Social Worker Presence in Outpatient Fracture Clinics: A Batched Stepped-Wedge Cluster Randomized Trial Protocol

Protocol Number: SWRCT-27-March-2025

Version: 2.0

Date: May 12, 2025

Reviewed and approved by:	***Signature:***	***Date:***
Dr. Sheila Sprague *Principal Investigator*	DocuSigned by: Sheila Sprague 0FB2FF3A208B452...	12-May-2025

DOCUMENT REVISION HISTORY

Date	Version	Section	Summary of Changes	Author(s)
27March2025	1.0	All	Original Version	Natalie Fleming
12May2025	2.0	4.4	Removed “willing to provide informed consent” from the inclusion criteria, as it is also an exclusion criteria.	Natalie Fleming
		4.5	Clarified that patients should be approached by a circle of care member. Clarified the composition and process of the Central Adjudication Committee.	
		9.1	Added text to clarify that participants may use other available social work services or referrals as part of usual care.	

TABLE OF CONTENTS

Contents

TRIAL SUMMARY 5
1.0 INTRODUCTION 6
1.1 What is the problem to be addressed? 6
1.2 Why is a trial needed now? 7
2.0 OBJECTIVES 8
3.0 TRIAL DESIGN 8
3.1 Description of the Trial Design 8
4.0 METHODOLOGY 10
4.1 Trial Setting 10
4.2 Cluster Eligibility and Selection of Clusters 10
4.3 Cluster Allocation and Concealment 11
4.4 Participant Eligibility Criteria 11
4.5 Patient Screening and Informed Consent 11
4.6 Intervention 12
4.7 Outcomes 13
4.7.1 Number of Emergency Room and Urgent Care Center Visits 13
4.7.2 LIMB-Q 14
4.7.3 Satisfaction with Care Provided 14
4.7.4 Opioid Use 14
4.7.5 Missed Fracture Clinic Visits 14
4.7.6 Economic Analysis 14
4.7.7 Lived Experiences of Orthopaedic Trauma Patients, Social Workers, and Health Care Professionals in Fracture Clinics 15
4.8 Data Collection and Participant Follow-Up 15
4.8.1 Data Collection Procedures 15
4.8.2 Participant Follow-Up 15
4.9 Blinding 16
5.0 SAMPLE SIZE 16
6.0 DATA ANALYSIS 17
6.1 Outcomes Analysis 17
6.2 Sensitivity Analyses 19
6.3 Subgroup Analyses 20
6.4 Qualitative Analysis 21
6.5 Interim Analysis Plan 22
7.0 DATA MANAGEMENT 22
7.1 Case Report Forms and Data Transmission 22

7.2 Interview Management 22
7.3 Data Integrity 22
7.4 Trial Monitoring 22
7.5 Records Retention 22
8.0 ETHICS AND DISSEMINATION 23
8.1 Research Ethics Approval 23
8.2 Confidentiality 23
8.3 Protocol Amendments 23
8.4 Dissemination Policy 23
9.0 SAFETY 23
9.1 Risks to Participants 23
9.2 Safety Monitoring 24
10.0 REFERENCES 25

TRIAL SUMMARY

Name	Social Worker Presence in Outpatient Fracture Clinics: A Batched Stepped-Wedge Cluster Randomized, Trial
Methodology	Batched Stepped-Wedge Cluster Randomized Trial
Background	To address the unmet needs of orthopaedic trauma patients, we propose integrating a dedicated social worker within the fracture clinic setting.
Primary Objective	The primary objective is to determine if the integration of a dedicated social worker within the fracture clinic setting, compared to usual care, reduces all-cause return to emergency room or urgent care over 6 months.
Secondary Objectives	The secondary objectives of the definitive trial are to determine if the integration of a dedicated social worker within the fracture clinic setting, compared to usual care: 1. Reduces negative psychological impact; 2. Reduces negative financial impact; 3. Increases patient satisfaction with care; 4. Reduces opioid use; and 5. Reduces missed fracture clinic visits. We will assess the economic value of the intervention from the hospital (payer) perspective. Finally, we will explore the lived experiences of orthopaedic trauma patients, social workers, and health care professionals in fracture clinics through structured interviews.
Key Eligibility Criteria	The key eligibility criteria are: 1. Adult patient over the age of 18. 2. Patient presenting within 12 weeks of injury with an appendicular fracture that required surgical management. 3. Willing to comply with the trial protocol.
Intervention	Participants enrolled into the treatment group will meet with the social worker, which may include the following interventions: intake and assessment; formulation of goals; treatment planning and intervention; evaluation and conclusion. Participants in the usual care group will receive standard fracture care as determined by their treating surgeon.
Primary and Secondary Outcomes	The primary outcome is all cause visits to an emergency room or urgent care center within 6 months of enrollment. The secondary outcomes are: 1. LIMB-Q Psychological Impacts scale. 2. LIMB-Q Financial Impacts scale. 3. Satisfaction with care question. 4. Opioid use at 3 months and 6 months. 5. Fracture clinic visits attended and missed. 6. Economic analysis (EQ-5D and hospital use). 7. Qualitative interviews with participants, social workers, and health care professionals.
Sample Size	2000 patients
Significance	This trial has the potential for significant impact on patients including enhanced recovery and health outcomes, prevention of complications and improved long-term recovery. Specifically, this trial has the potential to identify areas in which social workers can have the most significant impact, providing evidence for hospital administrations to offer social work services in fracture clinics.

1.0 INTRODUCTION

1.1 What is the problem to be addressed?

Each year, approximately 15% of Canadians experience an orthopaedic injury serious enough to affect their ability to engage in everyday activities[1]. These injuries include fractures and dislocations that are typically managed operatively by an orthopaedic trauma surgeon and frequently result in prolonged recovery periods. Despite a comprehensive and well-researched approach to medical aspects of recovery, this patient population seldom receives adequate social support for the non-physical consequences of their injuries.

Following a serious orthopaedic injury, patients may face numerous life changes including negative impacts on relationships, independence, emotional well-being, financial stability, and ability to work or participate fully in daily activities. Patients may also experience new or worsening mental health problems. Studies have found orthopaedic trauma patients to have higher-than-average rates of many types of mental health disorders, including depression and anxiety[2]. A 2017 systematic review found that, post-injury, the weighted pooled prevalence of depression and post-traumatic stress disorder in orthopaedic trauma patients was 33% and 27%, respectively[3]. Post-injury, there is a correlation between symptoms of depression and reduced physical function and magnitude of disability[4].

