



RESEARCH ARTICLE

# Video-augmented vs standard consent in an early ICU cycling feasibility trial: a randomized embedded recruitment trial [version 1; peer review: 1 approved]

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**Abstract**

**Background:** In a trial of early in-bed cycling in critically ill patients, a video demonstrating use of the cycle in addition to verbal description may improve satisfaction with the informed consent process for all persons involved.

**Methods:** A convenience sample of in-person consent encounters for enrolment in TryCYCLE (NCT01885442), a 33-patient pilot study of in-bed cycling with mechanically ventilated patients in an intensive care unit, were recruited. In this study within a trial, using concealed allocation, we randomized consent encounters to a Video or Standard consent approach. Those in the Video group viewed a 2-minute video of a model using in-bed cycling plus the routine verbal description of the study. The Standard group received the routine verbal description only. Patients and/or substitute decision makers (SDMs) were blinded to the study purpose. After each encounter, patients and/or SDMs and the research coordinator submitted written satisfaction and comfort ratings using 7-point scales (higher scores better). We documented consent outcomes and analyzed between group differences with independent group t-tests.

**Results:** We randomized 14 encounters (6 Video, 8 Standard). Ten completed questionnaires (5 in each group) demonstrated no difference in patient and/or SDM satisfaction or comfort between Video or Standard (mean [standard deviation] Satisfaction: 6.8[0.45] vs. 7.0[0] vs. p=0.37; Comfort: 7.0[0] vs. 7.0[0], p>0.99). The research coordinator evaluated all randomized encounters, with no differences between Video or Standard (Satisfaction: 7.0[0] vs. 6.9[0.35], p=0.41; Comfort: 6.7[0.52] vs. 6.9[0.35], p=0.39). All 14 consent encounters enrolled in TryCYCLE.

**Conclusions:** Patient and/or SDM satisfaction and comfort with consent was very high for both the Video and Standard approaches. Further research, including use of videos to portray different study interventions, is

**Open Peer Review**

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**Reviewer Status**

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	Invited Reviewers
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<p><b>version 1</b> 24 Jan 2020</p>	 report
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<p><b>1 David Torgerson</b> , University of York, York, UK</p>	
<p>Any reports and responses or comments on the article can be found at the end of the article.</p>	

needed, including analysis of patient and/or SDM satisfaction, comfort, comprehension, and consent rates.

**Registration for host trial:** ClinicalTrials.gov, [NCT01885442](https://clinicaltrials.gov/ct2/show/study/NCT01885442), registered on June 25, 2013

### Keywords

Evidence-based Medicine, Randomized controlled Trials, Research design, Informed consent, Clinical trials, Audiovisual aids, mechanical ventilation, cycle ergometry, Studies within a trial

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**Author roles:** **Kho ME:** Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Supervision, Validation, Visualization, Writing – Original Draft Preparation; **Duffett M:** Methodology, Writing – Original Draft Preparation, Writing – Review & Editing; **Clarke FJ:** Investigation, Methodology, Validation, Writing – Review & Editing; **Shears M:** Data Curation, Writing – Review & Editing; **Molloy AJ:** Methodology, Validation, Writing – Review & Editing; **Cook DJ:** Conceptualization, Investigation, Methodology, Writing – Review & Editing

**Competing interests:** No competing interests were disclosed.

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## Introduction

In-bed cycling is a novel critical care rehabilitation intervention that could improve patients' physical function<sup>1</sup>. In-bed cycling is not commonly used in the intensive care unit (ICU)<sup>2</sup> and is likely unfamiliar to many patients and their substitute decision makers (SDMs). A video demonstrating the use of the cycle in addition to verbal informed consent may improve their satisfaction and comfort with the consent process. The purpose of this study within a trial (SWAT) was to determine the effect of video-augmented versus standard informed consent on patient and SDM satisfaction and comfort.

## Methods

The study protocol is available as *Extended data*<sup>3</sup>.

