# Designing multimedia patient education materials for adolescent idiopathic scoliosis: a protocol for a feasibility randomised controlled trial of patient education videos

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## ABSTRACT

**Background**: Multimedia patient education materials are increasingly used in healthcare.

**Design**: Double-masked three-armed feasibility parallel randomised controlled trial

**Methods**: Participants aged 10-18 with radiographically confirmed adolescent idiopathic scoliosis and recruited from community settings in Ireland will be randomised into usual care or into receiving multimedia educational videos with or without evidence-informed design principles. Participants will be masked in the two video intervention arms, as will the therapist sending the educational videos. Outcomes will include the number of participants recruited and randomised, the number analysed post-intervention and at week eight, and the outcomes for baseline, post-intervention, and week 8. Adverse events will also be reported.

**Conclusion**: This feasibility randomised controlled trial will offer insight into the feasibility of implementing advice from the literature in designing a trial of multimedia patient education materials for a population with adolescent idiopathic scoliosis.

Trial will be registered on ClinicalTrials.gov.

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## KEYWORDS

Multimedia

Patient Education

Health Education

Scoliosis

Adolescent Idiopathic Scoliosis

# INTRODUCTION

## Background

Patient education is a pillar of treatment that is recommended in many aspects of musculoskeletal (MSK) care [1-10], including adolescent idiopathic scoliosis (AIS) [11, 12]. Multimedia education is one option for conveying some of the information that healthcare workers may wish to pass on to a patient. While much healthcare research focuses on the content of educational materials, there are fewer interventional studies that examine the influence of design. Where such design research does exist, it is often in other medical areas[13-26] with the small amount of design recommendations in MSK healthcare are based mostly on literature arising narrative reviews [27-29] non-randomised studies, cross-sectional surveys, or case series [12]. Regardless, there is potential for educational materials to fill a gap where healthcare services are known to be under strain, which can occur due to a lack of resources or a rural/remote location [30]. Multimedia patient education materials also provide the accessibility, universality and usability that is desired in patient education aids [31].

Such under resourcing is found in public healthcare systems for scoliosis. Waitlists can prevail for scoliosis services [32-34], mirroring the dilemma of many musculoskeletal health services that cannot rely on immediate one-to-one clinical encounters to provide education, whether for reasons of restricted healthcare funding or due to rural/remote locations [35]. Scoliosis patients and their families have well-documented information needs [12, 36, 37]. Innovation has been required in healthcare to bring information and guidance to patients in these situations, with digital mediums providing such solutions. Multimedia education offers the advantage of dispersing healthcare information in a manner that is cheap, en masse [30, 38, 39], and without physical proximity [40, 41].

**Rationale**

Multimedia education has been examined extensively in the pedagogical literature, resulting in recommendations on how to best design materials in order to maximise engagement and learning [31, 42] While this information has informed the design of educational materials in healthcare [13-26] this has been less frequent in the MSK literature with only one RCT examining osteoarthritis-related pain [43], and other MSK conditions being informed by narrative advice only [27-29]. The use of such principles[42] has not been tested in a randomised controlled trial of education for a MSK population such as adolescent idiopathic scoliosis.

Given the uncertainty surrounding the recruitment of this age bracket from the community and the unknown ability to engage with patient education materials over a six-week period, a feasibility study is warranted to provide information on the design and implementation of a potential trial.

**Aims and Objectives**

The aim of the eventual three-armed parallel randomised controlled trial will be to compare the effectiveness of multimedia educational videos with and without evidence-informed design implementation against usual care for patients with adolescent idiopathic scoliosis. It will have an objective to examine if using evidence-informed design results in superior post-treatment, 8 week, and 26 week outcomes for video engagement, knowledge translation and retention, and patient reported outcomes compared to videos formatted to match existing online resources [44] or treatment as usual for this population with AIS. We hypothesise that such an intervention will result in superior outcomes for video engagement, knowledge translation and retention, and for patient reported outcomes.