As they often necessitate prolonged periods away from work, traumatic orthopaedic injuries significantly affect employment and income. For many, financial repercussions are immediate, leading to income loss even with minor injuries. It is not uncommon for physical impairment from orthopaedic injuries to keep patients from returning to work for 6 months or more, with compounding detrimental effects on relationships, self-worth, and future job prospects[5]. Research on the financial toll of orthopaedic injuries found that fractures were associated with substantial individual and household income loss up to 5 years after injury, and 1 in 5 patients sustained catastrophic income loss in the 2 years after their injury[6]. Navigating the bureaucratic and logistical challenges of securing employment insurance or Workplace Safety and Insurance Board benefits post-injury can be overwhelming, adding to the burden faced by the injured person or their caregivers.

The stress of a serious orthopaedic injury may also lead to or exacerbate substance abuse problems, which may include increased alcohol intake and drug use. In addition, opioids are a ubiquitous part of perioperative pain management following an orthopaedic injury. Despite increasing regulations, more than 80% of orthopaedic trauma patients are prescribed opioids in the post-surgical period[7]. Patients may have low levels of information about safe opioid use, alternative methods of pain management, and what to expect during recovery[8]. When coupled with other post-injury challenges, including mental health issues, job loss, and income reduction, these factors may lead to opioid addiction, potentially resulting in permanent job loss, being without a home, and even death.

The combined stress of physical recovery, financial strain, risk of addiction, changes in relationship dynamics, and the intricacies of obtaining aid or services can be emotionally and mentally taxing for orthopaedic patients and their support networks. Orthopaedic trauma patients urgently need outpatient support for their recovery from injury. The orthopaedic fracture clinic is the only outpatient care that these patients receive. Supplementing medical treatment with a comprehensive support system and strategies to mitigate the non-physical impacts of orthopaedic injury has the potential to significantly reduce the negative impact of these traumatic injuries. To address this urgent social need, we propose the integration of a dedicated social worker within the fracture clinic setting to provide support to patients with serious orthopaedic injuries. A clinical trial is needed to evaluate the efficacy of having a social worker in the fracture clinic before widespread hospital policy changes can be implemented.

1.2 Why is a trial needed now?

The functional impact of a serious orthopaedic injury significantly influences patients' ability to work, participate in activities of daily living, engage in exercise and sports, maintain social relationships, and feel like a valued member of their family and society – all areas in which a social worker can have a pivotal impact. Post-pandemic, North America has faced growing mental health, opioid use, and cost of living crises which have left Canadians susceptible to a post-injury cascade of social and financial consequences[9]. In preparation for the proposed trial, we conducted a search of the literature, which identified a trial that evaluated rates of osteoporosis treatment in hip fracture patients. The results of this trial directly led to the addition of an osteoporosis coordinator to assess the bone health of fracture patients in many fracture clinics across Canada. The success of the osteoporosis coordinator model became the basis for our hypothesis that a similar model providing dedicated social worker support in fracture clinics will reduce the negative life impact of orthopaedic injury on patients. Our search did not identify any trials evaluating social worker support in fracture patients.

We conducted a cross-sectional survey of practicing orthopaedic surgeons who treat patients with serious orthopaedic injuries and asked about their perceptions regarding the need for social worker support in their patient population. Orthopaedic surgeons identified that they are 'often' or 'always' seeing patients who are financially strained (84%), experiencing substance abuse (53%), have mental health problems (38%), or are underhoused (35%). In addition, 84% of respondents indicated that at least one social support required by their fracture patients was currently inadequate to a point of crisis.

To ensure that patients' voices are heard, we conducted a cross-sectional study of 200 patients receiving treatment for an orthopaedic injury in the fracture clinic setting. Critically, 94% of patients surveyed indicated that they believe that fracture patients like them would benefit from the support of a social worker[10]. From the patient perspective, patients identified multiple areas of support that a social worker could provide, with over 60% of respondents indicating patients like them could use assistance with benefits/insurance, coordination of care, counselling and emotional support, referrals, post-traumatic stress disorder, patient education, needs assessments, anxiety, inability to pay for care, depression, family support, patient advocacy, advocacy for vulnerable

population, crisis intervention, substance misuse, financial strain, intimate partner violence, and being unhoused or underhoused.

Our review of the literature, coupled with insights from orthopaedic surgeons and patients, has identified a critical gap in patient care in outpatient fracture clinic settings. Despite this need being recognized by many surgeons and patients with whom we have engaged, the current standard of care fails to address these non-physical concerns. Our body of work to date underscores the urgency and importance of bridging this gap: one in which social workers could enhance patient well-being and where they are uniquely poised to contribute to the current landscape of orthopaedic treatment. To address this issue, this trial aims to evaluate the impact of integrating a dedicated social worker into outpatient fracture clinics.

2.0 OBJECTIVES

The primary objective of this trial is to determine if the integration of a dedicated social worker within the fracture clinic setting, compared to usual care, reduces all-cause visits to the emergency room or urgent care over 6 months.

The secondary objectives of this trial are to determine if the integration of a dedicated social worker within the fracture clinic setting, compared to usual care:

1. Reduces negative psychological impact;
2. Reduces negative financial impact;
3. Increases patient satisfaction with care;
4. Reduces opioid use; and
5. Reduces missed fracture clinic visits.

We will assess the economic value of the intervention from the hospital (payer) perspective. We will also explore the lived experiences of orthopaedic trauma patients, social workers, and health care professionals in fracture clinics through structured interviews.

3.0 TRIAL DESIGN

3.1 Description of the Trial Design

To efficiently and effectively address the above objectives, we have designed this trial as a batched stepped-wedge cluster randomized trial. The batched stepped-wedge cluster randomized trial is a pragmatic design commonly used in the evaluation of service delivery interventions. In the batched stepped wedge trial, clusters (in this case, surgeon clinics) of patients can be randomized and move through the trial design in ‘batches’ (e.g. a group of four clusters), which allows for flexibility in the timing of initiation of different clusters. The stepped wedge design itself begins with each cluster in the batch being given a date for crossover into the treatment group, in a randomly determined order. All clusters then enter an initial period in which no patients are exposed to the intervention. Subsequently, at regular intervals (“steps”), clusters cross from the control to the intervention under evaluation. This process continues until all clusters have crossed over to the intervention. At the end of the batch period there is a period when the intervention is being

