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Complete List of Authors:	Dwyer, Christopher; National University of Ireland, Galway, Centre for Pain Research; National University of Ireland,Galway, School of Psychology Reynolds, Bronagh; National University of Ireland, Galway, Centre for Pain Research MacNeela, Padraig; National University of Ireland, Galway, School of Psychology Hamm, Robert; University of Oklahoma Health Sciences Center, Department of Family & Preventive Medicine Conneely, Sinead ; National University of Ireland, Galway, School of Psychology Durand, Hannah; National University of Ireland, Galway, Centre for Pain Research; National University of Ireland, Galway, School of Psychology Slattery, Brian ; National University of Ireland, Galway, Centre for Pain Research; National University of Ireland, Galway, School of Psychology Main, Chris; Keele University, Department of Behavioural Medicine O'Neill, Ciaran; National University of Ireland, Galway, Discipline of Health Economics Nic Gabhainn, Saoirse; National Universiry of Ireland, Galway, Health Promotion Murphy, Andrew Kropmans, Thomas; National University of Ireland, Galway, Discipline of Medical Informatics and Education McGuire, Brian; National University of Ireland, Galway, Ireland, School of Psychology & Centre for Pain Research
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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

Christopher P. Dwyer[1, 2]

Bronagh Reynolds[1]

Padraig MacNeela[2]

Robert M. Hamm[3]

Sinead Conneely[2]

Hannah Durand[1, 2]

Brian W. Slattery[1, 2]

Christopher J. Main [4]

Ciaran O'Neill[5]

Saoirse NicGabhainn[6]

Andrew W Murphy[7]

Thomas Kropmans[8]

Brian E. McGuire[1, 2]

ABSTRACT

Introduction: Chronic lower back pain (CLBP) is a major healthcare problem with wide ranging effects and thus, it is very important that CLBP be appropriately managed. Modern conceptualisations of pain adopt a biopsychosocial approach, which has been applied to judgments about future adjustment and recovery from pain and risk of long-term disability. The *Flags Approach* (1), provides a helpful model for understanding the importance of contextual interactions between psychosocial and biological variables in the experience of pain. Medical students and GP trainees are important groups to target with education about biopsychosocial conceptualisations of pain and related clinical implications.

Aim: The current study will compare the effects of an educational video, which focuses on a biopsychosocial model of pain, on the clinical judgments of medical students and trainees.

Methods and analysis: Medical student and GP trainee participants will be randomised to one of two study conditions: (a) Participants will be assigned to an 8-week e-learning intervention focused on the fundamentals of the Flags Approach to clinical judgment-making in the context of case scenarios about which participants must judge risk of future pain-related disability; compared with a (b) wait-list control group on several factors including judgment accuracy and weighting, knowledge of the Flags Approach, and attitudes and beliefs towards pain. Participants will be assessed pre-intervention and post-intervention. The primary outcome will be judgment accuracy and weighting. Secondary outcomes will include: Flags Approach knowledge, pain attitudes and beliefs; judgment speed and empathy.

Ethics and dissemination: The study will be performed in agreement with the Declaration of Helsinki and is approved by the National University of Ireland Galway Research Ethics Committee. 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.

Trial Registration: Submitted for Registration

STRENGTHS & WEAKNESSES

Strengths:

- The research study is novel with respect to its methodology and cohort to be assessed.
- The research aims to account for multiple conceptualisations of clinical judgment, including accuracy, weighting and speed.

Weaknesses:

- Given the cohort of participants required, the sample size may, arguably, be considered small.
- Given the cohort of participants required and their schedules, provision of a longer, voluntary intervention is not feasible.

INTRODUCTION

Chronic lower back pain (CLBP) is a major Irish healthcare burden, with figures from the Quarterly National Household Survey revealing 10% of the Irish population suffers from chronic back pain (2). The cost of chronic pain per patient has been estimated at €5.34 billion, or 2.86% of Ireland's GDP (3). CLBP is a further economic concern as it results in huge losses in productivity and increases in workplace absenteeism. Those who are working lose an average of

seventeen days annually due to CLBP, with 15% of those reporting job loss due to their condition (4). It is also the most common reason for individuals receiving disability income, with 27% of sufferers unable to work due to their condition. The wide ranging effects of CLBP for the individual, their family, society and the workplace, mean that it is a high priority for this condition to be appropriately managed in order to get individuals back to work (5). Furthermore, approximately 90% of cases of lower back pain are non-specific (i.e. there is no identifiable, discernible cause) (6). In that context, traditional treatment methods prescribed according to the biomedical model often fail to adequately manage CLBP and may even contribute to further patient disability (7-9). A biopsychosocial model of pain may provide a better foundation for understanding lower back pain (10, 11) and allow for recognition of the importance of biological, psychological and social interactions in both the individual's experience of their pain and the GP's clinical judgment (12).

There is wide support for this perspective in extant research - indicating that non-medical factors such as personal circumstances and pain beliefs are as important in the perpetuation of chronic pain and disability as biological aspects of pain(13, 14). For example, even after controlling for health variables, work environment and the nature of work-related tasks remain strong predictors of back pain disability (13-16). Furthermore, occupational factors predictive of disability are interconnected with psychosocial variables regarding return to work, as many have been found to be associated with prolonged work disability(8, 17, 18). For example, lower expectations of returning to work and a lack of confidence to carry out work-related tasks are examples of psychosocial risk factors associated with extended work disability (19, 20). In this context, an individual's beliefs and attitudes about their abilities may be influential in shaping their actual longer term ability to carry out work-related tasks.

When acknowledging these risk factors, it is important to recognise that they do not exist in a vacuum and should be considered within a broader context. Contextual and socioeconomic factors such as older age, healthcare provision, emotional impact on the patient's family and level of social integration are all interconnected with psychosocial and occupational risk factors (21, 22). Given the above, it is reasonable to suggest that there is a diverse range of biomedical, psychological and environmental influences which are involved in CLBP. As CLBP is one of the most common disorders presenting in primary care (3, 4, 23), it is essential for physicians to have a systematic approach to assess and treat this disorder (22, 24).

One useful method of assessing and managing psychosocial factors in lower back pain is the *flags approach* (25). This is a conceptual framework which integrates the identification of biopsychosocial and behavioural barriers to recovery; and involves the use of various *flags*, for example, consistent with the traditional medical notion of 'red flags' which are indicative of an observable physical pathology. This framework has been refined to include *yellow flags* as psychological risk factors related to the individual (26), such as fear-avoidance beliefs, catastrophizing about pain and concerns over returning to work.

Blue flags refer to workplace beliefs in light of CLBP, such as fear of re-injury, low expectations of being able to return to work and concerns over physical demands at work. *Black flags* encompass the 'context' surrounding the individual and their CLBP (e.g. relevant individuals such as family members and their reactions to the CLBP experienced by the individual, as well as systems and policies associated with attempts to get back to work). The flags framework is useful to clinicians as part of broader diagnostic criteria and in determining (un)suitable treatments for the management of CLBP, with its utility evident in empirical research(18). Interventions informed by the flags approach have been observed to successfully reduce pain-related work absences and increased return to work for individuals with sub-acute and CLBP (27-31). Though the model is part of international and European recommended guidelines for assessment and management of lower back pain, recent reports reveal that physicians' adherence to guidelines for physical and psychosocial assessment, which include the flags approach, is low (32-34).

There is little teaching time dedicated to pain management, more generally, in all types of healthcare training (4), including physicians (35). A lack of knowledge about psychosocial risk factors and low adherence to guidelines indicates that clinical decisions regarding the management of CLBP exclude important psychological cues which may improve how CLBP is managed (36). The early experiences of medical students in their placements and internships are times of constant learning, enabling them to develop appropriate attitudes towards their future as physicians (37). As the next generation of physicians, medical students and GP trainees are a population on which to assess clinical judgments and decision-making, regarding psychosocial influences in the diagnosis and treatment of CLBP. Extant research has examined the effects of biopsychosocial perspective educational interventions, such as through videos and vignettes, with results yielding significant changes in beliefs and attitudes of healthcare providers and clinical behaviour (38-40). These results are encouraging as potential changes in judgment -making may arise from a change in knowledge, attitudes and beliefs. However, further research is needed to determine how these changes translate into clinical judgments on the future management of CLBP (22, 34, 41). It is hypothesised that those who receive a training intervention will outperform 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.

METHODS AND ANALYSIS

Design

The design is a single-blind randomised controlled trial comparing the effects of an e-learning biopsychosocial model intervention with a waiting list control condition on the clinical judgments of medical students and GP trainees regarding future risk of disability of CLBP patients. Any modifications to the protocol which may impact on the conduct of the study will require a formal amendment to the protocol. Such amendment will be agreed on by the Irish Health Research Board Interdisciplinary Capacity Enhancement Award, grant number (ICE/2011/19) research group, and approved by the relevant ethics committee prior to the implementation of the modifications. Minor administrative changes to the protocol will be agreed on by the Irish Health Research Board Interdisciplinary Capacity Enhancement Award, grant number (ICE/2011/19) research group, and will be documented in a memorandum.

Recruitment, participants and randomisation

Recruitment of the participants (i.e. medical students and GP trainees) will be conducted via online advertisement and communication with administrating bodies for medical education in Irish third-level educational institutions. Though individuals interested in participating will be sent information about the trial, any information that could potentially prime participants or their performance will not be disseminated prior to the intervention. All participants will be fully debriefed upon completion of the intervention. Inclusion criteria are: current GP Trainee or medical student (year 3-5). All participants will provide full informed consent. Participants will be 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. Once the randomisation procedure has been completed, the participants in the intervention group will begin the intervention. The statistician involved in the analysis of the data will be blinded to group allocation.

Trial Aims

The e-learning biopsychosocial model intervention consists of a once-off, 20 minute purpose-developed Flags Approach video lecture (i.e. developed from information presented within *Tackling musculoskeletal problems: A guide for clinic and workplace*; (1). The e-learning intervention has been developed, based on guidelines for good-practice in multi-media e-Learning (42), by a postdoctoral psychologist who has research expertise in judgment and decision-making (CD); a psychologist (SC) and research assistant (BR) with research experience in chronic pain; a psychologist with expertise in clinical judgment-making (PMN); under the supervision of a licensed clinical psychologist specialising in pain management (BM).

The current study will take place during one two-hour session (see Figure 1). Two groups will take part in the study: those who participate in the e-learning Flags Approach to Clinical Judgment educational intervention and a wait-list control group. At the outset, participants will be provided information

regarding the nature of the study (i.e. that this study will assess clinical judgments regarding CLBP), but will not be advised about the Flags approach or the biopsychosocial model, so as to not bias participants before the beginning of the intervention. Participants will be informed of their rights and that they can withdraw from the study at any time. Participants will be administered the battery of assessments (i.e. judgment; knowledge; attitudes and beliefs; and empathy) and randomly allocated to either the intervention group or control group. Following the 20 minute intervention, both groups will again be administered the battery of assessments, after which all participants will be fully debriefed and thanked.