The more immediate aim of this feasibility RCT will be to assess the feasibility of running this trial with the objective of examining the recruiting, the intervention use, the intervention adherence, and the outcome assessment at baseline and eight weeks. It will be planned and evaluated using the RE-AIM framework [45] in order to optimise reach, effectiveness, adoption, implementation, and maintenance and determine the feasibility of this RCT and any aspects that cannot be pragmatically explored in sufficient depth will be explained to avoid shortcomings in reporting that have been previously observed [46-48].

## METHODS

This double-masked three-armed feasibility parallel randomised controlled trial conducted in Ireland will be prospectively registered on ClinicalTrials.gov. It will also be designed in consideration of the CONSORT guidelines for feasibility studies and the TIDieR [49] and RoB-2[50] appraisal tools. The RE-AIM framework[45] will be used to ensure proper consideration of sustainable adoption and implementation. While it is not expected or intended, any changes to the trial protocol will be reported along with reasons for such changes. The trial is approved by University College Dublin Human Research Ethics Committee (LS-23-15-VanOirschot-Doherty, 3 May 2023).

### Participants

The inclusion criteria will be as follows: aged 10-18 years, parent/guardian consent for those under 18 years of age, AIS as confirmed by Cobb angle ≥10deg on plain film radiographs, able to watch and listen to online educational materials as well as read and complete online surveys. Non-AIS scoliosis including but not limited to neurological conditions will be excluded.

### Patient and public Involvement

Two individuals over age 18 who have been through the adolescent care pathway for AIS will be consulted prior to commencement of the study for feedback on the design. Their opinion will also be sought about dissemination of the results, which parts of the results should be shared, and in which digital/or print format.

### Recruitment

Participants will be recruited in Ireland via digital and poster advertising through two private healthcare clinics serving an AIS population, two scoliosis advocacy groups based in Ireland, as well as through social media and word of mouth. The primary author, a PhD student and physiotherapist of 18 years' experience with a post-graduate musculoskeletal and sports masters degree, will conduct the preliminary screening and provide the participant information package to those who express interest. All participants will be screened by phone or by video call prior to inclusion, and all participants not meeting eligibility will have their exclusion reasons recorded but without any identifying information. Advertising and recruitment is anticipated to commence on 17 July 2023.

**Consent process**

Consent will be sought from all potential participants meeting the inclusion criteria. The primary author will discuss the trial methodology and answer any questions or concerns about the trial before taking consent / assent electronically. Those aged 18 will be able to consent for themselves, while potential participants under the age of 18 will require parent/guardian consent before granting assent themselves.

**Fidelity**

Treatment fidelity will be monitored through YouTube analytics which will show the lack of views for each participant with their video or with sections of video that are skipped over.

**Baseline Assessment**

Following informed consent, participants will electronically complete a series of baseline assessments of demographics and outcome measures, with the primary author being available by phone or electronically if assistance is required. A description of the baseline variables and their purpose is shown in Table 1.

Table 1: Baseline and outcome variables collected and their purpose, with the primary feasibility outcomes in **bold**