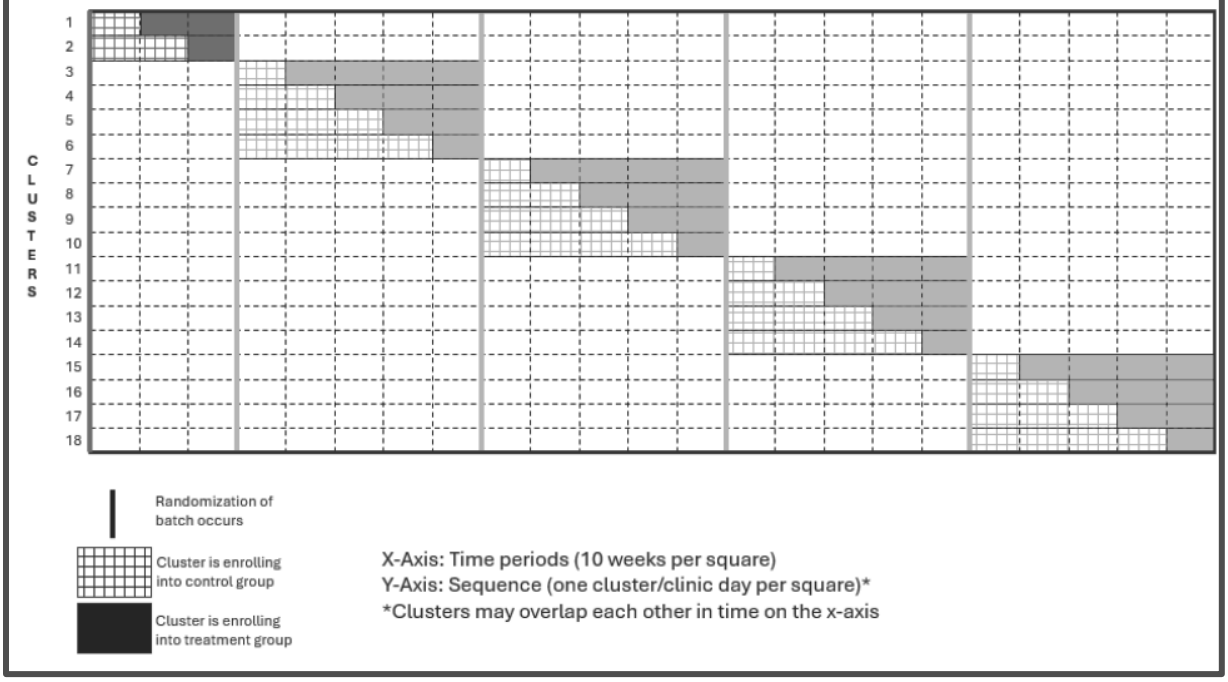
implemented at all clusters. Data collection takes place throughout the batch period, so that all clusters contribute observations under both control and intervention observation periods. We will define a cluster as an individual orthopaedic surgeon fracture clinic.

We will conduct this trial in two to four batches, with four clusters in each batch. The number of batches will depend on the enrollment rates during the previous batches. For each batch, before participant enrollment begins, the Methods Centre will randomize the clusters (i.e. clinics) to determine when they will begin the intervention (i.e. social worker support in the fracture clinic). All clinics in the batch will begin participant enrollment into the non-intervention arm (i.e. usual care with no social worker services). At 10 weeks, one clinic will begin the intervention while the others will continue enrolling in the non-intervention arm as per randomization. At 20 weeks the second clinic will cross over to begin treatment, and at 30 weeks the third clinic will crossover. The fourth clinic will cross over after 40 weeks. All clinics (clusters) will enroll for 12 months.

To ensure feasibility of this design, we will conduct a Vanguard phase that will include two clusters who will enroll for a period of 8 months. As per the above, both clusters will being participant enrollment into the non-intervention arm (i.e. usual care with no social worker services). At 10 weeks, one cluster will begin the intervention while the other cluster will continue enrolling in the non-intervention arm as per randomization. At 20 weeks the second cluster will cross over to begin treatment. Participant enrollment in both clusters will continue for 10 additional weeks. Data from the vanguard phase will be included in the trial, if there are no significant changes to the protocol.

Figure one shows the trial design, which includes the vanguard phase (in purple) and then a batched stepped-wedge design (in green). Batch timelines may also overlap each other, and the timing will depend upon funding and the readiness of different clusters to begin recruitment. The overall sample size for the trial will be approximately 2,000 participants.

Figure 1: Enrollment Phases for Batched Stepped Wedge Randomized Trial Design



4.0 METHODOLOGY

4.1 Trial Setting

The Surgery Methods Centre in the Department of Surgery at McMaster University will coordinate this trial. The Methods Centre will register this trial on ClinicalTrials.gov prior to initiating enrollment. The Principal Investigator will chair the trial's Steering Committee, which will provide oversight and guidance for the trial. Methods Centre personnel will obtain research ethics board approval for the trial. Research personnel at each selected cluster (the institution affiliated with each cluster) will obtain local Research Ethics Board approval prior to initiating local trial activities. Clusters will be selected at hospitals in the United States and Canada.

4.2 Cluster Eligibility and Selection of Clusters

Clusters will be defined by orthopaedic surgeon clinical practices and participating sites may contribute one or more clusters. Clusters will be selected in batches of four. Methods Centre personnel will carefully screen potential clusters for eligibility. Cluster inclusion criteria are: 1) adequate research personnel infrastructure to manage the trial; 2) adequate surgically managed fracture volume to complete enrollment within the timelines; and 3) ability to secure a qualified social worker to perform the trial intervention. The exclusion criteria are: 1) lack of interest in the trial; 2) anticipated challenges with complying with the protocol; 3) conflicting studies that would inhibit patient participation; and 4) budgeting or contract constraints.

The screening process will begin with potential clusters (orthopaedic surgeons' clinics) completing a feasibility questionnaire that includes the cluster eligibility criteria. Clusters that meet the

eligibility criteria at this stage will be invited to participate in a meeting to review local logistics and to confirm interest and eligibility. Study personnel will document reasons for cluster ineligibility.

Of note, clusters (individual orthopaedic surgeons clinic days) within the same batch and across the batches may be at the same or different hospital and/or university.

We will document key demographic information for each cluster.

4.3 Cluster Allocation and Concealment

The Methods Centre will randomize each batch of clusters prior to the start of patient recruitment to determine when they will begin the intervention. At the time of randomization, Methods Centre personnel will notify each cluster of the timing of their crossover from usual care to the treatment phase of the trial.

