

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 Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/10/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/06/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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?

Professor Melanie Calvert

Dr Sarah Hughes

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Study website

<https://www.rdm.ox.ac.uk/about/our-clinical-facilities-and-mrc-units/nihr-btru-in-precision-cellular-therapeutics>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

320036

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 57797, NIHR203339, IRAS 320036

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

Study design

Interventional non-randomized

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment, Safety

Participant information sheet

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

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

Pharmaceutical study type(s)

Therapy

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Chimeric Antigen Receptor T-cell (CAR-T) therapy

Primary outcome measure

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 and 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.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/04/2022

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 150; UK Sample Size: 150

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

England

United Kingdom

Study participating centre

University Hospitals Birmingham NHS Foundation Trust

Queen Elizabeth Hospital

Mindelsohn Way

Edgbaston

Birmingham

United Kingdom

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Sponsor information

Organisation

University of Birmingham

Sponsor details

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researchgovernance@contacts.bham.ac.uk

Sponsor type

University/education

Website

http://www.birmingham.ac.uk/index.aspx

ROR

https://ror.org/03angcq70

Funder(s)

Funder type

Government

Funder Name

NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/03/2028

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