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

Submission date
02/08/2023

Recruitment status
No longer recruiting

Registration date
11/09/2023

Overall study status
Completed

Last Edited
04/10/2023

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
301109

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Quality of life, Safety, Efficacy

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(s)
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

Key secondary outcome(s))
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

Completion date
01/04/2024

Eligibility

Key inclusion criteria
Inclusion for Arm 1:
Patient/carer 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

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
United Kingdom

England

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
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
King's College Hospital

ROR
https://ror.org/044nptt90

Funder(s)

Funder type
Industry

Funder Name
Itecho Health

Results and Publications

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