4.4 Participant Eligibility Criteria

The screening population for this trial is patients 18 years of age or older with an injury to the appendicular skeleton which occurred in past 12 weeks and required surgical management who present to a participating fracture clinic.

The inclusion criteria are:

1. Aged 18 or older.
2. Had a fracture of the appendicular skeleton.
3. Fracture required surgical management.
4. Fracture occurred within the past 12 weeks.
5. Willing to comply with the protocol.

The exclusion criteria are:

1. Incarceration.
2. Expected injury survival of less than 6 months.
3. Terminal illness with expected survival of less than 6 months.
4. Currently enrolled in a trial that does not permit co-enrollment.
5. Unable to engage in protocol in the languages available in the local cluster.
6. Prior enrollment in the trial.
7. Declined to provide informed consent.
8. Not approached at (or prior to) the first post-surgery fracture clinic visit (missed participant).
9. Other reason to exclude the patient, as approved by the Methods Centre.

4.5 Patient Screening and Informed Consent

A member of the circle of care will screen patients for broad eligibility and approach them to see if they are interested in participating in a research study. If they agree, research personnel will

confirm their eligibility. After an initial screening process following local research ethic board guidelines, eligible patients will engage in the informed consent process. To obtain informed consent, personnel at each cluster will adhere to the following procedures:

1. Present trial information in a manner that is understandable to the patient.
2. Discuss the trial with the patient and answer any questions they have.
3. Confirm that the patient understands the risks and benefits of participating in the trial and that their participation is voluntary.
4. Complete the consent process and obtain signatures from the patient and person obtaining consent.

Site research personnel will follow the process of obtaining and documenting informed consent forms in accordance with Good Clinical Practice[11]. Participants may withdraw their consent at any time.

If a potentially ineligible participant is enrolled, at least one member of the Central Adjudication Committee will review de-identified medical records to determine eligibility. *The Central Adjudication Committee will be comprised of three members who are orthopaedic surgeons.* Their decision will be based on the information available at the time of informed consent.

4.6 Intervention

Research personnel at each cluster will inform individual participants of their treatment allocation **after** they have provided informed consent. Participants enrolled during the usual care phase at their clinic will attend appointments as usual on a schedule determined by their surgeon and will not have access to social worker support in the fracture clinic.

Participants enrolled during the treatment phase at their clinic will receive social work support (see Table 1) for 6 months from the time of enrollment. They will have an intake appointment with the social worker before or during their initial fracture clinic visit to assess their needs, identify goals that they can address with the support of the social worker, and collaboratively formulate a personalized care plan tailored to their specific circumstances. The social worker will then implement the plan, which may involve educating participants and their support network, coordinating delivery of care and benefits, making referrals to community services, advocating for the participant, and providing emotional support and brief counselling. The social worker will be accessible to participants for 6 months post-enrollment, following up via telephone, telemedicine or in-person to evaluate the effectiveness of the care plan and offer sustained ongoing support. During this time, the social worker will make detailed notes on communication and referrals provided.

Table 1: Social Worker Support
1. *Intake and Assessment:* The social worker will complete a standardized intake assessment questionnaire that will ask the participant about their social needs. This will include asking about safety, intimate partner violence, addictions, housing and utilities, finances, food insecurity, mental health, transportation, and injury recovery.
2. *Formulation of goals:* Based on the intake and assessment, the social worker will work with the participant to identify goals the social worker can help the participant achieve. An example of a goal is "plans for childcare during physiotherapy appointments"; "manage my stress and anxiety since the car accident"; "help to stop drinking"; "try to get off pain medications"; or "get a walker while on a fixed income".
3. *Treatment planning and intervention*: The social worker will perform interventions according to the established goals. These can include management of patient expectations, advocacy for participant, coordination of care and benefits, referrals to community service partners, patient and family education, and emotional support and brief counselling.
4. *Evaluation and Termination:* The social worker will revisit the planned goals with the participant at each follow-up appointment, discuss progress, and provide additional treatments, resources, and referrals.

4.7 Outcomes

The primary outcome measure is all cause visits to an emergency room or urgent care centre within six months of enrollment. *(See Section 4.7.1).*

Secondary outcome measures are:

1. LIMB-Q Psychological Impacts scale *(See Section 4.7.2).*
2. LIMB-Q Financial Impacts scale *(See Section 4.7.2).*
3. Satisfaction with care provided *(See Section 4.7.3)*
4. Opioid use *(See Section 4.7.4).*
5. Fracture clinic visits attended and missed (*See Section 4.7.5)*
6. Economic analysis (EQ-5D-5L and hospital use) (*See Section 4.7.6)*
7. Qualitative interviews with participants, social workers, and health care professionals *(See Section 4.7.7).*

4.*7.1 Number of Emergency Room and Urgent Care Center Visits*

Research personnel will ask participants if they went to the emergency room or to an urgent care facility at each of the follow-up visits 6 weeks, 3 months, and 6 months after consent. Additionally, research personnel will review the participant's medical records for emergency room and urgent care visits. We will document the date of any visits and the reason for the visit. We will also document whether the visit occurred at the same or different hospital and hospital system where the participant is receiving care for the fracture.

4.7.2 LIMB-Q

The LIMB-Q[12,13] is a validated questionnaire with 16 independently functioning scales designed specifically for patients with extremity injuries. This trial will use the LIMB-Q Psychological and Financial impact scales as secondary outcome measures. Research coordinators will administer all LIMB-Q scales at baseline, 6 weeks, 3 months, and 6 months after consent. LIMB-Q scale scores range from 0 (worst) to 100 (best). Higher scores for LIMB-Q scales reflect a better outcome. To provide a point of reference for the LIMB-Q, we will also administer the EQ-5D[14]. This is a standardized instrument for use as a measure of health status that has been validated in similar patient populations. It uses a descriptive system composed of 5 dimensions of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Each dimension is comprised of five levels: no problems, slight problems, moderate problems, severe problems and extreme problems. A unique EQ-5D health state is defined by combining 1 level from each of the 5 dimensions. It is also a cognitively simple test, taking only a few minutes to complete but with the capacity of collecting health utility data. Research coordinators will administer the EQ-5D at baseline, 6 weeks, 3 months and 6 months after consent.

4.7.3 Satisfaction with Care Provided

At each follow-up, participants will be asked a single, Likert-scale question about their level of satisfaction with the care they have received for their fracture(s).

4.7.4 Opioid Use

We will assess the use of opioid medications at baseline, 6 weeks, 3 months and 6 months post-consent.

