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# It's safe to move! A protocol for a randomised controlled trial investigating the effect of a video designed to increase people's confidence becoming more active despite back pain

Edel O'hagan
*Neuroscience Research Australia*

Adrian C. Traeger
*The University of Sydney School of Public Health*

Siobhan M. Schabrun
*Neuroscience Research Australia*, sschabru@uwo.ca

Sean O'neill
*Maridulu Budyari Gumal*

Benedict Martin Wand
*University of Notre Dame Australia*

*See next page for additional authors*

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# It's safe to move! A protocol for a randomised controlled trial investigating the effect of a video designed to increase people's confidence becoming more active despite back pain

Edel O'Hagan ,[1,2,3] Adrian C Traeger ,[4] Siobhan M Schabrun ,[1,3] Sean O'Neill,[3,5,6] Benedict Martin Wand,[7] Aidan Cashin ,[1,8] Christopher Michael Williams ,[4] Ian A Harris,[3,4,5,9] James H McAuley[1,3,8]

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For numbered affiliations see end of article.

**Correspondence to**
Dr Edel O'Hagan;
edel.ohagan@sydney.edu.au

## ABSTRACT

**Introduction** Social media provide promising contemporary platforms for sharing public health information with a broad audience. Before implementation, testing social media campaigns that are intended to engage audiences and initiate behaviour change is necessary. This trial aims to investigate the effectiveness of a public health campaign to increase people's confidence in becoming more active despite low back pain in comparison with no intervention.

**Methods and analysis** This is an online randomised controlled trial with two intervention groups and one control group in a 1:1:1 allocation. People over 18 years of age and fluent in English will be recruited via social media advertising. We developed a social media-based public health campaign to support recommendations for managing low back pain. The interventions are two videos. Participants in the control group will be asked questions about low back pain but will not view either video intervention. The primary outcome will be item 10 of the Pain Self-Efficacy Questionnaire, which asks participants to rate how confident they would feel to gradually become more active despite pain ranging from 0 (not at all confident) to 6 (completely confident). This outcome will be measured immediately in all participant groups. We will compare group mean of the three arms of the trial using univariate analyses of variance.

**Ethics and dissemination** This trial has been prospectively registered with the Australian New Zealand Clinical Trials Registry. We obtained ethical approval from our institutions Human Research Ethics Committee before data collection. We will publish the results in a peer-reviewed medical journal and on institution websites.

**Trial registration number** Australian New Zealand Clinical Trials Registry (ACTRN12622000466741).

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This randomised controlled trial (RCT) will investigate a new, simple, inexpensive approach to delivering a public health message about low back pain on a large scale.
⇒ A randomised controlled design allows for testing an intervention before being widely disseminated, which is not typical of mass media campaigns.
⇒ An entirely online RCT allows participation across the world to increase the generalisability of the results.
⇒ We will include qualitative methods to understand how to optimise the intervention.
⇒ We will investigate the effect on proximal outcomes only, therefore have a limited insight into the effect on distal outcomes such as healthcare use.

## INTRODUCTION

### Background and rationale

Low back pain is common and burdensome. The point prevalence of activity-limiting low back pain lasting more than one day is 7.8%, meaning that 577 million people have low back pain at any one time across the world.[1] Low back pain is the leading cause of disability worldwide, causing one of the largest absolute increases in the number of days lost to disability of any health condition over the last 20 years.[2] Experts from *The Lancet* Low Back Pain Series Working Group predict the cost of low back pain will continue to escalate.[3] Large scale initiatives are necessary to stem the cost of this global public health concern.[4]

Recent research suggests that people with low back pain value learning about causes of low back pain,[5] and people with low back pain who accept evidence-based messages, such as pain does not equal damage, are likely to intend to self-manage their low back pain.[6] Yet, inaccurate information is common in community healthcare settings[7] and on health websites.[8 9] Population-based surveys conducted in Ireland,[10] Australia,[11]

Norway,[12] Switzerland[13] and Canada[14] highlighted that an unhelpful, medicalised view of back pain is common. Challenging unhelpful beliefs about low back pain was identified as one of the top 10 priorities for researchers, considered vital to reverse the alarming global rise in low back pain disability and healthcare costs.[15]

