Research Involvement and Engagement

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Co-designing and pilot-testing an infographic to support the consent process in an adaptive platform trial for adults in ICU with community-acquired pneumonia or COVID-19: a mixed methods study within a trial (SWAT)

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Abstract

Background Informed consent documents educate patients and families about research participation and alternatives. However, given their length and complexity, consent documents can be challenging to understand, particularly in high-stress environments such as the Intensive Care Unit (ICU) and for complex study designs such as platform trials.

Methods This is an exploratory sequential mixed methods study-within-a-trial (SWAT) of REMAP-CAP (Randomized, Embedded, Multifactorial, Adaptive Platform Trial for Community-Acquired Pneumonia). *Phase 1:* We conducted focus groups with individuals with lived experience, including ICU survivors, substitute decision makers (SDMs) and research coordinators (RCs) to refine an infographic to augment a priori REMAP-CAP consent encounters. We analyzed data using inductive content analysis. *Phase 2:* We piloted the infographic with patients/SDMs approached a priori to participate in REMAP-CAP, who could communicate in English, at five sites in Ontario, Canada. We assessed implementation according to 1) eligible consent encounters (number of patients/SDMs eligible for SWAT / approached for REMAP-CAP), 2) receipt of infographic (number of patients/SDMs who received the infographic / eligible consent encounters), 3) consent to participation in this SWAT by patients/SDMs (number of patients/SDMs who consented / those approached), and 4) feedback questionnaire completion (number of patients/SDMs who completed the questionnaire / those who received it).

Results *Phase 1:* We conducted two, two-hour focus groups with 5 participants (10 participants total). Participants identified important infographic design considerations (visual presentation, language) and content (study details, participation in research).

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Integration: Results from Phase 1 were used to develop a final consent infographic.

Phase 2: Sixty-three patients were eligible for REMAP-CAP during the study period; 21 were eligible (33%) for the SWAT. Of these, 18 patients/SDMs (86%) received the infographic, 17 consented to the SWAT (94%) and 15 (88%) completed questionnaires. RCs completed case report forms for each consent encounter (n = 18, 100%).

Conclusions We engaged individuals with lived experience to co-design a consent infographic. We achieved three of four pre-specified feasibility objectives during pilot testing of the infographic for a priori REMAP-CAP consent encounters. Although there were fewer eligible consent encounters than anticipated, we identified acceptable rates of infographic delivery, consent to SWAT participation and questionnaire completion.

Trial Registration: The Northern Ireland Hub for Trials Methodology Research SWAT Repository (SWAT #176).

Keywords Co-design, Patient engagement, Pilot trial, Study within a trial, SWAT, Informed consent, Consent interventions

Plain English summary

Background Informed consent documents educate patients and families about research participation. However, given their increasing length and complexity, consent documents can be challenging to understand, particularly in high-stress environments such as the Intensive Care Unit (ICU). Patient/Family Partners (PFP) identified that consent documents for REMAP-CAP are challenging to understand. REMAP-CAP is a trial which studies treatments for patients admitted to the ICU with pneumonia or COVID-19. PFP wanted to support communication between research staff and patients/families during the consent process.

Our study The objective of our project was to develop and determine the feasibility of using an infographic, consisting of words and images, to supplement consent documents for REMAP-CAP. We planned to develop the infographic using input from patients, family members and research coordinators during focus groups. We also planned to use the infographic during real consent discussions for REMAP-CAP and to collect feedback from patients and family members who received the infographic, and research coordinators who used the infographic.

Our findings We successfully developed an infographic for use at five hospitals in Ontario, Canada. We did not have as many opportunities to use the infographic as we expected. However, when we did, it was feasible to use the infographic and to collect feedback from patients, families and research coordinators. Findings from our study can be used to inform the design of similar tools for other trials and to inform a future study to understand if the infographic can improve the consent process for patients, families and research coordinators.

Background

Clinical research is critical to the discovery of treatments and procedures that may optimize health and function. While there are benefits associated with clinical research participation, there are also inherent risks. For consent to be truly informed, potential research participants must be provided with information regarding the purpose, methods, potential risks and benefits, and alternatives to research participation [1–3].

Consent forms for clinical research are often long and technical, requiring significant time and energy for research coordinators (RCs) to explain and for potential participants to understand [4, 5]. Consent forms are further complicated and lengthened with complex research designs and contexts. Platform trials (also called adaptive trials or multi-arm, multistage designs) are more complex than a traditional two-arm randomized controlled trial (RCT) as they can simultaneously evaluate multiple treatments for a disease and use response-adaptive randomization to increase likelihood of receiving better performing treatments [6, 7]. These additional complexities for platform trials can be challenging for patients and families to understand during the informed consent process. [8]

REMAP-CAP (Randomized, Embedded, Multifactorial, Adaptive Platform Trial for Community-Acquired Pneumonia) is a platform trial that enrols adults in the Intensive Care Unit (ICU), a particularly challenging venue for consent encounters. Individuals admitted to the ICU face life-threatening illnesses, creating stress for patients and their families [9]. Typically, treatments are time-sensitive, requiring consent discussions to occur within hours of an ICU admission [9]. If a patient does not have the capacity to participate in a priori consent discussions, clinicians and/or researchers will approach the patient's substitute decision maker (SDM), who has the legal authority to

make medical and consent decisions on their behalf [10]. The severity of illness, the need for time-sensitive interventions and involvement of SDMs in decision-making on behalf of the patient all contribute to the complexity of research consent in the ICU.

There is a recognized need for empirical evidence supporting methods to enhance communication and understanding during informed consent, without lengthening already cumbersome consent forms [1, 4]. A systematic review of 39 RCTs explored the effectiveness of 54 interventions to improve understanding during a priori informed consent discussions across multiple populations [11]. Enhanced consent documents (e.g., simplified text, leaflets, infographics) demonstrated a statistically significant increase in patient understanding scores [standardized mean difference (95% CI): 1.73 (0.99, 2.47)]. While these results suggested the benefit of using enhanced consent documents in RCTs, it is unclear whether this evidence is applicable to more complex research designs such as platform trials conducted in the unique ICU environment, as none of the included studies were conducted in the ICU or with SDMs.

In addition, none of the 39 RCTs to our knowledge used a co-design approach to develop the interventions. Co-design involves individuals with lived experience in the development of such a tool [12, 13]. A recent systematic review identified the promise of co-design in the process of developing health service communication tools (e.g., decision-aids, program information products) [14]. For example, co-design was used to develop a primary health care intervention (Health TAPESTRY), intended to promote healthy aging for Canadians [15]. Almost half of the ideas generated by knowledge holders (patients, program volunteers, clinicians and community service providers) for the Health TAPESTRY intervention had not been previously considered by the research team, highlighting the novel perspective provided by knowledge holders in product development. In our context, co-design includes patients/SDMs and RCs with lived ICU research experience to develop an enhanced consent document. Use of co-design will increase the likelihood that the information provided in an enhanced consent document is helpful for its users and is presented in an understandable format.

