

Investigating digital follow-up monitoring for long-term stable blood conditions

Submission date 02/08/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/09/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/10/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This is an investigation into a new way of keeping in touch with patients with long-term stable blood conditions. Currently, these patients have to attend a clinic (in person or by telephone) every 6 months to check for any changes in their condition, which imposes on their routines and takes up valuable time for doctors and nurses. Instead, we will invite these patients to download a new app, which they can use to track their condition, view blood test results, and report any new symptoms for review by a clinician.

Who can participate?

This study is open to patients with eight different blood conditions in long-term stable follow-up and under the care of a participating Trust. These conditions are: chronic lymphocytic leukemia (CLL), haemochromatosis, iron-deficient anaemia, myelodysplastic syndromes (MDS), monoclonal gammopathy of uncertain significance (MGUS), smouldering/asymptomatic myeloma, sickle cell disease (SCD), Waldenstrom's macroglobulinemia.

What does the study involve?

This study is broken into several Arms. Some of these Arms use only existing patient information, gathered as retrospective anonymised data, or only recruit clinical staff, in order to include doctors' and nurses' perspectives. Those Arms that include patients are Arm 1 and Arm 5. In Arm 1, patients are recruited to participate in focus groups, interviews, and User Experience Testing, in order to help design the Ascelus app. Arm 5 will involve a large number of patients downloading the app to track their condition over the course of a year. The researchers will gather safety information from these patients directly via the app, and will also use the app to send them surveys and questionnaires regarding their quality of life and healthcare resource utilisation during the 12 months.

What are the possible benefits and risks of participating?

The benefits and risks of participation differ between Arms 1 and 5. For patients participating in Arm 1, the benefits will include space to think about existing follow-up processes, and how these could be different; there are very few risks, although participation will involve dedicating some time to the discussion. For patients participating in Arm 5, it is hoped that the Ascelus app will save time, provide reassurance through blood test reviews, and facilitate ease of reporting

new symptoms. This arm will also involve making time available for questionnaires and focus groups, and there is a small additional risk that standard of care will be impacted should the app prove difficult to use. Because both Arms involve the collection of data, there are risks around the security of data storage. However, the researchers have made every effort to minimise these risks – no one outside of their existing care team will access participants' confidential records, and all new records created will be anonymous, so they cannot be identified from them.

Where is the study run from?

King's College Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

April 2022 to April 2024

Who is funding the study?

Itecho Health (UK)

Who is the main contact?

Samiha Tahsin

Contact information

Type(s)

Principal Investigator

Contact name

Dr Reuben Benjamin

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

301109

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 301109, CPMS 55852

Study information

Scientific Title

A multi-centre investigation of the use of a digital follow-up pathway utilising the Ascelus app for monitoring long-term blood conditions, incorporating patient, carer, and healthcare professionals co-design and evaluation, clinical validation, and safety investigations

Acronym

Ascelus-H

Study objectives

This is a multi-centre prospective observational study of patients with long-term haematological conditions on a new digital follow-up pathway utilising the Ascelus platform. We are exploring this digital follow-up pathway as a means of better prioritising clinic time (both face-to-face and telephone/virtual) whilst giving long-term stable patients a less invasive means of tracking and reporting their condition.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 02/08/2022, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Newcastle Upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8141; leedswest.rec@hra.nhs.uk), ref: 22/YH/0149

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital, Other

Study type(s)

Quality of life, Safety, Efficacy

Participant information sheet

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

Health condition(s) or problem(s) studied

Chronic lymphocytic leukemia (CLL), haemochromatosis, iron-deficient anaemia, myelodysplastic syndromes (MDS), monoclonal gammopathy of uncertain significance (MGUS), smouldering /asymptomatic myeloma, sickle cell disease (SCD), Waldenstrom's macroglobulinemia

Interventions

This study has five arms:

Arm 1 – Patient and carer co-design, collecting qualitative data on patient satisfaction and empowerment on follow-up pathways, via focus groups and individual interviews

Arm 2 – Healthcare professionals co-design and feedback, collecting qualitative data on healthcare professionals' views and feedback on the digital follow-up pathways, via focus groups and interviews

Arm 3 – Key Opinion Leader (KOL) interviews, investigating issues of implementation, scalability, and commercialisation in the app design phase and in the post-implementation review phase

Arm 4 – Retrospective clinical review of patients on face-to-face, telephone, and virtual follow-up pathways in the 12 months prior to digital pathway commencement, and at 6 and 12 months post-implementation, collecting data on patient safety and outcome measures

Arm 5 – Patient group on the new digital pathway, participating in outcome, quality of life, and patient empowerment data collection measures (questionnaires, interviews, and data gathered from existing patient records)

Arms 1, 2, and 3 are qualitative co-design and implementation feasibility studies, utilising focus groups and individual interviews alongside User Experience testing (eye-tracking tests of the Ascelus app). An interpretative approach will determine patients', carers' and clinicians' perspectives to inform analysis. User experience testing will proceed with data analysis of participant laboratory sessions from the eye-tracking software used in each of the sessions.

