	
Planned Data-collection Period	Minimum 3 weeks pre-intervention baseline data collection.	
	Objectives	Outcome Measures
Primary	Deployment of low-cost monitors to measure matched indoor and outdoor air conditions for > 4 weeks duration before homes are retrofitted. The monitored parameters: PM _{2.5} via a particle count approach; CO ₂ ; temperature and relative humidity. All sensors are combined within a single monitor unit with a screen showing easy to read air quality indicators. To reduce the burden on the participants and contain study costs, one combined indoor monitor will be placed in the living room of each home, and one outside the property (so we can correct for relevant external factors). Monitors set to record at a minimum of 10-minute intervals.	Indoor concentration of PM _{2.5}
Secondary		Indoor concentration of CO ₂ , temperature and humidity
Secondary	Multiple approaches and data sources to quantify, assess and monitor domestic energy consumption (DEC). 1) a walk-through Level 1 Energy Audit to identify the various household energy uses (all homes in the study cohort), 2) up to 12-months gas and electricity bills reviewed for each home to understand energy usage patterns and seasonal variation (all homes on the study cohort),	energy consumption in homes

	<p>3) higher resolution data will be extracted and used for the analysis if the home has a smart meter installed</p> <p>4) to establish a baseline energy consumption for the selected bungalow archetype, a separate short-term (3 – 6 months) monitoring study for electricity and gas using energy data loggers and heat meters will be conducted on a limited number of homes, with data logged at 15-minute intervals to create daily, weekly and monthly profiles of energy use, in addition to a long-term (12 months) submetering period.</p>	
Secondary	<p>Use of modified standard questionnaire instruments to collect baseline data on i) home characteristics (e.g. Likert scale questions on thermal comfort within the building, prevalence of condensation, damp, mould) and activities/behaviours that influence indoor AQ, and ii) occupier characteristics (e.g. age, gender) and self-reported health and wellbeing collected for all adults in each household (SF-36v2 and modified ICECAP-A survey).</p>	<p>general health and wellbeing metrics</p>

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
National Institute for Health and Care Research (NIHR) Public Health Research (PHR) Programme	6 months financial funding under Call Title: 22/69 PHR Rapid Funding Scheme
Newcastle City Council (NCC)	<p>Staff time.</p> <p>Air pressure testing funded as part of NCC's intervention package.</p> <p>Financial support of £3K to support energy monitoring.</p>

In addition, relevant expertise is also provided by members of the Study Steering Committee (see Appendix 1)

v. ROLE OF SPONSOR

Northumbria University assumes overall responsibility for the initiation and management of the research. Ethical approval is with Northumbria University Research Ethics Committee (REC) and no members of the research team sit on REC to ensure independence.

vi. ROLES AND RESPONSIBILITIES OF MANAGEMENT COMMITTEES & GROUPS

Project Management Board

A monthly **Project Management Board** (PMB), comprising the entire multidisciplinary research team, are responsible for the research design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. The PMB will provide strategic oversight and decision-making and monitor progress towards milestones. Information on the Board can be found in Appendix 1.

Project Operation Team

Day-to-day project management (including data monitoring) will be through a **Project Operation Team**, with weekly meetings of the two PIs, the Council partner and the Senior Researcher (moving to bi-weekly from month 3) to ensure all practical details of the research delivery are progressing and working well and everyone within the research team understands them. Other members of the research team invited as relevant.

Study Steering Committee (SSC)

Chaired by Co-I Namdeo, the SSC will meet at the end of month 1 to consider and inform final version of the protocols and PPI activities, in month 4 to receive progress report and review PPI activities. SSC members will receive a copy of the final report for comment. Information on the committee (and membership) can be found in Appendix 1.

Community Steering Committee (CSC)

The Community Steering Committee (CSC), drawn from residents in the study location and chaired by the project PPI lead. The CSC provides advice on community engagement (newsletter drops, Newcastle Independent Tenants Voice (NITV) Facebook group, local engagement events), organises local meetings and confirms preferred shared communication platform for the group. A CSC member will join the SSG. Information on the committee (and membership) can be found in Appendix 1.

vii. PROTOCOL CONTRIBUTORS

Contributor	Affiliation	Relevant expertise
Prof. Jane A Entwistle	Northumbria University	Indoor Air Quality monitoring, PPI
Dr Richard McNally	Newcastle University	Statistics (health)
Dr Lindsay Bramwell	Northumbria University	PPI, Indoor/Outdoor Air Quality monitoring
Dr Tarek Ahmed	Northumbria University	Building performance and energy efficiency
Mr Colin White	Newcastle City Council	Housing Renewal Intervention lead
Dr Haibo Feng	Northumbria University	Building performance
Prof Anil Namdeo	Northumbria University	Air Quality Management
Dr Michael Deary	Northumbria University	Air Quality Monitoring
Prof Luke Vale	Newcastle University	Health economics

Community participants have been, and continue to be, involved in all elements of the protocol design (for further details see Appendix 2).

A range of relevant expertise is also provided by members of the SSC (for further details see Appendix 1).