Context

In Canada, REMAP-CAP is led by the Canadian Adaptive Platform Trial in Intensive Care (CAPTIC) program, a Canadian Institutes of Health Research (CIHR)-Strategy for Patient-Oriented Research (SPOR) funded initiative. The CAPTIC research program formed the CAPTIC Patient/Family Partners (PFP), including patients and families with lived ICU experience to gain their perspectives and to identify priorities for future research. A priority of the CAPTIC PFP has been to support communication between researchers, patients and families during research consent. Typically, patients and/or their families who meet REMAP-CAP inclusion criteria are approached within 24–48 h of their ICU admission for consent to participate in the study. They are provided with a consent form and a verbal description of the study. Given the high-stress environment and length and complexity of REMAP-CAP consent forms, one of our PFPs (KS) provided the idea for an infographic and steps were taken to develop an initial prototype. However, there was a need for further input on its content and design to represent perspectives of patients/SDMs and RCs external to the research team.

Objectives

The overall objective of this mixed methods study was to co-design and pilot test an infographic to augment the standard REMAP-CAP consent process. The objective of Phase 1 was to understand patient, SDM and RC perspectives on infographic prototypes, informing the development of a final infographic. The objective of Phase 2 was to determine the feasibility of adding a co-designed consent infographic to the standard consent process for a priori REMAP-CAP consent discussions.

Methods

This study was a prospective study-within-a-trial (SWAT) embedded within REMAP-CAP, an international platform trial with 36 Canadian sites, which studies treatments for adults admitted to the ICU with community-acquired pneumonia or COVID-19 (NCT02735707). [8, 16] A SWAT is a research study embedded within a larger "parent trial" (i.e., REMAP-CAP), and aims to explore specific aspect(s) of trial conduct or processes (i.e., informed consent) [16]. A platform trial studies a disease, rather than an intervention, and recruits patients to one or more of multiple domains and interventions [6]. Research ethics approval for this SWAT was obtained through Clinical Trials Ontario (Unity Health Toronto, CTO #3779), independently from REMAP-CAP.

We applied an exploratory sequential, mixed methods research design [17], which consisted of two phases: 1) qualitative data collection and analyses to inform infographic refinement, and 2) testing the infographic through quantitative data collection and analyses [17]. We report this study according to four guidelines: 1) the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) Short Form Checklist [18]; 2) the Mixed Methods Article Reporting Standards (MMARS) [19]; 3) the Journal Article Reporting Standards for Qualitative Research (JARS-Qual) [19]; and 4) the Consolidated

Standards of Reporting Trials (CONSORT) guidelines for pilot and feasibility studies (supplement) [20]. Our full study protocol was previously published. [21]

Phase 1 methods

Design: Phase 1 consisted of three activities: two, two-hour focus groups and a one-hour knowledge holder review meeting. We used the principles of qualitative description to explore participant perspectives of infographic prototypes. [22]

Setting: Participants were recruited from within Canada. All activities occurred remotely via Zoom (San Jose, California: Zoom Video Communications Inc.). We also used a web-based visual collaboration platform, Miro (Miro, San Francisco, CA, USA) to facilitate discussion during focus groups.

Outcomes: The primary outcome was an understanding of patient, SDM and RC perspectives of infographic prototypes, through identifying key themes from focus groups, to inform infographic refinement.

Sampling and Recruitment: Our recruitment and sampling strategies are described fully in the study protocol [21]. We included patients or SDMs with lived ICU experience and RCs with experience consenting for REMAP-CAP. Participants had to communicate in English and have access to technology to participate in virtual focus-groups. We planned to recruit 4–6 patients and/or SDMs, and 4–6 RCs (8–12 participants total) [23].

Data Collection: We planned and held two semi-structured focus groups to get feedback on infographic prototypes (supplement) and collected data using focus group audio recordings, transcripts and field notes. Focus groups, data analysis and infographic refinement were led by a design consultant external to the REMAP-CAP team. Both focus groups had patient/SDM and RC representation, were a maximum of two hours in length and covered the same content with the same questions and structure. All focus group participants were invited to a knowledge holder review meeting to elicit final feedback and to achieve consensus among study participants on a final infographic for pilot testing.

Data Analysis: Detailed methods for analysis are included in the study protocol [21]. We used a "tape-based" approach for analysis of focus group data [23]. Focus group recordings were also transcribed to facilitate data abstraction and triangulation of results.

Phase 2 methods

Study design and setting

We conducted a prospective pilot and feasibility study at five REMAP-CAP sites in Ontario, Canada. Hereafter, we distinguish between the Phase 2 pilot and feasibility study (SWAT) and the parent trial (REMAP-CAP). For the SWAT, we included patients or SDMs approached for a priori consent to participate in REMAP-CAP, who could read, write, and speak in English, to limit scope and maintain feasibility, and who received consent documents before or at the time of their consent discussion. We excluded patients enrolled in REMAP-CAP by deferred consent. We also included RCs conducting REMAP-CAP consent encounters at each of our five selected sites, who also screened patients/SDMs for eligibility.

SWAT participant recruitment and sample size

Eligible REMAP-CAP trial patients were assessed by RCs for eligibility for the SWAT. If eligible, the infographic was included as part of their standard a priori consent processes. At the conclusion of each REMAP-CAP trial consent encounter, RCs informed the patient/SDM about our SWAT and invited them to participate in a follow-up questionnaire, regardless of their REMAP-CAP consent decision. We tracked de-identified consent encounters using a unique ID by date and study site, allowing us to identify paired RCs and patients/SDMs. We planned to recruit 60 patients/SDMs to achieve our feasibility objectives [24]; methods for determining our sample size are reported in the study protocol [21].

Intervention

The original REMAP-CAP consent procedures were not altered. All Canadian REMAP-CAP sites use the same consent documents. The master consent form has 13 pages while the supplementary appendices which include descriptions of the domains have 4 pages. All SWAT participants received the standard REMAP-CAP consent documents, with a verbal description of the trial, and the consent infographic, available in both paper and electronic formats. Patients/SDMs who consented to this SWAT had the option of completing a paper or electronic version of our questionnaire.

Feasibility outcomes

We defined implementation success using the following four metrics, explained in detail in our study protocol: 1) eligible consent encounters > 68%; 2) receipt of infographic > 80%; 3) consent rate for SWAT > 71%; and questionnaire response rate > 71%.

