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It's ok 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.

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It's ok 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.

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Trial Registration

The trial is registered with the Australia New Zealand Clinical Trials Registry (ANZCTR)
Trial Id: ACTRN12622000466741
The protocol is uploaded to the Open Science Framework website, under embargo.
https://osf.io/c7j8t/

Protocol

This protocol is reported following the SPIRIT checklist. [1] This is protocol version 1.

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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 means 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 (HREC) before data collection. We will publish the results in a peer-reviewed medical journal and on institution websites.

Strengths and limitations

- This randomised controlled trial 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 randomised controlled trial 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. [2] 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. [3] Experts from The Lancet Low Back Pain Series Working Group predict the cost of low back pain will continue to escalate. [4] Large scale initiatives are necessary to stem the cost of this global public health concern. [5]

Recent research suggests that people with low back pain value learning about causes of low back pain, [6] 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. [7] Yet, inaccurate information is common in community healthcare settings [8] and on health web-sites. [9] [10] Population based surveys conducted in Ireland, [11] Australia, [12] Norway, [13] Switzerland [14] and Canada [15] highlighted that an unhelpful, medicalised view of back pain is common. Challenging unhelpful beliefs about low back pain was identified as one of top ten priorities for researchers, considered vital to reverse the alarming global rise in low back pain disability and health care costs. [16]

One approach that has been successful at decreasing low back pain related costs on a large scale are mass media campaigns [17] [18] that deliver a public health message to a broad audience. [19] [20] An Australian mass media public health campaign effectively changed beliefs about low back pain and reduced associated costs.[17] [21] However, similar campaigns in Norway, [22] [23] Scotland, [24] Ireland, [25] and Canada [26] 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. [18] Social media provide promising contemporary platforms for sharing public health information with a broad audience. [27] Social media campaigns have the capacity for broad reach as there are 3.8 billion active social media users worldwide. [28] When a social media campaign is engaging, it can generate increasing likes and shares, termed "viral". [29]

A viral campaign creates a self-proliferating message, further extending reach. [29] [30] A poorly developed campaign could fail to engage the targeted group. [31] 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. [32] 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 to 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.

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 of videos described in brief below and in more detail in accordance with the TIDieR checklist in 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. 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.

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 is item 10 of the Pain Self-Efficacy Questionnaire (PSEQ) [26], a commonly used measure of self-efficacy for people with chronic pain. [33] 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).

Secondary outcome

The secondary outcomes will be Factor 1 of the AxEL-Q Questionnaire. [34] The AxEL-Q is a questionnaire designed to assess attitudes toward first-line care 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. Firstly, to understand the helpfulness of the video, we will ask participants four questions rated on a 7-point Numeric Rating Scale. Secondly, 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.

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? If you viewed this video on your feed or timeline would "like" it? 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 (e.g. 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? (i.e. what emotions did you experience while watching the video?)

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 means 0.5 and standard deviation 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 social media channels, Facebook, Twitter, Instagram and TikTok.

Sequence generation, allocation concealment and blinding

Using the Qualtrics survey platform, [35] 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 stored according to UNSW data security standards using Qualtrics. [35] Qualtrics allows for a direct export as a CSV file, which will then be uploaded to the R environment for statistical computing [36] for analysis.

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

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) range 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. 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 on request from the corresponding author on completion of this trial. We will store data securely for seven 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 (SPHERE), before proceeding to the next stage. The consumer group provided suggestions which were implemented in the revised versions including changes to language 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 burden of the intervention and the time 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.

Competing interests

The authors have no known declarations.

Funding

We received funding from Maridulu Budyari Gumal (SPHERE) for this project.

Contributorship Statement

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
AGC 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 of the manuscript

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Figure 1- Participant progress through the study

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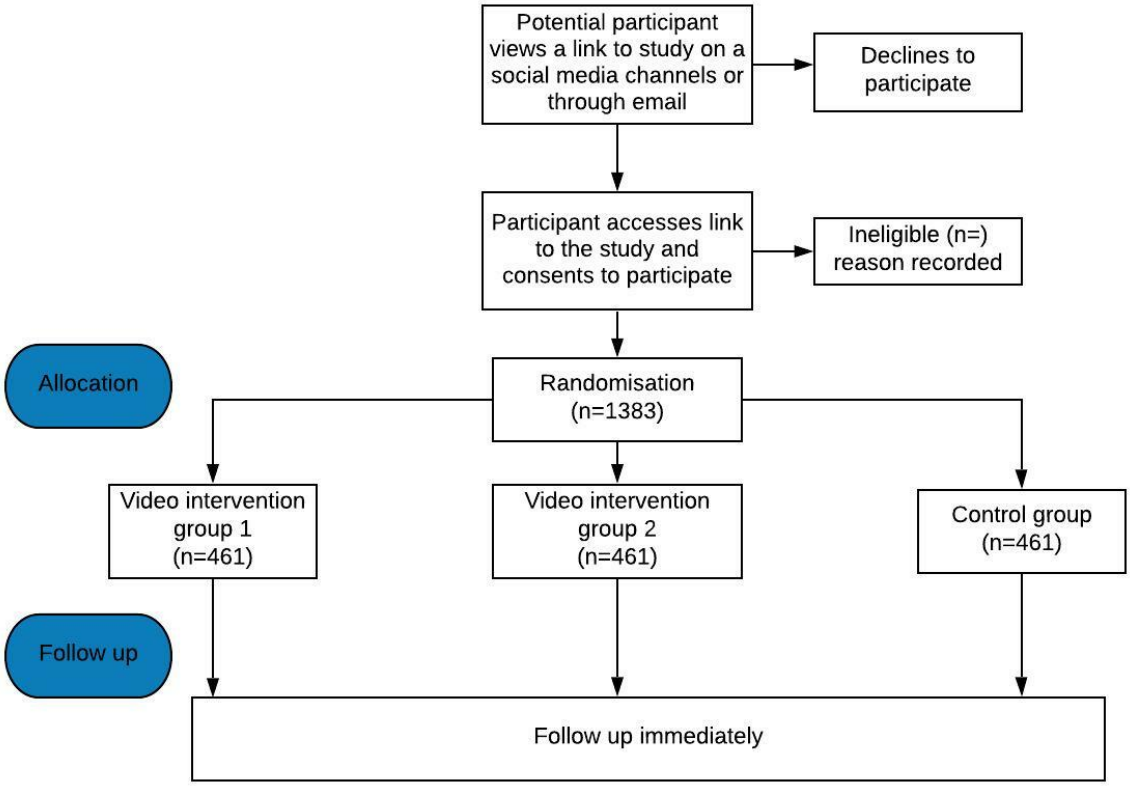

TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	A video designed for dissemination on social media to increase people's confidence becoming more active despite back pain.	1	
	WHY		
2.	A carefully considered, engaging social media message could provide a low-cost alternative to deliver a media campaign about low back pain.	3, 4	
	WHAT		
3.	Materials: The scientists involved in this study met to identify the most important message to be communicated to the general public about low back pain. Next, the scientists met with designers at an advertising agency to discuss and formalise a brief for the intervention. The advertising agency produced three initial storyboards to satisfy the brief for the video intervention, of which, one idea was refined over a series of meetings between the scientists and designers to form two video interventions used in this study. Before deciding on the final content and format the researchers presented the proposed video interventions to a consumer group for review. The consumer group recommend some changes to the language used in the superimposed text in both videos.	4, 5	
4.	Procedures: The final version of each video intervention is 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, but evidence suggests that it is safe to move despite back pain. The featured scientists report that they are unsure of how to convey this message to the public, which leads to the introduction of designers at the advertising agency brainstorming how to help deliver the message that it is safe to move. The advertising agency personnel suggest a dance. The video cuts back to the scientists who are	5	

