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Designing and testing a digital tool to gather self-reported information from blood cancer patients about their health after CAR-T cell therapy

Submission date
11/10/2023

Recruitment status
No longer recruiting

Registration date
27/10/2023

Overall study status
Ongoing

Last Edited
16/06/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chimeric Antigen Receptor T-cell (CAR-T) therapy is a new approach to cancer treatment in which the body's own immune cells, which fight infection, are used to recognise and kill off cancer cells. CAR-T therapy is promising but the side effects of treatment can be serious. Early detection of CAR-T side effects is important so people can receive the medicines they need to help treat them. One way of monitoring the effects of treatment is by using patient-reported outcomes (or 'PROs') which involve patients filling out questionnaires to record their symptoms and feeding back the questionnaire results to their healthcare team. Collecting PROs can be done using paper questionnaires but increasingly PROs are completed electronically, using handheld devices such as a patient's own smartphone or tablet. Digital tools to assess CAR-T patients' symptoms are not yet widely available.

This study will develop and feasibility test a new digital system to collect patient-reported symptoms and quality of life data from CAR-T patients to facilitate clinical intervention and promote patient safety.

Who can participate?
CAR-T patients aged 18 years or older, their family/carers, healthcare professionals with experience of CAR-T therapy.

What does the study involve?
We will work with patients, their family members and carers, healthcare professionals, researchers, and other stakeholders to co-design the digital system. We will review the literature to identify what symptom data should be collected and map these to existing, validated questionnaires. Through meetings with interested parties, we will reach a consensus on the design of the digital system (including symptoms to be measured, questionnaire selection, timing/frequency of questionnaire completion, and alert functionality). We will test the digital system's usability before deploying it in a clinical setting to assess its feasibility. We

will ask patients to complete questionnaires using the digital system before, during, and for 12 months after receiving CAR-T cell therapy. A qualitative sub-study (interviews) will explore patients’ and healthcare professionals’ experiences of using the digital system.

What are the possible benefits and risks of participating?
We want to understand patients', their family members' and other stakeholders' views on the design of a new app to collect self-reported information on symptoms and side effects after CAR-T cell therapy. Patients and their families may benefit from sharing their experiences with other patients. In the longer term, the new app will help improve patient care. Answering questions about health and experiences of treatment can sometimes be difficult for some people but there are no risks from taking part in this study.
No risks.

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

When is the study starting and how long is it expected to run for?
April 2022 to March 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
320036

Central Portfolio Management System (CPMS)
57797

National Institute for Health and Care Research (NIHR)
203339

Study information

Scientific Title
Development and feasibility testing of a digital platform to capture patient-reported outcomes (PROs) for CAR-T precision cellular therapies: A multiphase, mixed-methods study (The PRO-CAR-T™ Study)

Acronym
PRO-CAR-T™

Study objectives
To develop a new digital platform to capture patient-reported outcomes (PROs) for remote monitoring of symptoms, side effects and health-related quality of life in patients with haematological malignancies receiving CAR-T cellular therapies and assess its feasibility for use in the UK's National Health Service (NHS).

The key objectives are:
• To develop a conceptual framework for measurement that will underpin the PRO-CAR-T digital system.
• To identify and shortlist candidate patient-reported outcome measures (PROMs) and map

these to the digital system’s conceptual framework
• To select, through a consensus-building process with stakeholders, the PROMs for inclusion in the digital platform.
• To identify items in the included PROMs measuring symptoms/constructs of clinical concern requiring notifications to the clinical team through system alerts.
• To understand stakeholder needs in relation to PRO-based alert management within routine CAR-T care and to co-develop the alert functionality for the digital platform.
• To test usability of the new digital system to ensure the platform is effective, efficient and perceived as satisfactory by end users.
• To assess feasibility and acceptability of the new digital system to capture PROs within a routine CAR-T clinical setting.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/09/2023, Health and Social Care Research Ethics Committee B (HSC REC B) (Office for Research Ethics Committees Northern Ireland (ORECNI) Lissue Industrial Estate, 5 Rathdown Walk, Lisburn, BT28 2RF, United Kingdom; +44 28 95 361400; Info.orecni@hscni.net), ref: 23/NI /0104

Primary study design
Interventional

Study design
Interventional non-randomized

Study type(s)
Treatment, Safety

Health condition(s) or problem(s) studied
Large B-cell lymphoma or acute lymphoblastic leukaemia

Interventions
This study is comprised of three phases or work packages (WP). In WP1 we will design the PRO-CAR-T™ digital system. In WP2 we will work with Aparito Limited, a medical technology company, to build the digital system and test how easy it is for patients and healthcare professionals to use(a process called usability testing). In WP3 we will deploy the tool in an NHS CAR-T center to assess its feasibility for use in routine clinical practice.

WP1: Intervention development
We will invite CAR-T patients, their family members and carers, healthcare professionals, and other interested groups (policy-makers, regulators, and industry representatives) to take part in a series of workshops to co-design the PRO-CAR-T™ digital system. These workshops will include a Delphi review and
consensus workshop to select the PRO instruments to include, a co-design workshop to specify system requirements for the PRO-CAR-T™ digital system and to explore barriers and facilitators to implementation, and a consensus workshop to specify symptoms and side effects requiring clinical alerts and to design the PRO-CAR-T™ system's alert functionality.
Patient participants and their family members/carers will be recruited from an NHS CAR-T centre, known contacts (snowballing), and local patient and public involvement/support groups.