Insert Figure 1 around here

Outcome measures

All outcome measures will be conducted during the hour immediately pre-intervention and during the hour immediately post-intervention. Any adverse events and the rate of attrition among the participants during their completion of the intervention will also be recorded.

Demographic and clinical information

Participants will be asked to supply details regarding age and gender and current level of medical training.

Primary outcome measures

Judgment will be assessed online according to accuracy, speed and weight allotted to presenting symptoms within a series of 40 cases of male patients living with CLBP. All fictional patients are similarly categorised, for example, identified as being male, aged between 49 and 55; married with children (aged between 10 – 16 years); and currently on GP certified sick-leave from work due to a CLBP flare-up that has lasted the past 3 weeks, prescribed anti-inflammatories and non-opiate analgesics only, etc. (see Appendix A for patient background and presenting problems associated with CLBP). Participants will be asked to put themselves in the position of the GP for these 40 consultations and judge the patients' risk of future disability, which in this context is referred to "*the potential for significant work disability 9 months from now, i.e. impeding the person from remaining in their current job if the job*

responsibilities were to remain the same as present." Judgments are rated on a probability scale of 1-10 (1 = 10% chance of disability in 9 months, through 10 = 100% chance of disability in 9 months). For each case, a unique combination of six biopsychosocial case factors is provided (i.e. bio: mobility and sleep; psycho: motivation and self-esteem; social: close relationships and social activity), as are definitions and examples of each (see Appendix A). Low scores represent a low level problem on that factor; whereas high scores represent a high level problem on that factor (example in Figure 2). The 40 cases were developed via an adapted version of the case generator developed and used in research by Hamm, Beasley (43). Specifically, variables within each case are allotted scores regarding *level of problem*, from 10 to 95, via increments of five (though presented on a bar graph ranging from 0-100). Cases were generated randomly. In order to ensure similarity between generated cases and real-life cases, the six variables (i.e. two variables per factor) were randomised in a manner in which each pair (i.e. a pair each for bio, psycho and social factors) were correlated. To achieve this, two randomisation processes were conducted. In the first process, low (i.e. 10-35) moderate (i.e. 40-65) and high scores (i.e. 70-95) were randomly assigned to bio, psycho and social factors. Each range consisted of six possible scores. In the second randomisation procedure, each variable, within each pair, was then provided a randomised score relevant to the range identified in the first randomisation protocol. Following the randomisation process, Pearson analysis was conducted to ensure appropriate correlation. Results revealed that all six variables were significantly correlated with their paired variable: Mobility and sleep ($r = .57$, $p < .001$); Mood and motivation ($r = .58$, $p < .001$); and close relationships and social activity ($r = .54$, $p < .001$). Consistent with the perspective described, cumulative biological, psychological and social factors were all positively correlated, but not significantly, in order to allow test-takers an ability to observe discrepancy among factors. Means for each factor ranged from $M = 44.00$-56.88. Following the development analysis, the 40 cases were randomised twice to create Form A and Form B, in order to ensure uniformity at pre-and-post-testing. However, different case names (e.g. Jim, 48 years-old) were allotted to each case in Forms A and B, in order to avoid any practice effects. Two case booklets (each consisting of 40 cases) were independently judged by experts in clinical judgment and decision-making based on the flags approach: (1) to reflect real-life symptom presentation scenarios and (2) to identify the correct answer (i.e. judgment problem-level) for each case.

Insert Figure 2 around here

Judgment speed, or response time, will be measured 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) was clicked via mouse. The location of the mouse pointer is centred above the response scale at the beginning of each case presentation in order to avoid any location bias. There is a 1.5 second delay between each response and the appearance of the next case. Speed is quantified in terms of milliseconds and used as both a correlate of accuracy and to categorise *fast* and *slow* responders for further comparison.

Judgment weighting allotted to presenting symptoms within each case judgment will be assessed via *judgment analysis*, which utilises regression modelling to objectively describe professionals' decision-making (44, 45). Specifically, judgment analysis focuses on the weighting of importance given by decision-makers specific to case cues (i.e. in this context, mobility, sleep, self-esteem, motivation, close relationships and social activity), based on Brunswik (46) lens model.

Secondary outcome measures

Flags Approach Knowledge will be assessed using a purpose-developed multiple choice question test (i.e. each with five possible options and only one correct answer) at both pre-and-post-testing. Two separate 15-item assessments (A and B) were developed for the current study, in order to avoid practice effects. Both assessments are scored on a scale of 0-15. In total, 27 items were developed, based exclusively on information relevant to the biopsychosocial model, as presented within the lecture (see Kendall (47)); and piloted with 25 participants. Two items were removed based on difficulty, as no pilot participants answered them correctly. Five items appeared on both assessment A and B, given their central importance to the topic. The remaining 20 items were split amongst the two forms based on both (1) the nature of the question (i.e. specifically relating to pain, the biopsychosocial model or implications of the flags approach); and (2) difficulty (i.e. determined by percentage of individuals who identified the correct answer), in order to maintain even levels of difficulty. To further control for difficulty, assessment A and B will be counter-balanced at pre-and-post-testing.

The Pain Attitudes & Beliefs Scale (PABS; adapted by Houben, Becker (48) from Ostelo, Stomp-van den Berg (49)) will be used to measure healthcare practitioners' endorsement of a biomedical/biopsychosocial approach to CLBP. The PABS consists of 19-items, divided according to two factors: endorsement of a biomedical perspective on pain and tissue damage (10 items); and biopsychosocial orientation that functional problems can be overcome despite chronic pain (9 items). This measure has been recently used and validated in a study of Irish GPs (50) and has robust test reliability, with research indicating internal consistency ranging from α = .65- 83 (48, 49, 51).

The Interpersonal Reactivity Index (IRI;Davis (52)) measures empathy - conceptualised as reactions of one individual to the observed experiences of another. The index is divided into four sub-scales – two of which were administered in the current study (i.e. perspective-taking and empathic concern), consisting of seven items each. Perspective-taking refers to the tendency to adopt the psychological point of view of others; and empathic concern refers to the extent of one's feelings of compassion and concern for others. Internal consistency of the sub-scales range from α = .68 - .75 (53, 54). Empathy will be assessed to account for potential differences between groups due to the presence of patient vignettes within the video, which may potentially evoke empathic responses.

Statistical analysis

An *a priori* G*Power analysis was conducted based on a two tailed alpha value of .05, a beta value of .80, and a medium effect size, which yielded a recommended sample size of 34 for the present study (55). A 2x2 (condition: e-Learning intervention and control group) x 2 (time: pre-and-post-testing) Mixed MANCOVA will be used to compare the effects of an e-learning intervention, teaching the fundaments of the Flags Approach to clinical judgment, with a no-intervention control group on judgment accuracy, *Flags Approach* knowledge, attitudes and beliefs towards pain, while controlling for judgment speed and empathy. Judgment analysis (44, 45) will be used to analyse judgment weighting (i.e. weighting allotted to presenting symptoms within each judgment). Correlations among judgment accuracy, speed, weighting, knowledge, empathy and attitudes and beliefs will also be analysed. The sensitivity of the final results to missing data will be investigated using multiple imputation analysis based on chained equations and predictive mean matching. All analyses will be completed using IBM SPSS V.21 statistics packages. Each hypothesis will be tested using a two-tailed analysis at the α = 0.05 level of significance.

DATA MONITORING AND MANAGEMENT

This trial does not have a data and monitoring committee because: the study is minimal risk; judgment, knowledge and attitude assessment is non-harmful; and of the nature of the study population (i.e. adult, not considered vulnerable). All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access, or on encrypted electronic devices, as appropriate. All records that contain names or other personal identifiers will be stored separately from study records identified by code number. All local and online databases will be secured with password-protected access systems. Paper-based documents that link participant ID numbers to other identifying information will be stored in a

separate locked file in an area with limited access. Data stored on computer databases will be password-protected and access to files will be limited to research staff who require direct access. The trial statistician will work on depersonalised data where the participant's identifying information will be replaced by an unrelated sequence of characters. All principal investigators and post-doctoral researchers involved in the running of the trial will be given access to the cleaned data sets. All data sets will be password protected. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information.

DISSEMINATION

Regardless of the significance, direction or magnitude of effect, the trial findings will be submitted for publication in peer-reviewed journals. Trial findings will also be disseminated through conference abstracts. Once all of the data have been collected and cleaned, we will aim to submit the trial results for publication within 3 months.

Author Affiliations

[1]Centre for Pain Research, National University of Ireland, Galway, Ireland

[2]School of Psychology, National University of Ireland, Galway, Ireland

[3]Department of Family & Preventive Medicine, University of Oklahoma Health Sciences Center, U.S.

[4]Department of Behavioural Medicine, Keele University, Staffordshire, England

[5]Discipline of Economics, National University of Ireland, Galway, Ireland

[6]Discipline of Health Promotion, National University of Ireland, Galway, Ireland

[7]Discipline of General Practice, National University of Ireland, Galway, Ireland

[8]Discipline of Medical Informatics and Education, National University of Ireland, Galway, Ireland

Contributors: CPD was involved in and oversaw the design of the intervention; the literature review; statistical aspects of the trial; and the writing of the manuscript. BR was involved in the literature review and the statistical aspects of the trial. PMN contributed to the design of the intervention, statistical aspect of the trial and to the editing of the manuscript. SC and HD contributed to the statistical aspects of the trial and contributed to the editing of the manuscript. RMH and CJM contributed to the statistical aspects of the trial. BWS, CON, SNG, AWM and TK contributed to the editing of the manuscript. BEM contributed to the design of the intervention, supervised the study and also contributed to the editing of the manuscript.