viii. KEY WORDS

indoor air quality

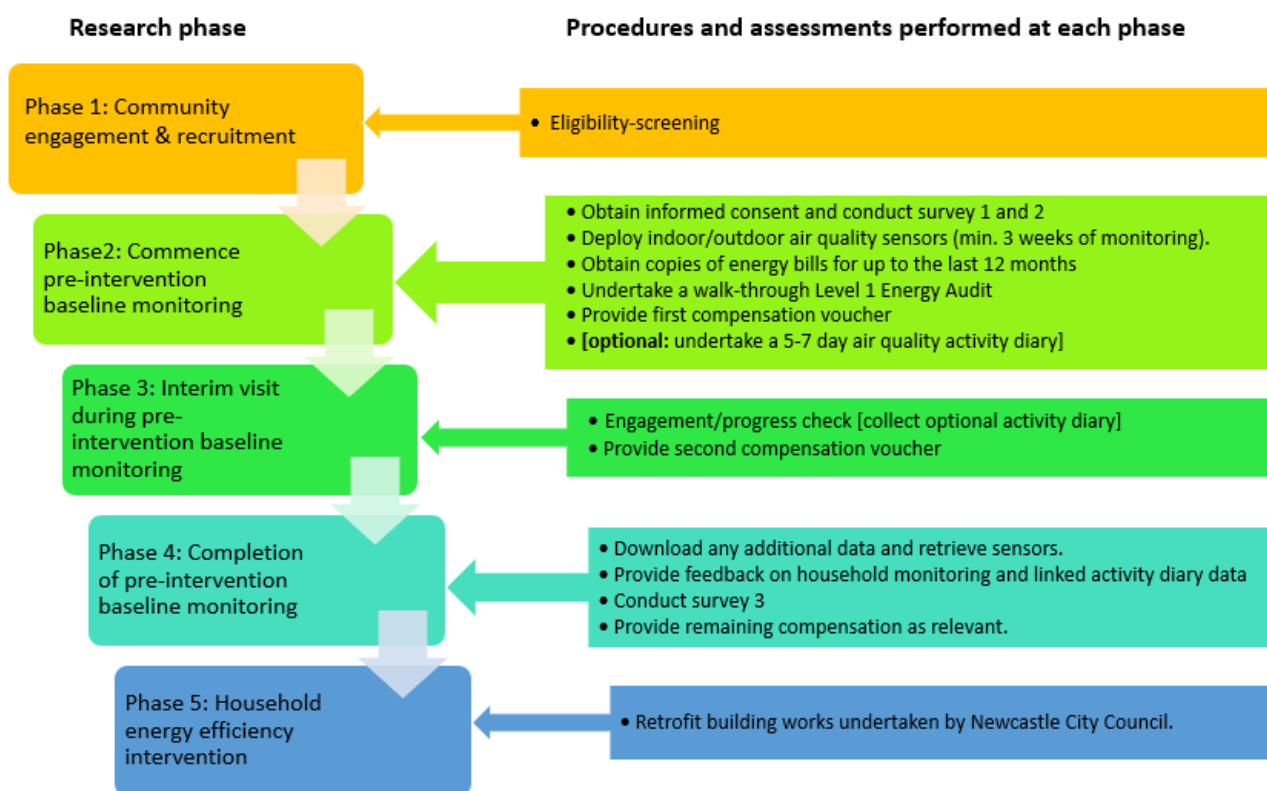
fuel efficiency

building fabric improvement measures

social housing decarbonisation

occupant self-reported general health and wellbeing

ix. PROJECT FLOW CHART



1 Background and Scientific Rationale

With an energy price crisis exacerbating the prevalence of fuel poverty, unprecedented increases in the cost of living and challenging targets to reduce the production of greenhouse gases (the 'net-zero' challenge), the energy efficiency of homes is of national and international importance. At the same time, air pollution is one of the main causes of ill health and premature deaths worldwide. Tackling climate change (through reduced household energy use), together with improving indoor air quality offers a significant opportunity to improve residents' health and wellbeing.

Air pollution is a leading cause of mortality and morbidity worldwide and a major driver in health inequality; it disproportionately affects the young (it can damage growing lungs and stunt growth), older people (who may spend significant periods in the home), those with compromised immune systems or with relevant pre-existing medical conditions (e.g. chronic obstructive pulmonary disease [COPD] and asthma) and those who live in deprived areas, typically with higher levels of air pollution (outdoor and indoor) and in poor quality housing [1]. Given we spend a great deal of our time indoors, indoor air quality (AQ) is central to our health and wellbeing and improvements to the indoor environment can be an important mechanism for addressing health disparities among low-income and vulnerable populations [2].

NICE guidelines [1] and systematic reviews of household air pollution [3,4] highlight health risks posed by poor indoor AQ. There is clear evidence that both short and long-term exposures to particulate matter (PM) are associated with increased mortality from all causes, cardiovascular disease, respiratory disease and lung cancer [5,6]. Recent epidemiologic studies demonstrate strong evidence for a causal relationship between short-term PM exposure and asthma exacerbation, COPD exacerbation, and combined respiratory-related diseases [7]. Given the significant public health implications of exposure to high levels of PM, especially in individuals who have asthma or other respiratory related health issues [1], our primary outcome measure will be indoor PM_{2.5} concentrations as a surrogate health indicator. Potential sources of PM indoors include the ingress of outside air, cooking, heating, smoking, cleaning, burning candles and a range of other occupant activities [1,8,9]. Although no legal limits exist for indoor PM concentrations the new, more stringent, WHO guideline values for annual mean PM_{2.5} (5 ug/m³) exposure reflect findings of health effects at much lower concentrations than previously suggested [10].

Whilst improving household energy efficiency can improve thermal comfort and reduce fuel poverty, air sealing of houses can result in poorer indoor AQ, increasing the subsequent risk of allergic and respiratory diseases. During the past decade, researchers have investigated the benefits of a wide range of green building practices and policies on energy efficiency, indoor AQ and human health and wellbeing [11]. Whilst improvements in general health and wellbeing in adults have been associated with green-retrofit interventions [12,13], results are often equivocal and typically reflect the range of interventions that are co-deployed under this broad term and other confounding variables, such as behaviours of the occupants and the presence or not of mechanical ventilation [14-18]. Ventilation with outdoor air plays an important role influencing human exposures to indoor pollutants [19]. Studies have shown homes without active mechanical ventilation can have PM concentrations approximately double those in homes with such systems [15]. Health problems associated with low building ventilation rates are well documented, though the need remains for further exploration in residential contexts [19]. A recent study of household energy efficiency interventions across social housing in SW England (n=706 homes) concluded that living in energy efficient homes may increase the risk of adult asthma, with a reported per unit increase in household energy efficiency associated with a 2–3% increased risk of adults seeing a doctor for asthma [20]. The reasons for this were unclear and indoor AQ was not directly monitored.

The 2019 Conservative Manifesto committed to a £3.8bn Social Housing Decarbonisation Fund over a 10-year period to improve the energy performance of social rented homes, on the pathway to Net Zero 2050. Due to the scale of the task a phased approach is required, prioritising a fabric first approach (with interventions like external wall, loft and under floor insulation), to reduce the energy demand and prioritising the poorest performing housing stock. A fabric first approach is a common low-tech intervention method to reduce energy demand and provide more comfortable environments for occupants. Yet few studies have evaluated the effect of a fabric first approach, with continuous

mechanical ventilation included in the retrofit design, on indoor AQ in occupied affordable housing. Affordable housing organisations operate on very limited budgets, and additional costs of mechanical ventilation above those required for minimum regulatory compliance can be prohibitive. Newcastle City Council (NCC) have recently secured a Social Housing Decarbonisation grant, providing a timely opportunity and a clear need to engage households with the home 'indoor air quality and energy challenge'. A unique contribution of the proposed study is that it is focused on the effects of energy efficient refurbishment, with mechanical ventilation, in existing affordable housing. To deliver net-zero changes across all social housing stock will take time and our findings will directly inform decision making of council retrofit teams across the UK and their ongoing decarbonisation plans with regards to energy and to health as we approach the UK Governments 2050 target.