Other groups will be recruited through known contacts (snowballing), research networks, and professional groups. Those individuals expressing an interest in participating in the workshops will be given or sent the relevant Participant Information Sheet electronically or by post prior to each workshop. In addition, the research team will explain the purpose of the research, the format of the workshop, and invite participants to ask questions. Participants must provide their informed consent prior to each workshop. The format of each workshop will vary slightly depending on the workshop aim and will include a combination of pre-workshop online surveys, presentations from the research team, discussions, design-focussed group activities, and voting /use of polls to establish consensus.

WP2: PRO-CAR-T™ system build and usability testing
Usability testing of the PRO-CAR-T™ digital system will involve CAR-T patients and healthcare professionals. Patient participants will be recruited from an NHS cellular therapy centre, known contacts (snowballing), and patient and public involvement/support groups. Healthcare professionals will be clinicians working at NHS cellular therapy centres. Patients will be asked to download and onboard onto the Atom5™ app to view the digital solution. They will be asked to perform a series of tasks, including completing the questionnaires and navigating around the app. After completing the tasks, they will take part in a cognitive debriefing interview where they will be asked to provide their views on the digital system and complete a questionnaire on usability called the System Usability Scale (SUS). Healthcare professionals will be asked to log on to the clinician dashboard and perform a series of tasks. After completing the tasks, they will take part in a cognitive debriefing interview where they will be asked to provide their views on the digital system and complete a questionnaire on usability called the System Usability Scale (SUS). All usability testing will take place in the Atom5™ test environment.

WP3: Feasibility study
This feasibility study is a single-site study. We will invite patients who meet the national candidacy criteria for CAR-T cell therapy and who have not yet received their CAR-T cell infusion to take part. Those patients who express an interest in taking part will be provided with a Participant Information Sheet and given the opportunity to ask any questions. Patients who consent to take part in the study will be asked to download the Atom5™ app and complete the questionnaires pre-infusion (baseline), on the day of infusion (Day 0), and at pre-specified intervals for 12 months. We will invite study participants and patients who withdraw from the study to take part in an interview to explore their experiences of using the digital solution during their treatment, and, if relevant, their reasons for withdrawal.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Chimeric Antigen Receptor T-cell (CAR-T) therapy

Primary outcome(s)
1. Recruitment: Number and proportion (%) of eligible patients who consent to take part.
2. Retention: Number and proportion of patients who complete the 12-month PRO assessment.
3. Adherence: Number of proportion of patients completing the PRO assessment.
4. Number of clinical alerts and number and proportion of patients reporting clinical alerts.
5. Number and proportion of patients who withdraw formally from the study and their reasons

for withdrawal.
6. Actions arising from alerts including number and proportion of patients attending clinic, hospitalisation following clinical alert reporting, estimated time between alert and response by clinical team.
7. Number of ad hoc PRO assessments completed and the number and proportion of patients submitting ad hoc PRO assessments.
8. Acceptability of the digital tool will be measured using the Feasibility of Intervention Measure (FIM) and Acceptability of Intervention Measure (AIM) at 3-month, 6-months, and 12-months post-infusion.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/03/2027

Eligibility

Key inclusion criteria
WP1: Intervention development
Individuals able to provide informed consent who have an interest in patient-reported, digital symptom monitoring for CAR-T cell therapies, including:
1. CAR-T patients (aged 18 years or older)
2. Their family members/carers
3. Healthcare professionals
4. Academic researchers
5. Policymakers/commissioners
6. Industry representatives
7. Regulators

WP2: Usability testing
1. CAR-T patients aged 18 years or older, able to provide informed consent, and willing to use the PRO-CAR-T™ digital system to report their symptoms.
2. Healthcare professionals who are members of a CAR-T clinical team in the NHS.

WP3: Feasibility study
1. CAR-T patients who are aged 18 years or older with a diagnosis of large B-cell lymphoma or acute lymphoblastic leukaemia (adults aged 18-25 years), are eligible for CAR-T cell therapy, and able to provide informed consent.
2. Healthcare professionals who are members of the patient’s clinical team with a delegated duty to monitor patients' symptom and side effects reports submitted via the PRO-CAR-T™ digital system.

NB.: Participants who do not have a good understanding of English will not be excluded from the study and the use of translators/interpreters will be encouraged.

Participant type(s)
Patient, Health professional, Carer, Employee

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
WP1: Intervention development
1. Individuals unable/unwilling to provide informed consent.
2. Individuals < 18 years of age.
3. Patients who are not candidates for/recipients of CAR-T cellular therapies.
4. Individuals without relevant expertise of CAR-T cellular therapies.
5. Individuals unwilling/unable to undertake the protocol activities.
6. Individuals deemed appropriate for exclusion by their CAR-T clinical team (i.e., on a palliative care pathway)

WP2: Usability testing
1. Individuals unable/unwilling to provide informed consent.
2. Individuals < 18 years of age.
3. Patients who are not candidates for/recipients of CAR-T cellular therapies.
4. Patients deemed appropriate for exclusion by their CAR-T clinical team (i.e., on a palliative care pathway).
5. Healthcare professionals without relevant expertise in CAR-T cellular therapies.
6. Individuals unwilling/unable to undertake the protocol activities.

WP3: Feasibility study
1. Individuals unable/unwilling to provide informed consent.
2. Individuals < 18 years of age.
3. Individuals without relevant expertise of CAR-T cellular therapies.
4. Individuals unwilling/unable to undertake the protocol activities.

Date of first enrolment
13/11/2023

Date of final enrolment
25/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
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Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Consensus building process to select PRO measures for inclusion in the PRO-CAR-T ePRO system	28/05/2025	16/06/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes