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Development of a pre-operative care website for patients waiting for total knee replacement surgery – a Virtual Knee School

Submission date
20/04/2020

Recruitment status
No longer recruiting

Registration date
24/04/2020

Overall study status
Completed

Last Edited
25/08/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Total knee replacement (TKR) is a very common operation mainly carried out in older people with knee arthritis. Although TKR surgery is usually successful, around one in six patients are not satisfied with their recovery following TKR surgery. Providing pre-operative care, such as information and exercises, can help patients prepare for TKR surgery and recover better after surgery. However, current pre-operative TKR services vary, do not meet all patients' needs and are expensive to deliver. Providing pre-operative TKR care using a website could help improve this, but existing TKR websites have many limitations. This study aim to address this by developing a new website – the 'Virtual Knee School' (VKS). The VKS will provide pre-operative care for patients waiting for TKR surgery.

Who can participate?
Adults aged at least 18 years old who are waiting for TKR surgery or who have had TKR surgery within the past two years

What does the study involve?
The researchers plan to develop the VKS using fourphases:
Phase 1: Develop an agreed list of recommendations on pre-operative TKR care using an approach known as a Delphi Consensus Technique. This involves a group of patients and professionals completing three online questionnaires
Phase 2: Use interviews and/or group discussions with patients to explore what might encourage patients to use the VKS or prevent them from using it.
Phase 3: Use theory (ideas about what affects people's behaviour) to guide the development of the VKS.
Phase 4: Develop an early version of the VKS based on the findings of Phases 1-3 and use patient feedback to gradually improve it.

The details in this record are for Phases 2-4 because Phase 1 was covered by a separate protocol and ethics application.

What are the possible benefits and risks of participating?
Some participants in this study will be able to try using the VKS. These participants may find that using the VKS helps them prepare for their TKR surgery. However, participants in this study may not gain any direct benefits from taking part. The researchers do not expect there to be any significant risks associated with taking part in this study.

Where is the study run from?
1. Chapel Allerton Hospital (UK)
2. University of Leeds (UK)

When is the study starting and how long is it expected to run for?
June 2019 to January 2022

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

Who is the main contact?
Anna Anderson
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
262809

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 45114, IRAS 262809

Study information

Scientific Title
Development of a pre-operative education and prehabilitation digital intervention for patients awaiting total knee replacement: a Virtual Knee School

Acronym
VKS

Study objectives
Current hypothesis as of 31/08/2021:
This study does not have a formal hypothesis because it is focused on developing a new intervention.

The aim of the study is to develop a pre-operative TKR education and prehabilitation digital intervention, the 'Virtual Knee School' (VKS).

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Previous hypothesis:
This study does not have a formal hypothesis because it is focused on developing a new intervention.

The aim of the study is to develop a pre-operative TKR education and prehabilitation digital intervention, the 'Virtual Knee School' (VKS), and explore its implementation and acceptability amongst patients awaiting TKR.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/04/2020, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048083; bradfordleeds.rec@hra.nhs.uk), REC ref: 20/YH/0095

Study design
Non-randomised; Both; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Rehabilitation, Other, Qualitative

Primary study design
Other

Secondary study design

Study setting(s)

Internet/virtual

Study type(s)
Other

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
Total knee replacement surgery

Interventions
Current intervention as of 31/08/2021:
The Virtual Knee School will be an interactive multimedia website that provides pre-operative care to patients waiting for total knee replacement (TKR) surgery. The Virtual Knee School will be developed during this study. Therefore, it is it is not possible to specify exactly what it will include at this stage. However, it is anticipated it will include pre-operative education, an exercise programme and support with making healthy lifestyle changes.

During Phase 4 of this study, participants will be asked to share their views of the Virtual Knee School through two interviews. During each interview, participants will be asked to work through the Virtual Knee School and say out loud whatever they are thinking. This is known as a 'think aloud interview'.

