ISRCTN52814289 https://doi.org/10.1186/ISRCTN52814289

# Family research of microbes linked to respiratory infections

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 16/09/2020 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 24/09/2020 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 23/03/2021 | Respiratory | [ ] Record updated in last year |

## Plain English summary of protocol

Background and study aims
This study aims to learn more about how healthy adults and children are protected, or not, against respiratory infections. Many children and adults carry bacteria in their noses and mouth. We constantly share these bacteria with our family members. The types and numbers of bacteria we carry change with our age and lifestyle habits. This change makes some people sharing households more likely to get a respiratory infection. It is hoped that in this study, by studying bacteria in the nose and mouth of family members and how different factors influence their change over time, this information can be used to better prevent and treat respiratory infections in the future.

The study team has developed an easy to use a sampling technique to self-collect saliva and fluid close to the lining of the nose at home. The study aims to find out if it is practical for families to collect these samples at home.

Who can participate?
Families of 4 members, with two adults aged 18-60 years, and two children aged 28 days-17 years, who are generally healthy.

What does the study involve?
A trained clinician will show participants how to collect samples of fluid from inside the nose, a small amount of saliva, and hand swabs, from both themselves and their children. Families will be then asked to collect samples themselves at home every 2 weeks for 6 months for all participating members.

What are the possible benefits and risks of participating?
While this study will not benefit families directly, it may help us to understand more about how healthy people are protected from respiratory infections to help us to prevent these in the future. We do not expect any discomfort as sampling techniques are not invasive. Eyes may sometimes water after placing the paper strip in the nose.

Where is the study run from?
Liverpool School of Tropical Medicine (UK) and Alder Hey Children's NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
From May 2020 to August 2021

Who is funding the study?
The Liverpool School of Tropical Medicine (UK)

Who is the main contact?
Dr Elissavet Nikolaou
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# Contact information

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Public

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# Additional identifiers

### Integrated Research Application System (IRAS)
284708

# Study information

### Scientific Title
Establishment of home sampling as a surveillance tool for understanding the role of the human oral and nasal microbiota in respiratory disease

### Acronym
FAMILY MICRO

### Study objectives
1. Home sampling is an effective and community acceptable methodology for sampling children and their family members long-term
2. The microbiome plays an important role in respiratory disease occurrence and transmission within household members

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 11/09/2020, North West - Greater Manchester West Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048384; gmwest.rec@hra.nhs.uk), ref: 20/NW/0304

### Primary study design
Observational

### Study design
Single-centre observational cross-sectional cohort study

### Study type(s)
Diagnostic

### Health condition(s) or problem(s) studied
Understanding respiratory disease occurrence and transmission in households of healthy participants

### Interventions
Adult participants will collect non-invasive mucosal samples from themselves and their children at home every 2 weeks for 6 months.

Participants will fill in questionnaires on demographics and epidemiological data at baseline, questionnaires describing practicality at each study day after sample collection, and keep a monthly diary of routine activities/habits.

Formative qualitative semi-structured interviews will be conducted at the end of the study, exploring the acceptability of the procedures.

### Intervention Type
Other

### Primary outcome(s)
1. Feasibility determined by the percentage (%) compliance measured as the number of samples stored in the fridge/freezer per volunteer to the total number of participants, where samples are collected every 2 weeks between baseline and 6 months
2. Acceptability determined by the percentage (%) long-term acceptability measured using the practicality questionnaire to the total number of participants, where the questionnaire is completed every 2 weeks between baseline and 6 months

### Key secondary outcome(s)
1. Microbiome taxonomic profiles will be generated by metagenomic 16S rRNA amplicon sequencing using Illumina technology of mucosal samples collected every 2 weeks between baseline and 6 months
2. Virome will be determined by multiplex qPCR of mucosal samples collected every 2 weeks between baseline and 6 months
3. Presence of AMR genes will be elucidated by conventional PCR of mucosal samples collected every 2 weeks between baseline and 6 months
4. Data will be related to epidemiological information and episodes of respiratory tract infection collected by epidemiological questionnaires completed by participants every 2 weeks between baseline and 6 months

### Completion date
31/08/2021

## Eligibility

### Key inclusion criteria
1. Adults aged 18-60 years and their children aged 28 days–17 years
2. Parent with fluent spoken English - to ensure a comprehensive understanding of the research project and the proposed involvement
3. Capacity of the parent to give informed consent

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Mixed

### Upper age limit
60 Years

### Sex
All

### Total final enrolment
160

### Key exclusion criteria
1. Taking daily medications that may affect the microbiome e.g. long-term antibiotics or immunosuppressants (including oral steroids)
2. Having received immunosuppressants or antibiotics in the preceding 28 days (recruitment can be delayed until the 28 days have passed)
3. History of respiratory infections requiring hospitalisation
4. Involved in a CTIMP or any trial that can affect the microbiome.
5. Disease or syndrome associated with altered immunity or altered respiratory or gut microbiome (including Crohn’s disease, ulcerative colitis or diabetes, and asthma or COPD) or other RTI conditions (including cystic fibrosis or bronchiectasis)
6. Current severe acute respiratory infection
7. Children with cognitive disabilities that lead to an inability to comply with study sampling

### Date of first enrolment
01/10/2020

### Date of final enrolment
28/02/2021

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Liverpool School of Tropical Medicine**
Liverpool Life Sciences Accelerator Building
1 Daulby Street
Liverpool
United Kingdom
L7 8XZ

### Study participating centre
**Alder Hey Children's NHS Foundation Trust**
East Prescot Rd
Liverpool

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# Sponsor information

**Organisation**
Liverpool School of Tropical Medicine

# Funder(s)

**Funder type**
University/education

**Funder Name**
Liverpool School of Tropical Medicine

**Alternative Name(s)**
LSTM

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
United Kingdom

# Results and Publications

**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

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | version v3.0 | 18/09/2020 | 08/10/2020 | No | Yes |

| | | | | | |
|---|---|---|---|---|---|
| Participant information sheet | version v2.0 | 04/09/2020 | 08/10/2020 | No | Yes |
| Participant information sheet | version v3.0 | 18/09/2020 | 08/10/2020 | No | Yes |