Consent encounter data

Patients/SDMs: We developed a modified version of the Consent Understanding Evaluation-Revised tool (CUE-R) [25]. The CUE-R 2 has 26 questions; 15 questions related to patient/SDM experience were assessed using a 5-point Likert scale. We calculated an overall response score by question (i.e., across all patients/SDMs) and by section (e.g., all questions related to experience with

infographic). The CUE-R 2 also included five demographic questions: age, sex, race, highest level of education, and previous research experience. Participants were provided with the questionnaire within 24 h and were asked to complete and return it within one-week of the initial consent encounter.

To obtain data from RCs, we used a modified version of a case report form (CRF) used in the SWAT of video-augmented consent for an ICU rehabilitation trial (supplement) [26]. The RC CRF had 15 questions; questions related to RC experience and perceptions were assessed using a 7-point Likert scale. RCs were asked to return the CRF within 24 h of the consent encounter to decrease recall bias.

Data analysis

Data were analyzed using Stata (v. 15.0, StataCorp LP, College Station, Texas). We evaluated continuous data using descriptive statistics, including counts, frequencies, and means (standard deviations) or medians (1st, 3rd quartiles) for Likert-style questions or if data were skewed.

For negatively framed Likert-style questions in the CUE-R 2, we reversed the scale so that all questions had the same polarity (higher scores representing positive responses). We calculated separate overall median scores for questions related to the infographic vs. standard consent documents. For knowledge-related questions, we assessed the median proportion of correct responses per respondent. All questions had an "unsure" response option, which was scored incorrect. We narratively summarized responses to open-ended questions.

Deviations from published protocol

Phase 2: Due to slower than anticipated recruitment, we extended our recruitment by 6-months (12 months total). Post-hoc, we conducted an analysis to understand paired consent data between the patient/SDM and RC for each consent discussion. For questions assessed by both patients/SDMs and RCs, we compared paired Likert-style questions. As patient/SDM questions were assessed on a 5-point scale, we converted responses to a 7-point scale to allow direct comparison (points 3–5 representing neutral). Given our small sample size however, we did not make statistical comparisons between paired data.

Results

Phase 1 results

Participants

We engaged 10 participants with lived ICU experience (2 patients, 2 SDMs, 2 individuals with experience as a patient and SDM, 4 RCs) in two focus groups (five participants in each; 4 patients/SDMs and 2 RCs) in April 2022. We organized focus group results according to two overarching themes: infographic design, and infographic content. Participants are identified by a participant number (e.g., P1) and focus group (G1 or G2). We also present results in tabular format (Table S1, S2).

Infographic design

Patients/SDMs and RCs identified considerations related to infographic design, including the visual presentation and the language used.

Visual Presentation: *1. Make text big where possible, highlighting key information that is easily read to another person.* A SDM (P4G2) said "It's not always the caregiver looking at the resource in the ICU. It might be someone more elderly, so it may be hard to read when the text is small". A patient (P5G2) said "Because of meds, my vision was blurred, and so I needed someone to read stuff to me" and a patient/SDM (P1G1) said "I like bullet point form—it's better for cognitive load". *2. Use imagery and colours to communicate information.* A SDM (P2G1) said "People are graphic so adding images will help" and a patient/SDM (P1G1) said "I prefer brighter or bolder colours to prioritize importance". Maybe brighter can mean more important, and duller can mean less important". A RC (P4G1) said "I found the use of colours more eye-catching". *3. Make the infographic modifiable.* A patient (P3G1) said "seeing something crossed out makes it feel personal—that someone spent time to review your file and crossed it out".

Language: *1. Use plain language, avoid jargon, and use an appropriate tone.* Patients/SDMs said "[the infographic] wasn't plain language for people whose language isn't English. You need simpler terms throughout the whole document, which seemed like it was for scholars and not the everyday population" (P2G2), "The whole document needs to be revisited by lay people to make it easier to understand" (P2G2), and "The language is cold and has no empathy. It didn't draw me in" (P1G1). A RC said "Language should be simpler. Words like 'domain' and 'intervention' should be omitted" (P3G2). *2. Explain uncommon terms.* A RC (P1G2) said "Patients might not know what 'standard of care' means. I also don't usually use 'usual care'", while patients/SDMs said "I don't know who is who, so I wouldn't know the difference between the healthcare

practitioners until I get to know people" (P3G1), and "why are we talking about a research coordinator?" (P1G1). *3. Ensure the focus is on the patient.* A patient (P5G2) said "make sure you're patient-focused, not solely research-focused".

Infographic content

Patients/SDMs and RCs identified priority items to include in the content of the infographic, with two key themes including study details and participation.

Study Details: *1. What condition do I have?* A patient/SDM (P2G2) said "if I'm in crisis at the hospital, I have no interest in reading a lot of information about something I don't have (e.g., COVID-19)". *2. What is the purpose of this study?* SDMs highlighted a desire to understand more about the study. One SDM (P4G2) said "the main thing is I want to know what the purpose of the study is", while another (P2G1) said "remind people of the end goal: if you participate, what we're trying to achieve with no ambiguity". *3. What is the consent process?* A patient/SDM (P1G1) said "You really have to tell people what to expect". *4. What treatments will I receive?* A RC (P4G1) said, "the resource must have what's going into my body and why I am taking this", while a SDM said "maybe have a description of antibiotics, what they do, and then research goal underneath" (P4G2). *5. How does the team decide which treatments to give me?* A patient (P5G1) said "it's important to know that the healthcare team has already picked things suitable for you." *6. Do I have a say in my treatment?* A SDM (P4G2) said "emphasize that you will be listened to, like teamwork", while a patient (P3G1) said "There must be choice: the ability to turn down chosen interventions".

Participation: *1. Why should I participate in this study?* One patient/SDM (P2G2) said "I like the idea of being informed that this study is going to help other patients. Being helpful is my tipping point to join." A SDM (P4G2) said "There is a lot of explanation about what it's all about, but I care about my loved one. What can I do for them? What's in it for me?" *2. Do I have to continue participation in this study?* A patient/SDM (P2G2) said "It's important to tell people that you can leave the study at any time." *3. Will participation affect my care?* A SDM said "It's very important that the level of care remains the same or better regardless of whether you participate. This should be positioned at the beginning of the resource." (P4G2) *4. Does the research team care more about me or the research results?* SDMs said "state at the beginning that if a treatment in the study is not working well, there will be revisions made ASAP for the best outcomes" (P2G1), and "stress that the healthcare team cares about you first before the research" (P4G2).

