

Protocol for the Development of a Core Outcome Set and Core Outcome Measurement Set for Studies Evaluating Interventions to Minimize Physical Restraint Use in Adult Intensive Care Units

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Abstract

Background: Heterogeneity in outcome selection and measurement methods has been noted in previous studies examining physical restraint minimization in adult intensive care units (ICUs). This variability undermines meaningful evidence synthesis, including systematic reviews and meta-analyses, thereby limiting the development of evidence-based clinical approaches in minimizing physical restraint use and improve patient outcomes.

Objective: This protocol outlines the methods for developing an international consensus on priority core outcomes, along with standardized measurement approaches for these outcomes in studies focused on minimizing physical restraint use in adult ICUs.

Methods: We will follow the guidelines outlined in the Core Outcome Measures in Effectiveness Trials Handbook. At the outset, representatives from key stakeholder groups—including former ICU survivors/ family members, ICU clinicians, and researchers—are involved in designing this protocol to enhance its relevance and applicability. Drawing on our previous work, including a scoping review of studies on physical restraint minimization that we will update, and interviews with family members about restraint use and minimization in the ICU, we will compile a comprehensive list of potential outcomes for stakeholders to use in the two-round Delphi process. In the first round, stakeholders will rank the identified outcomes using the Grading of Recommendations Assessment, Development and Evaluations (GRADE) scale. In the second round, they will be provided with a summary of the results from Round 1 for rescoring and further refinement. A series of consensus meetings using the modified nominal group technique will be held with representatives from our stakeholder groups to finalize the core outcome set, followed by another meeting to establish standardized measurement methods for the agreed-upon outcomes.

Results: We are in the process of finalizing the REB application for this protocol, which will be submitted shortly. The anticipated project start date is June/July 2025, with completion expected by October 2026.

Conclusions: This study will be the first to establish both a core outcome set, and a core measurement set for minimizing physical restraint use in adult ICUs. By standardizing outcomes and measurement methods, it will enhance comparability across future research and contribute to improved patient care in ICUs Clinical Trial: This protocol is registered in the Core Outcome Measurement in Effectiveness Trials (COMET) Initiative database registration: <https://cometinitiative.org/Studies/Details/3368>

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Original Manuscript

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Protocol for the Development of a Core Outcome Set and Core Outcome Measurement Set for Studies Evaluating Interventions to Minimize Physical Restraint Use in Adult Intensive Care Units

Abstract:

Introduction: Heterogeneity in outcome selection and measurement methods has been noted in previous studies examining physical restraint minimization in adult intensive care units (ICUs). This variability undermines meaningful evidence synthesis, including systematic reviews and meta-analyses, thereby limiting the development of evidence-based clinical approaches in minimizing physical restraint use and improve patient outcomes. This protocol outlines the methods for developing an international consensus on priority core outcomes, along with standardized measurement approaches for these outcomes in studies focused on minimizing physical restraint use in adult ICUs.

Methods and analysis: We will follow the guidelines outlined in the Core Outcome Measures in Effectiveness Trials Handbook. At the outset, representatives from key stakeholder groups—including former ICU survivors/ family members, ICU clinicians, and researchers—are involved in designing this protocol to enhance its relevance and applicability. Drawing on our previous work, including a scoping review of studies on physical restraint minimization that we will update, and interviews with family members about restraint use and minimization in the ICU, we will compile a comprehensive list of potential outcomes for stakeholders to use in the two-round Delphi process. In the first round, stakeholders will rank the identified outcomes using the Grading of Recommendations Assessment, Development and Evaluations (GRADE) scale. In the second round, they will be provided with a summary of the results from Round 1 for rescoring and further refinement. A series of consensus meetings using the modified nominal group technique will be held with representatives from our stakeholder groups to finalize the core outcome set, followed by another meeting to establish standardized measurement methods for the agreed-upon outcomes.