With the ageing population in the UK set to double, from 10 million in 2010 to 19 million by 2050 [22,23], comes an increasing demand for higher indoor air temperatures due to age-dependent changes in thermoregulation, exacerbated by longer periods of time spent at home [24]. With higher temperatures required for comfort and the daily heating period extended, this impacts significantly on both space heating demands and appliance use. Working in partnership with NCC, we have selected the bungalow archetype occupied by residents aged >65 years, located within the Green Estate, Walker, Newcastle upon Tyne. Walker is ranked 45 out of 32,844 in England in the latest Index of Multiple Deprivation scores where 1 is the most deprived. NCC's target and funding is for 91 bungalows to be retrofitted regardless of whether households chose to participate in the research study; due to economic constraints we are only able to monitor 30 of these homes but will survey all the older occupants residing in these 30 homes. Initial contact with tenants in this target community of 91 homes will be via NCC's Fairer Housing Unit and their housing management organisation (Your Homes Newcastle), using their established electronic and in-person communication mechanisms.

2 RESEARCH QUESTION, OBJECTIVES AND OUTCOME MEASURES

This 6-month study is a non-randomized natural experiment to collect baseline data as the foundation to answer our overarching research question:

What is the impact of energy efficient retrofit interventions on indoor air quality, household energy use and self-reported general health wellbeing, on older householders' living in social housing?

Working within budgetary constraints and to reduce uncertainties associated with different building typologies and occupier characteristics, this baseline study will focus on 30 bungalows with tenants > 65 years of age.

2.1 Outcome measures

Primary Outcome Measure: Indoor concentration of PM_{2.5}

Secondary Outcome Measure 1: Indoor concentration of CO₂, temperature and humidity

Secondary Outcome Measure 2: Household energy consumption

Secondary Outcome 3: General health and wellbeing metrics

3 PARTICIPANT ELIGIBILITY CRITERIA

This section sets out precise definitions of which participants are eligible for the study, defining both inclusion and exclusion criteria. The inclusion criteria define the population the study is aiming to include. Exclusion criteria excludes sub-groups of the population due to, for example, safety and other confounding variables.

3.1 Inclusion criteria

- participants capable of giving informed consent.
- current resident of the Green Estate bungalows, Walker
- resident in current dwelling for >4 months (residence for this study is defined as spending at least 5 nights per week in the home).
- plan to reside in the property throughout the next 18 months.
- not on a prepayment meter.
- if smoker, agreement to refrain from smoking indoors during the air monitoring period.

3.2 Exclusion criteria

- Participants who are unable to provide informed consent. We consider this exclusion to include vulnerable adults (most likely those requiring support worker/s).
- Participants younger than 55 years of age.
- Any participant who, in the judgment of the investigator (such as due to personal safety concerns), should not participate in the study.

4 STUDY PROCEDURES

4.1 Recruitment

This section describes how elderly human participants in social housing are identified and recruited and includes details of the participant eligibility screening process for the project.

4.1.1 Participant identification

NCC owns almost 25,000 homes in the city of Newcastle upon Tyne and it is estimated that to achieve net zero it will require the majority of these properties to be upgraded, costing £434m and reducing CO₂ emissions by 92%. This will require carrying out deep retrofit measures using a fabric first approach, improving air quality and reducing energy demand by increasing air tightness and insulation values and introducing new low carbon heating systems. These measures will significantly change the internal living environment. NCC has secured £3m from the UK Government Department for Business, Energy & Industrial Strategy Wave 1 Social Housing Decarbonisation Fund towards the £6m costs to insulate 277 properties in two estates in the east of the city. The first estate consists of 91 Council owned one bed bungalows occupied by elderly tenants; these homes form the target study cohort of 30 homes.

In late August 2022, the 91 homes and their occupants received details via communications from the delivery specialist team at Your Homes Newcastle of the planned retrofit works and information on voluntary participation in the In2Air study.

Working in collaboration with the delivery team at Your Homes Newcastle and the warden of the estate's community centre, a range of activities and resources are under development to drive interest and recruitment. Resources include: publicity flyer, project website, community engagement events.

For detailed information available for participants see the Participant Information Leaflet (PIL; appendix 2).

4.1.2 Eligibility Screening

Following participant expression of interest, members of the research team will set up a phone or F2F meeting to assess suitability against the noted inclusion and exclusion criteria. Participants who do not meet eligibility criteria will be informed immediately at the end of the screening interview.

4.1.3 Payment

To remove financial barriers to study participation we will provide financial incentives/compensation. Financial incentives/compensation for participation will cover costs incurred related to time spent with a researcher and energy use of the sensors. Up to £80 per household: £20 voucher at initial home visit; £20 voucher at end of first 4 weeks monitoring (month 1); £20 voucher at end of further 4 weeks of monitoring (month 2); £20 voucher at end of further 4 weeks of monitoring (month 3). A similar financial incentive/compensation is available for those households who host fuel monitoring equipment.

To remove mobility barriers participants can undertake all elements of the study from their home.

To remove language barriers we will provide translated study materials where relevant.

To remove time barriers we have co-developed easy to complete study materials through previous PPI and will continue to co-develop these materials.

4.2 Consent

The co-PIs retain overall responsibility for the conduct of research. Informed consent is to be obtained prior to the participant taking part in the study, recorded by a signed Participant Consent Form (PCF) following a verbal discussion between the potential participant and an individual knowledgeable about the research. This will allow the opportunity for potential participants to ask questions and for the researcher to outline the nature and objectives of the trial and possible risks associated with participation. As delegation of consent is granted to the Senior Researcher on the project the co-PIs will ensure that they are trained and competent to participate according to the ethically approved protocol.