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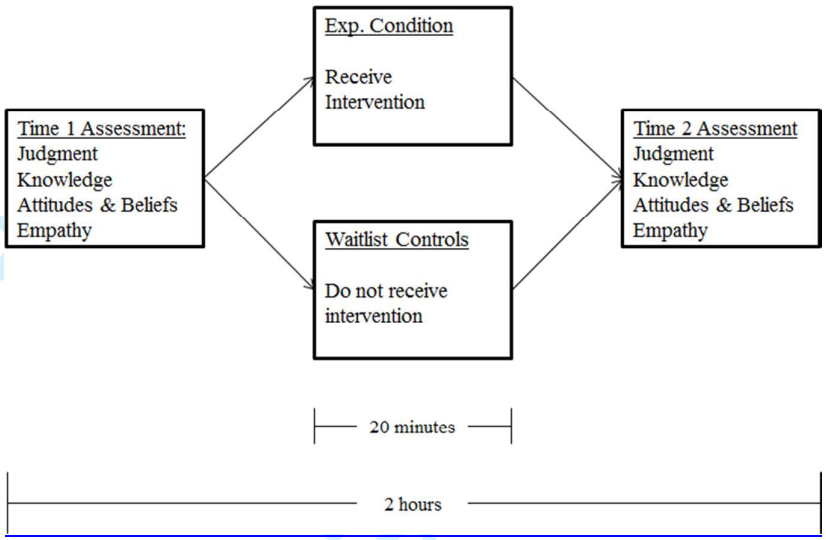

Figure 1: Schematic for Treatment Regiment

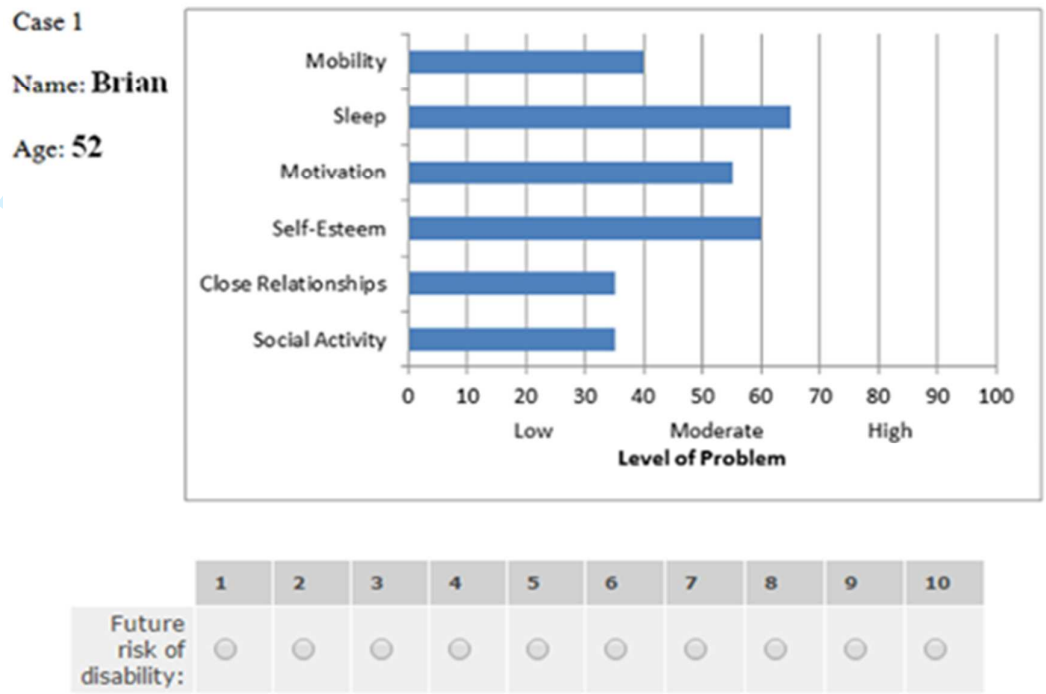

Figure 2: Example of a case to be judged by participants

Appendix A

Mobility

Visual observations of mobility of the back and spine

Low ↓ High
- Good range of movement, moves easily
- Movements full but painful, patient moves a little stiffly
- Some limited extension of spine, moving quite stiffly
- Limited flexion and movement, difficult moving to standing positio
- Very restricted, great difficulty moving from seated to standing

Sleep

Interruption and disturbance to restful sleep (NB: not early morning waking)

Low ↓ High
- Sleeping ok, may wake occasionally but generally restful sleep
- Not well rested, sleep is somewhat disrupted
- Quite fatigued from disrupted sleep, cannot get comfortable in bed
- Difficult falling or staying asleep, wakes in pain several times a nigl
- Significant disruption to sleep due to pain, no peace at night

Self Esteem

Mood, ideas and feelings about self

Low ↓ High
- In good form and confidence ok, normal ups and downs
- Feels a bit down at the moment, irritable through lack of progress
- Mood is poor, frustrated and blaming self
- Despairing at times, high levels of hostility
- Feels hopeless, angry and withdrawn

Motivation

Self-direction, willing to focus on treatment goals

Low ↓ High
- Eager to return to work, fully focused on future recovery
- Some reluctance to follow treatment advice, needs encouraging to comply with advice
- Worried about return to work, fears further damage and resists advice
- Focuses mainly on avoiding work and activity, poor treatment adherence
- Reluctant to discuss work at all, not engaged with treatment at all

Close Relationships

Intimate familial, romantic and/or friendship connections

Low ↓ High
- Strong mutual support network with close family and friends, many positive interactions with spouse
- Support from both close family and friends is accessible when needed, occasional quarrelling or miscommunication with spouse
- Some regular support from family members or from friends, but some 'ups and downs' in spousal relationship
- Sporadic support from family or friends, frequent disagreements with spouse
- Little support from family or from friends, significant marriage problems

Social Activity

Engagement with other(s) in communal interests, endeavours or pursuits

Low ↓ High
- Typically socialises with others 2 or 3 times each week, active role in local community group
- Tends to socialises with others once a week, chats regularly with neighbours
- Pattern of socialising on special occasions only, interacts with community members periodically
- Does not typically socialise outside the home, knows neighbours only to say 'hello'
- Very few social contacts, minimal engagement with community members

Case Histories

In the following pages, you will be presented with a series of 40 cases of men suffering from chronic lower back pain (CLBP). All patients are:

- Aged between 49 and 55,
- Are married with children (aged between 10 – 16 years) ; and are
- Currently on GP certified sick-leave from work, due to a CLBP flare-up that has lasted the past 3 weeks. This flare-up is self-described as particularly bad. Self-reported pain varies from 6 to 8 on a 10-point scale.
- All patients work in supervisory roles in production settings in multi-national companies, with some duties including minor physical exertion.

On average, each patient visits their GP four times per annum due to CLBP that emerged approximately 10 years ago. No definitive cause for CLBP is apparent in any case. There was no evidence of structural problems in x-rays taken 4 years ago and earlier this year.

Each patient has been prescribed the following only: anti-inflammatories (e.g., Difene 50-100mg bd), and non-opiate analgesics (e.g., paracetamol 500-1000mg qid, Tramadol 50mg prn). Patients have been compliant with medications and have attended physiotherapy several times, though have not been consistent in exercise.

All patients previously reported worry that pain levels will increase and fear painful movement. Patients are not happy at times with medical care. All patients were previously active and are social drinkers only (i.e. no indication of abuse). Their mood is low at times, but not diagnosed as clinically depressed.

Instructions

Please put yourself in the position of the GP for these 40 consultations today. For each case, you will be asked to judge the patient's **Risk of Future Disability**. Take this to refer to:

The potential for significant work disability 9 months from now, i.e. impeding the person from remaining in their current job if the job responsibilities were to remain the same as present.

Please make your judgment of future risk of disability by rating the case on a Probability Scale of 1-10 (1 = 10% chance of Disability in 9 months, through to 10 = 100% change of Disability in 9 months).

For each case, base your judgment of Risk of Future Disability on the six case factors provided. Each patient represents a unique combination of the case factors of Mobility, Sleep,

Motivation, Self-Esteem, Close Relationships, and Social Activity. The definition of each case factor below is accompanied by illustrative examples.

Low scores on a case factor represent a low problem level on that factor. High scores represent a high problem level on that factor. Assume the information in the case factors has been obtained in the consultation.

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The effectiveness of a biopsychosocial e-learning intervention on the clinical judgments of medical students and GP trainees regarding future risk of disability in chronic lower back pain patients: Study protocol for a randomised controlled trial

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Complete List of Authors:	Dwyer, Christopher; National University of Ireland, Galway, Centre for Pain Research; National University of Ireland,Galway, School of Psychology Durand, Hannah; National University of Ireland, Galway, Centre for Pain Research; National University of Ireland, Galway, School of Psychology MacNeela, Padraig; National University of Ireland, Galway, School of Psychology Reynolds, Bronagh; National University of Ireland, Galway, Centre for Pain Research Hamm, Robert; University of Oklahoma Health Sciences Center, Department of Family & Preventive Medicine Main, Chris; Keele University, Department of Behavioural Medicine O'Connor, Laura; National University of Ireland, Galway, Centre for Pain Research Conneely, Sinead ; National University of Ireland, Galway, School of Psychology Taheny, Darragh; National University of Ireland, Galway, Centre for Pain Slattery, Brian ; National University of Ireland, Galway, Centre for Pain Research; National University of Ireland, Galway, School of Psychology O'Neill, Ciaran; National University of Ireland, Galway, Discipline of Health Economics Nic Gabhainn, Saoirse; National Universiry of Ireland, Galway, Health Promotion Murphy, Andrew Kropmans, Thomas; National University of Ireland, Galway, Discipline of Medical Informatics and Education McGuire, Brian; National University of Ireland, Galway, Ireland, School of Psychology & Centre for Pain Research
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The effectiveness of a biopsychosocial e-learning intervention on the clinical judgments of medical students and GP trainees regarding future risk of disability in chronic lower back pain patients: Study protocol for a randomised controlled trial

Christopher P. Dwyer[1, 2]

Hannah Durand[1, 2]

Pádraig MacNeela[2]

Bronagh Reynolds[1]

Robert M. Hamm[3]

Christopher J. Main[4]

Laura L. O'Connor[1]

Sinéad Conneely[2]

Darragh Taheny[1]

Brian W. Slattery[1, 2]

Ciaran O'Neill[5]

Saoirse NicGabhainn[6]

Andrew W. Murphy[7]

Thomas Kropmans[8]

Brian E. McGuire[1, 2]

ABSTRACT

Introduction: Chronic lower back pain (CLBP) is a major healthcare problem with wide ranging effects. It is a priority for appropriate management of CLBP to get individuals back to work as early as possible. Interventions which identify biopsychosocial barriers to recovery have been observed to lead to successfully reduced pain-related work absences and increased return to work for individuals with CLBP. Modern conceptualisations of pain adopt a biopsychosocial approach, such as the *Flags Approach*. Biopsychosocial perspectives have been applied to judgments about future adjustment, recovery from pain and risk of long-term disability; and provide a helpful model for understanding the importance of contextual interactions between psychosocial and biological variables in the experience of pain. Medical students and GP trainees are important groups to target with education about biopsychosocial conceptualisations of pain and related clinical implications.

Aim: The current study will compare the effects of an e-learning intervention, which focuses on a biopsychosocial model of pain, on the clinical judgments of medical students and trainees.