Integration

Results of Phase 1 were used to modify original prototypes (supplement, pages 11–16) into a final consent infographic. The final infographic was double-sided, with a community-acquired pneumonia (Fig. 1) and a COVID-19 (supplement, pages 17–18) version, which were piloted in Phase 2.

Phase 2 results

Recruitment

We did not achieve our projected sample size of 60 patients/SDMs. Out of 5 sites (4 academic, 1 community), 2 did not enrol into our SWAT as they primarily used deferred consent. Sixty-three patients were eligible for REMAP-CAP during our 12-month study period (October 2022–2023) (Fig. 2).

Feasibility outcomes

Twenty-one out of 63 REMAP-CAP consent encounters (33%) were eligible for our SWAT, below our target of 68%. Forty-one (65%) were not eligible due to the use of deferred consent (Fig. 2). Four RCs led consent discussions at 3 enrolling centres (2 academic, 1 community).

Out of the 21 eligible consent encounters, 18 patients/SDMs (86%) received the infographic (10 patients, 8 SDMs) (Fig. 2), above our target of 80%. The median duration of consent discussions was 15 min (15, 25) (Table 1). Seventeen patients/SDMs who received the infographic (94%) consented to this SWAT (Fig. 2), above our target of 71%, while 10 (56%) consented to the REMAP-CAP study.

Out of the 17 patients/SDMs who consented to this SWAT, we received completed questionnaires from 15 (88%) (1 electronic, 14 paper) (Fig. 2), above our target of 71%. Thirteen questionnaires were fully completed (87%), while 2 (13%) were missing demographic questions. RCs provided fully completed CRFs for each of the 18 consent encounters where the infographic was used (Fig. 2).

Consent encounter data

Patient/SDM Characteristics: Out of the 13 participants with complete demographic data (8 patients, 5 SDMs), 5 were female (39%), with almost half between the ages of 65 to 74 (n = 6, 46%) (Table 1). Additional characteristics are reported in detail in Table 1.

CUE-R 2: Fifteen patients/SDMs out of 17 completed the CUE-R 2 for an 88% response rate, which we analyzed by sub-section.

Experience with consent documents: The median overall score related to the infographic was 5.0 (4.75, 5.0) compared to 4.0 (3.5, 4.5) for the standard consent documents (Fig. 3, Table S3). All questions related to

Fig. 1 REMAP-CAP Consent Infographic (community-acquired pneumonia version). Legend: This figure shows our two-sided infographic for community-acquired pneumonia. The infographic for COVID-19 is included in the supplement (pages 17–18)

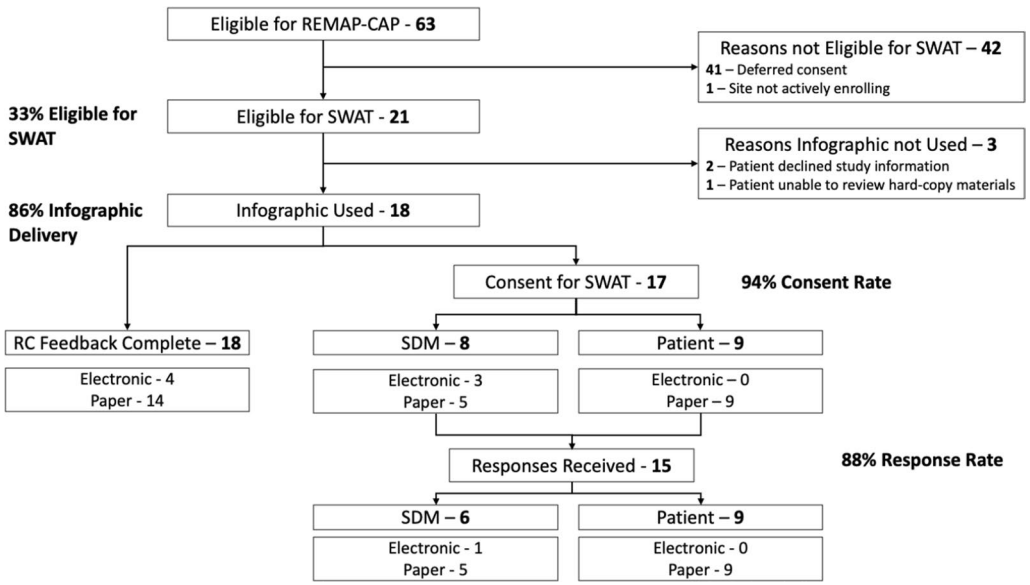

Fig. 2 Flow of participants

Table 1 Patient/SDM demographics and characteristics of consent encounters

		Overall n = 18
Demographics (n = 13)*		
Sex, n (%)	Female	5 (38.5)
Age Category, n (%)	25–34 years	1 (7.7)
	35–44 years	1 (7.7)
	45–54 years	1 (7.7)
	55–64 years	1 (7.7)
	65–74 years	6 (46.2)
	75–84 years	2 (15.4)
	85 years or older	1 (7.7)
Race, n (%)	Caucasian	12 (92.3)
	East/Southeast Asian	1 (7.7)
Previous Research Experience, n(%)	Yes	4 (30.8)
Highest Level of Education, n (%)	Master's Degree	2 (15.4)
	Bachelor's Degree	1 (7.7)
	College Diploma	3 (23.1)
	High School Diploma	4 (30.8)
	Less than High School Diploma	3 (23.1)
Consent Encounter Data		
Consent Role	Substitute Decision Maker	8(44.4)
	Patient	10 (55.6)
Enrolled in REMAP-CAP, n(%)	Yes	10 (55.6)
Duration of Consent Encounter, minutes	Median (1st, 3rd quartiles)	15 (15, 25)
	Range	10–60
How many questions did the patient/SDM ask? (n = 18)	0	2 (11.1)
	1–5	15 (83.3)
	6–10	1 (5.6)

* n = 13, data not available for five consent encounters (2 PTs, 3 SDMs)—two did not respond to demographic questions (1 PT, 1 SDM), two did not respond to the CUE-R 2 at all (2 SDMs) and one did not consent to providing feedback (PT)

