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Testing an artificial intelligence tool to reduce the spread of airborne infections in hospitals

Submission date
23/10/2025

Recruitment status
Recruiting

Registration date
19/11/2025

Overall study status
Ongoing

Last Edited
19/11/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
The Air Safety programme research team has developed an Artificial Intelligence air Safety Tool (AISaT): a computer software that guides users on how to best reduce airborne infection risks in hospitals, using cheap solutions like air filters, fans and screens. Clinical trials are a key part of the programme to assess the effectiveness of AISaT recommendations and to demonstrate reduced infection risks. This study aims to assess the effectiveness of AISaT recommendations in outpatient, day-case rooms, and wards to reduce risks of airborne disease transmission.

Who can participate?
Clinicians working at relevant clinical testing environments: outpatient clinic rooms, Aerosol Generating Procedure (AGP) rooms and hospital ward bays. All patients (and accompanying persons) attending those relevant clinical testing environments.

What does the study involve?
A small aerosol-producing device(s) will be installed within the room to generate saline aerosol droplets, and air particle counters (APCs) will be installed next to participating clinicians to measure the primary outcome, which is the average number of aerosol droplets per minute per clinical encounter as measured by an air particle counter. There will also be questionnaires and interviews.

What are the possible benefits and risks of participating?
Benefits:
Participants may benefit from improved air quality in clinical spaces due to the implementation of AISaT mitigation strategies. These strategies aim to reduce airborne particles and improve ventilation, potentially lowering the risk of exposure to airborne infections.

Risks:
The known and potential risks include trip hazards in all study stages when air safety mitigation devices are placed in unsuitable places when following the AISaT guidance, for example, in the middle of the floor, with leading wires left uncovered.

Where is the study run from?
University College London, UK.

When is the study starting and how long is it expected to run for?
January 2026 to September 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?
Laurence Lovat, l.lovat@ucl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Prof Laurence Lovat

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Additional identifiers

Integrated Research Application System (IRAS)
353916

National Institute for Health and Care Research (NIHR)
205439

Central Portfolio Management System (CPMS)
67415

Study information

Scientific Title
Assessing effectiveness of Artificial Intelligence air Safety Tool (AISaT) recommendations in outpatient, day-case rooms, and wards to reduce risks of airborne disease transmission

Acronym

AISaT

Study objectives
These trials are to investigate:

A) Whether placing mitigations for airborne disease transmission according to the recommendations of the AISaT software tool reduces airborne disease transmission risks in outpatient consulting rooms, aerosol-generating procedure rooms and hospital wards.

B) Whether it is feasible to implement these mitigations at different hospital sites (and identify any variation in implementation).

C) Whether patients and hospital staff find the AISaT recommendations acceptable

Primary Objective: To determine in hospital consulting rooms, aerosol generating procedure rooms and wards, when using mitigations for airborne disease transmission according to recommendations of the AISaT software tool, the reduction in the relative number of airborne aerosol droplets per standard time period breathed by any staff member present compared to when no mitigations are used or when mitigations are used as decided by the clinician using the relevant space.
Outcome Measure: Number of aerosol droplets on average per minute per clinical encounter as measured by an air particle counter (APC) installed next to the clinician and at up to 4 other fixed locations in the room or ward bay.

Secondary Objective: Mixed methods evaluation of staff experiences of using the tool and the mitigation approaches that are recommended (based on analysis of acceptability by staff and feasibility of implementation).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/08/2025, East Midlands – Leicester Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8118; leicestercentral.rec@hra.nhs.uk), ref: 25/EM/0156

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Crossover

Purpose
Health services research, Prevention, Screening

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Airborne disease transmission in hospitals

Interventions
The Air Safety programme research team has developed an Artificial Intelligence Air Safety Tool (AISaT) - a computer software that guides users on how to reduce airborne infection risks in hospitals using cost-effective solutions like air filters, fans, and screens.

