ISRCTN11298549 https://doi.org/10.1186/ISRCTN11298549

Home monitoring for acutely unwell patients being managed at home as part of a virual ward care pathway: a feasibility study

Submission date 20/11/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/02/2024	**Overall study status** Ongoing	
Last Edited 27/01/2025	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
The Oxford University Hospital (OUH) acute hospital-at-home service cares for patients in their own homes. The VIABLE study will use vital-sign monitoring devices that automatically transmit patient measurements to the hospital. Here, the measurements can be reviewed by the responsible clinicians via a digital dashboard. The VIABLE study will check that data collected via the monitoring system is efficient and accurate. The study will assess whether blood pressure monitoring and thermometer use (which can be difficult for patients to manage by themselves) are feasible in this potentially frail and elderly cohort. The study will also confirm that all the equipment is not intrusive and is easy to use. Clinical staff will be invited to contribute to the refinement of the clinical dashboard to ensure it is helpful for remotely evaluating the patient's status and is easy to use. This feasibility study will inform the design of a future trial of the monitoring system. This trial will test whether monitoring using the remote system reduces the number of home visits required, improves the scheduling of home visits when they are needed, and reduces the need for further hospital assessments when compared to current care protocols.

Who can participate?
Patients with an acute illness (such as breathlessness or an acute infection) aged 18 years old and over

What does the study involve?
The VIABLE feasibility study will look at 35 patients using the remote vital sign monitoring platform whilst admitted to the acute hospital-at-home service. This will include a pulse oximeter to measure blood oxygen levels and a vital-sign chest patch that will measure pulse and breathing rate. Each patient will also be provided with a blood pressure monitor and a thermometer. Patients taking part in the study will have an acute illness (such as breathlessness or an acute infection) and will have been assigned ongoing care via the virtual ward. Participants will be asked to complete a short interview about their experiences at the end of their study period. They will also be asked to provide permission to link their study data to selected data from the OUH data warehouse.

What are the possible benefits and risks of participating?
Participating patients may benefit from the increased monitoring as their caring clinicians may be more aware of their condition and response to treatments due to the monitoring data being presented on the digital clinicians' dashboard. This could lead to an improved quality of care and more efficient and informed visits from their healthcare professionals over the course of their time on the virtual ward. As usual care will continue for all participants the risks of participating are minimal. There is the possibility of some discomfort caused by the blood pressure monitor when taking readings or of minor skin irritation by the vital-sign chest patch.

Where is the study run from?
The University of Oxford (UK)

When is the study starting and how long is it expected to run for?
May 2023 to September 2025

Who is funding the study?
NIHR Oxford Biomedical Research Centre (UK)

Who is the main contact?
Prof Andrew Farmer, andrew.farmer@phc.ox.ac.uk (UK)

Study website
https://www.phc.ox.ac.uk/research/DLTC/studies/viable

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
325766

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 325766

Study information

Scientific Title
Remote monitoring in virtual wards for acutely unwell patients being managed and treated on an ambulatory care pathway: feasibility study

Acronym
VIABLE

Study objectives
It is feasible to remotely monitor NHS virtual ward patients in their own home.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/07/2023, London - Camden & Kings Cross Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048086; CamdenandKingsCross.REC@hra.nhs.uk), ref: 23/LO/0559

Study design
Non-interventional feasibility study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Home, Hospital

Study type(s)
Other

Participant information sheet
Patient information material can be found at: https://www.phc.ox.ac.uk/research/DLTC/studies/viable

Health condition(s) or problem(s) studied

Acutely unwell patients receiving care from the Oxford University Hospital (OUH) acute hospital-at-home services

Interventions
Participants will be provided with the VIABLE monitoring system which consists of an adhesive chest patch that will collect vital signs data (e.g. heart rate), and a pulse oximeter; both devices relay data continuously to a tablet computer that transfers data to a clinician's dashboard. Participants will also be provided with a blood pressure monitor and an in-ear thermometer and will be asked to take regular measurements with these devices and record these in a participant diary.

Intervention Type
Other

Primary outcome measure
Feasibility of continuous remote vital-sign monitoring measured using data coverage (data received remotely on each day of virtual ward care) including reliable heart rate in any 4-hour sliding window and reliable blood oxygen level (SpO2) received in any 12-hour sliding window over the monitoring period.

Secondary outcome measures
1. To test the acceptability of remote vital-sign monitoring participants will be asked to complete a Technology Assessment Questionnaire 1 - 4 weeks after the end of monitoring
2. To determine the feasibility of intermittent blood pressure and temperature monitoring, the proportion of individuals able to place monitors, activate measurements and then provide data during the monitoring period will be analysed.
3. Collect clinical data using the VIABLE system over the course of the monitoring period to determine the optimal combination of vital sign data and frequency of review required to monitor acute virtual ward patients remotely.
4. Collect clinical data using the VIABLE system over the course of the monitoring period to refine threshold limits for safety, changes in clinical treatment and prioritisation for review as presented on the clinical dashboard.
5. Collect clinical data from the Oxford University Hospital (OUH) Clinical Data Warehouse approximately 6 months after the end of the monitoring period to develop clinically appropriate outcome measures for further evaluation.
6. Collect clinical data from the OUH Clinical Data Warehouse approximately 6 months after the end of the monitoring period to link to vital-sign data to demonstrate the feasibility of data linkage for refining clinical prediction rules.

Overall study start date
01/05/2023

Completion date
01/09/2025

Eligibility

Key inclusion criteria
1. The AAU clinical team has determined it is clinically appropriate to manage the patient at home and the patient will be admitted to the Hospital at Home virtual ward

2. Acutely ill (a deterioration in health that has taken place over days or weeks) and assessed as requiring diagnostic tests and treatments including the following interventions (oxygen, fluids, diuretics, intravenous antibiotics) that can be delivered at home.
3. Assessed as having at least one of the following diagnoses (multiple acute problems may present together):
3.1. Lowerrespiratorytractinfection
3.2. Cellulitis
3.3. Urinary tract infection
3.4. Systemic evidence of acute infection but unclear primary source of infection
3.5. Acute Kidney Injury due to dehydration, infection, medication, or heart failure
3.6. Heart failure with acute fluid overload
4. Willing and able to go home with a skin contact vital-sign monitoring system (chest patch)
5. Resides within the area served by an acute hospital at-home service
6. Participant is EITHER:
6.1. Willing and able to give informed consent for participation in the study, OR
6.2. Favourable consultee advice is provided for those lacking capacity
7. Male or Female aged 18 years or above

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
35

Total final enrolment
29

Key exclusion criteria
1. The research team is not satisfied that remote monitoring can be safely established in the patient’s home
2. Pregnancy
3. Unable to comply with the study procedures
4. The mobile phone network at the patient’s residence is unsuitable for safe and effective monitoring

Date of first enrolment
05/12/2023

Date of final enrolment
03/11/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Governance, Ethics and Assurance Joint Research Office
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Sponsor type
University/education

Website
https://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

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

Intention to publish date
01/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the VIABLE study are not expected to be made available due to this being a small feasibility study with a small patient cohort.

IPD sharing plan summary
Not expected to be made available