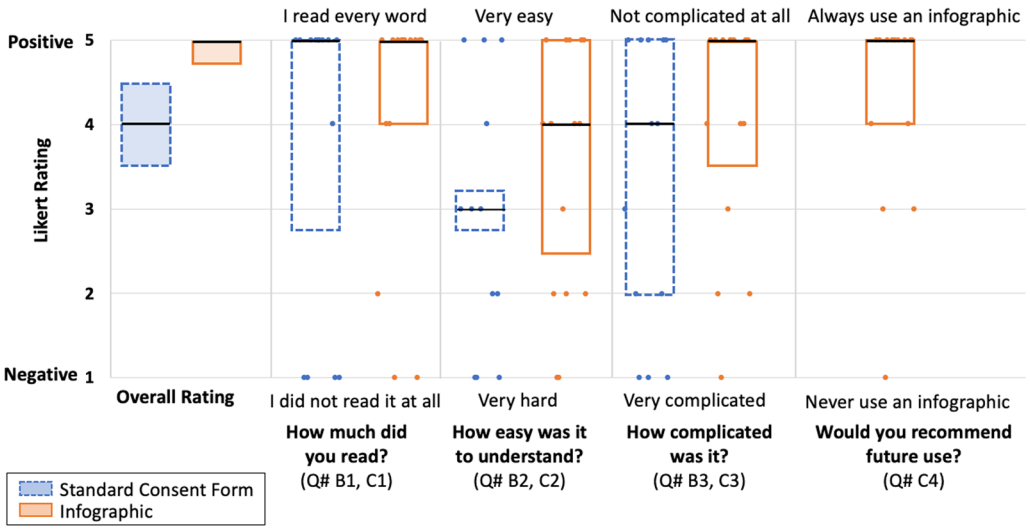

Fig. 3 Patient/SDM experience with consent documents (standard consent form + infographic). Legend: This figure summarizes individual patient/SDM responses and overall medians (Table S3). CUE-R 2 question numbers are denoted beneath each item. Each circle represents an individual patient/SDM response. Blue represents responses related to the standard consent form, while orange represents responses related to the infographic. Box plots represent the median participant score and quartiles. The horizontal, black line within the box plot represents the median, while the bottom represents the 1st quartile, and the top side represents the 3rd quartile. Instances where the black bar is the top or bottom of the box represent instances when the median was the same as one of the quartiles. For example, the median response for reading the consent form was 5.0 (2.75, 5.0)

the infographic had a median response score of 4.0 or greater, while standard consent documents ranged from 3.0–5.0 (Fig. 3). Strengths and weaknesses of both the infographic and standard consent documents are summarized in Figures S2-S5.

Patient/SDM trial-related knowledge: Respondents had a median of 75.0% (50.0%, 75.0%) correct responses (Fig. 4). 57.1% of participants (n = 8) understood the concept of response-adaptive randomization, while 53.9% (n = 7) understood the treatments provided (Fig. 4). One fifth of respondents did not understand concepts related to informed consent (Fig. 4).

Patient/SDM experience of the consent encounter: Thirteen patients/SDMs (out of 15 total respondents) rated their satisfaction and confidence in their decision, with a median of 6.0 (4.0, 6.0) out of 7 and 6.0 (5.0, 6.75) out of 7, respectively (Figure S1). Thirteen participants responded to questions related to the information received (Figure S6). Most participants said they received the right amount of information (84.6%, n = 11) and almost half had no questions at the end of the discussion (46.2%, n = 6).

RC experience with consent encounter (RC CRF): RCs completed a CRF for each consent encounter (n = 18). RCs rated their overall experience a median of 6.0 (6.0, 6.0) and all item-specific ratings were a median of 6.0 (Fig. 5).

Paired consent encounter data: RCs perceived patient/SDM satisfaction and confidence accurately, with a median response score of 6.0 (4.25, 6.0) for satisfaction and 6.0 (4.0, 6.0) for confidence (Figure S1).

Discussion

We conducted a sequential mixed methods SWAT to co-design and pilot test an infographic to support communication during a priori informed consent for REMAP-CAP. We successfully engaged patients/SDMs and frontline RCs in the Phase 1 infographic design. During Phase 2 pilot testing, we observed a high consent rate (94%), regardless of consent decisions for the REMAP-CAP parent trial. For eligible a priori consent encounters, infographic delivery and data collection were feasible. However, recruitment was slower than anticipated and two thirds (65%) of potential participants were ineligible for the infographic because they were enrolled in REMAP-CAP by deferred consent.

Infographic design

The final consent infographic differed significantly from initial prototypes. Patients, SDMs and RCs identified important, unique considerations for the final infographic design. These observations emphasize the importance of co-design and the engagement of individuals with diverse lived experience in the development of similar tools. In addition, while the content of focus groups was specific to REMAP-CAP, the themes identified by participants are relevant to other trials, particularly platform trials, and may be used to inform the design of similar tools in different contexts. For example, themes were similar to recommendations for written material for individuals with aphasia or dyslexia (e.g., short sentences, structured text with headings, icons, use of colour) [27], and may be considered in the development of materials to increase

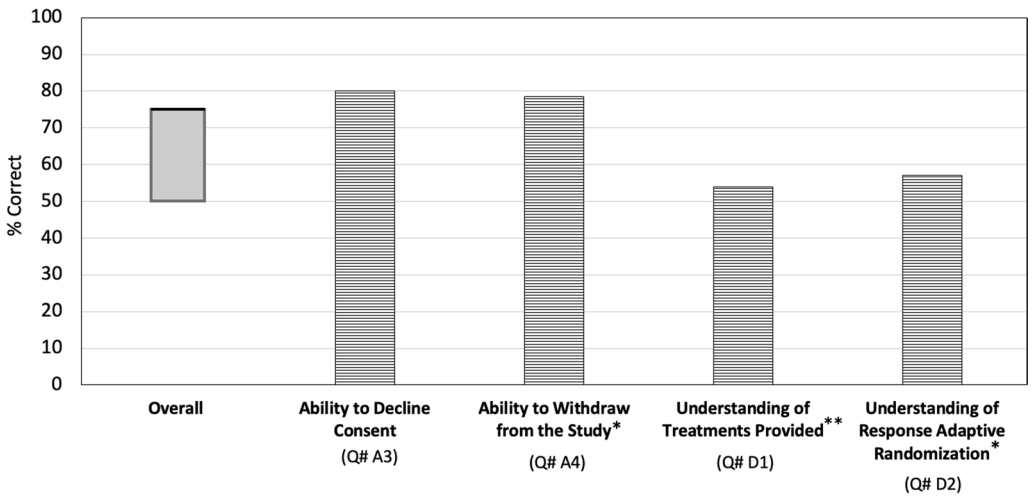

Fig. 4 Summary of patient/SDM responses for knowledge-related questions. Legend: This histogram summarizes correct responses to knowledge-related questions for 15 respondents. Overall score represents the median (1st, 3rd quartiles) number of correct responses per respondent. CUE-R 2 question numbers are denoted below each item. *One participant did not answer these questions, thus n = 14. **Two participants did not answer this question, thus n = 13