Methods and analysis: Medical student and GP trainee participants will be randomised to one of two study conditions: (a) a two-hour e-learning intervention focused on the fundamentals of the Flags Approach to clinical judgment-making regarding risk of future pain-related disability; compared with a (b) wait-list control group on judgment accuracy and weighting (i.e. primary outcomes); Flags Approach knowledge, attitudes and beliefs towards pain, judgment speed and empathy (i.e. secondary outcomes). Participants will be assessed at pre-and-post-intervention.

Ethics and dissemination: The study will be performed in agreement with the Declaration of Helsinki and is approved by the National University of Ireland Galway Research Ethics Committee. 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.

Trial Registration: ISRCTN53670726

STRENGTHS & WEAKNESSES

Strengths:

- The research study is novel with respect to its methodology and cohort to be assessed.
- The research aims to account for multiple conceptualisations of clinical judgment, including accuracy, weighting and speed.

Weaknesses:

- Given the cohort of participants required, the sample size may, arguably, be considered small.
- Given the cohort of participants required and their schedules, provision of a longer (i.e. follow-up, third testing time), voluntary intervention is not feasible.

INTRODUCTION

Chronic lower back pain (CLBP) is a major Irish healthcare burden, with figures from the Quarterly National Household Survey revealing 10% of the Irish population suffers from chronic back pain (1). The cost of chronic pain in Ireland has been estimated at €5.34 billion per annum, or 2.86% of Ireland's GDP (2). CLBP is a further economic concern as it results in huge losses in productivity and increases in workplace absenteeism. Those who are working lose an average of seventeen days annually due to CLBP, with 15% of those reporting job loss due to their condition (3). It is also the most common reason for individuals receiving disability income, with 27% of sufferers unable to work due to their condition. The wide ranging effects of CLBP for the individual, their family, society and the workplace, mean that it is a high priority for this condition to be appropriately managed in order to get individuals back to work (4, 5). Furthermore, approximately 90% of cases of lower back pain are non-specific (i.e. there is no identifiable, discernible cause) (6). In that context, traditional treatment methods prescribed according to the biomedical model often fail to adequately manage CLBP and may even contribute to further patient disability (7-10). Interventions which integrates cognitive and behavioural approaches via the identification of biopsychosocial barriers to recovery, have been observed to lead to successfully reduced pain-related work absences and increased return to work for individuals with CLBP. A biopsychosocial model of pain may provide a better foundation for understanding lower back pain (11-13) and allow for recognition of the importance of biological, psychological and social interactions in both the individual's experience of their pain and the GP's clinical judgment (14).

There is wide support for this perspective in extant research – indicating that non-medical factors such as personal circumstances and pain beliefs are as important in the perpetuation of chronic pain and disability as biological aspects of pain (15). For example, even after controlling for health variables, work environment and the nature of work-related tasks remain strong predictors of back pain disability (16, 17). Furthermore, occupational factors predictive of disability are interconnected with psychosocial variables regarding return to work, as many have been found to be associated with prolonged work disability (10, 18-21). For example, lower expectations of returning to work and a lack of confidence to carry out work-related tasks are examples of psychosocial risk factors associated with extended work disability (22, 23). In this context, an individual's beliefs and attitudes about their abilities may be influential in shaping their actual longer term ability to carry out work-related tasks.

When acknowledging these risk factors, it is important to recognise that they do not exist in a vacuum and should be considered within a broader context. Contextual and socioeconomic factors such as older age, healthcare provision, emotional impact on the patient's family and level of social integration are all interconnected with psychosocial and occupational risk factors (24, 25). Given the above, it is reasonable to suggest that there is a diverse range of biomedical, psychological and environmental influences which are involved in CLBP. As CLBP is one of the most common

disorders presenting in primary care (2, 3, 26), it is essential for physicians to have a systematic approach to assess and treat this disorder (25, 27).

One useful method of assessing and managing psychosocial factors in lower back pain is the *flags approach* (28). This is a conceptual framework which integrates the identification of biopsychosocial and behavioural barriers to recovery; and involves the use of various *flags*, for example, consistent with the traditional medical notion of 'red flags' which are indicative of an observable physical pathology. This framework has been refined to include *yellow flags* as psychological risk factors related to the individual (29), such as fear-avoidance beliefs, catastrophizing about pain and concerns over returning to work. *Blue flag*s refer to workplace beliefs in light of CLBP, such as fear of re-injury, low expectations of being able to return to work and concerns over physical demands at work. *Black flags* encompass the 'context' surrounding the individual and their CLBP (e.g. relevant individuals such as family members and their reactions to the CLBP experienced by the individual, as well as systems and policies associated with attempts to get back to work). The flags framework is useful to clinicians as part of broader diagnostic criteria and in determining (un)suitable treatments for the management of CLBP, with its utility evident in empirical research (10). Interventions informed by the flags approach have been observed to successfully reduce pain-related work absences and increased return to work for individuals with sub-acute and CLBP (30-34). Though the model is part of international and European recommended guidelines for assessment and management of lower back pain, recent reports reveal that physicians' adherence to guidelines for physical and psychosocial assessment, which include the flags approach, is low (35-37).

There is little teaching time dedicated to pain management, more generally, in all types of healthcare training (3), including physicians (38). A lack of knowledge about psychosocial risk factors and low adherence to guidelines indicates that clinical decisions regarding the management of CLBP exclude important psychological cues which may improve how CLBP is managed (39, 40). The early experiences of medical students in their placements and internships are times of constant learning, enabling them to develop appropriate attitudes towards their future as physicians (41). As the next generation of physicians, medical students and GP trainees are a population on which to assess clinical judgments and decision-making, regarding psychosocial influences in the diagnosis and treatment of CLBP. Extant research has examined the effects of biopsychosocial perspective educational interventions, such as through videos and vignettes, with results yielding significant changes in beliefs and attitudes of healthcare providers and clinical behaviour (42-44). These results are encouraging as potential changes in judgment-making may arise from a change in knowledge, attitudes and beliefs. However, further research is needed to determine how these changes translate into clinical judgments on the future management of CLBP (25, 37, 45). It is hypothesised that those who receive a training intervention will outperform 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.

METHODS AND ANALYSIS

Design

The design is a single-blind randomised controlled trial comparing the effects of an e-learning biopsychosocial model intervention with a waiting list control condition on the clinical judgments of medical students and GP trainees regarding future risk of disability of CLBP patients. Any modifications to the protocol which may impact on the conduct of the study will require a formal amendment to the protocol. Such amendment will be agreed on by the Irish Health Research Board Interdisciplinary Capacity Enhancement Award, grant number (ICE/2011/19) research group, and approved by the relevant ethics committee prior to the implementation of the modifications. Minor administrative changes to the protocol will be agreed on by the Irish Health Research Board Interdisciplinary Capacity Enhancement Award, grant number (ICE/2011/19) research group, and will be documented in a memorandum.

Recruitment, participants and randomisation

Recruitment of the participants (i.e. medical students and GP trainees) will be conducted via online advertisement and communication with administrating bodies for medical education in Irish third-level educational institutions. Specifically, willing administrating bodies will directly contact, via email, their eligible medical students and GP trainees to advertise participation in the research programme. Though individuals interested in participating will be sent information about the trial, any information that could potentially prime participants or their performance will not be disseminated prior to the intervention. All participants will be fully debriefed upon completion of the intervention. Inclusion criteria are: current GP Trainee or medical student (year 3-5). Notably, all participants will have completed their *curriculum-based* biopsychosocial education by the time of study participation. All participants will provide full informed consent. Participants will be 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. Once the randomisation procedure has been completed, the participants in the intervention group will begin the intervention. The statistician involved in the analysis of the data will be blinded to group allocation. In return for their participation, medical students and GP trainees will be awarded a €25 gift voucher.

Trial Aims

The aim of the trial is compare the effects of an e-learning intervention, which focuses on a biopsychosocial model of pain, on the clinical judgments (i.e. judgment accuracy, speed and weighting); biopsychosocial model knowledge; and the attitudes and beliefs towards pain of medical students and trainees. The e-learning biopsychosocial model intervention consists of a once-off, 20-minute purpose-developed Flags Approach video lecture (i.e. developed from information presented within *Tackling musculoskeletal problems: A guide for clinic and workplace*; (46). The e-learning intervention has been developed by a postdoctoral psychologist who has research expertise in judgment and decision-making (CD); a psychologist (SC) and research assistant (BR) with research experience in chronic pain; a psychologist with expertise in clinical judgment-making (PMN); under the supervision of a licensed clinical psychologist specialising in pain management (BM).

The current study will take place during one two-hour session (see Figure 1). Two groups will take part in the study: those who participate in the e-learning Flags Approach to Clinical Judgment educational intervention and a wait-list control group. At the outset, participants will be provided information regarding the nature of the study (i.e. that this study will assess clinical judgments regarding CLBP), but will not be advised about the Flags approach or the biopsychosocial model, so as to not bias participants before the beginning of the intervention. Participants will be informed of their rights and that they can withdraw from the study at any time. Participants will be administered the battery of assessments (i.e. judgment; knowledge; attitudes and beliefs; and empathy) and randomly allocated to either the intervention group or control group. Following the 20 minute intervention, both groups will again be administered the battery of assessments, after which all participants will be fully debriefed and thanked.

Insert Figure 1 around here

Outcome measures

All outcome measures will be conducted during the hour immediately pre-intervention and during the hour immediately post-intervention. Any adverse events and the rate of attrition among the participants during their completion of the intervention will also be recorded.

Demographic and clinical information

Participants will be asked to supply details regarding age and gender and current level of medical training.