As detailed in the PIL, any participant has the right to refuse participation without giving reasons; remains free to withdraw at any time from the study without giving reasons and without prejudicing his/her further treatment and is provided with a contact point where he/she may obtain further information about the study; data and samples collected up to the point of withdrawal will only be used after withdrawal if the participant has consented for this (any intention to utilise such data are outlined in the consent literature).

Written materials provided to potential participants (e.g., participant information leaflet and consent form; included in Appendix 2) are approved by Northumbria University Research Ethics Committee (REC) and are in compliance with local regulatory and legal requirements. The PIL and PCF explain what information are being collected, how we are going to use it and the lawful basis under which the data is processed. Participants will also receive a copy of Northumbria University's Research Participant Privacy Notice.

4.3 Baseline data

Using an array of validated/well-established data collection methods, this 6-month study will collect the following baseline datasets before these 30 homes undergo a fabric-first intervention:

i) paired indoor and outdoor concentrations of particulate matter (PM_{2.5}); indoor carbon dioxide (CO₂) concentrations (elevated levels are regarded as sign of inadequate ventilation and often used as a surrogate measure of the amount of outdoor air introduced into the home [9,21]);

- ii) paired outdoor and indoor temperature and humidity (due to their effect on mould growth and thermal comfort [1]);
- iii) energy consumption, and
- iv) self-reported general health and wellbeing.

We will deploy low-cost monitors to measure matched indoor and outdoor air conditions for minimum 3 weeks duration before the homes are retrofitted. PM_{2.5} will be via a particle count approach making the unit quieter than is typical for gravimetric methods. All sensors are combined within a single monitor unit with a screen showing easy to read air quality indicators. Current literature on the length of monitoring required to establish an indoor AQ baseline varies widely from a few days (e.g. 4 days) with weekend/weekday and seasonal sampling, up to 12 months [2,17,25,26]. To reduce the burden on the participants and contain study costs, one combined indoor monitor will be placed in the living room of each home, and one outside the property (so we can correct for relevant external factors). Monitors will be set to record at a minimum of 10-minute intervals. Guidance on the positioning of sensors [26] will also be followed, as far as possible. Detailed approach undertaken for monitoring domestic air quality is available in supplementary information (SI) 1.

The study will use multiple approaches and data sources to monitor, assess and quantify domestic energy consumption (DEC). 1) a walk-through Level 1 Energy Audit will be conducted to identify the various household energy uses [27] and up to 12-months gas and electricity bills will be reviewed for each home to understand energy usage patterns and seasonal variation, 2) higher resolution data will be extracted and used for the analysis if the home has a smart meter installed. 3) To establish a baseline energy consumption for the selected bungalow archetype, a separate short-term (3 - 6 months) monitoring study for electricity and gas using energy data loggers and heat meters will be conducted on a limited number of homes. Here, data will be logged live and at short-intervals allowing us to create daily, weekly and monthly profiles of energy use. Energy monitoring will continue for a longer period to establish a 12-month DEC in compliance with the Department of Energy Measurement and Verification Protocol [28,29] and to capture the energy use for similar period to be used in the follow-up (post-intervention) study. Our approach undertaken for monitoring of DEC is available in SI-2.

We will use modified standard questionnaire instruments to collect baseline data on i) home characteristics (e.g. inclusion of Likert scale questions on thermal comfort within the building, prevalence of condensation, damp, mould) and activities/behaviours that influence indoor AQ, and ii) occupier characteristics (e.g. age, gender) and self-reported health and wellbeing collected for all adults in each household (SF-36v2 and use of modified ICECAP-A survey,). SF-36v2 is an established and widely used health-related quality of life measure [30]; ICECAP-A is validated for economic evaluations and a broad focus on overall health and wellbeing [31]. Deployed survey questions are available in SI-3.

5 STATISTICS AND DATA ANALYSIS

5.1 Sample size calculation

An enrolment target for this study was determined based on our primary outcome measure (changes in PM concentration) using data from our citizen-led indoor AQ feasibility study across 18 homes of varying typology in NE England (mean PM₁₀ concentration in non-smoking households was 15.9 +/- 8.0 ug/m³ [32]). Our power calculation, based on a paired t-test, found that a minimum of 22 homes are needed to see a statistically significant difference of 35-40% (with 90% power and alpha = 0.05) in PM between the two groups (i.e. the pre and the post-intervention data). We plan to recruit a cohort of 30 homes to account for some non-retention before the post-intervention monitoring period. With 30 homes, 80% power and an alpha of 0.05, we expect to be able to determine a statistically significant difference of 25-30%. In a recent similar study in the USA, where homes moved from on-demand mechanical ventilation to continuous mechanical ventilation an improvement of 21% was observed in PM_{2.5} (change in

geomean from 17.7 to 13.3 $\mu\text{g}/\text{m}^3$ [2]). Whilst increasing our sample size of homes would lower the statistically significant difference that we could determine, in the context of the bungalows in this study, as we will be moving from pre-intervention homes with no mechanical ventilation to post-intervention homes with continuous ventilation [33] we anticipate a 25-30% change in $\text{PM}_{2.5}$ is not an unrealistic expectation.

5.2 Planned recruitment rate

Baseline data collection on homes is scheduled to commence in project month 3. To achieve the target of 30 homes undergoing baseline data collection during the 6-month project, a recruitment rate of 7-8 homes in each of project month 2-5 is required i.e. recruitment in month 2 for project month 3 monitoring; recruitment in month 3 for project month 4 monitoring; recruitment in month 4 for project month 5 monitoring; recruitment in month 5 for project month 6 monitoring.

A second estate is also included as part of the NCC planned retrofit intervention. This second estate has 156 council owned and 30 private properties consisting of 3-bedroom non-traditional build Duo-Slab houses. In project month 3, if recruitment rate indicators on the target bungalow cohort are suggesting insufficient numbers of total participants then the project ethics will be reviewed with a plan to extend baseline monitoring into this second estate.

5.3 Statistical analysis plan

The study is for baseline data collection of 30 council owned homes and their elderly occupants pre-intervention.