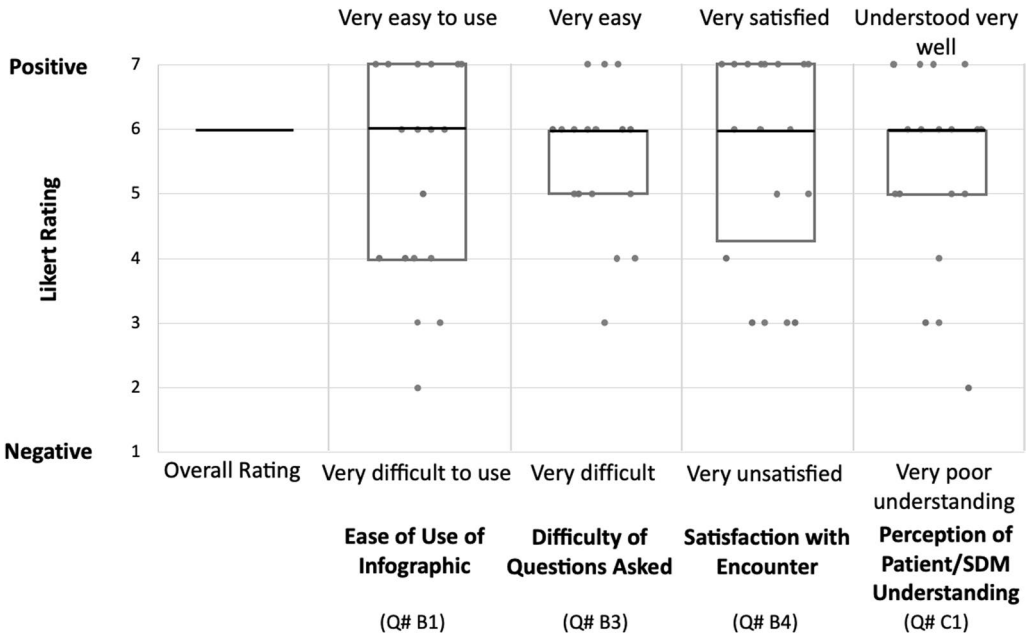

Fig. 5 Summary of Research Coordinator consent encounter experiences. Legend: This figure summarizes individual RC responses and overall medians. Question numbers are denoted below each item. Each circle represents an individual RC response. Box plots represent the median participant score and quartiles. The horizontal, black line within the box plot represents the median, while the bottom represents the 1st quartile, and the top side represents the 3rd quartile. Instances where the black bar is the top or bottom of the box represent instances when the median was the same as one of the quartiles. For example, the median overall rating was 6.0 (6.0, 6.0)

cognitive and/or linguistic accessibility of clinical trial information.

Feasibility outcomes

Thirty-three percent of patients/SDMs eligible for REMAP-CAP were also eligible for this SWAT. This was lower than our pre-specified cut-off for feasibility of 68%, which was based on an ICU-based SWAT of video consent [26]. In the video consent study, patients could only be enrolled in the parent trial by a priori consent, while in our SWAT, patients could be enrolled in the parent trial, REMAP-CAP, by a priori or deferred consent. We hypothesize that the use of deferred consent for REMAP-CAP was a result of the broader adoption of altered consent models during the COVID-19 pandemic. While deferred consent had been previously used in critical care research and in REMAP-CAP, it was increasingly adopted for pandemic-research to enrol patients into time-sensitive therapeutic trials, thus we underestimated the prevalence of its use. [10, 28, 29] Patients admitted to ICU with COVID-19 were often very sick and on ventilatory support shortly after admission, making first-person consent a challenge. [28]

We projected 60 potentially eligible patients for REMAP-CAP over six months and identified 38 (63%), thus extending recruitment for an additional six months. The REMAP-CAP trial studied treatments for patients with community-acquired pneumonia which became instrumental during the pandemic with its added COVID-19 arm. When we developed the protocol in Spring 2021, Canada was in the third wave of the COVID-19 pandemic which saw the greatest number of patients admitted to ICUs [30]. However, we did not begin enrollment until over 1 year later in November 2022 when ICU admission rates were steadily declining [31]. Given the unpredictable nature of the COVID-19 pandemic, it was challenging to predict the number of potentially eligible patients for REMAP-CAP. Recruitment challenges were not unique to this SWAT; in a narrative review of 2,814 trials for patients with COVID-19, small sample sizes and extended data collection were common barriers to trial execution [32]. In a future efficacy trial, consideration of the different consent models must be understood to ensure sample size targets are achieved given the complexity of this platform trial.

We achieved high intervention fidelity (delivery of infographic) according to pre-specified cut-offs (> 80%), with 86% of eligible patients/SDMs receiving the infographic [33]. We achieved a 94% consent rate for patient/SDM participation in this SWAT, higher than our pre-specified cut-off of 71%, informed by a systematic review where the median consent rate was 87% (71%, 94%) [34]. Of note, out of 18 patients/SDMs approached for REMAP-CAP, 10 agreed to participate in the platform trial; however, 17

agreed to participate in this SWAT. High consent rates for this SWAT may highlight the feasibility and relevance of our work for patients and families.

We achieved a high questionnaire response rate of 88% for patients/SDMs and 100% for RCs, compared to 71% for patients/SDMs and 100% for RCs in a similar SWAT [26]. The paper-copy infographics and paper-copy data collection were preferred by our sample. Of 17 patients/SDMs, only 3 preferred to receive an electronic questionnaire. Two of those did not complete the questionnaire, potentially highlighting feasibility challenges for electronic follow-up. These observations provide a potential opportunity to streamline processes and improve response rates in the future.

When determining whether to proceed with a main study after conducting pilot work, success must be determined by pre-specified feasibility metrics [24]. While we did not achieve our pre-specified feasibility target of > 68% eligible consent encounters, we achieved the remainder of our feasibility outcomes. Thus, we believe it is reasonable to proceed with a future evaluation study of the consent infographic with modifications to include additional sites both nationally and internationally to achieve target sample size calculations. The use of deferred consent at study sites must also be well understood when considering sample size and recruitment periods.

Consent encounter data

Preliminary data from patients/SDMs and research coordinators suggests promise for the consent infographic as a tool to support communication between patients/SDMs and RCs. The infographic was more favourably rated by patients/SDMs than the standard consent documents, most notably in its ease of use and simplicity. It is important to note however, that gaps in knowledge were identified for patients/SDMs, particularly with respect to study-related knowledge. Future work should consider additional study-related information to facilitate patient/SDM understanding.

Comparison to previous literature

A systematic review of enhanced documents to support communication during informed consent demonstrated improved participant understanding, similar to preliminary results from our study [11]. However, this review did not include any studies conducted in the ICU, nor did it include a platform trial. In addition, this review assessed participant understanding but did not assess outcomes related to intervention implementation or feasibility, making direct comparisons challenging. The positive feedback data from patients/SDMs in our SWAT is similar to two trials of simplified fact sheets in mixed populations [25, 35], and suggests promise for studying the infographic's impact on patient/SDM and RC-important outcomes in a future efficacy trial. In doing so, patients/SDMs and RCs must be engaged in identifying and/or defining what outcomes should be measured to determine whether an infographic can improve the quality of informed consent discussions.

Deferred consent for future research

Deferred consent is a model of consent whereby patients may be enrolled in a research study without a priori consent (i.e., before the receipt of study treatment) [28]. This occurs when a priori consent is not possible and treatments are time-sensitive [36]. Unlike waived consent models where no consent is required, patients and/or SDMs enrolled by deferred consent are approached after the initial trial enrollment for informed consent to continue participation in the research when they are able to make this decision [29, 37]. Deferred consent discussions differ from a priori consent, as RCs need to explain additional concepts such as reasons for enrollment without a priori consent, the treatments patients already received, and the choice to continue participation in study activities and/or ongoing data collection. Given these additional complexities, a tool such as an infographic may be of benefit, and considering the high use of deferred consent in REMAP-CAP, it is possible that this consent model will continue to be used for clinical research in acute care [36]. Future work should consider adaptation of the infographic to support these discussions.

Strengths

This intervention was co-designed with patients, families, and RCs, representing the voices of individuals with lived experience of participating in consent discussions. PFP ideated this study, and co-developed our research questions alongside REMAP-CAP investigators and researchers. All members of the team, including PFP, provided input at all stages throughout this study, including interpretation of data and manuscript preparation. We successfully engaged multiple sites, representing both community and academic hospitals, in recruitment and data collection. We offered the intervention and data collection tools in multiple formats. Through participant feedback, we identified ways to improve our intervention, strengthening future evaluation. We included patients/SDMs who both agreed and declined participation in the parent trial, likely reducing bias in our sample. To our knowledge, this is the first study of an infographic to support informed consent discussions in the ICU for a platform trial, and results from this pilot demonstrated implementation feasibility for a priori consent.

Limitations

Our study has important limitations. We did not collect demographic data for focus group participants, limiting our understanding of participants represented. We did not achieve our anticipated sample size of 60 potentially eligible patients/SDMs over six months, thus we lengthened our recruitment period to 12-months. Our study sites were limited in representation to only English-speaking sites in Southern Ontario. However, we did engage a community site (i.e., hospitals that provide general inpatient, outpatient and community services, tailored to their local community, and are typically underrepresented in research [38, 39]), where most participants were recruited. Lastly, we collected data from patients/SDMs using the CUE-R 2 tool, which we modified from the CUE-R tool, and may impact previously established psychometric properties. Given these limitations, results should be interpreted with caution. However, limitations will be addressed as we consider future work to evaluate the infographic. Of note, before progressing to evaluation, the infographic must be translated and cross-culturally validated to increase accessibility and inclusion of non-English speaking individuals.

Conclusions

In this sequential mixed-methods study, engagement of patients, substitute decision makers and research coordinators in the co-design of a consent infographic was critical. Use of the infographic to support communication during a priori consent discussions appears to be a feasible intervention for an ICU-based platform trial. Further work is needed to understand whether it improves understanding of treatment and study design. Given the high frequency of deferred consent observed in this pilot study, future research may consider how the infographic can be adapted for consent using the deferred consent model.

Abbreviations

CAPTIC	Canadian Adaptive Platform Trial in Intensive Care
ICU	Intensive Care Unit
RC	Research coordinator
SDM	Substitute decision maker
SWAT	Study within a trial
REMAP CAP	Randomized, Embedded, Multifactorial, Adaptive Platform Trial for Community-Acquired Pneumonia
RCT	Randomized controlled trial
MMARS	Mixed Methods Article Reporting Standards
JARS-Qual	Journal Article Reporting Standards for Qualitative Research
CONSORT	Consolidated Standards of Reporting Trails
CUE-R	Consent Understanding Evaluation-Revised Tool
CRF	Case report form

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40900-025-00705-3.

Supplementary material 1

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Author contributions

All authors contributed to study design. HKO prepared the manuscript. All authors read the manuscript, provided feedback, and approved the manuscript for submission.

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Availability of data and materials

Data are provided within the manuscript or supplementary information files.

Declarations

Ethics approval and consent to participate

CTO Project #3779.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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References

1. Bazzano LA, Durant J, Brantley PR. A modern history of informed consent and the role of key information. Ochsner J. 2021;21(1):81–5. https://doi.org/10.31486/toj.19.0105.
2. Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? JAMA. 2000;283(20):2701–11. https://doi.org/10.1001/jama.283.20.2701.
3. Bhutta ZA. Beyond informed consent. Bull World Health Organ. 2004;82:771–7. https://doi.org/10.1590/S0042-96862004001000013.