Primary outcome measures

Judgment will be assessed online according to accuracy and weight allotted to presenting symptoms within a series of 40 cases of male patients living with CLBP. All fictional patients are similarly categorised, for example, identified as being male, aged between 49 and 55; married with children (aged between 10 – 16 years); and currently on GP certified sick-leave from work due to a CLBP flare-up that has lasted the past 3 weeks, prescribed anti-inflammatories and non-opiate analgesics only, etc. (see Appendix A for patient background and presenting problems associated with CLBP). Gender, age, family and medical background, as well as other background information was designed to remain consistent across all 40 cases, in order to ensure that judgments would not be influenced by changes across such variables from case to case, *other* than the six contextual cues (i.e. case factors – see below) presented in the bar graphs for evaluation. Participants will be asked to put themselves in the position of the GP for these 40 consultations and judge the patients' risk of future disability, which in this context is referred to "*the potential for significant work disability 9 months from now, i.e. impeding the person from remaining in their current job if the job responsibilities were to remain the same as present."* Judgments are rated on a probability scale of 1-10 (1 = 10% chance of disability in 9 months, through 10 = 100% chance of disability in 9 months). For each case, a unique combination of six biopsychosocial case factors is provided (i.e. bio: mobility and sleep; psycho: motivation and self-esteem; social: close relationships and social activity), as are definitions and examples of each (see Appendix A). Low scores represent a low level problem on that factor; whereas high scores represent a high level problem on that factor (example in Figure 2). The 40 cases were developed via an adapted version of the case generator developed and used in research by Hamm, Beasley (47). Specifically, variables within each case are allotted scores regarding *level of problem*, from 10 to 95, via increments of five (though presented on a bar graph ranging from 0-100). Cases were generated randomly. In order to ensure similarity between generated cases and real-life cases, the six variables (i.e. two variables per factor) were randomised in a manner in which each pair (i.e. a pair each for bio, psycho and social factors) were correlated. To achieve this, two randomisation processes were conducted. In the first process, low (i.e. 10-35) moderate (i.e. 40-65) and high scores (i.e. 70-95) were randomly assigned to bio, psycho and social factors. Each range consisted of six possible scores. In the second randomisation procedure, each variable, within each pair, was then provided a randomised score relevant to the range identified in the first randomisation protocol. Following the randomisation process, Pearson analysis was conducted to ensure appropriate correlation. Results revealed that all six variables were significantly correlated with their paired variable: Mobility and sleep ($r = .57$, $p < .001$); Mood and motivation ($r = .58$, $p < .001$); and close relationships and social activity ($r = .54$, $p < .001$). Consistent with the perspective described, cumulative biological, psychological and social factors were all positively correlated, but not significantly, in order to allow test-takers an ability to observe discrepancy among factors. Means for each factor ranged from $M = 44.00$-56.88. Following the development analysis, the 40 cases were randomised twice to create Form A and Form B, in order

to ensure uniformity at pre-and-post-testing. However, different case names (e.g. Jim, 48 years-old) were allotted to each case in Forms A and B, in order to avoid any practice effects. Two case booklets (each consisting of 40 cases) were independently judged by experts in clinical judgment and decision-making based on the flags approach: (1) to reflect real-life symptom presentation scenarios and (2) to identify the correct answer (i.e. judgment problem-level) for each case. Specifically, *Expert 1* is a Professor of Clinical Psychology (Pain Management) with over 40 years' experience as a clinical psychologist and over 30 years specialising in pain management with over 140 publications and over 9,000 citations. He has published multiple books on the topic of pain management including biopsychosocial guidelines. *Expert 2* is also a Professor of Clinical Psychology, with expertise in pain management, having published in the field for over 15 years; and is the Joint Director of a Pain Research Centre in an internationally renowned University.

Insert Figure 2 around here

Judgment weighting allotted to presenting symptoms within each case judgment will be assessed via *judgment analysis*, which utilises regression modelling to objectively describe professionals' decision-making (48, 49). Specifically, judgment analysis focuses on the weighting of importance given by decision-makers specific to case cues (i.e. in this context, mobility, sleep, self-esteem, motivation, close relationships and social activity), based on Brunswik's (50) lens model.

Secondary outcome measures

Judgment speed, or response time, will be measured 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) was clicked via mouse. The location of the mouse pointer is centred above the response scale at the beginning of each case presentation in order to avoid any location bias. There is a 1.5 second delay between each response and the appearance of the next case. Speed is quantified in terms of milliseconds and used as both a correlate of accuracy and to categorise *fast* and *slow* responders for further comparison.

Flags Approach Knowledge will be assessed using a purpose-developed multiple choice question test (i.e. each with five possible options and only one correct answer) at both pre-and-post-testing. Two separate 15-item assessments (A and B) were developed for the current study, in order to avoid practice effects. Both assessments are scored on a scale of 0-15. In total, 27 items were developed, based exclusively on information relevant to the biopsychosocial model, as presented within the lecture (see Kendall (51)); and piloted with 25 participants. Two items were removed based on difficulty, as no pilot participants answered them correctly. Five items appeared on both

assessment A and B, given their central importance to the topic. The remaining 20 items were split amongst the two forms based on both (1) the nature of the question (i.e. specifically relating to pain, the biopsychosocial model or implications of the flags approach); and (2) difficulty (i.e. determined by percentage of individuals who identified the correct answer), in order to maintain even levels of difficulty. To further control for difficulty, assessment A and B will be counter-balanced at pre-and-post-testing.

The Pain Attitudes & Beliefs Scale (PABS; adapted by Houben, Becker (52) from Ostelo, Stomp-van den Berg (53)) will be used to measure healthcare practitioners' endorsement of a biomedical/biopsychosocial approach to CLBP. The PABS consists of 19-items, divided according to two factors: endorsement of a biomedical perspective on pain and tissue damage (10 items); and biopsychosocial orientation that functional problems can be overcome despite chronic pain (9 items). This measure has been recently used and validated in a study of Irish GPs (54) and has robust test reliability, with research indicating internal consistency ranging from α = .65-83 (52, 53, 55).

The Interpersonal Reactivity Index (IRI;Davis (56)) measures empathy – conceptualised as reactions of one individual to the observed experiences of another. The index is divided into four sub-scales – two of which were administered in the current study (i.e. perspective-taking and empathic concern), consisting of seven items each. Perspective-taking refers to the tendency to adopt the psychological point of view of others; and empathic concern refers to the extent of one's feelings of compassion and concern for others. Internal consistency of the sub-scales range from α = .68-.75 (57, 58). Empathy will be assessed via a four-point likert scale (56) and will account for potential differences between groups due to the presence of patient vignettes within the video, which may potentially evoke empathic responses.

Statistical analysis

An *a priori* G*Power analysis was conducted based on a two tailed alpha value of .05, a beta value of .80, and a medium effect size, which yielded a recommended sample size of 34 for the present study (59). A 2x2 (condition: e-Learning intervention and control group) x 2 (time: pre-and-post-testing) Mixed MANCOVA will be used to compare the effects of an e-learning intervention, teaching the fundaments of the Flags Approach to clinical judgment, with a no-intervention control group on judgment accuracy, *Flags Approach* knowledge, attitudes and beliefs towards pain, while controlling for judgment speed and empathy. Judgment analysis (48, 49) will be used to analyse judgment weighting (i.e. weighting allotted to presenting symptoms within each judgment). Correlations among judgment accuracy, speed, weighting, knowledge, empathy and attitudes and beliefs will also be analysed. The sensitivity of the final results to missing data will be investigated using multiple imputation analysis based on chained equations and predictive mean matching. All

analyses will be completed using IBM SPSS V.21 statistics packages. Each hypothesis will be tested using a two-tailed analysis at the $\alpha = 0.05$ level of significance.

DATA MONITORING AND MANAGEMENT

This trial does not have a data and monitoring committee because: the study is minimal risk; judgment, knowledge and attitude assessment is non-harmful; and of the nature of the study population (i.e. adult, not considered vulnerable). All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access, or on encrypted electronic devices, as appropriate. All records that contain names or other personal identifiers will be stored separately from study records identified by code number. All local and online databases will be secured with password-protected access systems. Paper-based documents that link participant ID numbers to other identifying information will be stored in a separate locked file in an area with limited access. Data stored on computer databases will be password-protected and access to files will be limited to research staff who require direct access. The trial statistician will work on depersonalised data where the participant's identifying information will be replaced by an unrelated sequence of characters. All principal investigators and post-doctoral researchers involved in the running of the trial will be given access to the cleaned data sets. All data sets will be password protected. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information.

DISSEMINATION

Regardless of the significance, direction or magnitude of effect, the trial findings will be submitted for publication in peer-reviewed journals. Trial findings will also be disseminated through both domestic (i.e. in Ireland) and international conference abstracts. Once all of the data have been collected and cleaned, we will aim to submit the trial results for publication within 3 months.

Author Affiliations

[1]Centre for Pain Research, National University of Ireland, Galway, Ireland

[2]School of Psychology, National University of Ireland, Galway, Ireland

[3]Department of Family & Preventive Medicine, University of Oklahoma Health Sciences Center, U.S.

[4]Department of Behavioural Medicine, Keele University, Staffordshire, England

[5]Discipline of Economics, National University of Ireland, Galway, Ireland

[6]Discipline of Health Promotion, National University of Ireland, Galway, Ireland

[7]Discipline of General Practice, National University of Ireland, Galway, Ireland

[8]Discipline of Medical Informatics and Education, National University of Ireland, Galway, Ireland

Contributors: CPD was involved in and oversaw the design of the intervention; the literature review; statistical aspects of the trial; and the writing of the manuscript. HD was involved in the literature review, contributed to the statistical aspects of the trial and the editing of the manuscript. PMN contributed to the design of the intervention, statistical aspect of the trial and to the editing of the manuscript. BR was involved in the literature review and the statistical aspects of the trial. RMH and CJM contributed to the statistical aspects of the trial. LLOC contributed to the design of the intervention and was involved in the development of the assessment protocol. SC and DT contributed to the statistical aspects of the trial and contributed to the editing of the manuscript. BWS, CON, SNG, AWM and TK contributed to the editing of the manuscript. BEM contributed to the design of the intervention, supervised the study and also contributed to the editing of the manuscript.

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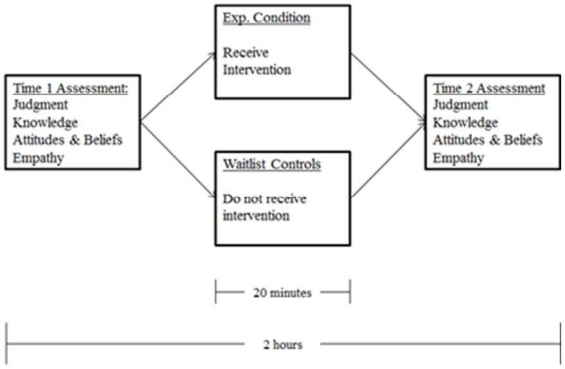

Figure 1: Schematic for Treatment Regiment

Figure 1: Schematic for Treatment Regiment
297x209mm (300 x 300 DPI)

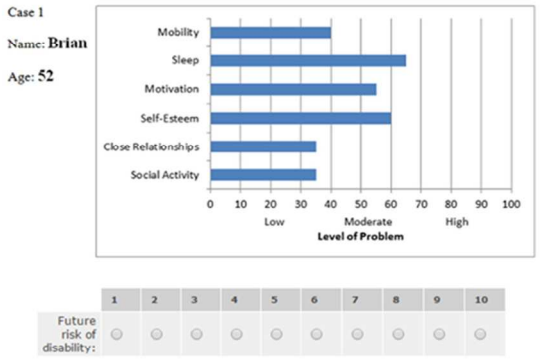

Figure 2: Example of a case to be judged by participants

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297x209mm (300 x 300 DPI)

Appendix A

Mobility

Visual observations of mobility of the back and spine

Low ↓ High

- Good range of movement, moves easily
- Movements full but painful, patient moves a little stiffly
- Some limited extension of spine, moving quite stiffly
- Limited flexion and movement, difficult moving to standing positio
- Very restricted, great difficulty moving from seated to standing

Sleep

Interruption and disturbance to restful sleep (NB: not early morning waking)

Low ↓ High

- Sleeping ok, may wake occasionally but generally restful sleep
- Not well rested, sleep is somewhat disrupted
- Quite fatigued from disrupted sleep, cannot get comfortable in bed
- Difficult falling or staying asleep, wakes in pain several times a nigl
- Significant disruption to sleep due to pain, no peace at night

Self Esteem

Mood, ideas and feelings about self

Low ↓ High

- In good form and confidence ok, normal ups and downs
- Feels a bit down at the moment, irritable through lack of progress
- Mood is poor, frustrated and blaming self
- Despairing at times, high levels of hostility
- Feels hopeless, angry and withdrawn

Motivation

Self-direction, willing to focus on treatment goals

Low ↓ High

- Eager to return to work, fully focused on future recovery
- Some reluctance to follow treatment advice, needs encouraging to comply with advice
- Worried about return to work, fears further damage and resists advice
- Focuses mainly on avoiding work and activity, poor treatment adherence
- Reluctant to discuss work at all, not engaged with treatment at all

Close Relationships

Intimate familial, romantic and/or friendship connections

Low ↓ High

- Strong mutual support network with close family and friends, many positive interactions with spouse
- Support from both close family and friends is accessible when needed, occasional quarrelling or miscommunication with spouse
- Some regular support from family members or from friends, but some 'ups and downs' in spousal relationship
- Sporadic support from family or friends, frequent disagreements with spouse
- Little support from family or from friends, significant marriage problems

Social Activity

Engagement with other(s) in communal interests, endeavours or pursuits

Low ↓ High

- Typically socialises with others 2 or 3 times each week, active role in local community group
- Tends to socialises with others once a week, chats regularly with neighbours
- Pattern of socialising on special occasions only, interacts with community members periodically
- Does not typically socialise outside the home, knows neighbours only to say 'hello'
- Very few social contacts, minimal engagement with community members

Case Histories

In the following pages, you will be presented with a series of 40 cases of men suffering from chronic lower back pain (CLBP). All patients are:

- Aged between 49 and 55,
- Are married with children (aged between 10 – 16 years) ; and are
- Currently on GP certified sick-leave from work, due to a CLBP flare-up that has lasted the past 3 weeks. This flare-up is self-described as particularly bad. Self-reported pain varies from 6 to 8 on a 10-point scale.
- All patients work in supervisory roles in production settings in multi-national companies, with some duties including minor physical exertion.

On average, each patient visits their GP four times per annum due to CLBP that emerged approximately 10 years ago. No definitive cause for CLBP is apparent in any case. There was no evidence of structural problems in x-rays taken 4 years ago and earlier this year.

Each patient has been prescribed the following only: anti-inflammatories (e.g., Difene 50-100mg bd), and non-opiate analgesics (e.g., paracetamol 500-1000mg qid, Tramadol 50mg prn). Patients have been compliant with medications and have attended physiotherapy several times, though have not been consistent in exercise.

All patients previously reported worry that pain levels will increase and fear painful movement. Patients are not happy at times with medical care. All patients were previously active and are social drinkers only (i.e. no indication of abuse). Their mood is low at times, but not diagnosed as clinically depressed.

Instructions

Please put yourself in the position of the GP for these 40 consultations today. For each case, you will be asked to judge the patient's **Risk of Future Disability**. Take this to refer to:

The potential for significant work disability 9 months from now, i.e. impeding the person from remaining in their current job if the job responsibilities were to remain the same as present.

Please make your judgment of future risk of disability by rating the case on a Probability Scale of 1-10 (1 = 10% chance of Disability in 9 months, through to 10 = 100% change of Disability in 9 months).

For each case, base your judgment of Risk of Future Disability on the six case factors provided. Each patient represents a unique combination of the case factors of Mobility, Sleep, Motivation, Self-Esteem, Close Relationships, and Social Activity. The definition of each case factor below is accompanied by illustrative examples.

Low scores on a case factor represent a low problem level on that factor. High scores represent a high problem level on that factor. Assume the information in the case factors has been obtained in the consultation.

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BMJ Open

The effectiveness of a biopsychosocial e-learning intervention on the clinical judgments of medical students and GP trainees regarding future risk of disability in chronic lower back pain patients: Study protocol for a randomised controlled trial

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The effectiveness of a biopsychosocial e-learning intervention on the clinical judgments of medical students and GP trainees regarding future risk of disability in chronic lower back pain patients: Study protocol for a randomised controlled trial

Corresponding author*
cdwyer@nuigalway.ie, painresearch@nuigalway.ie

Christopher P. Dwyer[1, 2*]

Hannah Durand[1, 2]

Pádraig MacNeela[2]

Bronagh Reynolds[1]

Robert M. Hamm[3]

Christopher J. Main[4]

Laura L. O'Connor[1]

Sinéad Conneely[2]

Darragh Taheny[1]

Brian W. Slattery[1, 2]

Ciaran O'Neill[5]

Saoirse NicGabhainn[6]

Andrew W. Murphy[7]

Thomas Kropmans[8]

Brian E. McGuire[1, 2]

ABSTRACT

Introduction: Chronic lower back pain (CLBP) is a major healthcare problem with wide ranging effects. It is a priority for appropriate management of CLBP to get individuals back to work as early as possible. Interventions which identify biopsychosocial barriers to recovery have been observed to lead to successfully reduced pain-related work absences and increased return to work for individuals with CLBP. Modern conceptualisations of pain adopt a biopsychosocial approach, such as the *Flags Approach*. Biopsychosocial perspectives have been applied to judgments about future adjustment, recovery from pain and risk of long-term disability; and provide a helpful model for understanding the importance of contextual interactions between psychosocial and biological variables in the experience of pain. Medical students and GP trainees are important groups to target with education about biopsychosocial conceptualisations of pain and related clinical implications.

Aim: The current study will compare the effects of an e-learning intervention, which focuses on a biopsychosocial model of pain, on the clinical judgments of medical students and trainees.

Methods and analysis: Medical student and GP trainee participants will be randomised to one of two study conditions: (a) a 20-minute e-learning intervention focused on the fundamentals of the Flags Approach to clinical judgment-making regarding risk of future pain-related disability; compared with a (b) wait-list control group on judgment accuracy and weighting (i.e. primary outcomes); Flags Approach knowledge, attitudes and beliefs towards pain, judgment speed and empathy (i.e. secondary outcomes). Participants will be assessed at pre-and-post-intervention.

Ethics and dissemination: The study will be performed in agreement with the Declaration of Helsinki and is approved by the National University of Ireland Galway Research Ethics Committee. 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.

Trial Registration: ISRCTN53670726

STRENGTHS & WEAKNESSES

Strengths:

- The research study is novel with respect to its methodology and cohort to be assessed.
- The research aims to account for multiple conceptualisations of clinical judgment, including accuracy, weighting and speed.

Weaknesses:

- Given the cohort of participants required, the sample size may, arguably, be considered small.
- Given the cohort of participants required and their schedules, provision of a longer (i.e. follow-up, third testing time), voluntary intervention is not feasible.

INTRODUCTION

Chronic lower back pain (CLBP) is a major Irish healthcare burden, with figures from the Prevalence, Impact and Cost of Chronic Pain (PRIME) study revealing 10% of the Irish population suffers from chronic back pain (1). The cost of chronic pain in Ireland has been estimated at €5.34 billion per annum or 2.86% of Ireland's gross domestic product (2). CLBP is a further economic concern as it results in huge losses in productivity and increases in workplace absenteeism. Those who are working lose an average of seventeen days annually due to CLBP, with 15% of those reporting job loss due to their condition (3). It is also the most common reason for individuals receiving disability income, with 27% of sufferers unable to work due to their condition. The wide ranging effects of CLBP for the individual, their family, society and the workplace, mean that it is a high priority for this condition to be appropriately managed in order to get individuals back to work[1] (4, 5). Furthermore, approximately 90% of cases of lower back pain are non-specific (i.e. there is no identifiable, discernible cause) (6). In that context, traditional treatment methods prescribed according to the biomedical model often fail to adequately manage CLBP and may even contribute to further patient disability (7-10). Interventions that integrate cognitive and behavioural approaches via the identification of biopsychosocial barriers to recovery have been observed to successfully reduce pain-related work absences and increase return to work for individuals with CLBP. A biopsychosocial model of pain may provide a better foundation for understanding lower back pain (11-13) and allow for recognition of the importance of biological, psychological and social interactions in both the individual's experience of their pain and the GP's clinical judgment (14).

There is wide support for this perspective in extant research – indicating that non-medical factors such as personal circumstances and pain beliefs are as important in the perpetuation of chronic pain and disability as biological aspects of pain (15). For example, even after controlling for health variables, work environment and the nature of work-related tasks remain strong predictors of back pain disability (16, 17). Furthermore, occupational factors predictive of disability are interconnected with psychosocial variables regarding return to work, as many have been found to be associated with prolonged work disability (10, 18-21). For example, lower expectations of returning to work and a lack of confidence to carry out work-related tasks are examples of psychosocial risk factors associated with extended work disability (22, 23). In this context, an individual's beliefs and attitudes about their abilities may be influential in shaping their actual longer term ability to carry out work-related tasks.

[1] Though the rationale justifies the importance of the occupational effects of CLBP and its relationship with future risk of disability, those who do not work or were not working prior to the onset of CLBP remain susceptible to being hindered by the effects of CLBP in conducting tasks important to them in the future. Thus, in cases of CLBP wherein staying or getting back to work are not applicable, future risk of disability remains an important outcome for consideration.

When acknowledging these risk factors, it is important to recognise that they do not exist in a vacuum and should be considered within a broader context. Contextual and socioeconomic factors such as older age, healthcare provision, emotional impact on the patient's family and level of social integration are all interconnected with psychosocial and occupational risk factors (24, 25). Given the above, it is reasonable to suggest that there is a diverse range of biomedical, psychological and environmental influences which are involved in CLBP. As CLBP is one of the most common disorders presenting in primary care (2, 3, 26), it is essential for physicians to have a systematic approach to assess and treat this disorder (25, 27).

