TRANSPARENCY IN INTIMATE PARTNER VIOLENCE RESEARCH

INTIMATE PARTNER VIOLENCE: AN EXPLORATION OF RESEARCH TRANSPARENCY, QUALITY, AND OPPORTUNITIES

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ABSTRACT

Intimate partner violence is also known as domestic violence or spouse abuse. It affects the physical, psychological, social, and financial well-being of many people around the world. Many researchers from health/medical, social, and psychological fields have studied intimate partner violence in an effort to prevent it or to improve overall health and well-being among victims. Ideally, decisions are best influenced by high quality evidence. However, little attention has focused on the quality of this research. This thesis focuses on the theme of transparency relating to study quality, specifically highlighting non-publication bias, biases related to outcome and study methodologies, and overall reporting quality in previously published IPV research. These lessons learned from this research have informed, in part, an original study on intimate partner violence. Finally, this thesis concludes with insights to improve methodological quality and transparency for researchers in the intimate partner violence field.

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LIST OF ABBREVIATIONS

Abbreviation	Definition
AMED	Allied and Complementary Medicine database
CDSR	Cochrane Database of Systematic Reviews
CI	Confidence interval
CIHR	Canadian Institutes of Health Research
CINAHL	Cumulative Index of Nursing and Allied Health Literature database
COA	Canadian Orthopaedic Association
COI	Conflict of interest
CONSORT	Consolidated Standards of Reporting Trials
DOI	Digital object identifier
DORA	Declaration on Research Assessment
DV	Domestic violence
DVSA	Domestic violence survivor assessment
EQ-5D	EuroQol-5 Dimensions
EQ-5D-5L	EuroQol-5 Dimensions (5 response option version)
EQUATOR	Enhancing the Quality and Transparency of Health Research
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act
FLOW	Fluid lavage of open wounds trial
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HCP	Health care professional
HIV	Human immunodeficiency virus
ICMJE	International Committee of Medical Journal Editors
IF	Impact factor
IPV	Intimate partner violence
ISI	Institute for Scientific Information
ISRCTN	International standard randomised controlled trials number
ISS	Injury severity scale
KTE	Knowledge translation and exchange
LMIC	Low and middle income countries
MCID	Minimal clinically important difference
NCT	National clincial trial identifier
NEJM	New England Journal of Medicine
NIH	National Institutes of Health
NR	Not reported
NTR	Netherlands Trial Register
PI	Principal investigator
PMID	PubMed identification
POSITIVE	Patient opinions of screening for IPV study
PRAISE	Prevalence of abuse and IPV surgical evaluation study

PRAISE-2	Prospective abuse and IPV surgical evaluation study
PTSD	Post-traumatic stress disorder
Q1-Q3	1st quartile and 3rd quartile (i.e. for interquartile range)
QALY	Quality-adjusted life years
RCT	Randomized controlled trial
RTF	Return to function questionnaire
SAE	Serious adverse event
SD	Standard deviaiton
SPSS	Statistical Package for the Social Sciences
TRUST	Trial to Re-evaluate Ultrasound for Tibial Fractures
VAS	Visual analog scale
WAST	Woman abuse screening tool
WHO	World Health Organization
WMA	World Medical Association

DECLARATION OF ACADEMIC ACHIEVEMENT

Chapter 1: This chapter is unpublished. KM is the sole author

Chapter 2: This chapter is published in *Clinical Orthopaedics and Related Research*. KM and MB designed the study. KM drafted the manuscript and MB made criticial revisions.

Chapter 3: This chapter is in review at *Trials*. KM and MB designed the study. KM, KT, and PS collected data. All authors analysed and/or interpreted data. KM drafted the manuscript. All authors made significant revisions.

Chapter 4: This chapter is published in *Women & Health*. KM and MB designed the study. KM, KT, ZA, PS, and MS colleacted data. KM and KT analyzed data and drafted the manuscript. All authors made critical revisions.

Chapter 5: This chapter is unpublished. KM designed the study. KM and MP collected data. KM drafted the manuscript and all authors provided critical revisions.

Chapter 6: This chapter is published in *Journal of Interpersonal Violence*. KM and NE designed the study. SS, LT, and MB refined the study design. KM, ED, TS, CSL, and PD collected study data. KM drafted the manuscript, and all authors critically revised the manuscript.