The research programme will investigate whether AISaT works, is acceptable, and cost-effective. Two clinical trials will be run in two hospitals:
University College London Hospital (UCLH), London
Lister Hospital, Stevenage (East and North Hertfordshire NHS Trust)

Study Process in Chronological Order:
Initially, clinicians at both sites will be identified, screened and invited to participate in the study. Obstetric, psychiatric and paediatric clinical areas will be excluded. If they consent, they will then be asked some demographic questions as stipulated in the protocol (activity level of participants, sex, age to nearest decade, approximate height and weight, ethnicity, history of respiratory difficulties). Appropriate weekly clinics run by the participant clinician will then be identified as the dates that the study team will attend and run the study.

This will take place over 3 consecutive weeks. Clinicians will be randomly assigned to one of three room configurations:
Configuration 1 - AISaT will be turned on, and air safety measures (air filters, fans, screens) will be implemented.
Configuration 2 - AISaT will be turned off completely with no extra air quality safety measures.
Configuration 3 - Air quality safety measures will be offered to the clinician to use and place as they see fit.

Patients due to have an appointment with an enrolled clinician on the clinic day will be screened (the only exclusion criterion is that they cannot be under 18 years old). Information leaflets will be sent to all eligible patients attending relevant clinics by post or email at least 24 hours before they attend for their appointments. Potential participants will then be approached by a member of the research team on the day that they attend to sign a consent form. If patients have an accompanying person attending their appointment with them, they will also need to be consented before the appointment. After consenting, the patient and accompanying persons will also complete the demographic questions. Patients and accompanying persons will not be randomised.

The consultation will then take place exactly the same as it would have as normal. The only difference is that the room will have been set up with some equipment in it depending on which configuration the clinician was assigned to. This includes air particle counters next to the clinician and up to 4 other fixed locations in the room, a device used for the Al software 'AISaT' (laptop or tablet), a small aerosol-producing device (emitting small aerolised droplets of saline, which is salt water), air filter(s) and an infrared camera to generate heat maps of the room. The

air particle counters will measure the primary outcome, which is the average number of aerosol droplets per minute per clinical encounter.

The clinical trials will assess AISaT's effectiveness following the above process in three settings:
1. Outpatient consulting rooms
2. Aerosol-generating procedure rooms (such as endoscopy suites)
3. Wards

Alongside the clinical trials, qualitative implementation research will also be conducted, which will involve exploring issues such as usability and acceptability of the AISaT tool with key stakeholders (such as patients, clinicians and estates staff). The research will explore how a successful AISaT tool would be implemented and identify barriers to implementation. A subset of these participants will be invited to take part in the implementation research (e.g. clinicians, patients and estates staff). There are separate optional consenting processes for each of the following: ethnography research (staff only), usability testing (staff and patients), questionnaires and interviews (staff and patients). Please see the uploaded topic guides for interviews, as well as the Normalisation MeAsure Development (NoMAD) questionnaire.

Any personal data collected as part of the qualitative evaluation will be stored in a data safe haven, a technical solution for storing, handling and analysing identifiable data. The UCL Data Safe Haven has been certified to the ISO27001 information security standard and conforms to NHS Digital's Information Governance Toolkit. For the Air Safety NIHR programme, it has been contractually agreed that UCL will own IP.

Data will be transferred from UCLH to UCL, as well as from East and North Hertfordshire NHS Trust to UCL. Personalised data will be identifiable and stored in UCL Data Safe Haven. The data controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk. The data processor is University College London and East and North Hertfordshire NHS Trust (for Lister Hospital). The data custodian is Professor Ramani Moonesinghe, Professor of Perioperative Medicine at UCL and Chief Investigator of the Central London Patient Safety Research Collaborative.

