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The safety and performance of an automated robotic system (DAISY) for the triage and assessment of acutely unwell patients in an Emergency Department

Submission date 30/10/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 13/11/2024	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 20/08/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Long waits in Emergency Departments have put a strain on staff and systems. DAISY aims to collect, organise and perform the initial analysis of patients to free up staff and reduce waiting times. The study will investigate patients' acceptability of DAISY and its ability to process undifferentiated clinical symptoms. It will also assess the DAISY consultation process looking at timelines, patient engagement and satisfaction and the concordance of the report generated from DAISY.

Who can participate?
Patients who self-present to the Emergency Department with acute clinical needs, male or female, aged 18 years old and above, able-bodied and can give informed consent.

What does the study involve?
Adults who present to the Emergency Department will be invited to participate in the use of an automated triage process while they await the regular human triage personnel. Potential participants may be primarily identified by the reception staff, after which they undergo an initial screening by a member of the investigating team who consents to the patient for the study according to the protocol specifications. The participants will then interact with DAISY to complete a consultation, after which an anonymised report is generated as the initial CRF. The participant returns to their original position in the traditional triage queue without an advantage or disadvantage in the 'time-to-see' a clinician. Their return signifies the end of their active participation in the trial. Participants are expected to spend less than 30 minutes for the automated consultation. They may choose to discontinue their engagement with the study at any point during the process.

What are the possible benefits and risks of participating?
Benefits – No direct benefits for patients taking part as the study is investigating the benefit of using DAISY in the future.

Risks – The blood pressure cuff may become quite tight on the participant's arm, in the event this happens, a research staff member present will help release the pressure.

Where is the study run from?
In the A&E department at Scarborough Hospital, which is part of York and Scarborough Teaching Hospitals NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
April 2024 to March 2026

Who is funding the study?
The Elsie May Sykes Funding Award, York & Scarborough Hospitals Charity

Who is the main contact?
Dr Deborah Phillips, yhs-tr.research.enquiries@nhs.net

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
343550

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 63764, Engineering and Physical Sciences Research Council (EPSRC) Grant Code: TAS_PP_00125

Study information

Scientific Title
Diagnostic AI System for robotic and automated triage and asses

Acronym
DAISY

Study objectives
The DAISY system is acceptable to patients in the ED as a form of triage and assessment.

The primary objective is to investigate patients' acceptability of the DAISY system as it performs a Triage and Assessment process on ED patients with undifferentiated clinical symptoms.

The secondary objectives are to assess the duration of interaction and timeliness of the DAISY consultation process, patient engagement and satisfaction with the automated process and the concordance of the generated report with the clinician's documented opinion.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/07/2024, Yorkshire & The Humber – Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0) 2071048083; Bradfordleeds.rec@hra.nhs.uk), ref: 24/YH/0138

Study design
Non-randomized cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Using a diagnostic AI system for robotic and automated triage and assessment

Interventions
This is a single-site feasibility study to assess patient acceptability of DAISY, a humanoid robot to be used for triage and assessment during their visit to the ED (Emergency Department). 100 patients who attend the ED at Scarborough General Hospital with acute clinical needs will be approached to enter the study. Patients will meet the eligibility criteria noted in the study protocol. The study will have a timeline of 5 months and there will be no interim analysis. Statistical analysis will follow as per plan. Patient and Public involvement has taken place to inform the study generation and design. The study will be conducted adhering to GCP, approval guidance and local R&D standard operating procedures. All research personnel will have valid GCP training dated within 3 years. All safety events occurring during the study observed by the investigator and Interaction Observer, or reported by the participant, whether or not attributed to the system devices under investigation will be recorded as per R&D Standard Operating Procedures. These will be reviewed twice per week. All study data will be entered into a secure database that is validated according to the hospital Trust's local Research and Development Standard Operating Protocols. The participants will only be identified by a study-specific participant number and/or code in any database.

Potential participants may be primarily identified by the reception staff who will provide them with the Patient Information Sheet. Patients will then undergo initial screening by a member of the research team who will complete taking patient consent into the study. Patients may participate either before or after they have been assessed by the Triage Nurse. Patients will then begin their interaction with DAISY which should take no longer than 30 minutes and will take place in a private cubicle. There will be an Interaction Observer from the research team in the cubicle with the patient but they will not intervene unless requested by the patient. The patient may have a carer or relative with them to support and assist as needed. To begin with, the patient will enter their symptoms via a touch screen on DAISY. This is a silent process and will use the English language. DAISY will then direct the patient to use the devices provided in the cubicle to record their temperature, blood pressure, respiratory rate, heart rate and oxygen saturation. All devices will be CE-marked and calibrated as per local procedures. Once complete the patient will be presented with a short questionnaire of 5 questions to assess their satisfaction with the DAISY consultation. They will then return to their place in the usual ED triage queue without advantage or disadvantage in their waiting time. DAISY will then generate an anonymised report using the information input by the patient. This will be considered the Case Report Form (CRF) for the patient for data collection purposes. The Interaction Observer will also complete a short questionnaire about patient engagement. Patients who do not complete the above activity will still be included in the final data analysis unless they express their wishes not to be. If a patient is called by triage during their research activity then the interaction observer will alert the patient who can then choose whether to continue with the

research activity or whether to terminate this and see the nurse/clinician who was calling them. If the patient continues with the research activity they will be seen by the nurse/clinician immediately after their interaction.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The generation of a ‘Triage and Assessment’ report by the DAISY process measured using data collected in the primary case report form (CRF) at the time of conclusion of the patient consultation

Secondary outcome measures
The completion of a survey document by the participant that assesses their engagement and satisfaction with the DAISY process. In addition, an ‘Interaction Observer’ member of the investigating team will be present during the patient-DAISY interaction, and they will complete a short questionnaire on patient engagement. Both are completed at the time of the conclusion of the patient consultation.

Overall study start date
16/04/2024

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male, Female or Other, aged 18 years or above, pregnant or otherwise
3. Able (in the investigator's opinion) and willing to comply with all study requirements
4. Able to engage or operate the automated system, either unaided or with help from own carers

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 150; UK Sample Size: 150

Key exclusion criteria
1. Patients less than 18 years of age
2. Decreased consciousness and/or affect
3. Patients in need of urgent transfer to the resuscitation area
4. Deemed unsuitable or too unwell by the recruiting investigator

Date of first enrolment
21/02/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Scarborough Hospital
Woodlands Drive
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United Kingdom
YO12 6QL

Sponsor information

Organisation
York and Scarborough Teaching Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.yorkhospitals.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
York & Scarborough Hospitals Charity

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/06/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to associated Intellectual Property.

IPD sharing plan summary
Not expected to be made available