

BMJ Open Effectiveness of a biopsychosocial e-learning intervention on the clinical judgements of medical students and GP trainees regarding future risk of disability in patients with chronic lower back pain: study protocol for a randomised controlled trial

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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 that 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 judgements 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 general practitioner (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 that focuses on a biopsychosocial model of pain, on the clinical judgements of medical students and trainees.

Methods and analysis: Medical student and GP trainee participants will be randomised to 1 of 2 study conditions: (1) a 20 min e-learning intervention focused on the fundamentals of the flags approach to clinical judgement-making regarding risk of future pain-related disability; compared with a (2) wait-list control group on judgement accuracy and weighting (ie, primary outcomes); flags approach knowledge, attitudes and beliefs towards pain, judgement speed and empathy (ie, secondary outcomes). Participants

Strengths and limitations of this study

- 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 judgement, including accuracy, weighting and speed. 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 (ie, follow-up, third testing time), voluntary intervention is not feasible.

will be assessed at preintervention and postintervention.

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 number: ISRCTN53670726; Pre-results.

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 that 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 17 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, ~90% of cases of lower back pain are non-specific (ie, 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 general practitioner's (GP) clinical judgement.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.

[†]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 that 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 that 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' that 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, catastrophising about pain and concerns over returning to work. 'Blue flags' refer to workplace beliefs in light of CLBP, such as fear of reinjury, 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 (eg, 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 subacute 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 that of physicians.³⁸ A lack of knowledge about psychosocial risk factors and low adherence to guidelines indicate that clinical decisions regarding the management of CLBP exclude important psychological cues that 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 toward their future as physicians.⁴¹ As the next generation of physicians, medical students and GP trainees are a

population in which to assess clinical judgements 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 judgement-making may arise from a change in knowledge, attitudes and beliefs. However, further research is needed to determine how these changes translate into clinical judgements on the future management of CLBP.^{25 37 45} It is hypothesised that those who receive a training intervention will outperform controls on judgement accuracy regarding future risk of disability and biopsychosocial model (flags approach) knowledge from pretesting to post-testing; will demonstrate attitudes and beliefs towards pain more consistent with the biopsychosocial model than controls from pretesting to post-testing; and will distribute the weight of their judgements more evenly (ie, across biopsychosocial factors) than controls from pretesting 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 judgements of medical students and GP trainees regarding future risk of disability of patients with CLBP. Any modifications to the protocol that 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 (ie, 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

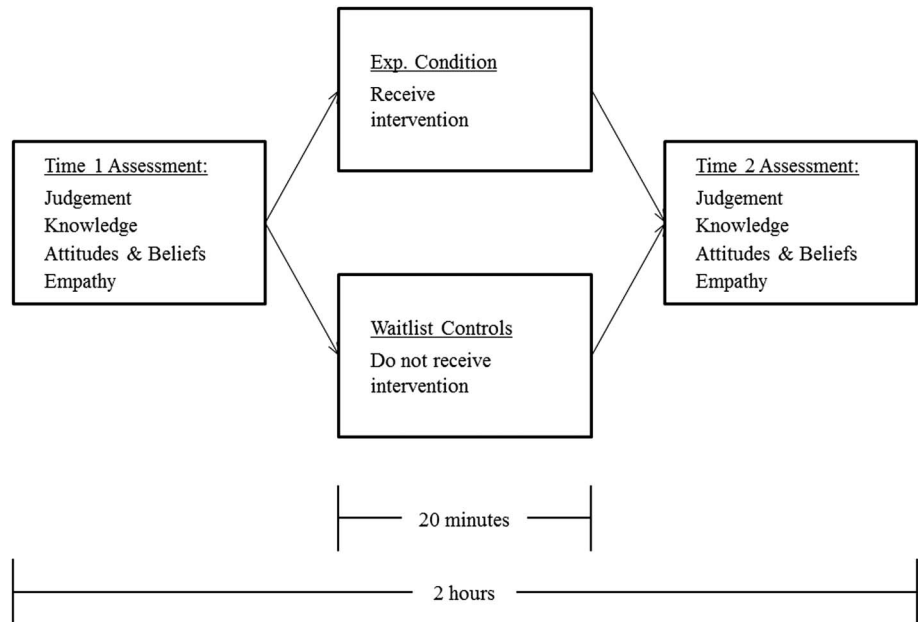
prior to the intervention. All participants will be fully debriefed on completion of the intervention. Inclusion criteria are: current GP trainee or medical student (year 3–5). Notably, all participants will have completed their curriculum-based biopsychosocial education by the time of study participation. All participants will provide full informed consent. Participants will be randomised to the intervention or waiting list control group, 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 to compare the effects of an e-learning intervention that focuses on a biopsychosocial model of pain, on the clinical judgements (ie, judgement 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 min purpose-developed flags approach video lecture (ie, 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 judgement and decision-making (CPD); a psychologist (SC) and research assistant (BR) with research experience in chronic pain; and a psychologist with expertise in clinical judgement-making (PM)—under the supervision of a licensed clinical psychologist specialising in pain management (BEM).

The current study will take place during one 2-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 (ie, that this study will assess clinical judgements regarding CLBP), but will be advised about neither the flags approach nor the biopsychosocial model, so as not to bias participants before the beginning of the intervention. Participants will be informed of their rights and assured that they can withdraw from the study at any time. Participants will be administered the battery of assessments (ie, judgement, knowledge, attitudes and beliefs, and empathy) and randomly allocated to either the intervention group or control group. Following the 20 min intervention, both groups will again be

Figure 1 Schematic for treatment regimen.



administered the battery of assessments, after which all participants will be fully debriefed and thanked.

Outcome measures

All outcome measures will be conducted during the hour immediately preintervention and during the hour immediately postintervention. 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

Judgement 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 years; married with children (aged between 10 and 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 online supplementary appendix A for patient background and presenting problems associated with CLBP). Gender, age, and family and medical background, as well as other background information, was designed to remain consistent across all 40 cases, in order to ensure that judgements would not be influenced by changes across such variables from case to case, other than the six contextual cues (ie, 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 as 'the potential for significant work disability 9 months from now, that is, impeding the person from remaining in their current job if the job responsibilities were to remain the same as present'. Judgements 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 (ie, bio: mobility and sleep; psycho: motivation and self-esteem; social: close relationships and social activity), as are definitions and examples of each (see online supplementary 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 *et al.*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 to 100). Cases were generated randomly. In order to ensure similarity between generated cases and real-life cases, the six variables (ie, two variables per factor) were randomised in a manner in which each pair (ie, a pair each for bio, psycho and social factors) were correlated. To achieve this, two randomisation processes were conducted. In the first process, low (ie, 10–35), moderate (ie, 40–65) and high scores (ie, 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:

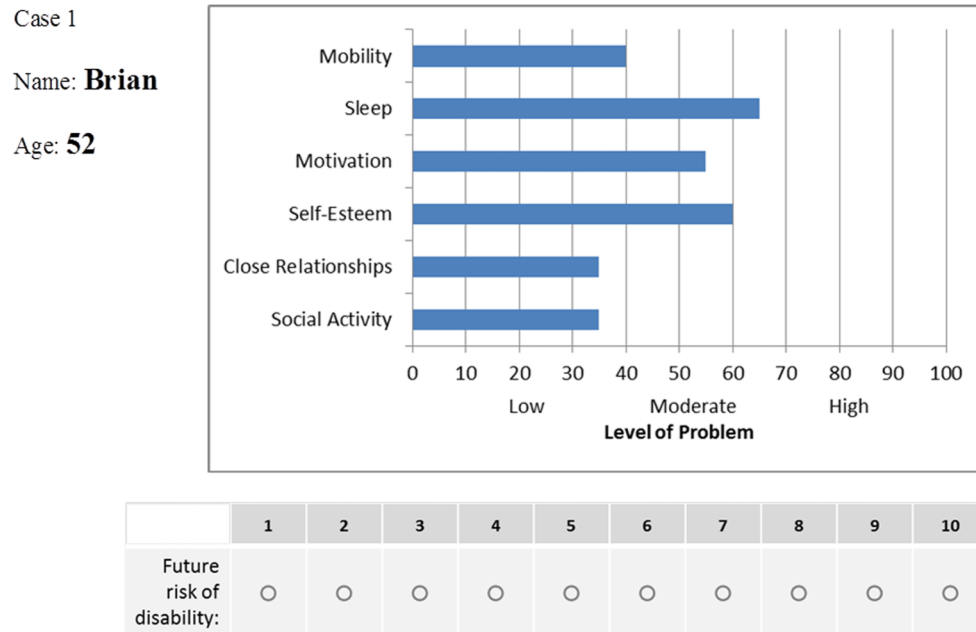


Figure 2 Example of a case to be judged by participants.