Intervention Type
Drug/Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Artificial Intelligence Air Safety Tool (AISaT)

Primary outcome(s)
Number of aerosol droplets on average per minute per clinical encounter measured using an air particle counter (APC) installed next to the clinician and at up to 4 other fixed locations in the room or ward bay at each of the sessions over the 3-week intervention period

Key secondary outcome(s))
1. Implementation processes are measured using the Normalisation Measure Development Questionnaire (NoMAD), collected at one time point alongside the clinical trial
2. Hospital staff views on the importance of AISaT, usability and management of the AISaT

software, challenges to fidelity in implementation, and how team members can work together effectively to support implementation are measured using ethnographic observation and formal and informal interviews. These will take place across each site, in both pilot and main trial phases, and in each of the three trial settings at one time point alongside the clinical trial
3. Cost efficiency of AISaT is measured using resource use collected as an outcome, to which cost estimates are applied. The resource use measures are defined in the protocol and include inputs including size of the room, number of beds/patients seen, training, clinical, engineering and other staff and costs of the AI system; as well as outputs with regard to droplets removed. The unit of analysis is the service, not the patient, and data collection occurs during each session over the 3-week intervention period, consistent with the timepoints used for droplet measurement.

Completion date
27/09/2027

Eligibility

Key inclusion criteria
1. Clinicians working at relevant clinical testing environments (1st trial outpatient clinic room, 2nd trial AGP room, 3rd trial ward bay)
2. All patients (and accompanying persons) attending those relevant clinical testing environments
3. The mixed method evaluation may include people working in estates teams, hospital managers and other healthcare staff.

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Obstetric, psychiatric and paediatric clinical areas will be excluded, to minimise the risks of ethical complications involving children, pregnant women or patients with psychiatric illnesses that may have difficulty consenting
2. People under the age of 18 years old

Date of first enrolment
05/01/2026

Date of final enrolment
27/07/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
England
NW1 2PG

Study participating centre
East and North Hertfordshire Teaching NHS Trust
Lister Hospital
Coreys Mill Lane
Stevenage
England
SG1 4AB

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Chief Investigator Professor Laurence Lovat, email: l.lovat@ucl.ac.uk.

1. The type of data that will be shared
The study will be collecting the following personal data, which will be collected directly from participants and from the medical records of patient participants: activity level of participants, sex, age, height, weight, ethnicity, and history of respiratory difficulties. The Case Report Forms (CRFs) will also include the participant's initials and trial identification number. For all subsequent analyses, pseudo-anonymised data will be used.

2. Timing for availability
Data will be stored for the time recommended by UCL for non-interventional clinical trials used in regulatory submissions, as it is conceivable that a regulatory submission could develop following this work. This is set at 10 years.

3. Whether consent from participants was required and obtained
This will be clearly explained in the participant information sheet (PIS). Participant consent for this will be sought.

4. Comments on data anonymization
For all subsequent analyses, pseudo-anonymised data will be used. The data and the linking code

will be maintained securely in separate locations using encrypted digital files within password-protected folders and storage media. Identifiable data will not be transferred outside the study team or outside UCL.

5. Any ethical or legal restrictions
The study will be compliant with the requirements of the General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018). All Investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regard to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles.

6. Any additional comments
UCL is the data controller; the UCL Data Protection Officer is data-protection@ucl.ac.uk. The data processor is University College London and East and North Hertfordshire NHS Trust (for Lister Hospital). The data custodian is Professor Ramani Moonesinghe, Professor of Perioperative Medicine at UCL and Chief Investigator of the Central London Patient Safety Research Collaborative. Data access will be limited to the minimum number of individuals necessary for quality control, audit and analysis. Participants will have provided informed consent for their anonymised data to be used in future ethically approved research. All shared data will be fully de-identified in accordance with GDPR and UCL data protection policies. Access will be granted only to researchers with appropriate ethical approval and data sharing agreements in place. There are no known legal or ethical restrictions beyond those described above.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	17/07/2025	05/11/2025	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file	Study website	17/07/2025	05/11/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes