

# Feasibility of TRAK to support physio in anterior cruciate ligament rehabilitation

<b>Submission date</b> 22/07/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/07/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/08/2023	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Rupture of the anterior cruciate ligament (ACL) is common, especially in the active population. In defining the problem of ACL rehabilitation, this study draws from the knowledge that improved self-care, strength, and fitness are associated with better outcomes. Traditional rehabilitation involves regular physiotherapy but there is much variation in how services are provided. Additionally, current rehabilitation models in the National Health Service (NHS) struggle with catering to large volumes of patients and the lengthy time span over which rehabilitation is delivered. The use of eHealth (the Internet in health care) has been successful at delivering behaviour change to a number of diverse patient groups. In physiotherapy, problems such as exercise compliance, exercise technique, and managing a broad program of rehabilitation and advice can be challenging. An eHealth intervention called TRAK to support self-management and behaviour change has been developed by patients and clinicians as a tool to support ACL rehabilitation with personalized plans, prompts, and logs to help adherence and videos and instructions to improve quality and address queries. The patients have their own logins and can email their physiotherapist through the website. Patients' exercise programs and duration of treatment are still based on individual needs, but use of the website may offer improved self-management and function and reduced health resource use. This is a feasibility study to establish recruitment, retention, sample size estimates, and practicality of collecting outcome measures to inform a future trial comparing the TRAK intervention, which has been rigorously designed to address the challenges of ACL rehabilitation, to usual care. The study will provide essential information to support the development and powering of a future clinical trial of eHealth and physiotherapy for patients with ACL reconstruction in the NHS.

### Who can participate?

Patients immediately after undergoing ACL reconstruction

### What does the study involve?

Participants are randomly allocated to either treatment as usual or treatment as usual plus the TRAK website. Both groups receive the usual care for their hospital trust. The TRAK group are able to monitor the exercises on the website, log their progress, and receive prompts and

reminders about their exercises. Their physiotherapist regularly updates their exercise plan on TRAK when they attend the class. All participants are assessed at the start of the study and after 3 and 6 months.

What are the possible benefits and risks of participating?

The benefits of taking part include opportunity to access the TRAK intervention which was designed with patients and physiotherapists to support improved self-management in ACL care. There are no identifiable risks as treatment takes place alongside usual care.

Where is the study run from?

1. Homerton University Hospital NHS Foundation Trust (UK)
2. Guy's and St Thomas' NHS Foundation Trust (UK)

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

January 2016 to June 2020

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Emma Dunphy  
emma.dunphy@nhs.net

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Emma Dunphy

### Contact details

Physiotherapy Department  
Homerton Hospital  
Homerton Row

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United Kingdom

E3 4RT

+44 (0)2085107835

emma.dunphy@ucl.ac.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

## Study information

### Scientific Title

Testing the feasibility of TRAK, an eHealth intervention to support physiotherapy rehabilitation for patients following anterior cruciate ligament reconstructive surgery

### Study objectives

Rupture of the anterior cruciate ligament (ACL) is common, especially in the active population. In defining the problem of ACL rehabilitation, this study draws from the knowledge that improved self-care, strength, and fitness are associated with better outcomes. Traditional rehabilitation involves regular physiotherapy but there is much variation in how services are provided. Additionally, current rehabilitation models in the National Health Service (NHS) struggle with catering to large volumes of patients and the lengthy time span over which rehabilitation is delivered.

The use of eHealth (the Internet in health care) has been successful at delivering behaviour change to a number of diverse patient groups. In physiotherapy, problems such as exercise compliance, exercise technique, and managing a broad program of rehabilitation and advice can be challenging. An eHealth intervention called TRAK to support self-management and behaviour change has been developed by patients and clinicians as a tool to support ACL rehabilitation with personalized plans, prompts, and logs to help adherence and videos and instructions to improve quality and address queries. The patients have their own log-ins and can email their physiotherapist through the website. Patients' exercise programs and duration of treatment are still based on individual needs, but use of the website may offer improved self-management when they are doing their rehabilitation programme in between appointments.

This is a feasibility study to establish recruitment, retention, sample size estimates, and practicality of collecting outcome measures to inform a future trial comparing the TRAK intervention, which has been rigorously designed to address the challenges of ACL rehabilitation, to usual care. The study will provide essential information to support the development and powering of a future clinical trial of eHealth and physiotherapy for patients with ACL reconstruction in the NHS.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 19/03/2018, London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, Barlow House 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; Tel: +44 (0)207 104 8002; Email: nrescommittee.london-bloomsbury@nhs.net), ref: 18/LO/0403

### Study design

Randomised; Both; Design type: Treatment, Process of Care, Education or Self-Management, Physical, Rehabilitation, Qualitative

### Primary study design

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Rupture of the anterior cruciate ligament

## **Interventions**

This study will use convergent parallel mixed methods where both qualitative and quantitative types are important for thorough understanding of the objectives and where qualitative data may help to interpret quantitative data.

