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Development and preliminary evaluation of a chronic pain preventive intervention in extremity trauma patients

Submission date
13/11/2015

Recruitment status
No longer recruiting

Registration date
08/12/2015

Overall study status
Completed

Last Edited
18/01/2024

Condition category
Signs and Symptoms

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Orthopaedic injuries (injuries to muscles or bones) including extremity trauma (ET) (for example, injuries to the hands or feet) affect the majority of people who have been injured. More have half of all ET patients report that they are suffering from moderate to severe pain when they are discharged from hospital. The pain goes on to become chronic (long-term) in 86% of cases. People with chronic pain have a reduced quality of life when compared to patients suffering from common chronic diseases, making chronic pain the most frequent reason for seeking medical attention. Up to 60% of active people who live with chronic pain, including those with ET, find that their pain interferes with their day-to-day living, eventually losing their job or seeing their professional responsibilities decrease. Consequently, chronic pain is associated to a high socio-economic burden in terms of healthcare costs and lost productivity. Considering the impact of chronic pain, the Institute of Medicine of the National Academies Academies recently made “pain prevention” the highest priority for pain relief. The development of chronic pain is thought to be associated with a combination of biological, psychological and social risk factors (otherwise referred to as biopsychosocial risk factors) and protective factors. Severe acute pain and lower extremity (e.g. feet) injuries have been the sole biologically related risk factors of chronic pain repeatedly seen in ET patients. Several psychological risk factors also seem to be involved, more precisely pain catastrophizing (viewing it as worse than it actually is), pain-related fear, anxiety and depression. Moreover, pain self-efficacy (SE) (that is, a person’s belief that they can manage their pain) and pain acceptance have been identified to help protect against chronic pain. Research suggests that cognitive-behavioral interventions (treatments) have been the most successful way of addressing psychological factors in people suffering from chronic pain. These interventions focus on helping people with pain to realize that they can, in fact, manage their pain, and provide them with skills to respond in a more adaptive way. There is evidence to suggest that cognitive-behavioral interventions could prevent acute pain from developing into chronic pain several months after an injury. However, no such interventions have yet been developed nor tested in ET patients. Accordingly, a cognitive-behavioral intervention given to patients in acute pain after a recent trauma injury could help prevent it from becoming chronic

pain. The aims of this study are to see whether such an intervention is appropriate, suitable and convenient and then see if it works at reducing the amount of pain a patient experiences and also its effects on daily life 6 months after the injury has occurred.

Who can participate?
Adults (aged at least 18) at risk of developing chronic pain after ET.

What does the study involve?
The study is split into two phases. In the first phase, clinicians and patients evaluate a preliminary (first) version of the intervention to allow researchers to determine how acceptable it is. This version consists of six 30-45 minute sessions (four regular and two booster) first taking place in the hospital and then continuing once the patient has been discharged from hospital for up to three months after the injury occurs. In the second phase, participants are randomly allocated into one of two groups. Those in group 1 (experimental) receive both the intervention and their usual pain management treatment. The intervention involves seven short-length sessions. The first three sessions are delivered via the internet and are combined with face-to-face contact while in hospital. The two other regular sessions (i.e., sessions 4 and 5) are delivered on a weekly basis face-to-face or by telephone if it is not possible to meet the patient. Two booster sessions (i.e., sessions 6 and 7) are given by telephone or at the orthopedic outpatient clinic at 6 weeks and 3 months post-injury. Participants in group 2 (control) receive an educational pamphlet from the research nurse after hospital admission in addition to usual care.

What are the possible benefits and risks of participating?
Participants could experience less acute pain and the treatment may help prevent the pain becoming chronic pain. However, considering it is not yet known how well the treatment will perform, this cannot be confirmed. Possible risks include stress, anxiety or worsening of pain caused by activities of the intervention.