### Study design

We included a convenience sample of consent encounters in TryCYCLE (NCT01885442), a 33-patient, single-centered, safety and feasibility study of in-bed cycling in critically ill patients<sup>4</sup>. The TryCYCLE study required a priori informed consent. Patients and SDMs who were approached for in-person informed consent for TryCYCLE in our mixed medical-surgical ICU (St Joseph's Healthcare ICU) in Hamilton, ON were eligible for this substudy. We excluded encounters where initial consent was received by phone, as respondents could not view the video as part of their initial deliberations.

### Randomization

Using concealed allocation with variable undisclosed block size, we randomized consent encounters to receive augmented video consent in addition to verbal consent discussion (Video) or verbal consent discussion only (Standard) in a 1:1 ratio. To maintain allocation concealment, we used third-party assignment. An individual not otherwise involved in the study (MD) prepared a computer-generated randomization sequence and provided the group assignment immediately prior to each consent encounter.

### Intervention

The research coordinator used a tablet computer to show and describe how an ICU patient would bike in the TryCYCLE study. The 2-minute video included footage of a model on the bike and an ICU patient biking while mechanically ventilated. The research coordinator also provided a verbal description of the research study, which was not scripted to allow for spontaneous exchange. The research coordinator and patient and/or SDM had the consent encounter guided by the usual principles of informed consent for ICU studies previously published<sup>5</sup>. The video did not include sound.

*Comparison:* Verbal description only.

### Outcomes

Our primary outcomes were patient and/or SDM satisfaction and comfort with the consent encounter. Secondary outcomes included patient and/or SDM perception of video helpfulness,

and research coordinator assessments of satisfaction with the consent process, their own comfort with the consent encounter, patient and/or SDM study comprehension, and the number and perceived difficulty of questions asked by patient and/or SDM. Respondents assessed outcomes after the consent encounter using 7-point Likert-type scales, with higher scores representing more favorable ratings (see *Extended data*<sup>3</sup>). We invited patients and/or SDMs to return the 1-page, self-administered questionnaire within 24 hours in a pre-addressed, sealable envelope. The research coordinator documented consent outcome and duration of the encounter.

### Blinding

Patients and SDMs were not aware of the comparison study at the time of the consent encounter. Both groups received the same consent forms for the TryCYCLE study<sup>3</sup>. The analyst was blinded to treatment group.

### Sample size and data analysis

We did not calculate a sample size a priori for this SWAT. We reported continuous variables as mean (standard deviation [SD]) and categorical values as count (percent). We used Student's t-tests to compare the results of the two groups, Pearson's Chi Square for categorical comparisons, and  $p=0.05$  as the criterion for statistical significance. We conducted all analyses with SPSS version 25.0 (IBM, Armonk, New York).