5.3.1 Air-quality dataset

After QC checks, descriptive statistics will be computed (e.g. geometric mean 24hr $\text{PM}_{2.5}$) and box plots will be used to check for any apparent outliers which will then be excluded from subsequent analyses. Each parameter will be checked for normality, with log-transformation used as necessary. We will investigate the key factors reported to influence indoor PM concentrations (e.g. smoking indoors; frequency of reports of musty odours; outdoor PM levels; window use), and CO_2 concentrations (e.g. number of household occupants; frequency of musty odours; gas cooker). Associations between key factors and indoor PM will be investigated using regression modelling. For example, simple linear regression models will be used to explore the putative associations between the exposures and a range of household measurements (e.g. the association between $\text{PM}_{2.5}$ and room temperature). Statistically significant household variables will then be included as covariates in a multivariable regression model and the outcome measure will be PM or CO_2 concentration.

5.3.2 Energy performance dataset

In-depth statistical analysis of the acquired energy data at 10-min. intervals will be validated against the occupant's survey results and used to identify energy use patterns. Using multiple regression models and the heating degree day (HDD) method, data gathered will be normalised to account for, and quantify, electricity and gas consumption related to occupancy and external weather conditions. We will therefore, be able to establish a baseline energy consumption for those archetypes, quantify the energy savings as a result of the intervention and identify atypical events within the dataset.

5.3.3 General health, household and wellbeing dataset

Histograms, boxplots and descriptive statistics will be used to summarise these data. Three key domains will be presented: the household, a physical health and a mental health component summary. Given behavioural changes are likely (e.g., increased active ventilation via window opening and use of cooker extraction hood) this domain is included as part of the general household questionnaire. These data will be coded for reporting and subsequent analysis. Responses to the SF-36v2 will be converted into the

SF6D and a scoring algorithm will be used to convert ICECAP-A responses into a single score. This will then be suitable for an economic evaluation as part of a follow-on research study.

5.3.4 Procedure(s) to account for missing or spurious data

Community engagement events and communication with participants will promote and maximise follow-up and reduce missing data. Any missing data (e.g. from surveys or measurements) will be logged to allow an audit record. Missing air quality and energy consumption data will be handled, where feasible, by using validated methods including single and/or multiple imputation methods. Sensitivity analyses will be employed to assess the robustness of results under different methods of handling missing data.

5.3.5 Economic evaluation

The focus of this project is on baseline data collection, collecting the necessary baseline data to enable economic evaluation as part of a follow-on research study.

6 DATA MANAGEMENT

A detailed data management plan is available in SI-4.

All source documents (e.g. all original signed informed consent forms; participants' air quality recording diaries; researcher records following home visits [monitor set up locations etc]; uncoded, original questionnaire responses) and recorded data from automated instruments will be kept at least 7 years after completion of the study so audit trails can be undertaken to demonstrate the validity of the data (both during and after the study).

Data will be retained in an appropriate format for a period of at least 7 years as a high-risk project, in accordance with NU's Research Records Retention Schedule (principle of storage limitation).

An audit trail of data changes will be maintained.

Data security measures to protect against unauthorized access, backup of the data and archiving of source data (i.e. hard copy and electronic) is detailed in the DMP (see SI-4).

Direct access will be granted to authorised representatives from the Co-PIs to permit study-related monitoring, audits and inspections in-line with participant consent.

7 ETHICAL CONSIDERATIONS

Ethical approval for the study has been granted from Northumbria University REC (submission reference 51426) based on this protocol and subject to continued compliance with the University policies on ethics, informed consent, and other policies applicable to this study.

Once finalised, all protocols are to be submitted via an Ethics Amendment Form to maintain compliance.

Any incidents which have an adverse effect on participants, researchers or study outcomes are to be reported via an ethical incident form to the REC.

7.1 Peer review

The protocols will be independently peer reviewed by external, expert members of the SSC.

7.2 Public and Patient Involvement

This study works with members of the public not patients or service users. Members of the public have been and will continue to be involved in the research process as described below. Meetings and engagement events with community members will be conducted using recommendations from the INVOLVE website <http://www.invo.org.uk/>.

7.2.1 Design of the research

The indoor AQ investigation methods, questionnaire, informed consent form and monitoring equipment choice have been directly informed by several rounds of interaction with a consumer panel and a community group (drawn from a similar geographical location and socioeconomic group to our target population). Activities were supported through a Public Involvement Fund (award rds3897) from the Research Design Service North-East and Cumbria. Further information is available in Appendix 2. We will continue to co-develop and refine the study design and materials throughout the project.

7.2.2 Management of the research and undertaking the research

A Community Steering Committee (CSC), drawn from residents in the study location will inform the research management. CSC will, for e.g., provide advice on community engagement (newsletter drops, using the Newcastle Independent Tenants Voice (NITV) Facebook group, local engagement events), meetings and confirm preferred shared communication platform for the group. A CSC member will join the SSG. We will support members of the community to contribute to the research through events in the local neighbourhood to encourage community members to participate, share experiences, and feedback on acceptable methods to engage and retain participants in future studies.

7.2.3 Analysis of results

The CSC and community will be encouraged to inform the research team on aspects of the study findings of particular interest to them to ensure this is addressed in the results analysis.

7.2.4 Dissemination of findings

The CSC and community will be encouraged to inform the research team on preferred pathways for participant and community feedback e.g. written communications and event invitations via NITV, local community information boards and newsletter drops to homes in the participating housing estate, household report on monitored data.

The proposed PPI activities include:

- Information on purpose and participation in the study distributed via NITV, letters from NCC to tenants regarding retrofit works, and to relevant local community groups and venues
- Establish CSC and review study PPI protocol
- Public engagement and recruitment events: including meet the research team, study participation information, research team finds out about community's air quality concerns and barriers to participation
- Optional household time-activity diary as part of air quality awareness raising
- Study progress updates shared via CSC, NITV and any other routes recommended by CSC.
- Community feedback collected through the same channels
- Study support telephone number (researcher has pre-prepared Q&A sheets)
- Local public engagement event to thank community and CSC, share findings and experiences, provide Q&A opportunity, collect feedback

7.3 Participant safety

An assessment of unanticipated outcomes has been undertaken. Unanticipated outcomes of the study could include: raised anxiety levels among participants about increased energy costs (due to the monitoring instrumentation and mechanical ventilation as part of the intervention), exposure to indoor air pollution, reduced fresh air indoors and electrical faults with the monitoring equipment. To reduce incidences of anxiety we will: de-brief participants during researcher visits to discuss concerns; provide a study contact telephone number/email with researchers having pre-prepared Q&A responses; ensure that AQ monitoring equipment will be PAT tested where relevant. Where participants may feel uncomfortable answering survey questions, the researcher will move on to the next question.