Chapter 7: This chapter is unpublished. KM and MB designed the study. KM and SP drafted the paper and all authors made revisions.

Chapter 8: This chapter is published in *PeerJ Preprint*, which is a preprint server. KM designed the study. DHA and LT provided statistical expertise. HJ provided economic expertise. KM drafted the manuscript and all authors made critical revisions.

Chapter 9: This chapter is unpublished. KM is the sole author.

Chapters 3, 4, and 5 have some overlap in the methods sections because they came form the same systematic review.

PART A: SETTING THE SCENE

Chapter 1: Introduction

TRANSPARENCY AND RESEARCH QUALITY

"Transparency and detail are everything in science."
-Ben Goldacre, physician-scientist and science writer.

When we talk about research quality we are referring to the potential for bias, which is defined as systematic sources of error that can result in findings that do not represent the truth or are inaccurate. Adequate study design and execution can minimize the potential for bias and improve study quality. This thesis will argue that study quality and transparency are highly related and that improving transparency can help with identifying and preventing bias.

We have known for some time about the connection between financial conflicts of interest (COI) and study bias. For example, a recent Cochrane systematic review found that industry funding was significantly associated with more favourable outcomes and fewer harms reported[1]. This finding is likely due to financial conflicts of interest that are inherent in industry-funded trials. A salient example from orthopaedics is the TRUST trial[2] which was stopped early by the industry sponsor due to "futility" based on an uplanned interim analysis[3]. The solution to financial COIs generally includes three components: 1) prevention; 2) mitigation, and 3) disclosure. Prevention can involve recusing oneself from situations where a bias is evident or perceived. Mitigation can involve putting procedures in place to minimize potential for biases. In clinical trials where there is a potentially biased funder, agreements can be put in place to ensure that trials are published regardless of the outcome, and placing limits on the conflicted party's role in results interpretation and reporting[4]. The third point, disclosure, is particularly relevant to transparency. If a COI can't be prevented or mitigated, it should be fully and transparently disclosed to allow for knowledge users to judge the potential for bias[5]. Working with industry on medical research has its benefits, and not all industry-funded research is biased, but it is best practice to disclose potential conflicts of interest so that readers can judge for themselves[6].

This principle that transparency and research quality are linked extends to other areas of methodology. For example, prospective trial registration in a publicly available trial registry such as clinicaltrials.gov or the International Standard Randomised Controlled Trials Number database (ISRCTN) encourages investigators to adequately plan study methodology in advance and disclose the planned methodology publicly[7]. This is important because, in some cases, changing methodology partway through a study, particularly after one becomes aware of a result that is uninteresting or unwelcome, can seriously affect the quality of the study[8–10]. Prospective trial registration is meant to, among other things, prevent switching to a more favourable outcome (i.e. selective outcome reporting bias). Research has shown that trials that are prospectively registered are more likely to adhere to the study protocol than those that are not[11]. Certain clinical trials of interventions are required by law to be registered, particularly in the United States[7]. The World Health Organization (WHO), and International Committee of Medical Journal Editors (ICMJE) have expanded this requirement to include all clinical trials[12,13]. Although the WHO and ICMJE reccomendations are not legally binding, failing to register a trial can preclude

publication in certain journals. One may argue that all clinical studies that may influence health care decisions should be prospectively registered before patients are enrolled, or in the case of systematic reviews, before the initial literature search is conducted.

Additionally, trial registration is meant to hold investigators accountable to report the results of their studies[14]. This concept is important for several reasons. Studies that are unreported are, fundamentally, a waste of resources and have even been equated to scientific misconduct[15,16]. Studies that are publicly funded and are never reported are a misuse of public funds. Even if not publicly funded, unreported trials often rely on volunteers who take risks by undergoing treatments that are under study. Even in non-interventional or low-risk research, research participants take the time and effort to follow the study protocol with the understanding that this will benefit others in the future. By not making the results of research available, investigators let down the participants in their trial and future patients who may benefit from that research[17]. Another aspect of failing to report the results of research is that the results are not available for use in synthesis research (e.g. systematic reviews, clinical practice guidelines)[18]. Negative studies are disproportionately unpublished, which artificially makes interventions appear more effective than they really are[19].

