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Feasibility of TRAK to support physio in anterior cruciate ligament rehabilitation

Submission date
22/07/2019

Recruitment status
No longer recruiting

Registration date
24/07/2019

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Study website
http://www.researchprotocols.org/2016/4/e234/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
37879

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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 measure
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

Secondary outcome measures
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

Overall study start date
15/01/2016

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

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
England

United Kingdom

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

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01zpp3d44

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan

1. Peer reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website

The researchers will seek publication of the findings in an appropriate journal and also make them available on the TRAK website so participants can access them. They may use the media or social media such as Twitter to make findings known but this will be done through the NHS communications team.

Intention to publish date
01/10/2020

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) 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?
Protocol article	protocol	05/12/2016	24/07/2019	Yes	No
HRA research summary			28/06/2023	No	No
Results article		05/05/2021	18/08/2023	Yes	No