7.4 Protocol compliance and recording/reporting of breaches to protocol

Departures from the approved protocol (i.e. protocol non-compliances), where not considered serious breaches (i.e. those that can be accommodated within the scientific scope of the study) will be adequately documented and reported to NU REC on the appropriate Ethics Amendment Form.

Deviations from the protocol which are found to frequently recur will require immediate action and could potentially be classified as a serious breach. A "serious breach" is a breach which is likely to effect to a significant degree –

- (a) the safety or physical or mental integrity of the participants of the study; or
- (b) the scientific value of the study

In this situation the NU REC and the funder will be notified immediately of any instances where the above definition applies during the study. Where appropriate, the study protocol will be amended within 7 days of becoming aware of the serious breach.

7.4 Data protection and participant confidentiality

The data collected in the study relates directly to the objectives of the project and is required to achieve the outcomes of the research. As such, the research team processes the special categories of personal data under Article 9(2)(j) GDPR, which permits processing that is necessary for scientific research purposes, providing we have appropriate security safeguards in place.

All investigators must comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Ethical guidelines, in accordance with the University's information security policy (principle of integrity and confidentiality) will be followed for securely anonymising, separating, and holding information on household and personal identifiers to ensure confidentiality obligations. Personally identifiable data will be anonymised or pseudonymised as soon after collection as possible. Study records for data analysis will use only personal identifiers/study identification numbers and computer data files will be password protected to protect participants confidentiality. This personal quantitative data will remain confidential to the project researchers and will not be shared with other agencies.

Sensitive data and the linking code will be securely maintained in separate locations using password protected digital files on password protected storage media. In addition, a single hard copy record of the personal identifiers/study identification numbers will be maintained for a minimum of 7 years post project end date in a locked draw in the PIs office. At the end of this period the document will be submitted to confidential waste.

Online surveys will be delivered via JISC Online Surveys (GDPR compliant and certified to ISO 27001 standard) and Quality Metric, the licensed provider for the SF36-v2 wellbeing questionnaire.

7.5 Indemnity

The study collaboration agreement details the indemnity arrangements for the study. All partners are signatories to this collaboration agreement.

7.6 Post study participant follow-up

We intend to follow up this baseline study with post intervention monitoring (successful funding bid permitting). No post study clinical care will be required for participants as this is not a clinical trial.

8 RISK MANAGEMENT AND CONTINGENCY

A set of possible risks has been identified and contingency planning has been undertaken to limit the impact on the project deliverables. Risk analysis has been carried out to: define the risk; evaluate the probability that such a risk may occur during the project; identify the seriousness of the risk and its impact on the project; specify the countermeasures in order to mitigate the effect of the risk to the project and/or to prevent the risk occurring. Table 8.1 summarises the risks identified and proposed risk-mitigation measures.

Table 8.1 summarises the risks identified and proposed risk-mitigation measures

Description of risk	level of likelihood	Proposed risk-mitigation measures
Limited engagement/ take-up by participants	Medium	The project uses a multifaceted approach to the recruitment of participants and their on-going support to facilitate engagement. If recruitment rate is low (see section 5.2) we will review the inclusion/exclusion criteria.
Issues related to Covid-19	Medium	Regular review of researcher-community engagement and interaction plans. For example, participant informed consent and delivery/set up of air quality monitoring equipment can be altered to enable delivery without entering the residence if significant concerns occur in relation to Covid-19.
Delay in kit procurement	Medium	Whilst the project timeline has been carefully considered, additional time-flexibility has been built into contingency plans to allow for extended delays. For example, the Senior Research has a contract of employment at NU for 4 months beyond the NIHR funded timeline.
Delay in intervention delivery timeline	Low	
Fuel cost concerns	Medium	Increase incentive/compensation rate.
Staff departure to another HEI	Low	Tasks will be allocated to another member of the research team (given the overlapping/complementary research expertise of the project researchers), or the signed collaboration agreement will be reviewed to include the new HEI
Extended researcher illness	Low	Tasks will be allocated to another member of the research team or co-opt a new member of staff to cover the skills/expertise.

9 DISSEMINATION POLICY

The study collaboration agreement details ownership of the data arising from the study and who has the rights to publish any of the data.

The funding body must be acknowledged within any publications arising from the study.

9.1 Study protocols

Scalable Standard Operating Procedures/Protocols for collecting baseline data to facilitate an evaluation of the impact of retrofitting on indoor AQ, household energy use, general health and wellbeing will be made publicly available on the project website within 2 months of study end date.

9.2 Access to the study dataset

All of the named researchers involved in the project will have access to the full dataset during the final month of the project to facilitate data analysis.

Access to the draft study report will be granted to all members of the project committees to enable peer review and co-production.

The baseline data arising from this study will be embargoed for 24 months after the end of study to allow time for post-intervention monitoring, although there are no embargo periods on any data included in publications arising from the current study within this timeframe.

A detailed data management plan is available in SI-4 and outlines the plans to make the data arising from this study publicly available.

9.3 Other dissemination pathways

Within 2 months of completion of this 6-month baseline project, the study report will be made publicly available on the project website.

Participants will receive reports of their individual AQ findings and advice on improving indoor AQ.

The Standard Operating Procedures/Protocols will be disseminated to local authorities, retrofit and housing industry.

New awareness of indoor conditions, energy use, general health and wellbeing across a previously under-represented community will be disseminated at stakeholder events, along with new insights and learning from research engagement with a previously under-represented community.

Wider dissemination of the research findings will be achieved via hosting an online capacity building workshop.