Consent will be obtained and recorded by the research assistant and the principal investigator. The study involves patients submitting to the randomisation process and then being allocated to either treatment as usual or treatment as usual plus the TRAK website. Randomisation is used at the advice of the clinical trials unit to avoid bias in the selection and to assess whether it is possible to recruit to both arms of the study; usual care and usual care plus TRAK.

Both groups will receive the usual care for their hospital trust. The TRAK group will be able to monitor the exercises on the website, log their progress and receive prompts and reminders about their exercises. Their physiotherapist will regularly update their exercise plan on TRAK when they attend the class.

All study participants will be asked to complete outcome measures at baseline and 3 months and 6 months. Outcome measures will be taken by the physiotherapy research assistant who is not directly involved in treatment of the patients or in this study.

The study will attempt to recruit participants from the ACL rehabilitation pathway at two North London NHS Hospitals. It explores patient acceptance of the randomisation process and of the burden of participation in a study such as submitting to demography profiling, outcome collection, attending training sessions and committing to use the intervention as well as submitting to interviews.

The feasibility trial is supported by the clinical trials unit at UCL with dedicated support from a statistician and qualitative expert as well as a health economist. These CTU members along with the PI and supervisors will make up the trial steering committee.

Collecting information for an economic evaluation as part of research is important for informing policy. The economic evaluation will assess the feasibility of collecting EQ-5D-5L which would be used to calculate QALY's in a full trial and on health care resource use and both arms of the study. Descriptive statistics and data completeness for 'health care resource use' questionnaires will be reported. Methods, ease and data completeness of collecting number and duration of physiotherapy appointments will be a particular focus of the work. This work will be supervised by a Clinical Trial Unit Health Economist who will inform the standard practice of the feasibility trial including shaping of ideas, preparation and procedure throughout the trial. They will influence how data is captured and reported and provide guidance on how to deal with uncertainty in the data.

Semi-structured interviews will be conducted with patients, physiotherapists and service providers on their experiences of using TRAK. A schedule of questions will be used to provide an

in-depth understanding of the user perspective of TRAK the intervention and the participation burden of the study that may have implications for a future trial. Conversations will be taped, transcribed verbatim and analysed using a thematic analysis.

## **Intervention Type**

Other

## **Primary outcome(s)**

1. Recruitment measured by number of eligible patients who consent to participate from 16/07/2018 until 31/03/2019, and submitted to baseline measures and randomisation
2. Retention measured by number of patients still in trial and consenting to outcomes at 3 and 6 months after recruitment date
3. Feasibility of collecting outcomes measured by collecting outcomes relevant for a future trial at baseline, 3 and 6 months
4. Feasibility of collecting strength outcome measured by submitting patient to leg symmetry testing at 3 and 6 months

## **Key secondary outcome(s)**

1. Usage of the intervention is measured by number of logins, number of pages visited and number of videos watched at 3 and 6 months
2. Knee function measured by KOOS (knee injury & osteoarthritis outcome score) at baseline, 3 months and 6 months
3. Health resource use measured by CSRI at baseline, 3 and 6 months
4. Self-efficacy measured by Stanford self-efficacy questionnaire at baseline, 3 and 6 months
5. Quality of life years calculated by EQ5D5L measured at baseline, 3 and 6 months
6. Health economic data collected by WPAI (work productivity and activity impairment questionnaire: general health) measured at baseline, 3 and 6 months

## **Completion date**

30/06/2020

# **Eligibility**

## **Key inclusion criteria**

1. Adults immediately post ACL reconstruction
2. Referred to a structured NHS rehabilitation programme
3. Be able to read and write English to engage with learning materials on TRAK
4. Be able to give written informed consent themselves
5. Have access to the internet at home or on their phone

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Adult

## **Sex**

All

### **Key exclusion criteria**

1. Individuals with complex co-morbidities or surgeries such as multi-ligament reconstruction or fracture
2. Lack of internet or smart phone access
3. Unable to read and write English

### **Date of first enrolment**

16/07/2018

### **Date of final enrolment**

31/03/2019

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

**Homerton University Hospital NHS Foundation Trust**

Homerton Row

London

United Kingdom

E9 6SR

### **Study participating centre**

**Guy's and St Thomas' NHS Foundation Trust**

Trust Offices

Guy's Hospital

Great Maze Pond

London

United Kingdom

SE1 9RT

## **Sponsor information**

### **Organisation**

Homerton University Hospital NHS Foundation Trust

**ROR**

## Funder(s)

### Funder type

Government

### Funder Name

NIHR Academy; Grant Codes: ICA-CDRF-2016-02-027

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from

Emma Dunphy ([emma.dunphy@ucl.ac.uk](mailto:emma.dunphy@ucl.ac.uk)) via the UCL data safe haven. Following publication the raw anonymous demographic and feasibility data will be made available to journals, peer reviewers or for further relevant analysis to members of the research team. This is in keeping with the participant information sheet and consent. The terms of the participant consent state that data will not be kept after 15 years. Access must be obtained through application to the UCL data safe haven.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		05/05/2021	18/08/2023	Yes	No
<a href="#">Protocol article</a>	protocol	05/12/2016	24/07/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes