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Using a smartphone to improve recovery and reduce the risk of postoperative pain after major orthopaedic surgery: evaluating the iCanCope Post-Op smartphone app

Submission date
22/02/2022

Recruitment status
No longer recruiting

Registration date
17/05/2022

Overall study status
Completed

Last Edited
22/02/2024

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims

20% of adolescents undergoing surgery will develop chronic postoperative pain. Unrelieved or poorly treated postoperative pain can lead to delayed re-mobilization, increased medication use and reduced health-related quality of life, such as sleep, anxiety, social, and school functioning. Psychological variables have been highlighted as risk factors for reporting acute postoperative pain and interventions that address these variables have proven successful in assisting acute postoperative pain management. Smartphone devices with Internet capabilities may improve pain self-management for adolescents with postoperative pain by improving health self-monitoring in everyday environments (e.g., home, school), promoting appropriate self-care (e.g., taking all required medication, ways to cope with pain) and reducing barriers to optimal pain treatment (e.g., lack of transportation to appointments, access to health care providers). A recent review found that pain self-management apps available at the moment for patients undergoing surgery lacked (i) goal-setting/social support functions; (ii) comprehensive pain self-management content; (iii) scientific evaluation; and (iv) consultation with end-users in app design. No apps in the review were designed for paediatric patients.

To address this problem, this project seeks to develop and determine the feasibility and preliminary effectiveness of iCanCope with Post-Operative Pain (or iCanCope PostOp), a self-management smartphone app that provides remote “just-in-time” evidence-based advice to improve pain management and quality of life for adolescents following surgery.

The iCanCope platform is a Canadian smartphone-based (iOS and Android) self-management app for youth with different types of persistent pain (iCanCope.ca). iCanCope includes the core features of symptom tracking, symptom trends, SMART goal-setting, and a library of pain education and self-management strategies.

The aim of this study is to evaluate the effectiveness of the newly developed iCanCope PostOp smartphone app for reducing preoperative anxiety, improving postoperative pain self-management, reducing the impact of acute postsurgical pain and improving physical and psychological outcomesfor adolescents undergoing limb reconstruction surgery.

Who can participate?
Adolescents aged 12-18 years who will be undergoing limb reconstruction surgery

What does the study involve?
Participants will be put into one of two groups, the intervention group or the control group. As well as receiving their normal medical treatment, the intervention group will use the iCanCope PostOp smartphone app for 4-10 weeks before surgery and 12 weeks after surgery. The control group will not use the app, receiving just their normal medical treatment. All participants will fill out a series of questionnaires at five timepoints across the study. After the study, both groups will be analyzed to see if using the iCanCope PostOp app was effective in reducing preoperative anxiety and the interference of postoperative pain.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in preoperative anxiety and postoperative pain interference. The researchers do not foresee any risks due to taking part in this study.

Where is the study run from?
NUI Galway (Ireland)

When is the study starting and how long is it expected to run for?
October 2017 to December 2023

Who is funding the study?
Health Research Board (Ireland)

Who is the main contact?
Prof. Brian McGuire
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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
Nil known

Study information

Scientific Title
Feasibility and preliminary efficacy study of an online pain management programme for children undergoing major orthopaedic surgery: iCanCope Post-Op Surgery

Acronym
iCC

Study objectives
The iCanCope PostOp smartphone app, app intervention, control and outcomes measures can be implemented as planned (fidelity). The iCanCope PostOp smartphone app can reduce anxiety 1 week before surgery, reduce the impact of acute postoperative pain interference and positively impact other key health outcomes – pain intensity, depression, anxiety, sleep and physical function, overall health and school attendance - for 12-18-year-old patients undergoing surgery for limb reconstruction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 15/10/2019, CHI Crumlin (Cooley Road, Crumlin, Dublin, D12 N512, Ireland; +353 (0) 1 4096100; claire.rice@olchc.ie), ref: GEN/688/18
2. Approved 10/12/2019, CHI Temple Street (Temple Street , Rotunda, Dublin 1, D01 XD99, Ireland; +353 (0)1 8784200; lennonje@tcd.ie), ref: 19.047

3. Approved 27/07/2020, Blackrock Clinic (Rock Road, Intake, Blackrock, Co.Dublin, Ireland; +353 (0)1 2832222; aoife.cooke@blackrock-clinic.com), ref: not applicable
4. Approval pending, National Orthopaedic Hospital Cappagh (Cappagh Road, Cappoge, Dublin 11, D11 EV29, Ireland; +353 (0)1 8140400; Mary.Byrne@nohc.ie), ref: CAPP/2018/ETH/SH-DCEO-232

Study design
Multi-centre parallel-group pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Preoperative anxiety and postoperative pain for adolescents aged 12- 18 years undergoing surgery for limb reconstruction

Interventions
A multi-centre, parallel groups pilot RCT design will be conducted with at least 60 adolescents. Adolescent patients (12-18 years) who are to undergo surgery for limb reconstruction will be recruited:
1. Through NUI Galway, School of Psychology and Centre for Pain Research official websites and social media – Facebook and Twitter - study and research team contact information will be advertised and interested families can make contact
2. Local and national press – e.g. Galway Advertiser, iRadio - study and research team contact information will be advertised and interested families can make contact.
3. From waiting lists of those scheduled to undergo limb reconstruction surgery at a number of collaborating hospitals

Adolescent patients (12-18 years) on waiting lists for limb reconstruction surgery will be screened by the clinical nurse specialist according to the inclusion and exclusion criteria. Eligible patients and their families will be approached by the clinical nurse specialist, informed of the study and asked if their details can be passed on to the research team. The research team will contact interested patients and their families to provide more details of the study and find out whether they would like to take part in the study. If they agree to take part, consent/assent will be obtained. If families do not wish to agree to take part there and then, they will be given the contact details of the research team and can make contact if they wish to take part.

Alternatively, members of the research team will attend the pre-op clinics and eligible patients and their families will be referred to the research team by the clinical nurse specialist, who will explain the study to them in detail. If families agree to take part, consent/assent will be obtained there and then. If families do not wish to agree to take part there and then, they will be given the contact details of the research team and can make contact if they wish to take part. Due to the current COVID-19 restrictions, an optional remote video recruitment meeting - using the WhatsApp platform – is included in the recruitment process. This is to provide a personal introduction to the study in lieu of meeting the family face-to-face.

Patients and their families who agree to take part in the study will receive an app-instructional /use meeting by a member of the research team or an on-site clinician at their pre-op visit or at the pre-op clinic. During this introduction, they will be shown how to use the app and guided through the main functions.
In lieu of being able to carry out this 'app-instructional/use meeting' face-to-face with patients at their pre-op clinic due to COVID-19 restrictions or because no face-to-face contact with participants has occurred (e.g. recruited via social media), a remote video meeting may be set-up to walk patients through app use and explain the main functions of the app. Similar to the remote video recruitment meeting, this will be done via Whatsapp and will only be carried out if an on-site clinician is not able to run through this with patients.

Participants will then be randomized into either a control group or an intervention group. Randomization will be conducted securely online using the REDCap secure web application. Following randomization, participants will be instructed on the procedures to be followed within their assigned study group.

Intervention group:
In addition to receiving treatment as usual, participants in the intervention group will be given the iCanCope PostOp smartphone app to use before and after surgery. Participants will use the app 4-10 weeks preoperatively and 12 weeks postoperatively.

Control group:
Patients in the control group will receive treatment as usual.

Descriptive variables will be collected securely online using the REDCap secure web application via questionnaires including sociodemographic characteristics, surgery-related characteristics, pain-related characteristics; adolescent access, use, and comfort level with smartphones.

Intervention Type
Other

Primary outcome measure
1. Accrual and dropout rates measured using the study enrolment logs throughout the study period, with total rates calculated at study completion
2. Fidelity measured using the study enrolment logs. The researchers will track any technical or other issues with enrolling participants in the study enrolment loss so they can calculate a rate of successful app onboarding, and measure completion. Tracking of this is done throughout the study and rates are calculated at study completion
3. Adolescents' perceptions regarding app acceptability and satisfaction measured using qualitative interviews after the trial has ended
4. App engagement measured for intervention participants only using the analytics dashboard. Specifically, the researchers measure the rate of check-in completion, articles read and goals set at study completion

Secondary outcome measures
1. Pain intensity measured using Pain Intensity Questionnaire at T0, T1, T2, T3 & T4
2. Pain interference measured using PROMIS Pediatric – Pain Interference at T0, T1, T2, T3 & T4
3. Pain catastrophizing measured using Pain Catastrophizing Scale Children at T0, T1, T2, T3 & T4
4. Pain self-efficacy measured using Pain Intensity Questionnaire at T0, T1, T2, T3 & T4
5. Depression measured using PROMIS Pediatric – Depressive Symptoms at T0, T1, T2, T3 & T4
6. Anxiety measured using PROMIS Pediatric – Anxiety at T0, T1, T2, T3 & T4
7. Sleep measured using PROMIS Pediatric – Sleep Disturbance at T0, T1, T2, T3 & T4
8. Physical function measured using PROMIS Pediatric – Mobility at T0, T1, T2, T3 & T4
9. Patient's impressions of recovery using Patient Global Impression of Change at T4
10. Participants in the intervention group' acceptability of the iCanCope PostOp app using Acceptability e-Scale at T1 & T4
11. School attendance measured Health Services, Medication and School Attendance at T2, T3 & T4

T0/baseline = 6-8 weeks before surgery
T1 = 1 week before surgery
T2 = 2 weeks after surgery
T3 = 4 weeks after surgery
T4 = 12 weeks after surgery

Overall study start date
01/10/2017

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Aged 12 to 18 years
2. Own a smartphone compatible with the iCanCope app (iOS or Android)
3. Able to speak and read English
4. Scheduled to undergo limb reconstruction surgery

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Significant cognitive impairment or other co-existing medical condition that could limit the ability to use the iCanCope app, as identified by their health care provider
2. Diagnosed chronic pain condition not related to the surgical condition

Date of first enrolment
01/04/2022

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
Ireland

Study participating centre
CHI Crumlin
Cooley Road
Crumlin
Dublin
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D12 N512

Study participating centre
CHI Temple Street
Temple Street
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Organisation
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Sponsor type
University/education

Website
https://www.nuigalway.ie/colleges-and-schools/arts-social-sciences-and-celtic-studies/psychology/

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Ireland

Results and Publications

Publication and dissemination plan
Results will be submitted to suitable publications once analysis is complete.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
Raw data is not expected to be made available

IPD sharing plan summary
Not expected to be made available