Of studies that go on to be published, many are not reported in a transparent manner[20,21]. Methodology should be fully and accurately disclosed in a particular way to allow for transparency in all aspects of planning, design, execution, and reporting of clinical research so that knowledge users can accurately judge the quality of the research and assess the limitations and applicability. Numerous reporting guidelines have been developed to assist researchers to improve transparency, typically consisting of reporting checklists to prompt authors to report each aspect of methodology and results that are important for readers to know in order to judge the quality of the study. Probably the most well-known of these reporting guidelines is the Consolidated Standards of Reporting of Trials (CONSORT) guidelines, checklist, and flow diagram which was first published in 1996[22] and most recently updated in 2010[23].

Peer-reviewed publication is not the only way to disseminate the results of research. Less conventional methods include online dissemination through social media, online news sources, and websites[24,25]. Using online dissemination methods allows for faster dissemination than peer-reviewed journals, and it allows wider access to research results, and may help with publication bias. There are limitations to online dissemination, including that online citations are not typically given academic credit like traditional journal citations, there may be reduced quality control compared to standard peer/editorial review, content can still be located behind a paywall which limits access, and messages can be misinterpreted or diluted especially when aimed at the general public[26]. However, tools like preprint servers can minimize a number of these concerns. Preprint servers are repositories that allow researchers to post research reports before peer-reviewed publication. They are free and open access, can be updated easily after posting (with tracked versions), are usually published within days after submission, and many have a

commenting feature that allows for peers to comment on research before it is submitted to a peer-reviewed journal[27,28]. All of these features lead to improved access, faster dissemination, and improved transparency of research. One limitation is that the submissions only undergo a basic review rather than formal peer review. However, most preprint servers state clearly that the submission has not been peer-reviewed.

PURPOSE AND CONTENTS OF THIS THESIS

"I have seen many women over the course of my career struggling with the negative impacts of abuse by their partners where they have been robbed of their self-worth, sense of control and safety. When putting the right supports in place women are able to rebuild themselves and their lives. I never cease to be amazed by the strength of the female spirit."

-Diana Tikasz, social worker and advocate for IPV survivors

Intimate partner violence (IPV) is also known as domestic violence, spouse abuse, or partner abuse and can include stalking behaviours, physical abuse, verbal abuse, sexual abuse, and other abusive or controlling behaviours in an intimate relationship. Although there is a large and growing body of literature in the field of intimate partner violence (**Figure 1**), there has been very little research to date on the quality of research methodology, nor how to improve it. Many other fields of health research have focused on key methodological issues such as publication bias[29], selective outcome reporting bias[8], stopping early[30], accurate and complete reporting[31], and many others. The purpose of this thesis is to describe some of the key issues that affect the quality of research in the IPV field, with a particular focus on the intersection of quality and transparency.

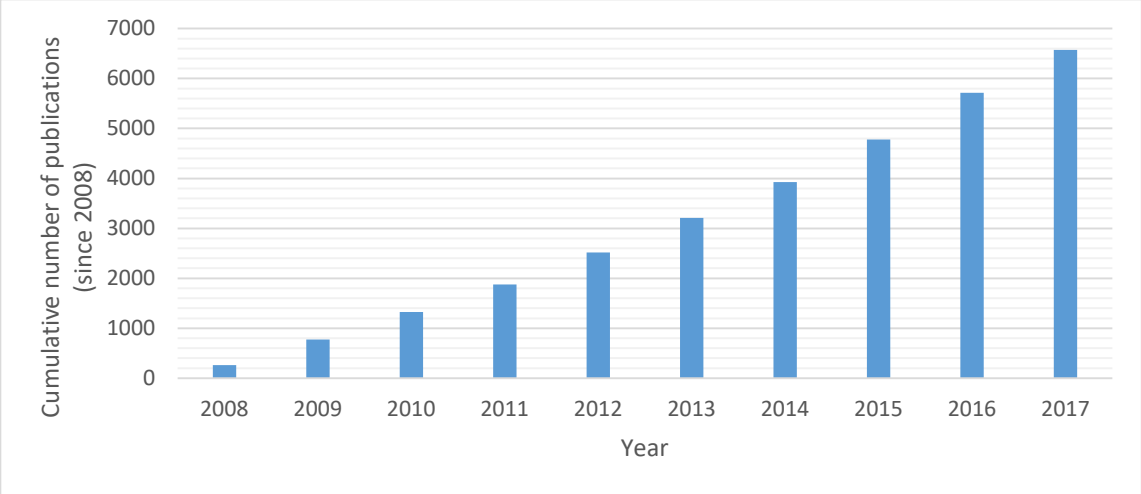

Figure 1: Cumulative number of intimate partner violence publications in PubMed from 2008 to 2017

Chapter 2 is an overview of the issue of IPV in orthopaedics and a summary of some of the controversies and questions remaining in the field. The chapter ends with a summary of what orthopaedic surgeons can do to assist victims of IPV in their clinics.

Chapters 3, 4, and 5 report the results of a systematic review of IPV studies registered on clinicaltrials.gov and other trial registries. **Chapter 3** explores how many registered IPV studies remain unpublished 18 months after completion. **Chapter 4** describes the methodological differences between trial registration records and the associated publication. **Chapter 5** explores adherence to reporting guidelines for those studies that were published, and identifies which aspects of reporting are usually done well and which items could use improvement. Together, these three chapters address publication bias, selective outcome reporting bias, and transparency in reporting.

Chapter 6 reports results of a scoping review of IPV screening, advocacy, and education studies. This chapter focuses on one modern aspect of knowledge dissemination of IPV studies: online dissemination. Online dissemination complements traditional knowledge dissemination strategies such as publishing in peer-reviewed journals and presenting at conferences. Non-traditional methods of knowledge dissemination enhance transparency by allowing a broader range of potential knowledge users to access the information.

Chapters 7 and 8 report on an original pilot prospective cohort study that is informed, in part, by the lessons learned about transparency and research quality in Parts A and B. The Prospective Abuse and Intimate Partner Violence Surgical Evaluation (PRAISE-2) pilot study aims to evaluate the feasibility of a prospective cohort study that follows orthopaedic patients for 12 months to determine changes in IPV experiences after an orthopaedic injury, as well as how a history of IPV is associated with orthopaedic outcomes. **Chapter 7** describes the recruitment feasibility of the pilot study and the participants' baseline characteristics. **Chapter 8** is the statistical analysis plan for the PRAISE-2 pilot study, which comprehensively outlines the statistical methodology that will be used upon completion of the study. The emphasis on transparency is very important in this study. The PRAISE-2 pilot study was prospectively registered on clinicaltrials.gov before the first patient was recruited. The full study protocol is available at the open access journal *Pilot and Feasibility Studies*. We made every effort to follow reporting guidelines and clearly note any departures from the study protocol with justification, where aplicable. By posting the statistical analysis plan on a freely accessible preprint server, we made our statistical choices clear before the study is analyzed.

This thesis ends with **Chapter 9**, which is a discussion of all of the previous chapters' findings in the context of the enrtire thesis, as well as an exploration of future opportunities and directions for IPV studies based on lessons learned from this thesis.

Chapter 2: Screening women for intimate partner violence in healthcare settings (review)

Kim Madden, Mohit Bhandari. Cochrane in CORR: Screening women for intimate partner violence in healthcare settings.

Published in: Clin Orthop Relat Res. 2016 Sep;474(9):1897-903.

Cochrane in *CORR*®: Screening Women for Intimate Partner Violence in Healthcare Settings (Review)

A Note from the Editor-in-Chief: We are pleased to publish the next installment of Cochrane in CORR, our partnership between CORR, The Cochrane Collaboration, and McMaster University's Evidence-Based Orthopaedics Group. In it, researchers from McMaster University will provide expert perspective on an abstract originally published in The Cochrane Library that we think is especially important, (O'Doherty L, Hegarty K, Ramsay J, Davidson LL, Feder G, Taft A. Screening women for intimate partner violence in healthcare settings. Cochrane Database of Systematic Reviews 2015, Issue 7. Art. No.:CD007007. DOI: 10.1002/14651858.CD007007.pub3.) This Cochrane in CORR column refers to the abstract available at: DOI: 10.1002/14651858.CD007007.pub3.

Importance of the Topic

The orthopaedic surgeon's role in the identification and care of patients experiencing intimate partner violence (IPV) has gained considerable interest in the surgical community during the last few years. With the publication of the Prevalence of Abuse and Intimate Partner Violence Surgical Evaluation (PRAISE) study[32] that determined the global prevalence of IPV in orthopaedic clinics, and a series of subsequent studies specifically focusing on IPV in orthopaedic settings[33–35], orthopaedic surgeons are becoming aware that IPV affects a staggeringly large number of the women whom they treat. One in six women in fracture clinics has experienced IPV in the past year and one in 50 women present to fracture clinics with IPV-related injuries[32]. More than one in four women (28%) in IPV-therapy programs who have experienced abuse have musculoskeletal injuries requiring medical attention[36]. Since 45% of women who are killed by their intimate partner present to emergency departments within 2 years before their death[37], physicians and orthopaedic surgeons have an important opportunity to prevent further injuries and death for their patients.

In recent years, a number of IPV screening and assistance programs have been implemented and tested in medical settings. These screening programs typically aim to ask every woman presenting for treatment a set of standardized questions to elicit disclosure of IPV. Assistance programs take this concept one step further by processes of referral, advocacy, or counseling once patients disclose IPV in order to reduce the health, social, economic and/or psychological consequences of IPV. Despite the availability of published randomized trials, recommendations about screening for IPV from health organizations have been conflicting[38,39] and the value of screening is highly debated[40].

This Cochrane review evaluated the efficacy of screening programs for IPV in clinical settings[41]. Based on evidence from 13 randomized trials (14,959 women) the authors concluded that there is insufficient evidence to recommend screening all women for IPV in clinical settings. It should be noted that the review did not evaluate IPV screening programs that also included a counseling, advocacy, or social services intervention. It should also be noted that, although domestic violence can affect men and women and is harmful to all

persons affected, the review focuses only on interventions directed at women who have experienced IPV.

Upon Closer Inspection

While IPV screening programs demonstrated a considerable improvement in IPV identification, there were no major differences in referring patients to social services or counselling. The review also evaluated reduction of IPV, physical health, psychosocial health, and resource use. The authors were unable to pool these outcomes, but none showed significant differences between groups in individual trials. The authors concluded that these IPV screening programs that focus on identification of patients who have experienced IPV only are ineffective.

Although this meta-analysis was thorough and of high quality, identification and referral rates, the focus of the study, are not patient-important outcomes. Studies that evaluate the effects of patient-important outcomes such as physical and mental health outcomes would be more valuable in reporting efficacy of IPV interventions. Indeed, there was little data on outcomes that could be classified as patient-important. Additionally, patients in these studies were only asked about IPV once. It is important to ask patients about IPV multiple times during the course of their care, since patients may need to establish a relationship with the healthcare professional before they feel ready to disclose[35]. This is part of the reason that orthopaedic surgeons have an advantage compared to emergency physicians when it comes to discussing IPV with patients.

It should also be noted that no trials were conducted in an orthopaedic setting (the PRAISE study was not interventional), so applicability to orthopaedic clinics is unclear. Further research is recommended evaluating interventions specifically for orthopaedic settings.

Take-home Messages

The conclusion from the authors that screening is ineffective does not mean that healthcare professionals should abandon the idea of identifying and helping patients who have experienced IPV. In fact, these findings highlight the fact that screening alone does not necessarily lead to improvements in any meaningful outcomes for patients, and perhaps a more rigorous "active" intervention is warranted. Trials evaluating IPV identification paired with referral or counselling services, which were not included in this review, demonstrate a positive impact on the lives of patients who have experienced IPV[42,43]. We recommend that IPV interventions go beyond identification alone, and are evaluated based on patient-important outcomes such as reduction in IPV frequency and/or severity, or IPV-related health outcomes that directly impact a patient's health and well-being.

The American Academy of Orthopaedic Surgeons and other orthopaedic organizations have position statements that encourage orthopaedic surgeons to become familiar with IPV and their role in caring for abused women[44,45].

Personnel in orthopaedic clinics can do five simple things to help the women whom they treat who may be experiencing IPV, even without establishing a formal screening and intervention program[45].

1. Be aware that IPV affects about one in six of the women whom you treat.
2. If you feel comfortable asking your patients about IPV, here is a suggested method: "Because violence is so common in many women's lives, and because there is help available for women being abused, I now ask every patient about domestic violence." Follow with three validated questions: (1) Have you been hit, kicked, punched, or otherwise hurt by someone in the past year? (2) Do you feel safe in your current relationship? (3) Is there a partner from a previous relationship who is making you feel unsafe now?[44]
3. If a patient discloses IPV, be supportive and validate her disclosure; tell her that the abuse is not her fault.
4. Become familiar with local resources, including hospital/clinic social services and community-based resources. For example, call the National Domestic Violence Hotline (1-800-799-SAFE) in the United States or visit sheltersafe.ca in Canada.
5. If reporting is not mandatory in your jurisdiction and no children are at risk, always ensure that you have the patient's permission to contact outside services like police or shelters.

PART B: TRANSPARENCY IN THE IPV LITERATURE

Chapter 3: What happens to intimate partner violence studies registered on clinicaltrials.gov?

Kim Madden , Kerry Tai, Patricia Schneider, Nathan Evaniew, Michelle Ghert, Mohit Bhandari. What Happens to Intimate Partner Violence Studies Registered on clinicaltrials.gov? A Systematic Review of a Clinical Trials Registry.

Submitted to: Trials [Oct 2017]

What Happens to Intimate Partner Violence Studies Registered on clinicaltrials.gov? A Systematic Review of a Clinical Trials Registry

Background: There is an increasing number of interventions aimed at reducing the incidence and improving the identification and management of intimate partner violence (IPV), which are being tested in randomized clinical trials. Publication bias, improper reporting, and selective reporting in clinical trials have led to widespread adoption of pre-registration of clinical trials. Non-publication of study results leads to inefficiency, ethical issues, and scientific issues with the IPV literature. When study results and methodology are not made available through publication or other public means, the results cannot be used to their full potential. The objective of this study was to determine the publication rates of IPV trials registered in a large clinical trial registry.

Methods: We conducted a systematic review of all IPV-related clinicaltrials.gov records and determined whether the studies that had been completed for 18 months or longer have been published in a peer-reviewed journal or in the clinicaltrials.gov registry. Two authors extensively searched the literature and contacted study investigators to locate full-text publications for each included study.

Results: Of 83 completed IPV-related trials registered on clinicaltrials.gov, 64 (77.1%) were subsequently published in full-text form. The median time to publication was 32 months (95% CI 21.8 to 42.2 months). Of the 19 unpublished studies, authors confirmed that there was no publication for 11 studies and we were unable to contact the investigator or locate a publication for the remaining 8 studies. Only 4 studies (all published) posted their results on clinicaltrials.gov upon completion.

Conclusion: Approximately 1 in 4 IPV trials are not published 18 months following completion, indicating that clinicians, researchers, and other evidence users should consider whether publication bias might affect their interpretation of the IPV literature. Further research is warranted to understand reasons for non-publication of IPV research and methods to improve publication rates.

Registration: none – not clinical

BACKGROUND

Intimate partner violence (IPV), also known as spouse abuse and domestic violence, affects 1 in 3 women globally[46]. IPV is an important social issue that has well-documented health implications, including poor mental health[47] musculoskeletal injuries[36,48] reduced quality of life[49], and even death in severe cases[50]. There is a growing number of interventions in health care settings for victims of IPV, and these interventions are increasingly being evaluated by clinical trials[51,52]. As the literature on IPV interventions grows, it is important to ensure transparency of study design, accurate trial reporting, and to evaluate potential bias in the literature, so that evidence users are not misled by inaccurate or inappropriate reporting. Additionally, since the effectiveness of IPV interventions is often highly controversial[38,39,53] it is important to have as much high quality published evidence as possible.

Several health regulatory bodies globally, including the United States Food and Drug Administration (FDA), require by law that clinical trials of drug or device interventions are registered in an approved clinical trials registry[54]. Many medical journals and the International Committee of Medical Journal Editors (ICMJE) now require that all clinical trials be registered as a condition of publication[12]. The World Health Organization (WHO) strongly recommends registering all intervention trials and has set a list of minimum information required in a trial registry[13]. The widely-endorsed Consolidated Standards of Reporting Trials (CONSORT) statement requires that the clinical trials registration number is reported on all publications of randomized trials regardless of the type of intervention[23]. Clinicaltrials.gov is the largest trial registry and the most common trial registry used in North America[14].