Arm 4 is a retrospective clinical review of patients from relevant disease groups on existing face-to-face, telephone, and virtual follow-up pathways in the 12 months prior to digital pathway commencement. Quantitative measures of clinical safety and patient satisfaction will be gathered via a review of routine data gathered by existing Trust mechanisms (e.g. complaint reporting).

Arm 5 is the app users quality of life cohort. Participants will complete outcome, quality of life, and patient empowerment data collection measures (questionnaires, interviews, and data gathered from existing patient records).

Intervention Type

Other

Primary outcome measure

Patient satisfaction, empowerment, and quality of life on a new digital follow-up pathway, using EQ5D and PAM-13 questionnaires at baseline, 6, and 12 months following enrolment, alongside focus groups and interviews at 6 months following enrolment

Secondary outcome measures

1. Safety of the digital follow-up pathway, using progression and adverse incident data taken from clinical records. This will be measured retrospectively for the cohort in the 6 months prior to enrolment, and at 6 and 12 months following enrolment
2. Cost-effectiveness of the digital follow-up pathway when compared to face-to-face and telephone appointments, using a detailed Healthcare Resource Utilisation survey taken at baseline, 6, and 12 months following enrolment
3. Healthcare professionals' satisfaction with the digital follow-up pathway, using clinician focus groups prior to app implementation and at 6 months following patient enrolment

Overall study start date

01/04/2022

Completion date

01/04/2024

Eligibility

Key inclusion criteria

Inclusion for Arm 1:

Patient/carers with a relevant condition at a participating Trust

Inclusion for Arm 2:

Healthcare professionals or other healthcare professional in relevant discipline

Inclusion for Arm 3:

Healthcare professional in a relevant discipline or with a relevant special interest

Inclusion for Arm 4:

1. Diagnosis with a relevant stable condition
2. 16 years of age or older at the start date for data collection
3. Under the care of a participating Trust

Inclusion criteria for Arm 5:

1. Diagnosis with a relevant stable condition
2. 16 years of age or older at the study start
3. Under the care of a participating Trust
4. Able to access and use the Ascelus platform

Participant type(s)

Patient, Health professional, Carer

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

2440

Key exclusion criteria

Exclusion for Arms 1 - 4:

None

Exclusion for Arm 5:

Presence of co-morbidities that would require regular review in the clinic

Date of first enrolment

01/09/2022

Date of final enrolment

01/02/2024

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

King's College Hospital NHS Foundation Trust

Denmark Hill

London

United Kingdom

SE5 9RS

Study participating centre

Sheffield Teaching Hospitals NHS Foundation Trust

Northern General Hospital

Herries Road

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S5 7AU

Sponsor information

Organisation

King's College Hospital

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Sponsor type

Hospital/treatment centre

Website

<https://www.kch.nhs.uk/>

ROR

<https://ror.org/044nptt90>

Funder(s)

Funder type

Industry

Funder Name

Itecho Health

Results and Publications

Publication and dissemination plan

The patient studies to which this protocol applies are part of an overall project supported by the NIHR Invention for Innovation (i4i) Challenge scheme. This is a translational research funding scheme, only available to SMEs as lead investigators, aimed at de-risking early-to-late stage medical devices, in vitro diagnostics and high-impact patient-focused digital health technologies for ultimate NHS use. As such, it is recognised that ownership of the data rests with the lead SME (Itecho Health Ltd) and that there may be confidentiality and commercial issues, which can only be properly judged by Itecho Health Ltd, which will make the final judgement on the timing and nature of the dissemination and publication processes.

Nevertheless, the importance of publication and dissemination is fully recognised. The success of the clinical study depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated in the study, through authorship and contributorship. Uniform requirements for authorship for manuscripts submitted to medical journals will guide authorship decisions. These state that authorship credit should be based only on substantial contribution to:

1. Conception and design, or acquisition of data, or analysis and interpretation of data
2. Drafting the article or revising it critically for important intellectual content
3. Final approval of the version to be published.

To accompany this policy the collaborators are developing a publication and dissemination strategy as a way to optimise opportunities to publish data and share learning from the project, which is consistent with NIHR priorities.

Intention to publish date

01/04/2025

Individual participant data (IPD) sharing plan

The datasets gathered during the current study are not expected to be made available, due to the consent conditions that the patients have agreed to.

IPD sharing plan summary

Not expected to be made available