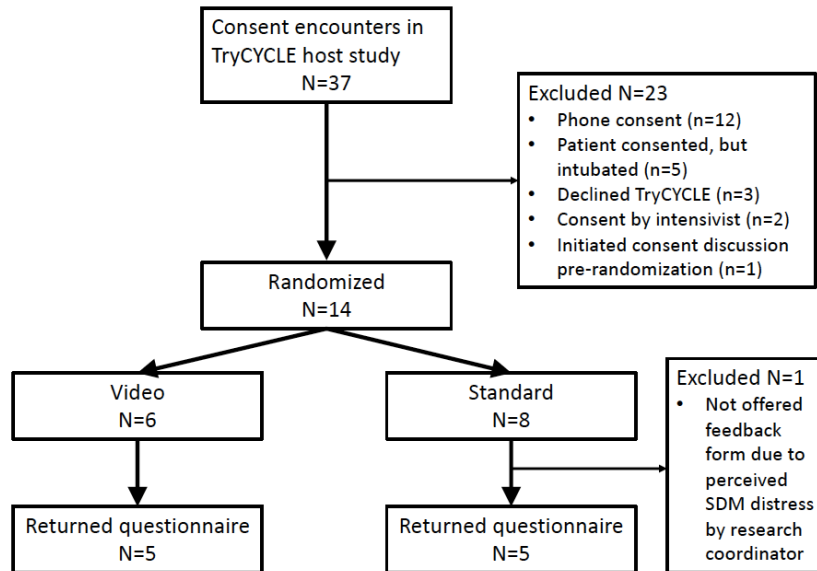
### Ethics

This study, and the host study (TryCYCLE) were approved by the Hamilton Integrated Research Ethics Board (HIREB 13-173), which waived the need for consent for this substudy. Study participants could opt-out of this substudy by declining to return the follow-up questionnaire.

### Results

We randomized 14 of the 37 consent encounters for TryCYCLE between October 2013 and August 2014: 6 to Video and 8 to Standard (Figure 1). Table 1 summarizes the characteristics of the convenience sample in this study. We received 10 completed questionnaires (5 from each group), which contributed to estimates of effect. We report all comparisons as Video vs. Standard. Patient and/or SDM rating of satisfaction was not different between groups, the mean [SD] was 6.8 [0.5] vs. 7.0 [0] ( $p=0.37$ ). Patient and/or SDM rating of comfort was the same for both groups (7.0 [0],  $p>0.99$ ). Patient and/or SDM rating of video helpfulness was 6.6 [0.54]. All 14 (100%) patients and/or SDMs provided consent to participate in the TryCYCLE study (the overall consent rate for TryCYCLE was 91.9%)<sup>4</sup>.

Of the 14 consent encounters rated by the research coordinator, satisfaction (7.0 [0] vs. 6.9 [0.35],  $p=0.41$ ) and comfort (6.7 [0.52] vs. 6.9 [0.35],  $p=0.39$ ) were similar. There was no difference in perceived patient and/or SDM understanding of the research study (6.67 [0.51] vs. 7.0 [0] vs.,  $p=0.11$ ), number of questions asked (1-5 questions: 6 (75.0%) vs. 5 (83.3%),  $p=0.66$ ), nor perceived difficulty of clarifying questions (2.67 [1.86] vs.



**Figure 1. Consent encounter flow diagram for this study.** Of the 23 non-randomized patients who had consent encounters, 12 occurred by phone, 5 were in-person by intubated patients who were unable to complete the feedback form, 3 declined participation in the host study and these consent encounters occurred without the option for enrolment in the SWAT, 2 in-person consents were obtained by a consultant intensivist, and in 1 instance we already initiated the consent discussion before consideration of randomization in this trial. Post-randomization, 1 person was not offered the feedback form due to perceived emotional distress by the research coordinator.

**Table 1. Participant characteristics involved in the consent encounter.** SDM= substitute decision maker.

n (%)	Overall (n=14)	Video + Verbal (n=6)	Verbal (n=8)
Female	8 (57%)	2 (33%)	5 (63%)
Included in video substudy:			
SDM	11 (79%)	4 (66%)	7 (88%)
Patient	1 (7%)	1 (17%)	0
SDM and Patient	2 (14%)	1 (17%)	1 (3%)
Consented for TryCYCLE	17 (100%)	6 (100%)	8 (100%)

1.86 [1.4],  $p=0.40$ ). The encounter duration was not different (18.3[14.7] vs. 13.3[3.7] minutes,  $p=0.20$ ).

## Discussion

In this small randomized study of video-augmented versus standard consent for in-bed cycling in the ICU, there was no difference in satisfaction or comfort between groups. Our results are similar to previous studies included in a systematic review of audiovisual plus standard versus standard informed consent, identifying no difference in consent rate between groups<sup>6</sup>. Given the universally high ratings for satisfaction and comfort by consent recipients, we hypothesize that video-augmented consent could be useful for describing more complex interventions or facilitating conversations when research centres or coordinators are new to conducting clinical trials. Involving

patient-family advisory groups may help guide use and content of video adjuncts for future consent encounters.