Where is the study run from?
Sacred Heart Hospital of Montréal (Hôpital du Sacré-Coeur de Montréal) (Canada)

When is the study starting and how long is it expected to run for?
November 2015 to March 2018

Who is funding the study?
1. Canadian Institutes of Health Research (Canada)
2. Quebec Research Funds in Health (Canada)
3. Quebec Nursing Intervention Research Network (Canada)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Development and pilot randomized controlled trial of a hybrid web-based and in-person self-management intervention to prevent acute to chronic pain transition post major lower extremity trauma

Study objectives
Research questions:
1. Is the preliminary version of the preventive cognitive-behavioral intervention acceptable from the perspective of clinicians and ET patients in terms of its effectiveness, appropriateness, suitability and convenience ?
2. Is the preventive cognitive-behavioral intervention feasible?
3. Are the research methods feasible?
4. What is the difference in pain intensity and pain interference with daily living activities between the intervention and control groups at 6 months post-injury?
5. What is the difference in pain SE, pain acceptance, pain catastrophizing, pain-related fear, anxiety, depression and healthcare service utilization at 6 months post-injury?
6. Does the refined intervention remain acceptable to ET patients?

Hypotheses:
1. The experimental group will experience less pain intensity and pain interference with daily living activities (primary outcomes) compared to the control group at 6 months post-injury
2. The experimental group will present increase pain SE and pain acceptance as well as a reduction in pain catastrophizing, pain-related fear, anxiety, depression and healthcare service utilization (secondary outcomes) in contrast to the control group at 6 months post-injury

Ethics approval required
Old ethics approval format

Ethics approval(s)
Phase I: The ethics committee of research and evaluation of health technologies (HSCM), 23/11 /2015, ref: 2016-1226
Phase II: The ethics committee of research and evaluation of health technologies (HSCM), 29/06 /2016, ref: 2017-1333

Study design
Phase I: Formal evaluation of the intervention acceptability by clinicians and patients
Phase II: Two-arm single-blind pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Acute to chronic pain transition in extremity trauma patients

Interventions
Current interventions as of 03/05/2017:
Following the first phase of the study (acceptability assessment of the intervention according to clinicians' and patients' perspectives), the intervention was modified as follows:
1. Experimental group: Participants will receive five individual 15- to 30-minute on-line, face-to-face and telephone sessions delivered by a nurse starting from 24 hours post-admission and surgery when required. The intervention also includes two face-to-face or telephone-based booster sessions of 15 to 20 minutes duration. Then, the iPACT-E-Trauma intervention includes 7 short-length sessions. The first three sessions are planned to be delivered via the web with the Traitement et Assistance Virtuelle Infirmière et Enseignement (TAVIE) platform (i.e., Soulage TAVIE Post-Trauma) and is combined with a face-to-face mode of delivery during patient hospitalization. The two other regular sessions (i.e., sessions 4 and 5) will be delivered on a weekly basis face-to-face or by telephone if it is not possible to meet the patient live. Two booster sessions (i.e., sessions 6 and 7) will be given by telephone or at the orthopedic outpatient clinic at 6 weeks and 3 months post-injury.
2. Control group: Participants will receive an educational pamphlet administered by the research nurse ≥ 24 hours but within 7 days post-hospital admission in addition to usual care.

Previous interventions:
1. Experimental group: Participants will receive a preventive cognitive-behavioral intervention

comprising 4 regular sessions and 2 booster sessions of 30 to 45 minutes and usual care (i.e., analgesics and physiotherapy). The first session will be initiated 48 hours after hospital admission or 24 hours in postoperative phase. The last booster session will be provided at 3 months post-injury
2. Control group: Participants will receive usual care defined as analgesics and physiotherapy

Intervention Type
Behavioural

Primary outcome measure
Pain intensity and pain interference with daily activities, measured by the modified Brief Pain Inventory at baseline (48 hours after hospital admission or 24 hours in postoperative phase), 3 months (at intervention end) and at 6 months

Updated 03/05/2017: Outcome measures will be recorded 24 hours to 7 days post-injury (baseline) and 3 and 6 months later (follow-up).