Previous intervention:
The Virtual Knee School will be an interactive multimedia website that provides pre-operative care to patients waiting for total knee replacement surgery. The Virtual Knee School will be developed during this study. Therefore, it is it is not possible to specify exactly what it will include at this stage. However, it is anticipated it will include pre-operative education, an exercise programme and support with making healthy lifestyle changes.

The researchers will give patients access to the VKS, monitor how they use it for 4 weeks, and explore their views of it using questionnaires and interviews.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 31/08/2021:
This study does not include any primary and secondary outcome measures because it is focused on developing a new intervention.

The majority of the data collected during this study will be qualitative. However, information about participants’ clinical and sociodemographic characteristics will also be collected.

Previous primary outcome measure:
This study does not include any primary and secondary outcome measures because it is focused on developing a new intervention.

The majority of the data collected during this study will be qualitative. However, during Phase 5, information will be collected about: participants' clinical and sociodemographic characteristics, their use of technology, the TKR care they have received, their views of the VKS, their engagement with the VKS and the safety of the VKS, using online questionnaires administered at baseline and 4 weeks. In addition, during Phase 5, data about participants' use of the VKS will be automatically recorded through the VKS.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/06/2019

Completion date
20/01/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 31/08/2021:
1. Adult (aged 18 years old or older)
2. Able to communicate in English
3. Listed for primary TKR at a hospital in the United Kingdom and/or have undergone primary TKR at a hospital in the United Kingdom within the past two years
4. Able to use and have access to the Internet and email (Phase 2 only)
5. Able to use and have access to the Internet and email and/or be willing and able to be interviewed in person (Phase 4 only). Potential participants will be considered able to be interviewed in person if they live in West Yorkshire and meeting in person is permitted by the most up-to-date COVID-19 guidance from the government and University of Leeds.

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Previous inclusion criteria:
Phases 2, 4 and 5:
1. Adult (aged 18 years old or older)
2. Able to communicate in English
3. Able to use and have access to the Internet and email

Phases 2 and 4 only:
1. Listed for primary TKR at a hospital in the United Kingdom or have undergone primary TKR at a hospital in the United Kingdom within the past two years

Phase 5 only:
1. Listed for primary TKR at a hospital in the United Kingdom

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: Approximately 21; UK Sample Size: Approximately 21 (Phases 2 and 4)

Total final enrolment
24

Key exclusion criteria
Current exclusion criteria as of 01/09/2021:
1. Unable to provide informed consent

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Previous exclusion criteria:
Phases 2, 4 and 5:
1. Unable to provide informed consent

Phase 5 only:
1. Currently participating in any other research investigating an intervention(s) delivered in the pre-operative phase of the TKR care pathway

Date of first enrolment
30/04/2020

Date of final enrolment
20/01/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Teaching Hospitals NHS Trust
Chapel Allerton Hospital
Chapeltown Road
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United Kingdom
LS7 4SA

Study participating centre
University of Leeds
Woodhouse Lane
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United Kingdom
LS2 9JT

Sponsor information

Organisation
University of Leeds

Sponsor details
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Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: ICA-CDRF-2018-04-ST2-006

Results and Publications

Publication and dissemination plan
The researchers do not have any plans to make additional documents available.

The dissemination and reporting plans for this study will be finalised with the Project Advisory Group and are anticipated to include:
1. Provision of plain English summaries for participants
2. Presentation(s) to the NIHR Leeds Biomedical Research Centre Patient and Public Involvement group
3. Publication in a peer-reviewed journal(s)
4. Presentation at a professional conference(s)
5. Sharing with professionals, patients and the public through social media
6. Reporting in Anna Anderson's PhD thesis
It is anticipated the final results will be published by June 2023

Intention to publish date
01/06/2023

Individual participant data (IPD) sharing plan
The datasets generated during the current study are not expected to be made available because they will relate to the specific digital intervention being developed and so will not have wider applicability.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	04/08/2021	22/08/2022	No	No
Thesis results		02/12/2022	19/12/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		22/08/2023	25/08/2023	Yes	No