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11. APPENDICIES

Appendix 1 - Representation on the Committees/Boards

Project Management Board

Contributor	Affiliation	Relevant expertise
Prof. Jane A Entwistle (Chair)	Northumbria University	Indoor Air Quality monitoring, PPI
Dr Richard McNally (co-Chair)	Newcastle University	Statistics (health)
Dr Lindsay Bramwell (Sec.)	Northumbria University	PPI, Indoor/Outdoor Air Quality monitoring
Dr Tarek Ahmed	Northumbria University	Building performance
Mr Colin White	Newcastle City Council	Housing Renewal Intervention lead
Dr Haibo Feng	Northumbria University	Building performance
Prof Anil Namdeo	Northumbria University	Air Quality Management
Dr Michael Deary	Northumbria University	Air Quality Monitoring
Prof Luke Vale	Newcastle University	Health economics

Community Steering Committee (CSC)

Contributor	Affiliation	Role
Dr Lindsay Bramwell	Northumbria University	Chair
Maureen Ball	Community Centre Warden at Wellbeck Green, Walker, Newcastle	Member
Janice Farrell	Community Centre Warden at Kingston & Monkchester Green, Walker, Newcastle	Member
Dean Holmes	Your Homes Newcastle, Newcastle	Member

Study Steering Committee (SSC)

Contributor	Affiliation
Prof Anil Namdeo (Chair)	Northumbria University Anil.namdeo@northumbria.ac.uk
Dr Lindsay Bramwell (Sec.)	Northumbria University Lindsay.bramwell@northumbria.ac.uk
Dr Malcom Brodlie	Director of the North-East NIHR Integrated Academic Training Programme for Doctors and Dentists Honorary Consultant in Paediatric Respiratory Medicine Great North Children's Hospital Royal Victoria Infirmary

	Newcastle upon Tyne
Lorna Smith	Consultant in Public Health and Interim Director of Public Health Newcastle City Council, Civic Centre, Newcastle upon Tyne lorna.smith@newcastle.gov.uk
Dr Jamie Bond/Dr Stuart Aldridge	Air Quality and Public Health Group Environmental Hazards and Emergencies Department Centre for Radiation, Chemical and Environmental Hazards Public Health England, Didcot, Oxon stuart.aldridge@phe.gov.uk
Dr Andy Dengel	BRE Environment Building Research Establishment (BRE) Ltd Watford andy.dengel@bregroup.com
Rob Charlton	CEO Space Group Newcastle upon Tyne hello@spacegroup.co.uk
Maureen Ball	Community Centre Warden at Wellbeck Green, Walker, Newcastle
Janice Farrell	Community Centre Warden at Kingston & Monkchester Green, Walker, Newcastle
Prof Jane Entwistle	Northumbria University Jane.entwistle@northumbria.ac.uk

Appendix 2 – Public involvement in protocol development, PIL and PCF

How the public have been involved in developing this proposal.

The indoor AQ investigation methods, questionnaire, informed consent, and monitoring equipment choice have been directly informed by several rounds of interaction with a consumer panel and a community group (drawn from a similar geographical location and socioeconomic group to our target population). Activities were supported through a Public Involvement Fund (award rds3897) from the Research Design Service North-East and Cumbria.

As a result of our public involvement work we built-in considerations to reduce reporting bias (e.g. completing the online questionnaire as a conversation with a researcher or community research champion; providing a set of answer options to choose from; providing images). We also reduced the range of activities required. The community highlighted the benefits of working with someone already trusted by the community.

Following a monitoring trial of indoor AQ with two households, amendments were made to:

- the range of parameters monitored; reduced to minimise the number of units required per household and replacement of noisy monitors
- allow remote access to the data enabling collection of baseline data with minimum disturbance to participants
- separate out a shorter period of indoor AQ reporting (requiring a household activity diary; completion of an activity diary reduced considerably after 3 days, and information about activity in kitchens was not as consistent as that for living areas), from a longer period of baseline data collection
- the indoor AQ feedback report for each household with a need to continue to modify the household feedback report with input from members of the study cohort
- our inclusion criteria. Some families were not eligible to participate, due to exclusion of smokers; indoor smoking creates such high concentrations of PM indoors that it masks other sources. If we are unable to recruit 30 households in a sufficient timescale, we will remove this blanket barrier to smokers but request they refrain from smoking indoors, or near outdoor AQ monitor. We will ask for a record to be kept of any deviations to this request.
- our informed consent procedure. This now requires a researcher to visit the home to deliver the informed consent process, guide location and set up of environmental monitoring equipment (ensure data is logging), and for the researcher to complete the online survey with the household and enter responses into a laptop in real time during the home visit, instead of completing the questionnaire by hand and transferring the data into an electronic format later, or online remotely by the participant.
- the location of air quality instrumentation during the extended period (1-3 months) of sampling. The instrumentation may interfere with the occupant's daily activities during that period and requires a power supply. As a result, compensation for households of up to £80 was agreed (£20 for the drop off/installation and collection of survey data (potentially for 2-3 hours), in addition to a monthly compensation of £20 (up to 3 months of payments)
- include a member of the community group on the Study Steering Committee.



In2Air: Measuring indoor air quality, energy use and residents' wellbeing before (and after) energy efficiency renovation works

Participant Consent Form

I have read and understood the information for participants in the In2Air research project of Northumbria University, a project in collaboration with Newcastle City Council and Newcastle University. I understand that this research will explore how home energy efficiency modifications affect indoor air quality, energy use and the general health and wellbeing of the study participants.

The study has been explained to me by

Name:

I understand that taking part is voluntary and that I can change my mind at any time without giving any reason, without penalty

☐

I understand that the information I provide will be treated with the strictest confidence and stored securely.

☐

I am aware I will be asked to provide the following:

- Survey responses (including questions on my general health and wellbeing)
- Gas and electricity bills
- Access to gas and electricity meters

☐
☐
☐

I consent to the collection of indoor air quality data in my home

☐

I agree to E-meter energy usage research equipment being installed and operated in my home for 12 months

yes	no	n/a
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

I agree that all these data will be stored in an anonymised form at Northumbria University and will be used for further related research

☐

The Data Protection Officer for Northumbria University is Duncan James.

If you have any questions which you feel have not been covered by the Participant Information Leaflet, or if you have concerns or a complaint in relation to the University processing your personal data, please do not hesitate to email us at: dp.officer@northumbria.ac.uk. If your request is urgent, please call 0191 243 7357.

I have also received a copy of the In2Air Research Participant Privacy Notice

☐

I would like to be informed of the research findings for my home

☐

Please provide the email or postal address where you would like the results sent to

.....

I agree to take part in the study.

☐

Signed:

Name:

Date:

I confirm that the above person has received the participant information leaflet about the In2Air study. I have explained the nature of the study and allowed an opportunity to ask questions about the study.