4.7.5 Missed Fracture Clinic Visits

We will assess the proportion of missed clinic visits by tracking the number of fracture clinic visits each participant attends as well as tracking any missed clinic visits. We will ask the participant about appointment attendance as well as verify information from their medical record.

4.7.6 Economic Analysis

We will conduct a cost-effectiveness analysis from the payer's perspective which will include utilities obtained from the Euro-Quol-5 Dimensions 5 Levels (EQ-5D-5L), the cost of the social worker, and the hospital care costs. The EQ-5D is a widely-used, standardized instrument for measuring health-related quality of life, which has been validated for the proposed patient population[14]. The EQ-5D-5L allows the calculation of a health utility score, which is necessary to calculate quality-adjusted life years (QALYs). QALYs combine quantity of life with Health-Related Quality of Life and are used in cost-effectiveness analyses to compare outcomes between interventions. We will calculate QALYs for each intervention by weighing the utility scores by time spent in health states using an area under the curve approach. Participants will be asked to record hospital visits and research personnel will verify this information in their medical record. This data will be modeled within the economic analysis to compare the social worker intervention versus usual care.

4.7.7 Lived Experiences of Orthopaedic Trauma Patients, Social Workers, and Health Care Professionals in Fracture Clinics

We will conduct qualitative interviews in alignment with the CORE-Q guidelines for qualitative research[15]. We have selected qualitative description as the theoretical basis the qualitative component of this trial. Qualitative description is a low-interpretation method of analyzing qualitative interviews that does not describe themes in terms of a conceptual, philosophical or other highly abstract framework or system[16]. We will also use this approach for the social worker and health care professional interviews.

We will conduct one-on-one interviews with 25-30 participants who have completed the trial. The interviews will be structured, with approximately 20 questions expected to allow for 30-45 minutes interview length. Interviews will take place over Zoom, telephone, or in-person, depending on the preference of the participant. The interviews will be audio-recorded for transcription. Sampling for the interviews will be split equally between participants from the intervention and usual care groups and will follow a maximum variation technique, in order to provide information from a broad range of perspectives[16].

Separately, we will conduct interviews with each of the social workers and 10-12 interviews with health care professionals in the fracture clinics. These interviews will follow the same process as the participant interviews. We will follow an informed consent procedure with social workers and health care professionals who participate in qualitative interviews to address the exploratory objective.

4.8 Data Collection and Participant Follow-Up

4.8.1 Data Collection Procedures

After obtaining informed consent from a participant, research personnel will complete the baseline case report forms (CRFs). Baseline data will be obtained from the participant, the participant's medical record, and/or the participant's treating physicians and entered by the Research Coordinator. Baseline data collection points include participant and injury characteristics such as age, sex, gender, socioeconomic status, co-morbidities, mechanism of injury, among others. At baseline, participants will also complete the LIMB-Q scales, the satisfaction with care question, opioid use question, and the EQ-5D.

4.8.2 Participant Follow-Up

We will follow participants for 6 months after enrollment, as this aligns with the usual clinical follow-up timeline for orthopaedic injuries. Table 1 below indicates the timeline for baseline and follow-up completion of CRFs. Follow-up may be completed in-person at the fracture clinic, by telephone, by mail, or via secure electronic methods. Research personnel may also review the participant's medical records for emergency room and urgent care visits.

The social worker at each clinic will document the social work interactions by maintaining a log that documents each point of contact they have with each participant. This log will include the

medium of contact, themes discussed, and number of referrals made. At each trial follow-up visit, we will ask participants if they saw a social worker outside of the fracture clinic and document any care referrals that they received.

Table 1: Follow-up Schedule

	Enrollment and Baseline	6 Weeks (Day 42) (22 to 62 days post-enrollment)	3 Months (Day 90) (63 to 117 days post-enrollment)	6 Months (Day 180) (118 to 242 days post-enrollment)
Demographics and comorbidities	X			
Injury and treatment details	X			
Social worker interactions and referrals	Ongoing			
Emergency room and urgent care visits		X	X	X
LIMB-Q Psychological Impacts Scale	X	X	X	X
LIMB-Q Financial Impacts Scale	X	X	X	X
Satisfaction with care question	X	X	X	X
Opioid use	X	X	X	X
Fracture clinic visit attendance	X	X	X	X
EQ-5D questionnaire	X	X	X	X
Hospital use questions	X	X	X	X

4.9 Blinding

Due to the nature of the intervention, it will not be possible to blind participants, trial personnel, or clinicians to treatment allocation. Data analysts and investigators responsible for interpreting results will be blinded to treatment allocation until all data have been analyzed and interpreted.

5.0 SAMPLE SIZE

We chose our sample size to detect differences between the social worker intervention and usual care groups for all-cause visits to emergency room or urgent care centers (primary outcome). We estimated our sample size in accordance with the methodology of Kasza et al. using the R swdpwr package.[17,18] For a binary outcome, the required cluster period size in a batched stepped wedge cluster randomized trial for a desired level of power depends on the number of time periods, number of clusters assigned to each sequence, number of sequences, number of batches, number of periods of overlap between successive batches, effect size, and ICC parameters. We will assume

80% study power with a two-sided Type I error rate of 5%, either two, three, or four batches of four sequences over five time periods, one cluster allocated to each sequence, no period overlaps, a 10% prevalence rate in the treatment group, a 14.8% prevalence rate in the control group[19], and a within-period intra-cluster correlation coefficient of 0.05. Based on these assumptions, we will require a total sample size of 1880 patients (cluster size of 47 patients per period) for two batches, 1800 patients (cluster size of 30 patients per period) for three batches, and 1760 patients (cluster size of 22 patients per period) for four batches. (**Table 2**). To account for a 10% loss to follow-up rate, the total sample size, regardless of the batch size, will be rounded to 2000.

Table 2: Sample Size Calculations

		Prevalence of Outcome in Treatment Group		
		8%	**10%**	**12%**
		Two Batches		
Intracluster Correlation Coefficient (ICC)	**0.005**	760	1680	5560
	0.01	800	1760	5680
	0.05	880	1880	5840
	0.1	920	1920	5880
		Three Batches		
	0.005	720	1620	5400
	0.01	780	1680	5580
	0.05	840	1800	5700
	0.1	900	1860	5760
		Four Batches		
	0.005	720	1600	5360
	0.01	720	1680	5520
	0.05	800	1760	5680
	0.1	880	1760	5520

Note: *α = 0.05, power = 80%, sampling structure = cross-sectional sample, sequences = 4, periods=5, number of periods of overlap between successive batches = 0, prevalence of outcome in control group = 14.8%*

6.0 DATA ANALYSIS

We will prepare a detailed statistical analysis plan (SAP) prior to completion of the trial which will provide a detailed description of all planned statistical analyses. Sections 6.1 to 6.5 provide a brief overview of the planned statistical approach.

6.1 Outcomes Analysis

The primary and secondary analyses will be conducted following intention-to-treat (ITT) principles, ensuring that participants are analyzed in their originally assigned treatment groups, regardless of adherence or protocol deviations. Reporting of the trial results will follow the 2010 CONSORT statement and the extension statements for a batched, stepped-wedge cluster randomized trial.[20]

For the primary analysis of time to any all-cause return visits to emergency room or urgent care centers, we will perform a Cox proportional hazards regression model, with treatment included as the independent variable, and cluster pre-specified variables prognostic of the outcome, such as pre-injury work status, included as covariates. Results will be presented as a hazard ratio and corresponding 95% confidence interval (CI) (**Table 3**).

Table 3: Primary Analysis Overview

Objective	Outcome		Hypothesis	Method of Analysis
	Name	Type		
To determine if a dedicated social worker within the fracture clinic setting reduces all-cause return visits to emergency room or urgent care centers over 6 months	Any all-cause visits to the emergency room or urgent care centers	Binary	Participants receiving social work support will have fewer return visits to emergency room and urgent care centers in the 6 months following enrollment.	Cox proportional hazards regression model

For secondary analyses, we will follow mixed effects linear regression modelling for the LIMB-Q and satisfaction with care to account for repeated measures, with treatment, time of assessment, and pre-specified variables prognostic of each outcome included as independent variables in fixed effects. Each model will also include a cluster indicator as the random intercept. These secondary outcomes will be summarized as adjusted mean differences between groups with corresponding 95% CIs.

We will use logistic regression modeling for self-reported opioid use at 3 and 6 months using. Self-reported opioid use will be included as the dependent variable and each model will include the treatment variable, cluster, and pre-specified variables prognostic of the outcome as independent variables. We will present results as adjusted odds ratios with corresponding 95% CIs.

We will conduct a cost-effectiveness analysis from the payer's (hospital) perspective incorporating both participant utilities and direct healthcare costs and intervention costs. We will obtain health utilities from the EQ-5D. Costs will include the cost of employing a social worker, as well as healthcare use costs, such as fracture clinic visits, emergency room visits, urgent care facilities, and hospitalizations. We will compare these costs between the social worker intervention versus usual care groups using a cost-effectiveness analysis framework. The SAP will provide additional details on economic analysis plans.

We will also descriptively report the interactions made between the social worker and participants regarding the medium of contact, themes discussed, and the number and types of referrals made.

Table 4: Secondary Analyses Overview

Objective	Outcome		Hypothesis	Method of Analysis
	Name	Type		
To determine if a dedicated social worker within the fracture clinic setting reduces negative psychological impact over 6 months	LIMB-Q Psychological scale	Continuous	Participants receiving social work support will have higher LIMB-Q Psychological scores over 6 months compared to participants receiving usual care.	Mixed effects linear regression
To determine if a dedicated social worker within the fracture clinic setting reduces negative financial impact over 6 months	LIMB-Q Financial Impacts scale	Continuous	Participants receiving social work support will have higher LIMB-Q Financial Impacts scores over 6 months compared to participants receiving usual care.	Mixed effects linear regression
To determine if a dedicated social worker within the fracture clinic setting increases patient satisfaction with care over 6 months	Satisfaction with care	Continuous	Participants receiving social work support will have higher level of satisfaction with their care compared to participants receiving usual care.	Mixed effects linear regression
To determine if a dedicated social worker within the fracture clinic setting reduces self-reported opioid use at 3 and 6 months	Opioid use at 3 months and 6 months	Binary	Participants receiving social work support will have lower opioid use at 3 and 6 months compared to participants receiving usual care.	Logistic regression
To determine if a dedicated social worker within the fracture clinic setting reduces the number of missed fracture clinic visits over 6 months	Missed clinic visits	Continuous	Participants receiving social work support will have fewer missed visits over 6 months compared to participants receiving usual care.	Negative binomial model
To determine the cost-effectiveness of having a dedicated social worker within the fracture clinic setting over 6 months	Cost-effectiveness analysis from a payer's perspective	Continuous	Social work support will result in higher utilities and lower cost compared to the usual care group over 6 months	Economic analysis

6.2 Sensitivity Analyses

We will conduct a sensitivity analysis to include only those participants who had at least one visit with a social worker. This analysis will follow the same analyses methods as described for the

primary outcome, including appropriate regression models and adjustments for stratification variables.

We will conduct a sensitivity analysis that varies definition of return to emergency room and urgent care centre to include only visits that occurred at the same hospital/health system where the participant is receiving care for their fracture (e.g. participating cluster location). This analysis will follow the same methods listed for the primary outcome, including appropriate regression models and adjustments for stratification variables.

We will conduct a third sensitivity analysis that will also vary the definition of return to the emergency room and urgent care centre to include all visits. We will follow mixed effects linear regression modeling to account for repeated measures, with treatment, time of assessment, and pre-specified variables prognostic of each outcome included as independent variables in fixed effects. The model will also include a cluster indicator as the random intercept. The outcome will be summarized as an adjusted mean difference between groups with corresponding 95% CIs.

6.3 Subgroup Analyses

We plan to conduct subgroup analyses on gender and sex as potential factors influencing the effectiveness of the social worker intervention. Extensive literature spanning the past two decades suggests that patients tend to respond differently to offers of assistance and may perceive the experience of being helped differently depending on their gender identity. Unfortunately, definitions of sex and gender in older research are often used interchangeably. We hypothesize that individuals identifying as women and those assigned female at birth may demonstrate a heightened receptiveness to assistance and engagement through social worker services. Using the currently accepted definitions, we will evaluate subgroups of female vs. male and women vs. men. Non-binary gender identities will be included in the baseline survey and will be analyzed separately where numbers permit. Additionally, we plan to conduct subgroup analyses based on injury severity, pre-injury work status and opioid use at enrollment (**Table 5**). These analyses will be approached and reported in accordance with best practices and guidelines for subgroup analyses.[21–25] For positive subgroup effects, we will use the criteria suggested by Schandelmaier et al. to guide inferences about the credibility of our subgroup analyses.[25]

