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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?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
284708

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design
Single-centre observational cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home

Study type(s)
Diagnostic

Participant information sheet
See additional files

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 measure
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

Secondary outcome measures
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

Overall study start date
01/05/2020

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

Age group
Mixed

Upper age limit
60 Years

Sex
Both

Target number of participants
We aim to recruit 32 families of 4 members so in total 128 participants (64 parents and 64 children). To account for dropouts or inadequate samples, this target will be adjusted to a maximum of 40 families (32 more participants, maximum 160 participants).

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
England

United Kingdom

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
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Sponsor information

Organisation
Liverpool School of Tropical Medicine

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Sponsor type
Charity

Website
http://www.lstmed.ac.uk

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

Publication and dissemination plan
We will produce a lay report of our findings, which will be made available to all participants on the LSTM website. The findings from this study will be shared among the scientific community by publishing our findings in peer-reviewed open-access scientific journals and presenting data at appropriate local, national and international conferences.

Intention to publish date
01/01/2022

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?
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
HRA research summary			28/06/2023	No	No