4. Beardsley E, Jefford M, Mileshkin L. Longer consent forms for clinical trials compromise patient understanding: so why are they lengthening? J Clin Oncol Off J Am Soc Clin Oncol. 2007;25(9):e13–4. https://doi.org/10.1200/jco.2006.10.3341.
5. Ecarnot F, Quenot JP, Besch G, Piton G. Ethical challenges involved in obtaining consent for research from patients hospitalized in the intensive care unit. Ann Transl Med. 2017;5:41. https://doi.org/10.21037/atm.2017.04.42.
6. Berry SM, Connor JT, Lewis RJ. The platform trial: an efficient strategy for evaluating multiple treatments. JAMA. 2015;313(16):1619. https://doi.org/10.1001/jama.2015.2316.
7. Park JJH, Harari O, Dron L, Lester RT, Thorlund K, Mills EJ. An overview of platform trials with a checklist for clinical readers. J Clin Epidemiol. 2020;125:1–8. https://doi.org/10.1016/j.jclinepi.2020.04.025.
8. REMAP-CAP Trial. REMAP-CAP Trial. Accessed March 18, 2021. https://www.remapcap.org
9. Burns KEA, Zubrinich C, Marshall J, Cook D. The 'Consent to Research' paradigm in critical care: challenges and potential solutions. Intensive Care Med. 2009;35(10):1655–8. https://doi.org/10.1007/s00134-009-1562-9.
10. Garg H, Khanna P. Consent in covid: a researcher's dilemma. Trends Anaesth Crit Care. 2021;38:10–2. https://doi.org/10.1016/j.tacc.2021.03.010.
11. Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, McCormick JB. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. BMC Med Ethics. 2013;14(1):28. https://doi.org/10.1186/1472-6939-14-28.
12. Mulvale G, Moll S, Miatello A, et al. Codesigning health and other public services with vulnerable and disadvantaged populations: insights from an international collaboration. Health Expect. 2019;22(3):284–97. https://doi.org/10.1111/hex.12864.
13. Moll S, Wyndham-West M, Mulvale G, et al. Are you really doing 'codesign'? Critical reflections when working with vulnerable populations. BMJ Open. 2020;10(11): e038339. https://doi.org/10.1136/bmjopen-2020-038339.
14. Lloyd N, Kenny A, Hyett N. Evaluating health service outcomes of public involvement in health service design in high-income countries: a systematic review. BMC Health Serv Res. 2021;21(1):364. https://doi.org/10.1186/s12913-021-06319-1.
15. Valaitis R, Longaphy J, Ploeg J, et al. Health TAPESTRY: co-designing interprofessional primary care programs for older adults using the persona-scenario method. BMC Fam Pract. 2019;20(1):122. https://doi.org/10.1186/s12875-019-1013-9.
16. Treweek S, Bevan S, Bower P, et al. Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)? Trials. 2018;19(1):139. https://doi.org/10.1186/s13063-018-2535-5.
17. Creswell JW, Plano Clark VL. *Designing and Conducting Mixed Methods Research*.; 2018.
18. Staniszewska S, Brett J, Simera I, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. BMJ. 2017;358: j3453. https://doi.org/10.1136/bmj.j3453.
19. Levitt HM, Bamberg M, Creswell JW, Frost DM, Josselson R, Suárez-Orozco C. Journal article reporting standards for qualitative primary, qualitative meta-analytic, and mixed methods research in psychology: the APA Publications and Communications Board task force report. Am Psychol. 2018;73(1):26–46. https://doi.org/10.1037/amp0000151.
20. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355: i5239. https://doi.org/10.1136/bmj.i5239.
21. O'Grady HK, Bhimani Z, Dalziel S, et al. Co-designing and pilot testing an infographic to support patients/families through the REMAP-CAP consent process: a mixed-methods study protocol. Pilot Feasibility Stud. 2023;9(1):58. https://doi.org/10.1186/s40814-023-01290-6.
22. Sandelowski M. Whatever happened to qualitative description? Res Nurs Health. 2000;23(4):334–40. https://doi.org/10.1002/1098-240X(200008)23:4%3c334::AID-NUR9%3e3.0.CO;2-G.
23. Onwuegbuzie AJ, Dickinson WB, Leech NL, Zoran AG. A qualitative framework for collecting and analyzing data in focus group research. Int J Qual Methods. 2009;8(3):1–21. https://doi.org/10.1177/160940690900800301.
24. Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: the what, why and how. BMC Med Res Methodol. 2010;10(1):1. https://doi.org/10.1186/1471-2288-10-1.
25. Taylor HA, Washington D, Wang NY, et al. Randomized comparison of two interventions to enhance understanding during the informed consent process for research. Clin Trials. 2021. https://doi.org/10.1177/17407745211009529.
26. Kho ME, Duffett M, Clarke FJ, Shears M, Molloy AJ, Cook DJ. Video-augmented vs standard consent in an early ICU cycling feasibility trial: a randomized embedded recruitment trial. F1000Research. 2020;9:45. https://doi.org/10.12688/f1000research.21750.1.
27. Brennan A, Worrall L, McKenna K. The relationship between specific features of aphasia-friendly written material and comprehension of written material for people with aphasia: an exploratory study. Aphasiology. 2005;19(8):693–711. https://doi.org/10.1080/02687030444000958.
28. van der Graaf R, Hoogerwerf MA, de Vries MC. The ethics of deferred consent in times of pandemics. Nat Med. 2020;26(9):1328–30. https://doi.org/10.1038/s41591-020-0999-9.
29. Fitzpatrick A, Wood F, Shepherd V. Trials using deferred consent in the emergency setting: a systematic review and narrative synthesis of stakeholders' attitudes. Trials. 2022;23(1):411. https://doi.org/10.1186/s13063-022-06304-x.
30. Detsky AS, Bogoch II. COVID-19 in Canada: experience and response to waves 2 and 3. JAMA. 2021;326(12):1145–6. https://doi.org/10.1001/jama.2021.14797.
31. Secretariat TB of C, Secretariat TB of C. Public Health Infobase - Data on COVID-19 in Canada - Open Government Portal. Accessed June 25, 2023. https://open.canada.ca/data/en/dataset/261c32ab-4cfd-4f81-9dea-7b64065690dc
32. Janiaud P, Hemkens LG, Ioannidis JPA. Challenges and lessons learned from COVID-19 trials: Should we be doing clinical trials differently? Can J Cardiol. 2021;37(9):1353–64. https://doi.org/10.1016/j.cjca.2021.05.009.
33. Borrelli B. The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. J Public Health Dent. 2011;71(s1):S52–63. https://doi.org/10.1111/j.1752-7325.2011.00233.x.
34. Garde A, O'Hearn K, Nicholls S, Menon K. Reporting of consent rates in critical care studies: room for improvement. J Clin Epidemiol. 2016;74:51–6. https://doi.org/10.1016/j.jclinepi.2015.11.015.
35. Kass NE, Taylor HA, Ali J, Hallez K, Chaisson L. A pilot study of simple interventions to improve informed consent in clinical research: feasibility, approach, and results. Clin Trials. 2015;12(1):54–66. https://doi.org/10.1177/1740774514560831.
36. Casey JD, Beskow LM, Brown J, et al. Use of pragmatic and explanatory trial designs in acute care research: lessons from COVID-19. Lancet Respir Med. 2022;10(7):700–14. https://doi.org/10.1016/S2213-2600(22)00044-3.
37. Loosman I, Nickel PJ. Towards a design toolkit of informed consent models across fields: a systematic review. Sci Eng Ethics. 2022;28(5):42. https://doi.org/10.1007/s11948-022-00398-x.
38. Gehrke P, Binnie A, Chan SPT, et al. Fostering community hospital research. CMAJ. 2019;191(35):E962–6. https://doi.org/10.1503/cmaj.190055.
39. Ontario Hospital Association Ontario's Hospitals. Accessed March 12, 2025. https://www.oha.com/about-oha/Ontario-Hospitals#:~:text=Often%20characterized%20as%20General%20Hospitals%2C%20Community%20Hospitals,medical%20schools%20and%20have%20a%20teaching%20mandate.%E2%80%8B

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