	reluctant to endorse one specific movement, such as dance and conclude that it does not matter what you do as long as you move. The video concludes with the text, "It's safe to move", "Your backbone has backbone". The second video is exactly the same as the first, except when the advertising agency recommends the dance, the scientists try it out and to add humour, there are some video clips of the scientists dancing.		
	WHO PROVIDED		
5.	Participants will access the survey via an email or an anonymous link on social media.	7	
	HOW		
6.	The video will run as an item in the survey, that the participant will click to access as part of survey process.	7	
	WHERE		
7.	Each intervention will be delivered online.	7	
	WHEN and HOW MUCH		
8.	Each intervention will be delivered, immediately after obtaining consent. Participants will have access to the allocated video intervention once.	8	
	TAILORING		
9.	The researcher team will conduct a qualitative evaluation to enable tailoring of the intervention in future.	9	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	NA	
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	NA	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	NA	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

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It's ok 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.

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Trial Registration

The trial is registered with the Australia New Zealand Clinical Trials Registry (ANZCTR)
Trial Id: ACTRN12622000466741
The protocol is uploaded to the Open Science Framework website, under embargo.
https://osf.io/c7j8t/

Protocol

This protocol is reported following the SPIRIT checklist. This is protocol version 1.

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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 means 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 (HREC) before data collection. We will publish the results in a peer-reviewed medical journal and on institution websites.

Strengths and limitations

- This randomised controlled trial 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 randomised controlled trial 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 web-sites. [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 top ten priorities for researchers, considered vital to reverse the alarming global rise in low back pain disability and health care 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 to 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 SPIRIT 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 of videos described in brief below and in more detail in accordance with the TIDieR checklist in 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 is 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 outcomes will be Factor 1 of the AxEL-Q Questionnaire. [36] The AxEL-Q is a questionnaire designed to assess attitudes toward first-line care 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. Firstly, to understand the helpfulness of the video, we will ask participants four questions rated on a 7-point Numeric Rating Scale. Secondly, 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.

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? If you viewed this video on your feed or timeline would "like" it? 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 (e.g. 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? (i.e. what emotions did you experience while watching the video?)

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 means 0.5 and standard deviation 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 social media channels, Facebook, Twitter, Instagram and TikTok.

Sequence generation, allocation concealment and blinding

Using the Qualtrics survey platform, [37] 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 stored according to UNSW data security standards using Qualtrics. [37] Qualtrics allows for a direct export as a CSV file, which will then be uploaded to the R environment for statistical computing [38] for analysis.

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

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) range 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 on request from the corresponding author on completion of this trial. We will store data securely for seven 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 (SPHERE), before proceeding to the next stage. The consumer group provided suggestions which were implemented in the revised versions including changes to language 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 burden of the intervention and the time 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, [39] 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.

Competing interests

The authors have no known declarations.

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We received funding from Maridulu Budyari Gumal (SPHERE) for this project.

Contributorship Statement

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
AGC 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 of the manuscript