Our study also contributes to global efforts to study efficiencies in trial conduct through SWATs<sup>7</sup>. It directly addresses Priority 4 (*What are the best approaches for designing and delivering information to members of the public who are invited to take part in a randomized trial*) of the top 10 trial recruitment issues informed by stakeholders, including members of the public, front line clinical and research staff, trial principal investigators, and funders<sup>8</sup>.

Our study has limitations, principally the small sample size and significant expertise in consent discussions from a single research coordinator with 20 years of experience in critical care

studies. We did not measure consent recipient knowledge. Our study also has several strengths. Patients and/or SDMs were blinded to the Video vs Standard comparison study. We evaluated practical aspects of the consent process, focusing on outcomes we anticipate are important to patients and SDMs. We addressed gaps in previous research by measuring SDM and clinical researcher satisfaction, and time to administer the video-augmented consent<sup>6</sup>.

## Conclusions

Overall, patient, SDM, and research coordinator satisfaction and comfort with consent was very high for both the video-augmented and standard approaches. Further research, including use of videos to portray different study interventions, is needed, including analysis of patient and/or SDM satisfaction, comfort, comprehension, and consent rates.

## Data availability

### Underlying data

Since the intervention video includes an identifiable critically ill patient, and permission to publish this was not obtained from the patient, patient's family or the research ethics board, this cannot be shared.

Open Science Framework: Video-augmented vs. standard consent in an early ICU cycling feasibility trial: a randomized embedded recruitment trial, <https://doi.org/10.17605/OSF.IO/4SPGA><sup>3</sup>

This project contains the following underlying data:

- TryCYCLE Video RCT data-SDM CRF.csv: data corresponding to data collection forms for patient/SDM
- TryCYCLE Video RCT data-RC CRF.csv: data corresponding to data collection forms for research coordinator

## Extended data

Open Science Framework: Video-augmented vs. standard consent in an early ICU cycling feasibility trial: a randomized embedded recruitment trial, <https://doi.org/10.17605/OSF.IO/4SPGA><sup>3</sup>

This project contains the following extended data:

- TryCYCLE Video consent study protocol.docx
- TryCYCLE Video consent data collection forms.docx

## Reporting guidelines

Open Science Framework: CONSORT checklist for 'Video-Augmented vs Standard Consent in an Early ICU Cycling Feasibility Trial: A Randomized Embedded Recruitment Trial', <https://doi.org/10.17605/OSF.IO/4SPGA><sup>3</sup>

Data are available under the terms of the [Creative Commons Zero "No rights reserved"](https://creativecommons.org/licenses/by/4.0/) data waiver (CC0 1.0 Public domain dedication).

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# Open Peer Review

Current Peer Review Status: 

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Version 1

Reviewer Report 28 January 2020

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**David Torgerson** 

York Trials Unit, Department of Health Sciences, University of York, York, UK

This is an interesting SWAT, which despite its small size is of interest. A few suggestions to improve the reporting:

- Have you registered the SWAT with the Northern Ireland Hub for Trials Methodology Research ( <https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSW/> ) this will allow others to replicate the study as this is obviously required.
- The reporting of the means should also include the differences and 95% confidence intervals of the differences.
- You used block randomisation - what block sizes were used?
- With a tiny sample size, I think some qualitative outcomes, if collected, would enhance the findings of the study.

**Is the work clearly and accurately presented and does it cite the current literature?**

Yes

**Is the study design appropriate and is the work technically sound?**

Yes

**Are sufficient details of methods and analysis provided to allow replication by others?**

Partly

**If applicable, is the statistical analysis and its interpretation appropriate?**

Partly

**Are all the source data underlying the results available to ensure full reproducibility?**

Partly

**Are the conclusions drawn adequately supported by the results?**

Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Interest in SWATS and their conduct as well as being the Director of Trials Unit

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

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