One approach that has been successful at decreasing low back pain-related costs on a large scale are mass media campaigns[16 17] that deliver a public health message to a broad audience.[18 19] An Australian mass media public health campaign effectively changed beliefs about low back pain and reduced associated costs.[16 20] However, similar campaigns in Norway,[21 22] Scotland,[23] Ireland[24] and Canada[25] failed to demonstrate any impact on low back pain-related health costs. One factor evident in the successful Australian campaign was the broad reach; the campaign reached 86% of the target population.[17] Social media provide promising contemporary platforms for sharing public health information with a broad audience.[26] Social media campaigns have the capacity for broad reach as there are 3.8 billion active social media users worldwide.[27] When a social media campaign is engaging, it can generate increasing likes and shares, termed 'viral'.[28] A viral campaign creates a self-proliferating message, further extending reach.[28 29] A poorly developed campaign could fail to engage the targeted group.[30] A recent process evaluation of health communication and promotion campaigns on social media found that campaigns often do not sufficiently engage audiences to impact health behaviour.[31] Before implementation, testing social media campaigns intended to engage audiences and initiate behaviour change is necessary.

In this trial, we will investigate the effectiveness of a campaign about low back pain compared with no intervention at improving an essential domain of pain-related self-efficacy. We will conduct qualitative testing, including evaluating engagement to maximise the impact of delivering a reassuring message about low back pain using social media.

## Objective

This trial aims to investigate the effectiveness of a public health campaign to increase people's confidence in becoming more active despite low back pain in comparison with no intervention.

## Trial design

This trial is a three-group, parallel, randomised controlled trial (RCT) with two intervention groups and one control group in a 1:1:1 allocation. This protocol is reported following the Standard Protocol Items: Recommendations for Interventional Trials checklist.[32]

## METHODS

### Participants and interventions and outcomes

#### Study setting

This will be an online community-based global trial. Participants will be recruited via social media advertising.

#### Eligibility criteria

People will be eligible for inclusion in this RCT if they are over 18 years of age and able to understand spoken and written English.

#### Interventions

In collaboration with an advertising agency, VMLY&R, we developed a public health campaign, delivered by social media, to support recommendations for managing low back pain. The interventions comprise videos described in brief below and in more detail in accordance with the TIDieR checklist in online supplemental appendix 1.

The video interventions are between 2 and 3 minutes long. Both follow the same narrative that scientists would like to reassure the public that low back pain is common, and that evidence suggests it is safe to move despite back pain. In addition, our previous evidence suggested the value of providing validation to people experiencing low back pain.[33] The earlier results showed that people seek validation on social media, one interpretation is due to feeling dismissed or invalidated by clinicians. We aimed to increase the credibility of the information and provide validation by using scientists and clinicians to narrate the video.

The featured scientists report that they are unsure of how to convey these messages to the public, which leads to designers at the advertising agency brainstorming how to help deliver the key message that it is safe to move. The advertising agency personnel suggest a dance. The video cuts back to the scientists who are reluctant to endorse one specific movement, such as a dance and conclude that it does not matter what you do as long as you move. The video ends with the superimposed text, 'It's safe to move', 'Your backbone has backbone'. The second video is the same as the first, except that when the advertising agency suggests the dance, the scientists try it out and to add humour, there are some video clips of the scientists dancing.

Participants in the control group will not view either video intervention. The video interventions will be uploaded to the study page on the Open Science Framework website (https://osf.io/c7j8t/). They will be embargoed until after the trial is completed.

#### Outcomes

We will conduct both a quantitative and qualitative evaluation. When completing the outcomes, those without low back pain will be presented with a scenario where they have low back pain. In addition to the primary and secondary outcomes, participants randomised to either video intervention group will be asked additional questions regarding the video content, their engagement level, and overall experience.

#### Baseline questionnaires

Baseline questionnaires will include questions on age and gender. In addition, we will ask participants about the presence of low back pain, pain intensity over the preceding 24 hours and the duration of the current episode of low back pain.