Discussion: This study will be the first to establish both a core outcome set, and a core measurement set for minimizing physical restraint use in adult ICUs. By standardizing outcomes and measurement methods, it will enhance comparability across future research and contribute to improved patient care in ICUs

Protocol registration: This protocol is registered in the Core Outcome Measurement in Effectiveness Trials (COMET) Initiative database registration: <https://cometinitiative.org/Studies/Details/3368>

Key words: Core outcome set, core measurement set, Delphi process, physical restraint minimization, ICU

Abstract: 332 (Maximum 350)

1. Introduction

Physical restraints are frequently used in intensive care units (ICUs) to prevent agitated patients from interfering with life-saving devices, such as endotracheal tubes (1, 2). However, emerging evidence indicates that restraints may not prevent device removal in critically ill patients, and could lead to a range of adverse psychological consequences for patients (3). These include an increased risk of developing or worsening preexisting delirium or agitation, and long-term effects such as a higher risk of post-traumatic stress disorder following ICU discharge (4, 5). The adverse impact of physical restraints extends beyond the patients themselves; family members frequently report feelings of helplessness and profound emotional responses, such as sadness and anxiety (6, 7). ICU clinicians also experience emotional uncertainty and moral conflict when making decisions about restraint use, as they navigate the complex balance between perceived risks and benefits (8, 9). Considering these adverse outcomes and the limited evidence supporting the effectiveness of physical restraints in preventing device removal, many international guidelines recommend minimizing their use in the ICU, and applying restraints only as a last resort after exhausting all potential alternatives (10-12).

With the growing recognition of the importance of restraint minimization in adult ICUs, studies evaluating interventions to reduce physical restraint use continue to proliferate. A critical gap in the current body of evidence on restraint use and minimization is the absence of a systematic approach to selecting, measuring, and reporting outcomes (13). This lack of standardization leads to substantial variability in the outcomes reported and the associated measures used, hindering meaningful evidence synthesis through systematic reviews and meta-analyses (14). Consequently, it becomes challenging to draw generalizable conclusions and accurately assess the true effect of interventions, ultimately impeding the development of evidence-based best practices (15). This limitation also complicates clinicians' and policymakers' efforts to make informed decisions regarding restraint practices (16). Furthermore, outcome selection in the existing literature on restraint use and minimization is often driven by researchers' perspectives, potentially overlooking outcomes that hold greater significance for patients and their families (13, 17).

To address these gaps in variability of outcome selection and measurement, the development of a core outcome set (COS) and core outcome measurement set (COMS) is crucial. A COS is a standardized list of outcomes that are reached through consensus as essential to report across all trials within a specific health condition or intervention area (18). A COMS is a set of standardized and agreed-upon measurement tools for assessing the outcomes identified in the COS (19). By promoting consistency in outcome selection and measurement, a COS and COMS enables meaningful comparisons across studies and enhances the capacity to aggregate data for meta-analysis (20). Additionally, by including a broader range of outcomes that reflect the perspectives of patients, families, and clinicians, a COS helps bridge the divide between clinical outcomes and patient-centered factors, ultimately improving the quality and relevance of research in restraint minimization (21, 22). This protocol outlines the methods we will use to establish an international consensus on the core outcomes to be prioritized and reported, as well as the standardized methods for measuring these outcomes in studies aimed at minimizing physical restraint use in adult ICUs.

2. Scope

2.1 Health Condition and Target Population

The focus of this COS and COMS are on adult patients who are subjected to physical

restraint use during their ICU stay. Additionally, this COS focuses on individuals at risk of restraint use, specifically those with an endotracheal tube. This population includes patients with various medical conditions for whom physical restraints may be used to promote safety or prevent device removal.

2.2 Intervention

This COS and COMS include any non-pharmacological intervention aimed at minimizing physical restraint use in adult ICU patients.

2.3 Context of Use

This COS and COMS are intended for use in adult ICUs across diverse healthcare settings, including academic medical centers and community hospitals. While the COS and COMS to be developed are intended for use in research, they can also be applied in clinical audits and quality improvement initiatives aimed at evaluating interventions to minimize physical restraint use in adult ICUs. The COS and COMS are applicable regardless of regional practices or institutional protocols, promoting consistency and comparability in outcome reporting.