Secondary outcome measures
1. Pain self-efficacy, measured by the Pain Self-Efficacy Questionnaire
2. Pain acceptance, measured by the Chronic Pain Acceptance Questionnaire-8 items
3. Pain catastrophizing, measured by the Pain Catastrophizing Scale
4. Pain-related fear, measured by the Tampa Scale for Kinesiophobia
5. Anxiety and depression, measured by the Hospital Anxiety and Depression Scale
6. Health status, measured by the SF-12v2
7. Patients overall evaluation with different aspects of their responses to treatment, including:
7.1. Pain relief
7.2. Improvement in functioning
7.3. Quality of life
7.4. Global condition, measured by the Patient Global Impression of Change

These outcomes will be measured at baseline (48 hours after hospital admission or 24 hours in postoperative phase), 3 months (at intervention end) and at 6 months

Updated 03/05/2017: Outcome measures will be recorded 24 hours to 7 days post-injury (baseline) and 3 and 6 months later (follow-up).

Overall study start date
05/11/2015

Completion date
31/03/2018

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Able to read and speak French
3. Have a lower ET
4. At risk of developing chronic pain

Although several chronic pain risk factors have been identified in ET patients, no screening tool is readily available. Since acute pain intensity has been the sole chronic pain risk factor consistently found in this population and the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials recommendation to consider such inclusion criterion , a decision was made to consider this factor when screening patients at risk of developing chronic pain. Hence, patients who will present pain intensity > 4/10 at least once a day upon movement in the first 48 hours post-injury, which corresponds to moderate to severe pain intensity, will be enrolled. This criterion is based on the experience of the investigator who has witnessed high pain intensities in such specific time periods. Considering that lower extremity injury has been identified as a chronic pain risk factor and the need to optimize sample homogeneity, only patients with such injuries will be recruited.

Updated 03/05/2017: Patients will be enrolled if they present pain intensity ≥4/10 upon movement 24 hours post-injury.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
56

Key exclusion criteria
1. Unable to understand French
2. Spinal cord injury
3. Other trauma associated with high-intensity pain [> two ribs fracture or surgical abdominal trauma
4. Transfer to a regional hospital (14% of ET patients are returned to their referral hospital)
5. Cognitive impairment [i.e., dementia, moderate-severe traumatic brain injury – Glasgow coma scale score < 13/15 limiting the capacity to participate to the intervention and to complete questionnaires
6. Hospitalized in the intensive care unit (ICU)
7. Need for more than 7 days of hospitalization in the ICU

Added 03/05/2017:
8. Amputation

Date of first enrolment
01/05/2016

Date of final enrolment
01/05/2017

Locations

Countries of recruitment
Canada

Study participating centre
Sacred Heart Hospital of Montréal (Hôpital du Sacré-Coeur de Montréal)
5400 Boulevard Gouin Ouest
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Sponsor information

Organisation
McGill University

Sponsor details
Ingram School of Nursing
Wilson Hall
3506 University Street
Montreal
Canada
H3A 2A7

Sponsor type
University/education

Website
http://www.mcgill.ca/nursing/

Organisation
Sacred Heart Hospital of Montréal (Hôpital du Sacré-Coeur de Montréal)

Sponsor details
5400 Boulevard Gouin Ouest
Montreal
Canada
H4J 1C5

Sponsor type
Hospital/treatment centre

Website
http://www.crhscm.ca/

Organisation
McGill University

Sponsor details
-
-
Canada
-

Sponsor type
University/education

Website
http://www.mcgill.ca/

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name

Quebec Research Funds in Health (Canada)

Funder Name
Quebec Nursing Intervention Research Network (Canada)

Results and Publications

Publication and dissemination plan
The following publications are planned:
1. Study protocol (Journal of Medical Internet Research: 15/06/2017)
2. Intervention development and acceptability assessment (Pain Management Nursing: 01/09/2017)
3. Feasibility and pilot RCT findings (Feasibility and pilot studies journal: 01/06/2018)

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/06/2017		Yes	No
Results article	results	30/04/2018		Yes	No
Participant information sheet		06/06/2016	18/01/2024	No	Yes