### Primary outcome

The intervention is intended to increase a person's confidence (or self-efficacy) that they can move safely despite low back pain. The primary outcome is therefore item 10 of the Pain Self-Efficacy Questionnaire (PSEQ),[26] a commonly used measure of self-efficacy for people with chronic pain.[34] A Rasch analysis of the PSEQ investigated each question to identify the extent to which a positive answer to that question reflected the attribute (self-efficacy).[35] The authors determined that item 10, 'increasing confidence becoming more active', was easiest for participants to *endorse*,[35] meaning, an optimal 'self-efficacy' intervention should target that item. Item 10 of the PSEQ asks participants to rate how confident they would feel to gradually become more active despite the pain with a range from 0 (not at all confident) to 6 (completely confident). Improving self-efficacy may facilitate symptom management, a proximal component of the broader, distal target of self-management.[33]

### Secondary outcome

The secondary outcome will be Factor 1 of the AxEL-Q Questionnaire.[36] The AxEL-Q is a questionnaire designed to assess attitudes toward first-line education and advice for low back pain, Factor 1 comprises nine items and evaluates *Attitude toward staying active*. The score range for Factor 1 is 0 to 54, with higher scores indicating a more positive attitude toward messages about staying active. This outcome will be measured immediately in all participant groups.

### Qualitative evaluation

We will conduct a mixed-methods qualitative evaluation consisting of three parts. First, to understand the helpfulness of the video, we will ask participants four questions rated on a 7-point Numeric Rating Scale.[37] Second, we will evaluate engagement with the video by asking participants six 'Yes/No' questions. Finally, we will ask participants four open-ended questions to understand their experience watching the video. The questions included in the qualitative evaluation are outlined in table 1.

### Participant timeline

Participant progress through the study is shown in figure 1. We will embed both video interventions into a survey which we will distribute online. Participants will access the survey via an anonymous link on social media channels Facebook, Twitter, Instagram and TikTok. The survey will include baseline questionnaires. Participants will be randomised to either of the intervention groups or the control group and then asked to complete primary and secondary outcomes. Participants randomised to each intervention group will be asked additional questions to evaluate the content of the videos.

### Sample size

We simulated multiple treatment and control comparisons using Dunnett's test to calculate the sample size assuming a difference in mean 0.5 and standard deviation (SD) of 3. Based on 2000 Monte Carlo samples from the null distributions we will require an average group size of 461 for a total sample size of 1383 to power a one-way design with two treatment groups and one control group. This design would achieve an any-pair power of 0.81 with an error rate of 0.05.

### Recruitment

Participants will be recruited through social media advertising. We will post an invitation to participate on the

**Table 1** Questions that participants will be asked to understand engagement with video interventions

| Helpfulness of the video (rated on a 7-point Numeric Rating Scale) | Engagement with the video (Yes/No) | Experience of watching the video (Open-ended) |
|---|---|---|
| Overall, did you find this video helpful, with a range from 0=not at all helpful to 6=extremely helpful | Did you like the video? | If any, what aspects were unclear to you? |
| The information in the video was relevant to me, with a range from 0=not at all relevant to 6=extremely relevant | If you noticed this video in your social media feed, would you view it?<br>If you viewed this video on your feed or timeline would 'like' it?<br>If you saw this video on your feed or timeline would share or re-tweet it? | What new things did you learn? |
| How much of the information in the video was NEW information for you, with a range from 0=no new information 6=great deal of new information | After watching the video, are you any less likely to request imaging (eg, X ray or MRI) for back pain? | What did you dislike? |
| Do you think the information in the video was true with a range from 0=not at all true to 6=completely true | Were any parts of the video unclear or didn't make sense? | How did this video make you feel about your back pain? (ie, what emotions did you experience while watching the video?) |

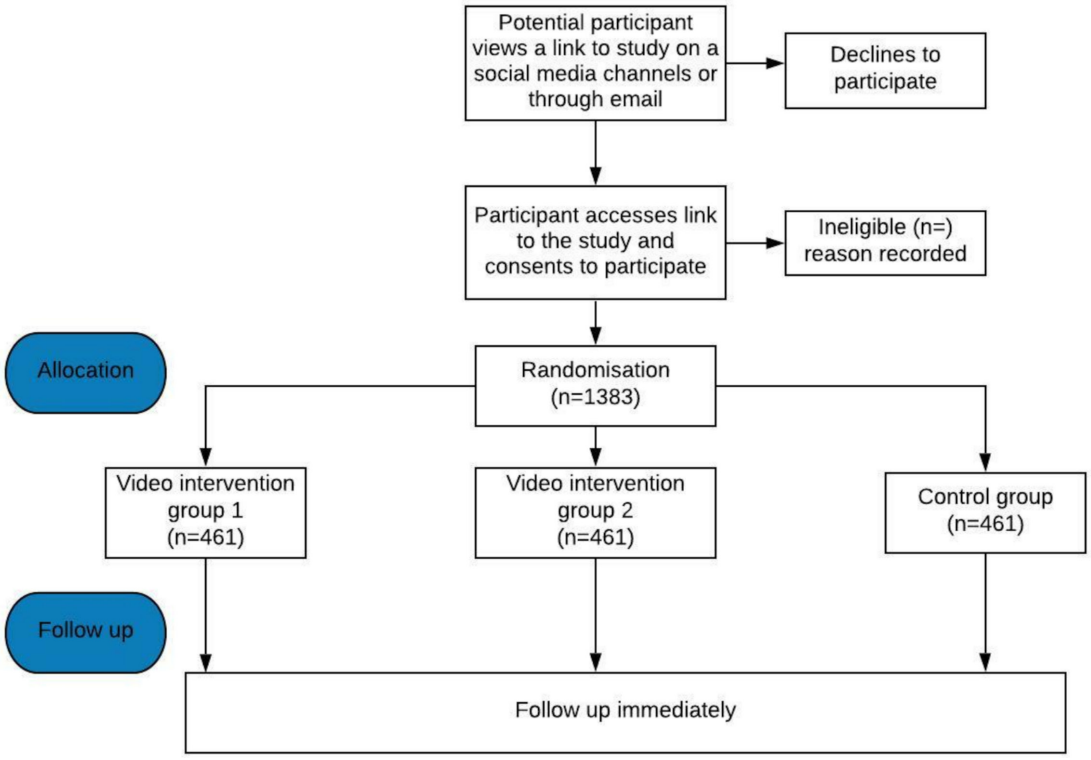


**Figure 1** Participant progress through the study.

social media channels, Facebook, Twitter, Instagram and TikTok.

### Sequence generation, allocation concealment and blinding

Using the Qualtrics survey platform,[38] we will add a 'randomiser' function to the survey flow. The 'randomiser' element will automatically assign respondents to one of the three groups and the corresponding block of questions. A researcher not involved in this study will have access to the randomisation sequence. The participants will self-enrol in the trial. We will blind all members of the research team to group allocation. To maintain blinding, we will not disclose the specific aim of the trial to participants. Instead, we will invite participants to be involved with back pain-related research.

### Data collection, management and analysis

The questionnaire will be electronic and data will be stored according to our institutions data security standards using Qualtrics.[38] Qualtrics allows for a direct export as a CSV file, which will then be uploaded to the R environment for statistical computing[39] for analysis.

We will analyse the data by intention-to-treat. We will use descriptive statistics to characterise the sample. We will report mean and SD for continuous variables. We will use frequencies and percentages to report categorical variables. For the primary and secondary outcomes, we compare between group mean between all three arms of the trial using univariate analyses of variance.

We will conduct subgroup analyses to investigate whether the size or direction of the effect on the primary or secondary outcomes differs between people with and without low back pain and with low back pain of different durations and intensities.

#### Qualitative evaluation

We will report the median and inter-quartile range (IQR) for the helpfulness questions and present these data with box plots. We will count and report the percentage of positive responses to the engagement questions. We will perform a thematic analysis to understand participants experience of watching the video and triangulate these data with the demographic, helpfulness and engagement data. We expect brief one line responses from these questions, that would facilitate a qualitative analysis that is useful but not onerous. These analyses may assist in understanding the relationship, if any, between demographic factors and the experience of watching the video.

### Monitoring

Trial data integrity will be monitored by regularly scrutinising data files for omissions and errors. We will set up the questionnaire platform, Qualtrics, to ensure that participants respond to every question before proceeding. We do not anticipate any harms. A senior investigator not involved in the day to day administration of the trial will audit the trial weekly.

### Ethics and dissemination

We obtained ethical approval from our institutions Human Research Ethics Committee (HREC), approval number HC210908. We will obtain informed consent from all participants before participating in the trial. Protocol amendments will be numbered and uploaded

to the trial site on the Open Science Framework platform. Participants can remain anonymous. We will collect general demographic data only. All authors will declare declarations of interest. Data will be available upon request from the corresponding author on completion of this trial. We will store data securely for 7 years as directed by our institutional HREC. We will publish the results in a peer-reviewed medical journal. We will also publish the results on institution websites.

## Patient and public involvement

Consumers with low back pain were consulted throughout the design of the intervention process. Each major milestone of the intervention development was reviewed by members of the Musculoskeletal Health Consumer Community Council for Maridulu Budyari Gumal before proceeding to the next stage. The consumer group provided suggestions which were implemented in the revised versions including changes to the language used and written text superimposed in both videos. We sought feedback from the consumer community council on the design of the survey to understand and minimise the time commitment required to participate. We will ask the consumer community council to assist with recruitment by sharing a link to the survey platform in their networks. We will continue to consult with the consumer community council when disseminating the study results to assist with choosing what information and results to share and in what format. We acknowledge that the impact of research can vary depending on where the research is conducted,[40] and there is a risk that the results have less impact with international audiences or minority groups. If successful we will seek guidance from international consumer and minority groups to understand how to reflect the preferences and needs of people from different communities in future iterations of this video.

**Author affiliations**
[1]Centre for Pain IMPACT, Neuroscience Research Australia, Randwick, New South Wales, Australia
[2]Prince of Wales Clinical School, University of New South Wales, Randwick, New South Wales, Australia
[3]Maridulu Budyari Gumal, Sydney, New South Wales, Australia
[4]Institute for Musculoskeletal Health, Sydney School of Public Health, The University of Sydney Faculty of Medicine and Health, Sydney, New South Wales, Australia
[5]South Western Sydney Clinical School, Liverpool Hospital, University of New South Wales, Sydney, New South Wales, Australia
[6]Institute of Bone and Joint Research, Kolling Institute, The University of Sydney, Sydney, New South Wales, Australia
[7]Faculty of Medicine, Nursing & Midwifery and Health Sciences, The University of Notre Dame Australia, Fremantle, Western Australia, Australia
[8]School of Health Sciences, Faculty of Medicine and Health, University of New South Wales, Sydney, New South Wales, Australia
[9]Ingham Institute of Applied Medical Research, Liverpool, New South Wales, Australia

**Twitter** Edel O'Hagan @EdelOH, Siobhan M Schabrun @DrSMSchabrun, Aidan Cashin @AidanCashin and Christopher Michael Williams @cmwillow

**Contributors** EO conceived the RCT, provided methodological expertise and wrote the protocol. ACT provided methodological expertise. SMS provided methodological expertise. SO provided methodological expertise. BMW provided methodological expertise. AC provided methodological expertise. CMW provided methodological expertise. IAH provided methodological expertise. JHM is the guarantor and conceived the RCT, provided methodological and clinical area expertise. All authors read, contributed to and approved the final version.

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**Competing interests** None declared.

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**ORCID iDs**
Edel O'Hagan http://orcid.org/0000-0002-1914-5918
Adrian C Traeger http://orcid.org/0000-0002-1646-1907
Siobhan M Schabrun http://orcid.org/0000-0002-9083-3107
Aidan Cashin http://orcid.org/0000-0003-4190-7912
Christopher Michael Williams http://orcid.org/0000-0001-8896-0978

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