3. Methods

We have developed this protocol in alignment with the Core Outcome Set-STANDARDISED Protocol (COS-STAP) statement (Appendix 1) and have adhered to the guidelines outlined in the Core Outcome Measures in Effectiveness Trials (COMET) Handbook (Version 1) (15, 23). This protocol has been registered in the COMET database: <https://cometinitiative.org/Studies/Details/3368>

3.1 Stakeholders

We will seek a purposive and maximum variation sample from three key stakeholder groups: ICU survivors and their family members, researchers, and clinicians, drawn from an international population (24, 25). ICU survivors and family members will be included as they may have perspectives on relevant outcomes that differ from clinicians and researchers. Clinicians and researchers will be recruited for their expertise, ensuring that the identified outcomes are clinically meaningful, measurable, and aligned with existing evidence and best practices. Appendix 2 outlines the key sampling characteristics for stakeholders. We will ensure that our participants represent a diverse mix of these characteristics to allow for maximum variation

3.1.1 Recruitment Methods

To recruit ICU survivors and family members, we will employ a multimethod strategy that includes the use of a dedicated study X (previously Twitter) account, engagement with relevant patient and family support and advocacy groups (e.g., The Canadian Critical Care Trials Group Patient & Family Partners Community), outreach through personal contacts, and snowball sampling. Participants will be included if they self-identify (or have a family member) as having experienced physical restraint in an ICU setting. Additionally, they must be able to read and speak English.

Researchers will include individuals who have published at least one clinical study related to any area of adult critical care. Clinicians will encompass physicians, registered nurses, respiratory therapists, and allied healthcare professionals (e.g., physical therapists) with varying levels of experience in adult ICUs. All participants must be able to read and speak English. Recruitment of both researchers and clinicians will be conducted through personal

contacts and snowball sampling. Additionally, for the researchers' group, recruitment emails will be sent to corresponding authors of studies included in our scoping review (described below, Section 3.4.1.1).

3.2 Study Steering Committee Composition

Our Steering Committee will include three experts with clinical and/or research expertise in physical restraint use in the ICU, along with a patient/family representative. As the study progresses, we will expand our Steering Committee to include representatives from key stakeholders across all participating countries. To guide and optimize our engagement with survivors and families throughout the development and execution of the COS study, we will utilize the COMET Checklist for Public Research Partners and the COS Study Developers Involved in Designing a COS Study (26).

3.3 Sample Size

There are no strict guidelines for determining the sample size in a COS consensus process, as it is influenced by practical considerations and the scope of the COS (15). However, it is emphasized that broad representation across all key stakeholder groups is crucial. To ensure comprehensive and inclusive input, we will aim to recruit a minimum of 60–80 participants, with 20–30 participants per individual stakeholder group (27), selected deliberately to represent all the characteristics outlined in Appendix 2.

3.4 Establishing an Outcome List and the Consensus Process for Core Outcome Set

3.4.1 Information Sources

3.4.1.1 Outcome List Generation

We will use the following data sources to generate a list of potential outcomes:

1. **Scoping Review:** We will utilize our previously conducted scoping review of studies on interventions to minimize physical restraints in adult ICUs to generate a list of outcomes reported in the included studies (13). The scoping review followed established methodology, with a search strategy developed iteratively and informed by an experienced information specialist. Seven databases, along with grey literature, were searched from inception to 2019. Two researchers independently screened and extracted data on study characteristics, outcomes, and outcome measurement instruments/definitions. Studies included were those where the primary goal was to minimize physical restraint in adult ICUs. Studies published in languages other than English were excluded. We will update our search strategy and execute a search to capture both published studies and ongoing trials from 2019 to 2025, using the same databases and grey literature sources. A table of outcomes, their definitions, and corresponding measurement tools will be created using studies included from the updated search, along with those already included in the previously conducted scoping review. We will calculate the proportion of studies reporting each outcome and rank them by frequency. Measurement tools will be evaluated for their psychometric properties using the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) checklist (28).
2. **Family Member Interviews:** We will review the transcripts from our previously conducted interviews with family members regarding their perspectives on physical restraint practices and minimization in adult ICUs (6). This was a qualitative descriptive study that involved one-on-one semi-structured interviews with 15 family

members in a medical-surgical trauma ICU in Toronto. The study inclusion criteria were as follows: 1) self-identification as a family member aged 18 or older who has observed the use of physical restraint on their loved one for at least six hours in the ICU; 2) having visited the patient in the ICU during the period when they were physically restrained; and 3) the ability to speak English. The Theoretical Domains Framework was used to guide both data collection and analysis, employing a deductive content analysis approach. Three themes emerged: (i) barriers and facilitators to restraint minimization; (ii) unilateral decision-making regarding physical restraint use, where clinicians made decisions without adequate communication with families or obtaining consent; and (iii) the emotional impact of physical restraint use, with families experiencing sadness and shock, and believing that patients would have similar emotional responses. We will thoroughly review the interview transcripts and create a comprehensive list of outcomes reported by family members.

3.4.1.2 Outcome List Reduction

Two researchers from the research team will independently review the outcomes list derived from the family interviews and merge it with the outcome list obtained from the scoping review, consolidating similar outcomes and eliminating redundancies. The two researchers will then independently group outcomes with similar definitions under the same outcome name. For example, "Duration of physical restraint use (hours)" and "Average number of hours per day a patient is restrained" will both be grouped under the outcome name "Duration of Restraint Use". The outcomes will then be classified into broader outcome domains in accordance with the COMET taxonomy (29). For instance, "Duration of Restraint Use" and "Type of Restraint Used" will be grouped under the "Clinical Outcomes" domain within the COMET taxonomy. Outcomes that do not duplicate those identified in the scoping review will be categorized according to the COMET taxonomy and marked as being identified exclusively by patients and family members. Any disagreements in the process of outcome reduction and categorization will be resolved through discussion, or if necessary, by consulting a third researcher serving as an independent arbiter. To mitigate the risk of a high number of outcomes reducing COS Delphi response rates, the two researchers will further refine the list by removing outcomes identified in fewer than 5% of studies, unless specifically highlighted in the family member interview transcripts (30, 31).

The final outcome list will undergo a thorough review by the steering committee to ensure accurate categorization of outcomes, clarity, and the use of simple language that can be easily understood by all stakeholder groups. Before the Delphi process begins, the Delphi survey will undergo pilot testing with at least four researchers/clinicians external to the core research team and four patient/family members to assess face validity and ensure the wording is clear and easily understood.

3.4.2 Consensus Process for Core Outcome Set

The consensus process will include two web-based modified Delphi rounds followed by a modified nominal group meeting.

3.4.2.1 Delphi Round (1)

The Delphi survey will be administered using the Delphi Manager software, version 5.0 (COMET Initiative, Liverpool, UK). The first part of the survey will collect baseline data to characterize the stakeholder sample and assign each participant a unique identifier. This identifier will allow for personalized follow-ups and reminders in subsequent rounds. Participants will be asked to self-select their stakeholder group (e.g., ICU survivors/family members, clinicians, and/or researchers).

The second part will present the list of outcomes described in lay terms, with any medical terms provided in parentheses, for participants to rate based on importance, without consideration of measurability or feasibility. The importance of each outcome will be rated using the Grading of Recommendations Assessment, Development and Evaluations (GRADE) approach on a 1–9 Likert scale: 1–3: Not important for inclusion, 4–6: Important but not critical, 7–9: Critical for inclusion (32). The GRADE scale has been selected as it is recommended by COMET to facilitate maximum discrimination between survey items (15, 33). To reduce incomplete responses, the survey will include an "unable to score" option. Participants will also have the opportunity to provide free-text comments and suggest additional outcomes. To minimize presentation bias, the order of outcome domains will be randomized within Delphi Manager. Participants will have three weeks to complete the survey, with two reminder emails sent: one at the start of the second week and another at the beginning of the third week.

3.4.2.1.1 Round (1) Analysis

For each outcome, we will calculate the proportion of participants rating it as 7–9 (Critical for inclusion), 4–6 (Important but not critical), and 1–3 (Not important for inclusion) for the entire stakeholder panel and each stakeholder group separately.

If new outcomes emerge in Round 1, the steering committee will carefully review them to ensure they represent distinct concepts, are clearly articulated, and are free from duplication before being included in Round 2. If needed, a third Delphi round may be conducted specifically for these new outcomes, allowing for two rounds of scoring for each outcome before the final consensus meeting.

3.4.2.2 Delphi Round (2)

Participants who complete Round 1 will be invited to take part in Round 2. All outcomes from Round 1 will be carried forward to Round 2. Any newly identified outcomes from Round 1 will also be introduced in Round 2 for scoring on the 1–9 GRADE Likert scale. Participants will receive a summary of responses from Round 1, including aggregated feedback from all stakeholder groups, a summary of responses for each stakeholder group, and their own individual responses. Participants will be asked to re-score each outcome using the GRADE scale. If a participant adjusts their rating, moving it into a new category (e.g., from "important but not critical" to "critical for inclusion"), they will be prompted to provide a free-text rationale for the change. The same three-week response window and two email reminders at the beginning of weeks 2 and 3 will be sent to all participants.

3.4.2.2.1 Round (2) Analysis

For Round 2, we will calculate the proportion of participants rating each outcome as "critical for inclusion." This will be analyzed both overall and by stakeholder group. As recommended by the COMET initiative, outcomes will only be brought forward to the consensus meeting if they meet the following criteria: they must be rated as "critical for inclusion" by at least 70% of respondents and as "not important" by fewer than 15%, considering the entire panel of participants as well as each key stakeholder group separately (15).

3.4.2.2.2 Attrition Bias Between Rounds

Attrition bias may arise if a subset of participants drops out or fails to respond between rounds, resulting in a non-representative final group (15). This could lead to the underestimation or overestimation of certain outcomes' importance. To mitigate this risk, participants will receive personalized invitations, multiple reminders, and direct access to the research team for support (34). The survey will be scheduled outside holiday periods, and its length will be optimized to reduce participant burden. A three-week response window will be provided, and participants will be acknowledged for their contributions through a personalized thank-you email. Regular updates on study progress and findings will also be shared to maintain engagement.

While there is no strict threshold for an acceptable response rate, an attrition rate of up to 20% is generally considered acceptable (15). If attrition exceeds this threshold between rounds one and two, we will extend the survey period and invite additional eligible participants to ensure sufficient representation.

3.4.2.3 Consensus Meetings for Core Outcome Set

To finalize the outcomes for inclusion in the COS, we will conduct a series of online consensus meetings via Zoom, ensuring broad international representation from our key stakeholder groups. Multiple scheduling options will be offered to accommodate different time zones and maximize participation. The research team will facilitate the meetings, utilizing Zoom features such as breakout rooms for small-group discussions, live polls, and chat functions to enhance engagement and streamline the consensus process. At the start of these meetings, participants will be reminded of the objective—to achieve consensus on the inclusion of outcomes in the COS—and will be presented with a refined list of outcomes that were rated as “critical for inclusion” by at least 70% of respondents and as “not important” by fewer than 15% in Round 2 of the Delphi survey.

The consensus meetings will follow the modified nominal group technique, incorporating structured small-group discussions, ranking exercises, and large-group deliberations. Participants will first engage in facilitated discussions within breakout rooms, critically evaluating the relevance and significance of each outcome. They will then complete a live ranking poll, prioritizing outcomes from most to least critical for inclusion in the COS. The poll results will be shared within the small groups, allowing further discussion to clarify perspectives. Following this, all participants will reconvene in a larger group to review the aggregated rankings, engage in broader deliberations, and address any remaining uncertainties. During the consensus meetings, participants will not be permitted to propose new outcomes, ensuring that the final set is based on systematically gathered input rather than last-minute additions that could undermine the consensus process.

A final ranking poll will be conducted to determine the prioritized outcomes. Consensus will be defined as at least 70% agreement on the top four or five outcomes for inclusion in the COS. If this threshold is not met, an additional consensus meeting will be scheduled.

3.5 Establishing the Core Outcome Measurement Set

3.5.1 Information Source

For each outcome that achieves consensus in our COS consensus meeting, we will identify the most relevant outcome measurement instruments and their corresponding measurement time horizons from the studies included in our scoping review. If an outcome identified during the consensus meeting was not captured in the scoping review, we will consult existing critical care-specific COS to determine appropriate measurement instruments and time horizons (35-37). To establish the reliability and validity of each outcome measure, we

will systematically identify and analyze published studies that evaluate its reliability and construct validity against a gold standard measure in critically ill adults. Additionally, feasibility will be assessed through discussions with study investigators who have direct experience using these instruments in practice.

In preparation for the COMS consensus meeting, we will develop comprehensive briefing documents detailing the scope of the COMS, descriptions of each proposed measurement instrument, and a structured assessment checklist using the COSMIN tool (31) to evaluate whether each instrument meets the criteria for reliability, validity, and feasibility in adult critical care populations.

3.5.2 Consensus Meetings for Core Outcome Measurement Set

We will send an invitation via email to stakeholders involved in the COS consensus meetings, inviting them to participate in online COMS consensus meetings on Zoom. To accommodate participants from different time zones and encourage maximum involvement, we will provide several scheduling options. We will ensure that attendees represent our key stakeholder groups.

Before the consensus meetings, stakeholders who have agreed to participate will be invited to propose additional measurement instruments for consideration. Any newly suggested instruments will undergo a rigorous evaluation by the research team to determine their validity, reliability, and feasibility before inclusion in the consensus discussions.

Members from the research team will facilitate the COMS consensus meetings. At the outset of these meetings, participants will be provided with a clear overview of the COMS scope, inclusion criteria for measures (i.e., reliability, validity, and feasibility), and the voting process. For each outcome, measurement instruments outlined in the briefing documents will be presented, followed by a structured small and large group discussion. Voting will be conducted using Zoom's polling function, with response options of "yes," "no," or "uncertain" for inclusion in the COMS. Each participant will vote for a single option per poll and will be encouraged to select "uncertain" rather than abstain if undecided. Consensus will be defined as at least 70% of participants voting "yes" for inclusion. If consensus is not reached in the first vote, additional discussion will follow before a second round of voting. If consensus remains unresolved, the reasons will be documented. After finalizing the selection of measurement instruments, participants will discuss and vote on appropriate measurement time horizons for those measures that reached consensus.

4. Ethics and Dissemination

We will obtain research ethics approval in accordance with the requirements of local authorities at all participating sites. Informed consent will be obtained from stakeholders prior to COS and COMS consensus meetings, with participation in Delphi rounds considered as implied consent. We will emphasize to stakeholders that participation is voluntary, and they may withdraw at any time without penalty. All data will be handled with strict confidentiality. Data will be encrypted and stored on a password-protected computer, with access limited to the research team unless explicit permission is granted by stakeholders.

The COS and COMS will be disseminated through multiple channels, including international organizations (e.g., the Restraint Reduction Network: <https://restraintreductionnetwork.org/>) for distribution within their networks, publication in peer-reviewed journals, and presentations at relevant conferences. A plain language summary of the findings will also be shared with stakeholders to ensure transparency and accessibility.

5. Discussion

Previous studies on physical restraint use and minimization have utilized a variety of outcomes and measurement tools, leading to significant heterogeneity that limits the ability to effectively synthesize evidence and inform clinical practice. The development of a COS and a COMS aims to standardize outcome selection and measurement, incorporating input from diverse stakeholders. A key strength of this COS and COMS protocol is its adherence to the recommendations outlined in the COMET Handbook. The protocol has been developed in accordance with relevant guidelines, including COS-STAP, ensuring methodological rigor. Additionally, multiple methods will be employed to enhance the comprehensiveness of COS and COMS development, including an updated scoping review, a review of previously conducted interviews with family members, a Delphi process, and consensus meetings. Another significant strength is the novelty of this work—no existing COS or COMS currently address this area, making its development both timely and essential. Furthermore, the inclusion of international stakeholders will enhance the global applicability and relevance of the final COS and COMS.

Limitations include restricting the inclusion of studies in our scoping review to those published in English, as well as recruiting only participants who can read and speak English. This may limit the ability to capture outcomes and measurements that are deemed significant by non-English speakers. Another limitation is that the qualitative interviews being reviewed were conducted solely with family members and were not originally designed to explore their perspectives on outcomes they believe should be selected and measured in restraint minimization studies. As a result, the identified outcomes from these interviews may not be comprehensive and may not fully reflect the patients' perspectives. However, by including both ICU survivors and family members in the steering committee and broader panel, we will ensure that the identified outcomes are not only relevant to their experiences but also capture any additional outcomes they deem significant.

6. Conclusion

The outlined methods will support the development of a COS and a COMS for studies on physical restraint minimization in adult ICUs. Establishing these standardized sets could strengthen evidence synthesis, drive meaningful practice change, and ultimately improve patient outcomes.

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There are no Acknowledgements.

8. Declarations

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- Authors' contributions:
 - Ziad Alostaz: Conception, methods development, and manuscript writing
 - Wendy Ellis: Methods development and manuscript editing
 - Sangeeta Mehta: Conception, methods development, and manuscript editing
 - Mohammed Aldalaykeh: Methods development and manuscript editing
 - Nasrin Alostaz: Methods development and manuscript editing
 - Raajpreet Sekhon: Methods development and manuscript editing

- o Craig Dale: Conception, methods development, and manuscript editing
- o Louise Rose: Conception, methods development, and manuscript editing



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Supplementary Files