mobility and sleep ($r=0.57$, $p<0.001$); mood and motivation ($r=0.58$, $p<0.001$); and close relationships and social activity ($r=0.54$, $p<0.001$). 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 $M=44.00$ to 56.88 . Following the development analysis, the 40 cases were randomised twice to create forms A and B, in order to ensure uniformity at pretesting and post-testing. However, different case names (eg, 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 judgement and decision-making, based on the flags approach: (1) to reflect real-life symptom presentation scenarios and (2) to identify the correct answer (ie, judgement problem-level) for each case. Specifically, expert 1 is a Professor of Clinical Psychology (pain management) with over 40 years of experience as a clinical psychologist and over 30 years specialising in pain management with over 140 publications and over 9000 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.

Judgement weighting allotted to presenting symptoms within each case judgement will be assessed via judgement analysis, which utilises regression modelling to objectively describe professionals' decision-making.^{48 49} Specifically, judgement analysis focuses on the weighting

of importance given by decision-makers specific to case cues (ie, in this context, mobility, sleep, self-esteem, motivation, close relationships and social activity), based on Brunswik's⁵⁰ lens model.

Secondary outcome measures

Judgement speed, or response time, will be measured as the length of time from the moment a case appears on screen until a response (ie, identifying, from 1 to 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 s 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 (ie, each with five possible options and only one correct answer) at both pretesting 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 Kendall⁵¹); and piloted with 25 participants. Two items were removed based on difficulty, as no pilot participants answered them correctly. Five items appeared on assessment A and B, given their central importance to the topic. The remaining 20 items were split between the two forms, based on both (1) the nature of the question (ie, specifically relating to pain, the biopsychosocial model or implications of the flags

approach); and (2) difficulty (ie, 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 pretesting and post-testing.

The Pain Attitudes and Beliefs Scale (PABS; adapted by Houben *et al*⁵² from Ostelo *et al*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 GPs⁵⁴ and has robust test reliability, with research indicating internal consistency ranging from $\alpha=0.65$ to 0.83 .^{52 53 55}

The Interpersonal Reactivity Index (IRI; Davis⁵⁶) measures empathy—conceptualised as reactions of one individual to the observed experiences of another. The index is divided into four subscales—two of which were administered in the current study (ie, 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 subscales range from $\alpha=0.68$ to 0.75 .^{56 57} Empathy will be assessed via a four-point Likert scale⁵⁸ 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 α value of 0.05, a β value of 0.80 and a medium effect size, which yielded a recommended sample size of 34 for the present study.⁵⁹ A 2×2 (condition: e-learning intervention and control group)×2 (time: pretesting and post-testing) mixed MANCOVA will be used to compare the effects of an e-learning intervention, teaching the fundamentals of the flags approach to clinical judgement, with a no-intervention control group on judgement accuracy, flags approach knowledge, attitudes and beliefs towards pain, while controlling for judgement speed and empathy. Judgement analysis^{48 49} will be used to analyse judgement weighting (ie, weighting allotted to presenting symptoms within each judgement). Correlations among judgement 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; judgement, knowledge and attitude assessment is non-harmful; and owing to the nature of the study population (ie, 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 postdoctoral 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 all 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 (ie, 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.

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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, and contributed to the statistical aspects of the trial and the editing of the manuscript. PM 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. LLO 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, CO, SN, 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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Competing interests None declared.

Patient consent Obtained.

Ethics approval Ethical approval has been granted by the National University of Ireland Galway Research Ethics Committee.

Provenance and peer review Not commissioned: externally peer reviewed.

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