ISRCTN53670726 https://doi.org/10.1186/ISRCTN53670726

An evaluation of medical students' judgment-making of chronic lower back pain cases

Submission date
23/10/2015

Recruitment status
No longer recruiting

Registration date
07/01/2016

Overall study status
Completed

Last Edited
04/03/2021

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Lower back pain is a common problem, which affects most people at some point in their lives. Many people who experience LBP will recover quickly with no significant impact to their lives, but for some people the pain turns into a long term condition which can affect their ability to work. When a sufferer experiences episodes which last for at least three months, it is known as chronic lower back pain (CLBP). People who suffer from CLBP are prone to repeated episodes (recurrent back pain), which can have a big impact on their family, social and working lives. In some cases, CLBP can lead to a long-term pain-related disability, where a person is in so much pain that it is preventing them from behaving normally. For many years, the "flags approach" has been used to judge how likely a person is to develop a long-term pain-related disability from their CLBP. This approach works by identifying factors which could get in the way of a person's recovery. These factors are represented by coloured flags and can be medical (red flags), psychological (yellow flags), social (blue flags) or work-related (black flags). By identifying whether a patient has any of these "flags", a doctor is able to judge the most appropriate action to take. The aim of this study is to find out whether an online educational video based on the flags approach can improve judgement in CLBP cases.

Who can participate?
Current GP trainees or third, fourth or fifth year medical students.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group (intervention group) are shown an 18 minute video, teaching them about the flags approach and how best to use it. Half way through this video, participants complete an exercise using a fictional case study in which they can practice these skills. Those in the second group are put on a waiting list. Immediately before and after the first group watch the video, both groups are given a number of fictional CLBP case studies. They are then asked to assess each case study and judge the future risk of pain-related disability for each of the cases. Their performance in this task is judged by the investigators in terms of accuracy, weighting and speed. After the study is completed, participants in the second group are given the opportunity to view the e-learning video.

What are the possible benefits and risks of participating?
Participants may gain better insight into the best ways to handle cases of CLBP, and so are better able to judge the more appropriate course of action in future. There are no risks of taking part in the study.

Where is the study run from?
National University of Ireland, Galway (Ireland)

When is the study starting and how long is it expected to run for?
June 2014 to November 2016

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

Who is the main contact?
Dr Christopher Dwyer

Contact information

Type(s)
Public

Contact name
Dr Christopher Dwyer

Contact details
Centre for Pain Research
School of Psychology
Arts Millennium Building
National University of Ireland
Galway
Ireland
-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Evaluating the effectiveness of a biopsychosocial e-learning intervention on medical students' and GP trainees' clinical judgment-making regarding future risk of disability in patients with CLBP: Study protocol for a randomised controlled trial

Study objectives
Those who receive a training intervention will out-perform controls on judgment accuracy regarding future risk of disability and biopsychosocial model (flags approach) knowledge from pre-to-post-testing; will demonstrate attitudes and beliefs towards pain more consistent with the biopsychosocial model than controls from pre-to-post-testing; and will distribute the weight of their judgments more evenly (i.e. across biopsychosocial factors) than controls from pre-to-post-testing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National University of Ireland Galway Research Ethics Committee, 15/05/2012, ref: 12-May-06

Study design
Single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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
Chronic Lower Back Pain

Interventions
Participants are randomised to the intervention or waiting list control group to using a web-based password secured and encrypted data management system to ensure that the groups are balanced.

Intervention group: Participants in the intervention group will complete the e-learning Flags Approach to Clinical Judgment educational intervention, which involves watching an 18-minute video, with an active learning exercise included in the middle, developed to teach the fundamentals of the bio-psychosocial model via the Flags Approach.

Control group: Participants will wait in an adjacent room where they will be provided non-medically-related magazines to read at their leisure.

Both groups will complete the full battery of assessments immediately before (time 1) and after (time 2) the intervention. Controls are wait-listed and will be provided an opportunity to view the intervention video following completion of the research.

Intervention Type
Other

Primary outcome measure
1. Judgement is measured using online tools according to responses to fictional case studies after the intervention
2. Judgment speed (response time) is measured in milliseconds as the length of time from the moment a case appeared on screen until a response (i.e. identifying, from 1-10, future risk of disability) is clicked via the mouse

Secondary outcome measures
1. Flags Approach knowledge is assessed using a multiple choice question test immediately before and after the intervention
2. Biomedical/biopsychosocial approach to chronic lower back pain is measured using the pain attitudes & beliefs scale (PABS) immediately before and after the intervention
3. Empathy is measured using the interpersonal reactivity index (IRI) immediately before and after the intervention

Overall study start date
01/06/2014

Completion date
31/01/2018

Eligibility

Key inclusion criteria
Current GP Trainee or medical student (year 3-5)

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
Sample size of 34 minimum (ie. 2 groups of 17 minimum)

Key exclusion criteria
Do not meet the inclusion criteria

Date of first enrolment
01/02/2015

Date of final enrolment
30/10/2015

Locations

Countries of recruitment
Ireland

Study participating centre
National University of Ireland
University Road
Galway
Ireland
-

Sponsor information

Organisation
Centre for Pain Research

Sponsor details
School of Psychology
National University of Ireland
Galway
Ireland
N/A

Sponsor type
Research organisation

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Research organisation

Funder Name

Health Research Board

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

Results and Publications

Publication and dissemination plan
The results of the trial will be published according to the CONSORT statement and will be presented at conferences and reported in peer-reviewed journals

Intention to publish date
31/07/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/05/2016		Yes	No
Results article	results	01/05/2020	04/03/2021	Yes	No