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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/11/2023		Protocol		
Registration date	Overall study status Completed Condition category Signs and Symptoms	Statistical analysis plan		
12/02/2024		Results		
Last Edited		Individual participant data		
03/09/2025		[X] Record updated in last year		

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)

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Prof Andrew Farmer

ORCID ID

https://orcid.org/0000-0002-6170-4402

Contact details

Gibson Building
1st Floor
Radcliffe Observatory Quarter
Woodstock Road
Oxford
United Kingdom
OX2 6GG
+44 (0)1865 617942
andrew.farmer@phc.ox.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

325766

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

Health condition(s) or problem(s) studied

Acutely unwell patients receiving care from the Oxford University Hospital (OUH) acute hospitalat-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(s)

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.

Key secondary outcome(s))

- 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.

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre Oxford University Hospitals

John Radcliffe Hospital Headley Way Headington Oxford United Kingdom OX3 9DU

Sponsor information

Organisation

University of Oxford

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, OxfordBRC, OxBRC

Funding Body Type

Private sector organisation

Funding Body Subtype

Research institutes and centers

Location

United Kingdom

Results and Publications

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

Study outputs

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