One useful method of assessing and managing psychosocial factors in lower back pain is the *flags approach* (28). This is a conceptual framework which integrates the identification of biopsychosocial and behavioural barriers to recovery; and involves the use of various *flags*, for example, consistent with the traditional medical notion of 'red flags' which are indicative of an observable physical pathology. This framework has been refined to include *yellow flags* as psychological risk factors related to the individual (29), such as fear-avoidance beliefs, catastrophizing about pain and concerns over returning to work. *Blue flag*s refer to workplace beliefs in light of CLBP, such as fear of re-injury, low expectations of being able to return to work and concerns over physical demands at work. *Black flags* encompass the 'context' surrounding the individual and their CLBP (e.g. relevant individuals such as family members and their reactions to the CLBP experienced by the individual, as well as systems and policies associated with attempts to get back to work). The flags framework is useful to clinicians as part of broader diagnostic criteria and in determining (un)suitable treatments for the management of CLBP, with its utility evident in empirical research (10). Interventions informed by the flags approach have been observed to successfully reduce pain-related work absences and increased return to work for individuals with sub-acute and CLBP (30-34). Though the model is part of international and European recommended guidelines for assessment and management of lower back pain, recent reports reveal that physicians' adherence to guidelines for physical and psychosocial assessment, which include the flags approach, is low (35-37).

There is little teaching time dedicated to pain management, more generally, in all types of healthcare training (3), including physicians (38). A lack of knowledge about psychosocial risk factors and low adherence to guidelines indicates that clinical decisions regarding the management of CLBP exclude important psychological cues which may improve how CLBP is managed (39, 40). The early experiences of medical students in their placements and internships are times of constant learning, enabling them to develop appropriate attitudes towards their future as physicians (41). As the next generation of physicians, medical students and GP trainees are a population on which to assess clinical judgments and decision-making, regarding psychosocial influences in the diagnosis and treatment of CLBP. Extant research has examined the effects of biopsychosocial perspective educational interventions, such as through videos and vignettes, with results yielding significant

changes in beliefs and attitudes of healthcare providers and clinical behaviour (42-44). These results are encouraging as potential changes in judgment-making may arise from a change in knowledge, attitudes and beliefs. However, further research is needed to determine how these changes translate into clinical judgments on the future management of CLBP (25, 37, 45). It is hypothesised that those who receive a training intervention will outperform 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.

METHODS AND ANALYSIS

Design

The design is a single-blind randomised controlled trial comparing the effects of an e-learning biopsychosocial model intervention with a waiting list control condition on the clinical judgments of medical students and GP trainees regarding future risk of disability of CLBP patients. Any modifications to the protocol which may impact on the conduct of the study will require a formal amendment to the protocol. Such amendment will be agreed on by the Irish Health Research Board Interdisciplinary Capacity Enhancement Award, grant number (ICE/2011/19) research group, and approved by the relevant ethics committee prior to the implementation of the modifications. Minor administrative changes to the protocol will be agreed on by the Irish Health Research Board Interdisciplinary Capacity Enhancement Award, grant number (ICE/2011/19) research group, and will be documented in a memorandum.

Recruitment, participants and randomisation

Recruitment of the participants (i.e. medical students and GP trainees) will be conducted via online advertisement and communication with administrating bodies for medical education in Irish third-level educational institutions. Specifically, willing administrating bodies will directly contact, via email, their eligible medical students and GP trainees to advertise participation in the research programme. Though individuals interested in participating will be sent information about the trial, any information that could potentially prime participants or their performance will not be disseminated prior to the intervention. All participants will be fully debriefed upon completion of the intervention. Inclusion criteria are: current GP Trainee or medical student (year 3-5). Notably, all participants will have completed their *curriculum-based* biopsychosocial education by the time of study participation. All participants will provide full informed consent. Participants will be 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. Once the randomisation procedure has been completed,

the participants in the intervention group will begin the intervention. The statistician involved in the analysis of the data will be blinded to group allocation. In return for their participation, medical students and GP trainees will be awarded a €25 gift voucher. Remuneration of participants was approved by both the funding and ethics bodies supporting the current research.

Trial Aims

The aim of the trial is compare the effects of an e-learning intervention, which focuses on a biopsychosocial model of pain, on the clinical judgments (i.e. judgment accuracy, speed and weighting); biopsychosocial model knowledge; and the attitudes and beliefs towards pain of medical students and trainees. The e-learning biopsychosocial model intervention consists of a once-off, 20-minute purpose-developed Flags Approach video lecture (i.e. developed from information presented within *Tackling musculoskeletal problems: A guide for clinic and workplace*; (46). The e-learning intervention has been developed by a postdoctoral psychologist who has research expertise in judgment and decision-making (CD); a psychologist (SC) and research assistant (BR) with research experience in chronic pain; a psychologist with expertise in clinical judgment-making (PMN); under the supervision of a licensed clinical psychologist specialising in pain management (BM).

The current study will take place during one two-hour session (see Figure 1). Two groups will take part in the study: those who participate in the e-learning Flags Approach to Clinical Judgment educational intervention and a wait-list control group. At the outset, participants will be provided information regarding the nature of the study (i.e. that this study will assess clinical judgments regarding CLBP), but will not be advised about the Flags approach or the biopsychosocial model, so as to not bias participants before the beginning of the intervention. Participants will be informed of their rights and that they can withdraw from the study at any time. Participants will be administered the battery of assessments (i.e. judgment; knowledge; attitudes and beliefs; and empathy) and randomly allocated to either the intervention group or control group. Following the 20 minute intervention, both groups will again be administered the battery of assessments, after which all participants will be fully debriefed and thanked.

Insert Figure 1 around here

Outcome measures

All outcome measures will be conducted during the hour immediately pre-intervention and during the hour immediately post-intervention. Any adverse events and the rate of attrition among the participants during their completion of the intervention will also be recorded.

Demographic and clinical information

Participants will be asked to supply details regarding age and gender and current level of medical training.

Primary outcome measures

Judgment will be assessed online according to accuracy and weight allotted to presenting symptoms within a series of 40 cases of male patients living with CLBP. All fictional patients are similarly categorised, for example, identified as being male, aged between 49 and 55; married with children (aged between 10 – 16 years); and currently on GP certified sick-leave from work due to a CLBP flare-up that has lasted the past 3 weeks, prescribed anti-inflammatories and non-opiate analgesics only, etc. (see Appendix A for patient background and presenting problems associated with CLBP). Gender, age, family and medical background, as well as other background information was designed to remain consistent across all 40 cases, in order to ensure that judgments would not be influenced by changes across such variables from case to case, *other* than the six contextual cues (i.e. case factors – see below) presented in the bar graphs for evaluation. Participants will be asked to put themselves in the position of the GP for these 40 consultations and judge the patients' risk of future disability, which in this context is referred to "*the potential for significant work disability 9 months from now, i.e. impeding the person from remaining in their current job if the job responsibilities were to remain the same as present."* Judgments are rated on a probability scale of 1-10 (1 = 10% chance of disability in 9 months, through 10 = 100% chance of disability in 9 months). For each case, a unique combination of six biopsychosocial case factors is provided (i.e. bio: mobility and sleep; psycho: motivation and self-esteem; social: close relationships and social activity), as are definitions and examples of each (see Appendix A). Low scores represent a low level problem on that factor; whereas high scores represent a high level problem on that factor (example in Figure 2). The 40 cases were developed via an adapted version of the case generator developed and used in research by Hamm, Beasley (47). Specifically, variables within each case are allotted scores regarding *level of problem*, from 10 to 95, via increments of five (though presented on a bar graph ranging from 0-100). Cases were generated randomly. In order to ensure similarity between generated cases and real-life cases, the six variables (i.e. two variables per factor) were randomised in a manner in which each pair (i.e. a pair each for bio, psycho and social factors) were correlated. To achieve this, two randomisation processes were conducted. In the first process, low (i.e. 10-35) moderate (i.e. 40-65) and high scores (i.e. 70-95) were randomly assigned to bio, psycho and social factors. Each range consisted of six possible scores. In the second randomisation procedure, each variable, within each pair, was then provided a randomised score relevant to the range identified in the first randomisation protocol. Following the randomisation process, Pearson analysis was conducted to ensure appropriate correlation. Results revealed that all six variables were significantly correlated with their paired variable: Mobility and sleep ($r = .57$, $p < .001$); Mood and motivation ($r = .58$, $p < .001$); and close relationships and social activity ($r = .54$, $p < .001$). Consistent with the perspective described, cumulative biological, psychological and social factors were all positively correlated, but not

significantly, in order to allow test-takers an ability to observe discrepancy among factors. Means for each factor ranged from M = 44.00-56.88. Following the development analysis, the 40 cases were randomised twice to create Form A and Form B, in order to ensure uniformity at pre-and-post-testing. However, different case names (e.g. Jim, 48 years-old) were allotted to each case in Forms A and B, in order to avoid any practice effects. Two case booklets (each consisting of 40 cases) were independently judged by experts in clinical judgment and decision-making based on the flags approach: (1) to reflect real-life symptom presentation scenarios and (2) to identify the correct answer (i.e. judgment problem-level) for each case. Specifically, *Expert 1* is a Professor of Clinical Psychology (Pain Management) with over 40 years' experience as a clinical psychologist and over 30 years specialising in pain management with over 140 publications and over 9,000 citations. He has published multiple books on the topic of pain management including biopsychosocial guidelines. *Expert 2* is also a Professor of Clinical Psychology, with expertise in pain management, having published in the field for over 15 years; and is the Joint Director of a Pain Research Centre in an internationally renowned University.

Insert Figure 2 around here

Judgment weighting allotted to presenting symptoms within each case judgment will be assessed via *judgment analysis*, which utilises regression modelling to objectively describe professionals' decision-making (48, 49). Specifically, judgment analysis focuses on the weighting of importance given by decision-makers specific to case cues (i.e. in this context, mobility, sleep, self-esteem, motivation, close relationships and social activity), based on Brunswik's (50) lens model.

Secondary outcome measures

Judgment speed, or response time, will be measured as the length of time from the moment a case appears on screen until a response (i.e. identifying, from 1-10, future risk of disability) is clicked via mouse. The location of the mouse pointer is centred above the response scale at the beginning of each case presentation in order to avoid any location bias. There is a 1.5 second delay between each response and the appearance of the next case. Speed is quantified in terms of milliseconds and used as both a correlate of accuracy and to categorise *fast* and *slow* responders for further comparison.

Flags Approach Knowledge will be assessed using a purpose-developed multiple choice question test (i.e. each with five possible options and only one correct answer) at both pre-and-post-testing. Two separate 15-item assessments (A and B) were developed for the current study, in order to avoid practice effects. Both assessments are scored on a scale of 0-15. In total, 27 items were developed, based exclusively on information relevant to the biopsychosocial model, as presented

within the lecture (see Kendall (51)); and piloted with 25 participants. Two items were removed based on difficulty, as no pilot participants answered them correctly. Five items appeared on both assessment A and B, given their central importance to the topic. The remaining 20 items were split amongst the two forms based on both (1) the nature of the question (i.e. specifically relating to pain, the biopsychosocial model or implications of the flags approach); and (2) difficulty (i.e. determined by percentage of individuals who identified the correct answer), in order to maintain even levels of difficulty. To further control for difficulty, assessment A and B will be counter-balanced at pre-and-post-testing.