Table 5: Subgroup Analyses Overview

Objective	Outcome		Hypothesis	Method of Analysis
	Name	Type		
Females versus males	Return to ER/Urgent Care Centre	Binary	Female participants receiving social work support will have fewer return visits to ER/urgent care centres over 6 months compared to male participants.	Cox proportional hazards regression model

Objective	Outcome		Hypothesis	Method of Analysis
	Name	Type		
Women versus men	Return to ER/Urgent Care Centre	Binary	Women receiving social work support will have fewer return visits to ER/urgent care centres over 6 months compared to men.	Cox proportional hazards regression model
Injury severity score (<9 versus ≥9)	Return to ER/Urgent Care Centre	Binary	Participants with a lower injury severity score (<9) receiving social work support will have fewer return visits to ER/urgent care centres 6 months compared to participants with a higher injury severity score (≥9).	Cox proportional hazards regression model
Employed pre-injury versus unemployed pre-injury	Return to ER/Urgent Care Centre	Binary	Employed participants receiving social work support will have fewer return visits to ER/urgent care centres over 6 months compared to unemployed participants.	Cox proportional hazards regression model
Opioid use at baseline versus no opioid use	Return to ER/Urgent Care Centre	Binary	Participants not using opioids at baseline receiving social work support will have fewer return visits to ER/urgent care centres over 6 months compared to participants using opioids at baseline.	Cox proportional hazards regression model

6.4 Qualitative Analysis

After the interviews have been conducted and transcribed, three Methods Centre personnel will independently review the text of each interview several times, in a process of inductive coding. Each reviewer will use these statements to identify larger subthemes individually, without consulting each other. They will then compare subthemes and work together to create overall themes that describe the experience of recovery from orthopaedic trauma. Researchers, including the interviewer, will, at some point during the research process, complete a written summary of their own experiences and context and situations that have influenced their experiences with respect to this research, making sure to cover all information required by the CORE-Q checklist. Researchers will engage in member-checking as part of the coding process, which will include sending themes and codes to participants to validate these findings. A separate SAP will fully describe the analysis plans for the qualitative components.

6.5 Interim Analysis Plan

Analyses will be conducted at the completion of the trial. There will be no planned interim efficacy or safety analyses.

7.0 DATA MANAGEMENT

7.1 Case Report Forms and Data Transmission

The Methods Centre will provide the research personnel at each institution with the trial case report forms (CRFs) prior to initiation of enrollment. Research personnel will submit the required data, as detailed on the CRFs, to the Methods Centre using the REDCap Cloud electronic data capture system. Research personnel will receive a unique login and password for the REDCap Cloud system and will be able to view and modify data for participants at their cluster(s).[46]

7.2 Interview Management

Interview data will be transcribed, and original interview recordings will be stored per the records retention procedures outlined in section 7.4. Transcriptions will be de-identified and labelled with participant number, then uploaded into Dedoose software (or a similar program) in a password protected project. Only those identified as performing the qualitative analysis of the data will have access to the project area. Some quantitative information will be included in the database such as age, gender, and treatment group, or in the case of health care professionals, position at the clinic.

7.3 Data Integrity

The Methods Centre data manager will program the EDC with multiple mechanisms for checking data at the time of entry including skip logic, range checks, and data type checks.[26] Upon receipt of new data, Methods Centre personnel will query all missing, implausible, or inconsistent data. Research personnel will be able to review open queries in the system and will be required to respond promptly.

7.4 Trial Monitoring

Methods Centre personnel will develop and implement a monitoring plan to guide trial monitoring activities. The purpose of monitoring will be to verify that: 1) The rights and wellbeing of research participants are protected. 2) The reported data are accurate, complete, and verifiable from source documents. 3) The trial is conducted according to the currently approved protocol and International Council for Harmonization Good Clinical Practice (ICH GCP)[11].

7.5 Records Retention

The Methods Centre will retain trial data and essential documents for 15 years after completion of the trial, in accordance with institutional requirements. Participating clusters will retain records and documents pertaining to the conduct of this trial, including eCRFs, informed consent forms, and source documents for the length of time required by local institutional policy. After the records retention period, the documents may be destroyed, in accordance with local policies.

8.0 ETHICS AND DISSEMINATION

8.1 Research Ethics Approval

The McMaster University Methods Centre and all participating institutions will obtain ethics approval prior to commencing participant enrollment. The Methods Centre will ensure they have received a copy of the relevant ethics approval prior to each cluster's commencement.

8.2 Confidentiality

All trial personnel will treat information about trial participants as confidential and will manage it in accordance with the below:

- All trial-related information will be stored securely.
- All information containing participant identifiers will be stored in locked file cabinets and accessible only to trial personnel.
- All electronic CRFs will contain only a coded participant number.
- All databases will be password-protected.

If a participant revokes authorization to collect or use personal health information, the Methods Centre retains the ability to use all information collected prior to the revocation of participant authorization.

8.3 Protocol Amendments

Any amendments to the protocol which may affect the conduct of the trial or the potential safety of or benefits to participants (e.g., changes to the trial objectives, design, sample size, or procedures) will require a formal amendment to the protocol. Any protocol amendments will be approved by the Principal Investigators and will require approval by all applicable ethics committees. Participating clusters will also be required to submit amendment requests to their local ethics committee to obtain approval for the amendment and to provide the Methods Centre with a copy of this approval.

8.4 Dissemination Policy

The results of this trial will be submitted for publication, regardless of the significance of the findings. Every attempt will be made to ensure that the amount of time between completion of data collection and release of study findings is minimized. We will also share the results of the trial with the participants who wish to learn the results.

9.0 SAFETY

9.1 Risks to Participants

As this trial provides support and services in addition to usual care, we do not anticipate any significant safety risks to participants. For patients receiving the social work intervention, discussing and addressing issues with a social worker may bring up challenging emotions, potentially leading to a transient increase in distress. For example, helping a participant to better

understand their injuries and the recovery process could initially create heightened anxiety as they cope with upsetting information regarding their prognosis. To mitigate this risk, the social worker will perform standard safety and emotional wellness assessments as part of their interaction with the patient. These assessments will provide an opportunity for early assistance with any increased anxieties that the participant may be experiencing. Participants in the usual care arm will receive care according to current practices at each participating cluster, including accessing any social work services currently available locally. Consequently, they will not experience any increased risk due to their participation in the trial.