Signed:

Name:

Date:



(PCF v1.2)



In2Air: Measuring indoor air quality, energy use and residents' wellbeing before (and after) energy efficiency renovation works

Participant Information Leaflet

We are inviting you to take part in a study to help explore how home energy efficiency modifications affect indoor air quality and energy use. Before deciding whether to participate, here is some information about the project and what you would be asked to do if you take part.

Why are we doing this study?

The UK Government has set challenging targets to reduce our production of greenhouse gases (the 'net-zero' challenge) as these gases cause the planet to warm and drive climate change. Homes play a large part in greenhouse gas emissions and in response, housing providers are making changes to homes to reduce household energy use. Local Authorities and private homeowners around the UK are adding extra insulation, reducing draughts and adding solar panels to make homes more energy efficient. We want to find out if these changes alter the amount of fresh air in the home or the health and wellbeing of residents.

We want to measure energy use, small inhalable particles, temperature, humidity and fresh air in bungalows in the Green Estate before the energy efficiency building works are carried out. Technology is now available that can do this with small, quiet monitors..

What will you be asked to do?

If you decide to take part in the study, your participation will involve the following:

1. Placing a small, quiet, air quality monitor in your living room and another outside your home. The monitors will record the very small (inhalable) particles in air, ventilation, temperature and humidity in the room. You will be able to view the measurements on its screen. The sensors will be left in place for at least 4 weeks, ideally longer, or until your retrofit works begin whichever is sooner.
2. Allow the researcher to see your energy bills for the previous 12 months.
3. Allow the researcher to read your gas and electricity meters at the start and end of your monitoring period.
4. Help us complete a survey about your health and wellbeing and about your home and things that affect what we are monitoring, like the number of people, their activities, ventilation, if you have damp problems and items in your home that may use lots of energy.

Who can take part?

Anyone living in a bungalow in the Green Estate, Walker, who will be having energy efficiency retrofit works on their home can participate. For households where someone smokes indoors, if the smoker agrees to smoke outside during the study, then the household can take part.

How will we process the data obtained from you?

Your questionnaire answers, activity records and air data will be stored in anonymised form on the password protected secure private network of Northumbria University. It will only be accessed by researchers working directly on this project.

If you do not want to continue participating in this research, what should you do?

You can change your mind and exit the study at any time without giving a reason. If you withdraw from the study, we will process the data according to your wishes, either retain, or delete it from our records. However, please note it is not possible to delete anonymised data once published (see below for further details).

What will happen to the results of the research and how will my confidentiality be protected?

Your personal information will be stored on a password protected secure private network at Northumbria University and will only be accessed by researchers working directly on this project. We will write up the findings of this study to share with all interested parties, however your information will not be identifiable (you will remain anonymous). If you would like, we will also provide you with a summary of the findings and your air quality data.

What are the possible benefits and disadvantages to taking part?

There are no expected disadvantages from taking part in this study. You will be reimbursed up to £80 for running the air quality monitor and for your time answering the questionnaires and completing the diary. We provide you with updates and you will gain understanding of activities that impact your home's indoor air quality.

Who is organising this research and what if there is a problem?

The research is being undertaken by Northumbria University, Newcastle University and Newcastle City Council. The work is led by Professor Jane Entwistle and Dr Richard McNally. If you have any questions, you can contact Lindsay Bramwell or Jane Entwistle on 0191 2273768 or ee.in2air@northumbria.ac.uk who will do their best to answer your questions.

You might also like to**Know more about how much different appliances in your house cost to run**

We are looking for two homes that would like to know more about their day-to-day energy use. We have equipment that can measure detailed energy use. The kit is small and would not be intrusive. If you would like to find out more about this, please contact Lindsay Bramwell on 0191 2273768 or ee.in2air@northumbria.ac.uk

Help us to design the study

We are looking for two Green Estate residents to join the Community Steering Committee to help us plan community activities and to make sure we target any of the community's worries and interests around air quality and fuel efficiency. If you would like to find out more about this role, please contact Lindsay Bramwell on 0191 2273768 or ee.in2air@northumbria.ac.uk

Appendix 3. Documentation amendment history

Ethical approval for the study has been granted (30/08/2022) from Northumbria University REC (submission reference 51426) based on draft protocol v0.2.

A record of changes made relative to the previous protocol are listed in the table below.

Protocol Amendment History

Amendment No.	[new] Protocol version no.	Date of update issued to REC committee	Author(s) of changes	Details of changes made
1	V1.0		Entwistle	<p>Updates to project flow chart (noting the one week activity diary is optional)</p> <p>Edits to energy paragraph to read: The study will use multiple approaches and data sources to monitor, assess and quantify domestic energy consumption (DEC). 1) a walk-through Level 1 Energy Audit will be conducted to identify the various household energy uses [27] and up to 12-months gas and electricity bills will be reviewed for each home to understand energy usage patterns and seasonal variation, 2) higher resolution data will be extracted and used for the analysis if the home has a smart meter installed. 3) To establish a baseline energy consumption for the selected bungalow archetype, a separate short-term (3 - 6 months) monitoring study for electricity and gas using energy data loggers and heat meters will be conducted on a limited number of homes. Here, data will be logged live and at short-intervals allowing us to create daily, weekly and monthly profiles of energy use. Energy monitoring will continue for a longer period to establish a 12-month DEC in compliance with the Department of Energy Measurement and Verification Protocol [28,29] and to capture the energy use for similar period to be used in the follow-up (post-intervention) study. Our approach undertaken for monitoring of DEC is available in SI-</p> <p>Updates to PIL and consent form</p> <p>Update to inclusion protocol to remove requirement for gas cooker as all homes on the estate have electric hob/ovens and minimum age to 55 rather than 65.</p> <p>Updates to the Community Steering Committee and Study Steering Committee membership</p>
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The following Supplementary Information (SI) files are associated with this protocol:

SI-1: Detailed approach undertaken for monitoring domestic air quality

SI-2: Auditing and monitoring domestic energy consumption

SI-3: Survey questions

SI-4: Data Management Plan

Ethical approval for the study has been granted (30/08/2022) from Northumbria University REC (submission reference 51426) based on draft protocol v0.2. A record of changes made relative to the finalised version of each SI (v1.0) are listed in the table below.

Supplementary Information Amendment History

Amendment No.	[new] SI version no.	Date of update issued to REC committee	Author(s) of changes	Details of changes made
1				
2				
3				
4				
5				
6				