| Variable | Measure | Time points (weeks) | Purpose & dimension of RE-AIM framework |
|---|---|---|---|
| Age | Date of birth | 0 | Describe population, reach |
| Gender | Male/female | 0 | Describe population, reach |
| Date of plain film radiographs confirming scoliosis | Weeks | 0 | Describe population, reach |
| Date of last radiograph | Weeks | 0 | Describe population, reach |
| Duration since care-seeking | Weeks | 0 | Describe population, reach |
| Major Cobb Angle | Degrees | 0 | Describe population |
| Minor Cobb Angle (if applicable) | Degrees | 0 | Describe population |
| Brace treatment | Yes/No | 0 | Describe population |
| Surgical treatment | Yes/No | 0 | Describe population |
| Physiotherapy treatment | Yes/No | 0 | Describe population |
| Quality of life | SRS-22 | 0, 8 | Secondary outcome |
| | EQ-5D-Y | 0, 8 | Secondary outcome |
| Physical Activity | PAQ-C | 0, 8 | Secondary outcome |
| Anxiety | STAI-Ch | 0, 8 | Secondary outcome |
| Immediate Knowledge translation Cognitive Engagement | 5-item MCQ | 1,2,3,4,5,6,8 | Secondary outcome |
| One week Knowledge retention | 5-item MCQ | 2,3,4,5,6,7,8 | Secondary outcome, maintenance |
| End of study Knowledge retention | 30-item MCQ | 0, 8 | Secondary outcome, maintenance |
| Affective engagement | YouTube Like/Dislike | 1,2,3,4,5,6 | Secondary outcome |
| **Intervention adherence / Behavioural Engagement** | **YouTube watch time %** | **1,2,3,4,5,6** | **Primary outcome, adoption, implementation** |
| | **YouTube # views** | **1,2,3,4,5,6** | **Primary outcome, adoption, implementation** |
| **Number recruited, rejected, randomised, dropped off, completed** | **Number** | **0,1,2,3,4,5,6,7,8** | **Primary outcome, implementation** |
| **Dropout reasons** | **Participant response** | **1,2,3,4,5,6,7,8** | **Primary outcome, implementation** |
| **Outcomes completed** | **%** | **8** | **Primary outcome, implementation** |
| **Adverse events** | **Number and type** | **1,2,3,4,5,6,8** | **Primary outcome, effectiveness** |
| **Satisfaction with care and treatment** | **Tailored question** | **8** | **Primary outcome, effectiveness** |

**Randomisation & Masking**

Upon consenting to participate in the study, participants will be randomised by a random number generator on a 1:1:1 ratio into one of the three intervention arms by the primary author. Participants will be told that the trial will compare usual care with two other multimedia video interventions. Participants in the usual care group will not be masked to their allocation but the participants in the two video interventions will not be aware of their allocation to videos with traditional format or evidence-informed format.

For the two video groups, an email will be sent by the supervising author, a registered Physiotherapist and researcher for twelve years, with a link to the correct video but this author will be masked to which intervention the link pertains to. The primary author will monitor all outcome inputs into the online SurveyMonkey platform and therefore remain unmasked when assessing follow-up outcomes.

**Interventions:**

In the usual care group, participants will continue along their existing healthcare pathway and will not receive any educational intervention beyond the usual education from their healthcare providers, which will not be determined by participation in the study and will not be funded by it.

In the video groups, participants will be sent a link multimedia videos using the information and format a typical online resource, in this case the Frequently Asked Questions section of Scoliosis Research Society website [44] and the outline of FAQs is shown in Table 2. This resource served as an outline with adjustments initially made to ensure spelling and grammar in Irish version English language and terms were altered to reflect Irish phrases i.e. consultant instead of specialist. The script was edited again following feedback from a scoliosis treating physio therapists and two patients who were over 18 and had been through the scoliosis healthcare pathway, and this assisted in updating statistics such as higher prevalence in girls vs boys [51-54]. The video channel will be set up as a private channel unique to each participant, so that the engagement statistics can be tracked for each participant. This will consist of six videos, sent once weekly from Week One to Week Six. Participants can skip forward back, and re-watch a released video an unlimited number of times until Week 8.

Table 2: Outline of educational content for six videos based on existing public-facing websites[44] and supported by qualitative literature on information needs [11, 36, 37, 55]

| | |
|---|---|
| Video 1 | What is scoliosis?<br>Is scoliosis more common in boys or girls?<br>What are the other types of scoliosis?<br>Does everyone with scoliosis wear a brace or need surgery?<br>Why do kids get scoliosis?<br>Does bad posture lead to scoliosis?<br>Are there exercises I can do to make my spine straight? |
| Video 2 | How does a doctor diagnose scoliosis?<br>Can scoliosis curves get better on their own?<br>How often will I need my scoliosis re-checked?<br>Will all of the x-rays harm me? |
| Video 3 | What can I do to prevent my scoliosis from getting worse?<br>How does a spine specialist decide what the treatment will be?<br>What is involved in observation?<br>Can you tell me about Bracing?<br>How do you know if a patient needs surgery?<br>Where can I find a specialist?<br>Should I try physical therapy or other alternative methods first? |
| Video 4 | Which kind of brace is right for me?<br>What are the different types of braces?<br>Why should I wear a brace?<br>Does it matter how many hours a day I wear the brace?<br>Can I take the brace off for PE at school, sports activities, swimming, etc.?<br>How will I know if the brace is working?<br>I wore a brace for two years and my curve was the same size when I stopped wearing it, why? Did I waste my time?<br>What does the Boston Brace or TLSO look like? |
| Video 5 | If I need scoliosis surgery, what can I expect?<br>Will surgery only stop my curve from growing or will it help straighten it?<br>How long will it take me to recover from surgery?<br>Does that include participation in sports?<br>Will I have my rods removed after my spine is fused?<br>Can the rods break? |
| Video 6 | Should I avoid certain activities because of my scoliosis?<br>Is carrying a heavy back-pack bad?<br>What if I have to wear a brace?<br>How do I cope with having scoliosis?<br>How can I connect with other kids who have scoliosis?<br>Will my curves get worse?<br>Can my scoliosis be cured?<br>If I have mild scoliosis, do I have to see a spine specialist?<br>Will I pass my scoliosis on to my future children? |

*Similarities between the two video groups:* the videos will contain identical information and it will be presented in the same sequence in both types of videos. The script will be identical except for specific components that are described below.

*Differences between the two video intervention groups:* For the video group with evidence-informed formatted videos (EVID), the text, graphics, and audio formatted in accordance with recommendations from the Cognitive Theory of Multimedia Learning and other advice from the literature [27-29, 31, 42].

The script will change slightly to accommodate CTML advice such as the personalisation principle, where the speaker in the video who uses a phrase such as “the patient’s spine” will be changed to “your spine.”

**Materials**

The multimedia materials for the TRAD and EVID video groups will be recorded using an iPhone13 to allow for content to be formatted to a phone screen format in case users view it on mobile devices and edited on Final Cut Pro X [56] with additional audio editing on Garage Band [57]. The final video will upload to a private YouTube channel setup by the primary author and the corresponding link will be sent via email. All participants will require internet access and a device to view and/or hear the educational materials. Participants in the two video intervention groups will be sent a link to a private YouTube channel, unique to each participant so that individual YouTube analytics can be tracked. The links can be revisited as often as desired by the participant. Further online surveys will collect additional outcomes via www.surveymonkey.com.

**Outcomes:**

As recommended in the CONSORT guidelines for feasibility studies [58, 59], the feasibility outcomes for this trial will be the number of participants recruited, rejected, dropped out and reasons; adherence to videos via behavioural engagement; number of outcomes completed, and adverse events. Adverse events will be recorded with preparations made for any adverse effects from asking about the participants’ mental health status or from being presented with unexpected information about scoliosis. The preparations are outlined Table 3.

Adherence to the RE-AIM framework will also ensure that there is an evaluation of the reach: recording of the percentage of excluded individuals, the percentage of individuals who participate, the characteristics of participants versus non-participants and the recording of qualitative indicators as to why participants were reached and/or recruited. The effectiveness will be measured using the knowledge outcomes and the overall quality of life outcomes in the SRS-22r and the EQ-5D-Y, a moderation analysis across the subgroups, and attrition analysis of the characteristics of these participants and their reasons. Adoption to specific settings is expected to be assessed easily by the online delivery of this intervention. Implementation