9.2 Safety Monitoring

This trial will not require a Data Safety and Monitoring Committee (DSMC) as the intervention is low risk to trial participants, and major morbidity, mortality, or other severe outcomes are not expected or evaluated. This decision aligns with the Food and Drug Administration guidelines for involving a DSMC in an RCT[27].

10.0 REFERENCES

1. Injuries in Canada: Insights from the Canadian Community Health Survey. Accessed February 2, 2024. https://www150.statcan.gc.ca/n1/pub/82-624-x/2011001/article/11506-eng.htm
2. Bhandari M, Busse JW, Hanson BP, Leece P, Ayeni OR, Schemitsch EH. Psychological distress and quality of life after orthopedic trauma: an observational study. *Can J Surg*. 2008;51(1):15-22.
3. Muscatelli S, Spurr H, O'Hara NN, O'Hara LM, Sprague SA, Slobogean GP. Prevalence of Depression and Posttraumatic Stress Disorder After Acute Orthopaedic Trauma: A Systematic Review and Meta-Analysis. *J Orthop Trauma*. 2017;31(1):47-55. doi:10.1097/BOT.0000000000000664
4. Stinner DJ, Mir HR. Patient Mental Health and Well-being: Its Impact on Orthopaedic Trauma Outcomes. *J Orthop Trauma*. 2022;36:S16. doi:10.1097/BOT.0000000000002450
5. Taylor P, Morin R, Kochhar R, et al. *The Impact of Long-Term Unemployment: Lost Income, Lost Friends - and Loss of Self-Respect*. Pew Research Centre; 2010:1-20.
6. O'Hara NN, Slobogean GP, Stockton DJ, Stewart CC, Klazinga NS. The socioeconomic impact of a femoral neck fracture on patients aged 18-50: A population-based study. *Injury*. 2019;50(7):1353-1357. doi:10.1016/j.injury.2019.05.029
7. Howard R, Brown CS, Lai YL, et al. Postoperative Opioid Prescribing and New Persistent Opioid Use: The Risk of Excessive Prescribing. *Ann Surg*. 2023;277(6):e1225. doi:10.1097/SLA.0000000000005392
8. Rahman R, Wallam S, Zhang B, et al. Appropriate Opioid Use After Spine Surgery: Psychobehavioral Barriers and Patient Knowledge. *World Neurosurg*. 2021;150(Complete):e600-e612. doi:10.1016/j.wneu.2021.03.066
9. Government of Canada SC. Food insecurity among Canadian families. November 14, 2023. Accessed February 28, 2024. https://www150.statcan.gc.ca/n1/pub/75-006-x/2023001/article/00013-eng.htm
10. Sprague S, Fleming N, Gonsalves M, et al. Patient perspectives on the desirability of social worker support in outpatient orthopaedic trauma clinics. *OTA Int*. 2025;8(1):e375. doi:10.1097/OI9.0000000000000375
11. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). Published online 2016.
12. Mundy LR, Klassen AF, Pusic AL, et al. The LIMB-Q: Reliability and Validity of a Novel Patient-Reported Outcome Measure for Lower Extremity Trauma Patients. *Plast Reconstr Surg*. Published online January 15, 2024. doi:10.1097/PRS.0000000000011293
13. Mundy LR, Klassen A, Grier J, et al. Development of a Patient-Reported Outcome Instrument for Patients With Severe Lower Extremity Trauma (LIMB-Q): Protocol for a Multiphase Mixed Methods Study. *JMIR Res Protoc*. 2019;8(10):e14397. doi:10.2196/14397
14. Hung MC, Lu WS, Chen SS, Hou WH, Hsieh CL, Wang JD. Validation of the EQ-5D in Patients with Traumatic Limb Injury. *J Occup Rehabil*. 2015;25(2):387-393. doi:10.1007/s10926-014-9547-0
15. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care*. 2007;19(6):349-357. doi:10.1093/intqhc/mzm042
16. Sandelowski M. Whatever happened to qualitative description? *Res Nurs Health*. 2000;23(4):334-340. doi:10.1002/1098-240X(200008)23:4<334::AID-NUR9>3.0.CO;2-G

17. Kasza J, Bowden R, Hooper R, Forbes AB. The batched stepped wedge design: A design robust to delays in cluster recruitment. *Stat Med*. 2022;41(18):3627-3641.
18. Chen J, Zhou X, Li F, Spiegelman. D. swdpwr: Power Calculation for Stepped Wedge Cluster Randomized Trials. Published online October 26, 2020:1.11. Accessed March 7, 2025. https://CRAN.R-project.org/package=swdpwr
19. Valan B, Therien A, Peairs E, et al. Predicting 90-day return to the emergency department in orthopaedic trauma patients in the Southeastern USA: a machine-learning approach. *Inj Prev*. Published online January 21, 2025. doi:10.1136/ip-2024-045358
20. Hemming K, Taljaard M, McKenzie JE, et al. Reporting of stepped wedge cluster randomised trials: extension of the CONSORT 2010 statement with explanation and elaboration. *BMJ*. 2018;363:k1614.
21. Wang R, Lagakos SW, Ware JH, Hunter DJ, Drazen JM. Statistics in Medicine — Reporting of Subgroup Analyses in Clinical Trials. *N Engl J Med*. 2007;357(21):2189-2194. doi:10.1056/NEJMsr077003
22. Sun X, Ioannidis JPA, Agoritsas T, Alba AC, Guyatt G. How to use a subgroup analysis: users' guide to the medical literature. *JAMA*. 2014;311(4):405-411. doi:10.1001/jama.2013.285063
23. Sun X, Briel M, Walter SD, Guyatt GH. Is a subgroup effect believable? Updating criteria to evaluate the credibility of subgroup analyses. *BMJ*. 2010;340:c117. doi:10.1136/bmj.c117
24. Sun X, Briel M, Busse JW, et al. Subgroup Analysis of Trials Is Rarely Easy (SATIRE): a study protocol for a systematic review to characterize the analysis, reporting, and claim of subgroup effects in randomized trials. *Trials*. 2009;10:101. doi:10.1186/1745-6215-10-101
25. Schandelmaier S, Briel M, Varadhan R, et al. Development of the Instrument to assess the Credibility of Effect Modification Analyses (ICEMAN) in randomized controlled trials and meta-analyses. *Can Med Assoc J*. 2020;192(32):E901-E906. doi:10.1503/cmaj.200077
26. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform*. 2019;95:103208. doi:10.1016/j.jbi.2019.103208
27. Food and Drug Administration (FDA). *Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees.*; 2006. https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127073.pdf