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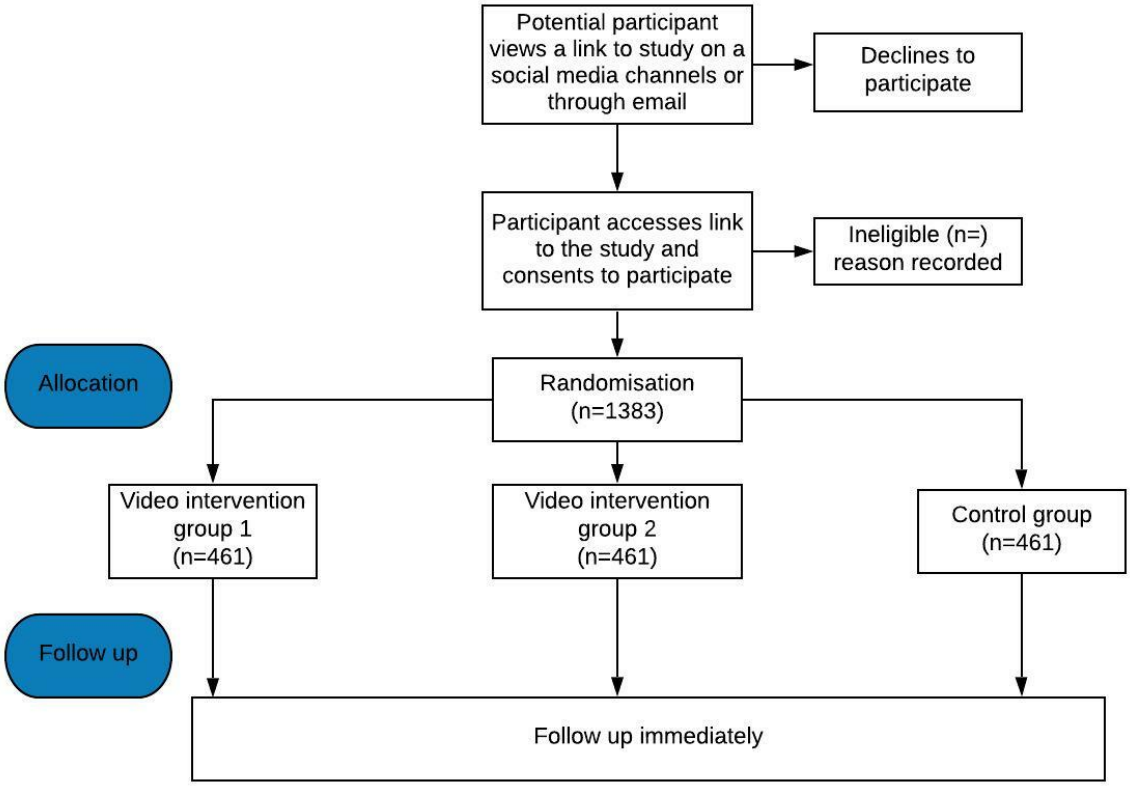
Figure 1- Participant progress through the study

Figure 1- Participant progress through the study



TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	A video designed for dissemination on social media to increase people's confidence becoming more active despite back pain.	1	
	WHY		
2.	A carefully considered, engaging social media message could provide a low-cost alternative to deliver a media campaign about low back pain.	3, 4	
	WHAT		
3.	Materials: The scientists involved in this study met to identify the most important message to be communicated to the general public about low back pain. Next, the scientists met with designers at an advertising agency to discuss and formalise a brief for the intervention. The advertising agency produced three initial storyboards to satisfy the brief for the video intervention, of which, one idea was refined over a series of meetings between the scientists and designers to form two video interventions used in this study. Before deciding on the final content and format the researchers presented the proposed video interventions to a consumer group for review. The consumer group recommend some changes to the language used in the superimposed text in both videos.	4, 5	
4.	Procedures: The final version of each video intervention is 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, but evidence suggests that it is safe to move despite back pain. The featured scientists report that they are unsure of how to convey this message to the public, which leads to the introduction of designers at the advertising agency brainstorming how to help deliver the message that it is safe to move. The advertising agency personnel suggest a dance. The video cuts back to the scientists who are	5	

	reluctant to endorse one specific movement, such as dance and conclude that it does not matter what you do as long as you move. The video concludes with the text, "It's safe to move", "Your backbone has backbone". The second video is exactly the same as the first, except when the advertising agency recommends the dance, the scientists try it out and to add humour, there are some video clips of the scientists dancing.		
	WHO PROVIDED		
5.	Participants will access the survey via an email or an anonymous link on social media.	7	
	HOW		
6.	The video will run as an item in the survey, that the participant will click to access as part of survey process.	7	
	WHERE		
7.	Each intervention will be delivered online.	7	
	WHEN and HOW MUCH		
8.	Each intervention will be delivered, immediately after obtaining consent. Participants will have access to the allocated video intervention once.	8	
	TAILORING		
9.	The researcher team will conduct a qualitative evaluation to enable tailoring of the intervention in future.	9	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	NA	
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	NA	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	NA	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).