Table 3: Protocol for potential adverse events

| Potential event | Research member responsible | Action to be taken |
|---|---|---|
| Participant distress from answering mental health questions | Primary author will be available by phone or electronic means | provide support and explain the rationale for the questions in the outcome measures and if needed, liaising with a psychologist with experience in treating an AIS population. |
| Participant distress from receiving unexpected information about AIS | primary author will be available by phone or electronic means | answer any AIS-related questions and provide reassurance where needed. Onward referral can be made back to any scoliosis-specialised health services that the participant is already attending, or to a healthcare practitioner known to the primary author who has experience with this population |

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The final fully-powered RCT, should it proceed based on results of this feasibility study, will assess a primary outcome of post-intervention cognitive engagement, meaning the knowledge translation for each video for weeks 1-6 and retention for all videos at Week 8. Secondary outcomes will be knowledge retention one week later for each of the six videos for weeks 2-7; affective & behavioural engagement from YouTube analytics determined by like/dislike , watch-time, number of views; health related quality of life measured by the SRS-22r and the EQ-5D-Y, anxiety measured by the STAI-Ch, and physical activity measured by the PAQ-C. Secondary outcomes will be measured at baseline and week 8.

**Statistical analysis**

Ratio and interval variables (YouTube analytics) will be analysed for differences by ANOVA. The remaining ordinal variables will have differences between groups analysed by Friedmans. Pre- post test changes will be analysed by Kruskal-Wallis. Comparisons will be made using intention-to-treat principles.

Generalised estimating equations (GEE) will be used to evaluate the relationship between the design characteristics and the measures of engagement. Each of the characteristics described above (Watch time / Total time (%), Retention (%), Time spent on specific segments, Average view duration (min:sec)) were included as co-variates in separate GEE models for each measure of engagement.

There was an audit of previous year's records to note that were approximately 60 eligible participants over twelve months in one of the private practice recruitment sites, and this will be in addition to social media and advocacy groups advertising (with two advocacy groups having 2542 and 579 followers in Ireland), as well as two other pending consultant clinics. Statistical power for the eventual RCT has been calculated using GPower [60] to detect a minimum change of 1 out of 5 in the primary outcome, knowledge quizzes, with a one way ANOVA to compare three groups with an alpha of 0.05 and determined that a sample size of 92 participants were needed. This feasibility study will assess the recruitment potential and is expected to recruit less than 92 participants.

## RESULTS

This trial will be reported in conformance with the CONSORT guideline for feasibility randomised controlled trials. A CONSORT flow diagram will outline the number of participants in each stage of the study as shown in the example in Figure 1. All anonymised data will be made available as per Open Science recommendations on www.OSF.io.