The Pain Attitudes & Beliefs Scale (PABS; adapted by Houben, Becker (52) from Ostelo, Stomp-van den Berg (53) will be used to measure healthcare practitioners' endorsement of a biomedical/biopsychosocial approach to CLBP. The PABS consists of 19-items, divided according to two factors: endorsement of a biomedical perspective on pain and tissue damage (10 items); and biopsychosocial orientation that functional problems can be overcome despite chronic pain (9 items). This measure has been recently used and validated in a study of Irish GPs (54) and has robust test reliability, with research indicating internal consistency ranging from α = .65-83 (52, 53, 55).

The Interpersonal Reactivity Index (IRI; Davis [56]) measures empathy – conceptualised as reactions of one individual to the observed experiences of another. The index is divided into four sub-scales – two of which were administered in the current study (i.e. perspective-taking and empathic concern), consisting of seven items each. Perspective-taking refers to the tendency to adopt the psychological point of view of others; and empathic concern refers to the extent of one's feelings of compassion and concern for others. Internal consistency of the sub-scales range from α = .68-.75 (56, 57). Empathy will be assessed via a four-point likert scale (58) and will account for potential differences between groups due to the presence of patient vignettes within the video, which may potentially evoke empathic responses.

Statistical analysis

An *a priori* G*Power analysis was conducted based on a two tailed alpha value of .05, a beta value of .80, and a medium effect size, which yielded a recommended sample size of 34 for the present study (59). A 2x2 (condition: e-Learning intervention and control group) x 2 (time: pre-and-post-testing) Mixed MANCOVA will be used to compare the effects of an e-learning intervention, teaching the fundaments of the Flags Approach to clinical judgment, with a no-intervention control group on judgment accuracy, *Flags Approach* knowledge, attitudes and beliefs towards pain, while controlling for judgment speed and empathy. Judgment analysis (48, 49) will be used to analyse judgment weighting (i.e. weighting allotted to presenting symptoms within each judgment). Correlations among judgment accuracy, speed, weighting, knowledge, empathy and attitudes and

beliefs will also be analysed. The sensitivity of the final results to missing data will be investigated using multiple imputation analysis based on chained equations and predictive mean matching. All analyses will be completed using IBM SPSS V.21 statistics packages. Each hypothesis will be tested using a two-tailed analysis at the $\alpha = 0.05$ level of significance.

DATA MONITORING AND MANAGEMENT

This trial does not have a data and monitoring committee because: the study is minimal risk; judgment, knowledge and attitude assessment is non-harmful; and of the nature of the study population (i.e. adult, not considered vulnerable). All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access, or on encrypted electronic devices, as appropriate. All records that contain names or other personal identifiers will be stored separately from study records identified by code number. All local and online databases will be secured with password-protected access systems. Paper-based documents that link participant ID numbers to other identifying information will be stored in a separate locked file in an area with limited access. Data stored on computer databases will be password-protected and access to files will be limited to research staff who require direct access. The trial statistician will work on depersonalised data where the participant's identifying information will be replaced by an unrelated sequence of characters. All principal investigators and post-doctoral researchers involved in the running of the trial will be given access to the cleaned data sets. All data sets will be password protected. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information.

DISSEMINATION

Regardless of the significance, direction or magnitude of effect, the trial findings will be submitted for publication in peer-reviewed journals. Trial findings will also be disseminated through both domestic (i.e. in Ireland) and international conference abstracts. Once all of the data have been collected and cleaned, we will aim to submit the trial results for publication within 3 months.

Author Affiliations

[1]Centre for Pain Research, National University of Ireland, Galway, Ireland

[2]School of Psychology, National University of Ireland, Galway, Ireland

[3]Department of Family & Preventive Medicine, University of Oklahoma Health Sciences Center, U.S.

[4]Department of Behavioural Medicine, Keele University, Staffordshire, England

[5]Discipline of Economics, National University of Ireland, Galway, Ireland

[6]Discipline of Health Promotion, National University of Ireland, Galway, Ireland

[7]Discipline of General Practice, National University of Ireland, Galway, Ireland

[8]Discipline of Medical Informatics and Education, National University of Ireland, Galway, Ireland

Contributors: CPD was involved in and oversaw the design of the intervention; the literature review; statistical aspects of the trial; and the writing of the manuscript. HD was involved in the literature review, contributed to the statistical aspects of the trial and the editing of the manuscript. PMN contributed to the design of the intervention, statistical aspect of the trial and to the editing of the manuscript. BR was involved in the literature review and the statistical aspects of the trial. RMH and CJM contributed to the statistical aspects of the trial. LLOC contributed to the design of the intervention and was involved in the development of the assessment protocol. SC and DT contributed to the statistical aspects of the trial and contributed to the editing of the manuscript. BWS, CON, SNG, AWM and TK contributed to the editing of the manuscript. BEM contributed to the design of the intervention, supervised the study and also contributed to the editing of the manuscript.

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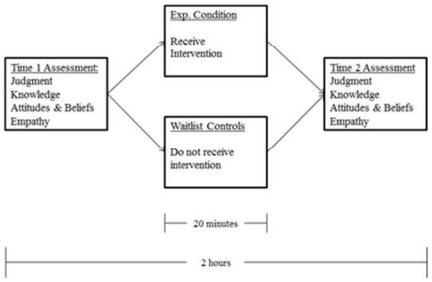

Figure 1: Schematic for Treatment Regiment

Schematic for Treatment Regiment
297x209mm (300 x 300 DPI)

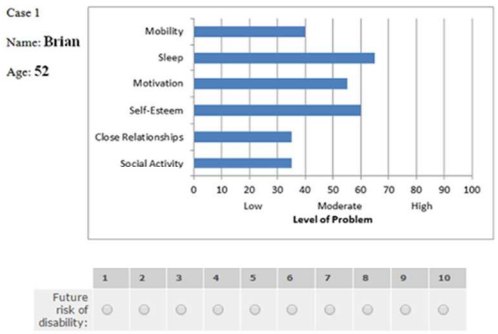

Figure 2: Example of a case to be judged by participants

Example of a case of to be judged by particapants
297x209mm (300 x 300 DPI)

Appendix A

Mobility

Visual observations of mobility of the back and spine

Low ↓ High

- Good range of movement, moves easily
- Movements full but painful, patient moves a little stiffly
- Some limited extension of spine, moving quite stiffly
- Limited flexion and movement, difficult moving to standing positio
- Very restricted, great difficulty moving from seated to standing

Sleep

Interruption and disturbance to restful sleep (NB: not early morning waking)

Low ↓ High

- Sleeping ok, may wake occasionally but generally restful sleep
- Not well rested, sleep is somewhat disrupted
- Quite fatigued from disrupted sleep, cannot get comfortable in bed
- Difficult falling or staying asleep, wakes in pain several times a nigl
- Significant disruption to sleep due to pain, no peace at night

Self Esteem

Mood, ideas and feelings about self

Low ↓ High

- In good form and confidence ok, normal ups and downs
- Feels a bit down at the moment, irritable through lack of progress
- Mood is poor, frustrated and blaming self
- Despairing at times, high levels of hostility
- Feels hopeless, angry and withdrawn

Motivation

Self-direction, willing to focus on treatment goals

Low ↓ High

- Eager to return to work, fully focused on future recovery
- Some reluctance to follow treatment advice, needs encouraging to comply with advice
- Worried about return to work, fears further damage and resists advice
- Focuses mainly on avoiding work and activity, poor treatment adherence
- Reluctant to discuss work at all, not engaged with treatment at all

Close Relationships

Intimate familial, romantic and/or friendship connections

Low ↓ High

- Strong mutual support network with close family and friends, many positive interactions with spouse
- Support from both close family and friends is accessible when needed, occasional quarrelling or miscommunication with spouse
- Some regular support from family members or from friends, but some 'ups and downs' in spousal relationship
- Sporadic support from family or friends, frequent disagreements with spouse
- Little support from family or from friends, significant marriage problems

Social Activity

Engagement with other(s) in communal interests, endeavours or pursuits

Low ↓ High

- Typically socialises with others 2 or 3 times each week, active role in local community group
- Tends to socialises with others once a week, chats regularly with neighbours
- Pattern of socialising on special occasions only, interacts with community members periodically
- Does not typically socialise outside the home, knows neighbours only to say 'hello'
- Very few social contacts, minimal engagement with community members

Case Histories

In the following pages, you will be presented with a series of 40 cases of men suffering from chronic lower back pain (CLBP). All patients are:

- Aged between 49 and 55,
- Are married with children (aged between 10 – 16 years) ; and are
- Currently on GP certified sick-leave from work, due to a CLBP flare-up that has lasted the past 3 weeks. This flare-up is self-described as particularly bad. Self-reported pain varies from 6 to 8 on a 10-point scale.
- All patients work in supervisory roles in production settings in multi-national companies, with some duties including minor physical exertion.

On average, each patient visits their GP four times per annum due to CLBP that emerged approximately 10 years ago. No definitive cause for CLBP is apparent in any case. There was no evidence of structural problems in x-rays taken 4 years ago and earlier this year.

Each patient has been prescribed the following only: anti-inflammatories (e.g., Difene 50-100mg bd), and non-opiate analgesics (e.g., paracetamol 500-1000mg qid, Tramadol 50mg prn). Patients have been compliant with medications and have attended physiotherapy several times, though have not been consistent in exercise.

All patients previously reported worry that pain levels will increase and fear painful movement. Patients are not happy at times with medical care. All patients were previously active and are social drinkers only (i.e. no indication of abuse). Their mood is low at times, but not diagnosed as clinically depressed.

Instructions

Please put yourself in the position of the GP for these 40 consultations today. For each case, you will be asked to judge the patient's **Risk of Future Disability**. Take this to refer to:

The potential for significant work disability 9 months from now, i.e. impeding the person from remaining in their current job if the job responsibilities were to remain the same as present.

Please make your judgment of future risk of disability by rating the case on a Probability Scale of 1-10 (1 = 10% chance of Disability in 9 months, through to 10 = 100% change of Disability in 9 months).

For each case, base your judgment of Risk of Future Disability on the six case factors provided. Each patient represents a unique combination of the case factors of Mobility, Sleep, Motivation, Self-Esteem, Close Relationships, and Social Activity. The definition of each case factor below is accompanied by illustrative examples.

Low scores on a case factor represent a low problem level on that factor. High scores represent a high problem level on that factor. Assume the information in the case factors has been obtained in the consultation.

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