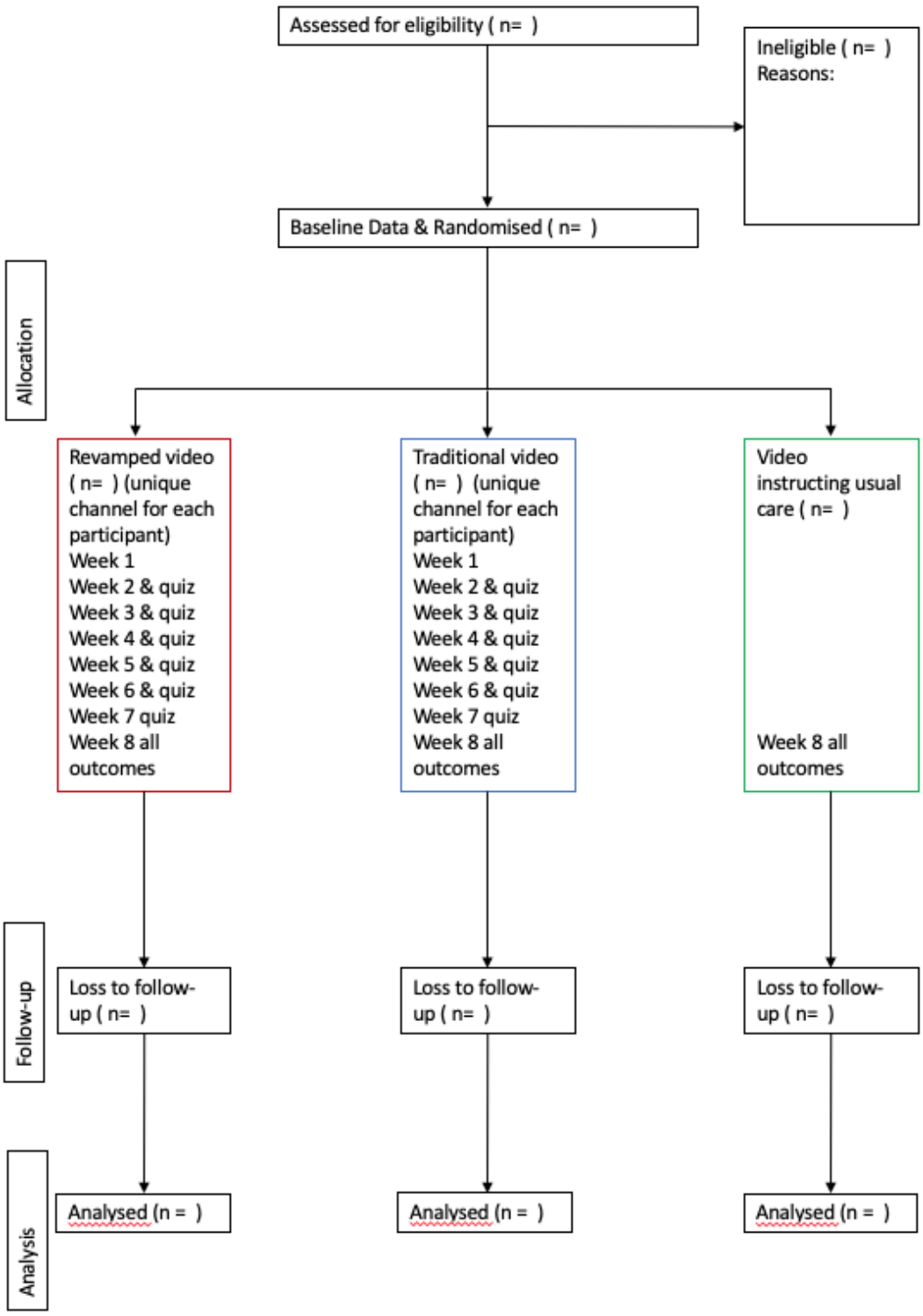


Figure 1: CONSORT flow diagram

## DISCUSSION

### Potential limitations and attempts to address

SRS-22r does not capture all aspects of physical functioning, such as mobility and self-care [61]. Additionally, SRS-22r was evaluated in the COS study that included all spinal deformities and thus limiting applicability to specific AIS [61] therefor additional quality of life measure will be taken via the EQ-5D-Y. It is acknowledged the EQ-5D-Y may require supplemental assessment tools for school function [62], and that it's correlation with the SRS-22r has been found to be good for non-scoliotic populations. [63]. Proxy reporting may occur with the EQ-5D-Y as participants complete at home in the presence of parent(s)/guardian(s), but this yields similar outcomes as the 3-layer predecessor [64].

### Future potential

This study could pave the way for a fully powered trial that may offer an option to provide basic information about AIS to patients and the general public. Its utility could be found in addressing those that are on the waitlists for many services related to AIS [11, 32, 33]. This could have further implications for countries with under resourced healthcare systems or rural and remote regions lacking access to clinicians that would often provide this specialty advice and education.

## CONCLUSION

This feasibility randomised controlled trial will offer insight into the feasibility of implementing advice from the literature in designing multimedia patient education materials for a population with adolescent idiopathic scoliosis and allow a comparison with materials that do not undergo similar redesign as well as a comparison with usual care.

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