It is important to register clinical trials for many reasons including ethical obligations, legal obligations, and scientific considerations. Major medical journals such as British Medical Journal, the Lancet, and New England Journal of Medicine, and all journals that follow ICMJE policies require clinical trials to be registered before enrolling their first patient or they will not be published[12]. Registering clinical trials allows patients and research participants to access information about clinical trials in which they could potentially participate (the registry's original purpose)[7]. Granting agencies and investigators can search trial registries to determine if there are any ongoing studies that might make a planned study redundant[7]. This usage aims to improve efficiency of clinical research and allocation of funding. Trial registries are also important for study methodology. Prospectively registering a study aims to reduce publication bias, selective reporting bias, and improve transparency[7]. Trial registries are publicly available databases, making it easy to find all trials that have been initiated for a particular intervention of interest. It is this transparency that should encourage investigators to publish their results regardless of whether they are positive, negative, or inconclusive, which has the potential to limit publication bias[55]. Because trial registry is required to occur before enrollment of the first patient, one can see in the trial record the originally planned eligibility criteria, intervention, comparison group, outcomes, and other important elements of the protocol. This means that registry records can be used to determine if the study plan changed over time so that

the reader can assess if there is a risk of bias from selective reporting. In 2008, clinicaltrials.gov launched a results database and in late 2009 it became mandatory by law to report a standardized summary of results for drug and device trials within one year of trial completion[14]. Investigators of trials not involving drugs or devices are also encouraged to post their results, but journals typically do not require posting of results as a condition of publication. Investigators are not currently required to register other study designs like observational studies, but it is encouraged.

Previous studies have reported very low rates of publication among studies registered on clincialtrials.gov and other trial registries. Ohnmeiss[56] found that only 38.9% of registered spine trials were published. Similarly, 22.8% of arthroplasty trials[57], 43.2% of trauma trials[58], 54% of macular degeneration trials[59], 54% of diagnostic accuracy studies[31], and 58.8% of sports medicine trials[60] are published. Industry funding is linked to a failure to publish particular outcomes or entire studies, especially those with negative or inconclusive results[8,9,29,61]. Since IPV studies are rarely industry-funded, it is unclear whether the IPV literature suffers from the same limitations as other specialties. No previous studies have reported on the publication rates of registered studies in the IPV field. The current study can shed light on the current state of the IPV literature in terms of publication rates and potential for publication bias.

We conducted a systematic review of IPV studies registered with clinicaltrials.gov with the objective of determining the proportion of studies that have been published within 18 months of the trial being reported as complete on clinicaltrials.gov. Additionally, we aimed to explore the characteristics of trials that are published versus those that are not published.

METHODS

Identification of Registry Records

We performed a search of the clinicaltrials.gov trial registry on 12 September 2017 using the terms “spouse abuse” OR “domestic violence” OR “partner violence” OR “partner abuse”. Two authors (KM and KT) independently reviewed all study titles, outcomes, interventions, and conditions that the search identified. Studies were excluded if they focused only on child abuse, or if the title, outcomes, interventions, and conditions did not mention intimate partner violence or a related term such as domestic violence. We included all study designs (e.g. randomized trials, non-randomized studies, prospective cohort studies).

Once the relevant studies were identified, we determined whether the studies were “completed” or “not yet complete” based on what was reported in the clinicaltrials.gov record. At this point we excluded studies that were listed as “terminated”, “withdrawn”, or “suspended” in the registry. Additionally, we excluded studies with a date of completion in the past 18 months, in order to account for a reasonable time delay between trial completion and publication. We chose 18 months as our cut-off to allow sufficient time after the end of enrollment for data cleaning, data analysis, and manuscript writing, plus several months for review by a journal and subsequent publication. The WHO recommends

publication within 12 months of study completion, but up to 24 months may be allowable[13]. Previous studies of publication rates of registered studies have used a cut-off of 18 months[56].

Identification of Publications

We searched for each publication in AMED (Allied and Complementary Medicine Database), Embase, Global Health, Healthstar, Medline, and PsycInfo using the Ovid search interface, plus Google Scholar. We searched the clinicaltrials.gov trial identification number first, then if the publication could not be found we searched the publication databases using the principal investigator's (PI) last name plus trial keywords. An additional author (KT and PS) attempted to find the publications that the first author (KM) could not locate. We also attempted on up to three occasions to contact the PI listed on the clinicaltrials.gov record for publications that could not be located and for publications where we were unsure if they matched the clinicaltrials.gov record. We defined "publication" as a paper published in a peer-reviewed journal (i.e. not an internal report to industry, funding agency, or government). In addition, the publication had to contain results to be considered complete (protocol papers and initial reports were excluded).

Data Collection

We exported the results of the clinicaltrials.gov search into a study database. For each study with a corresponding publication, one author (KM) extracted the month and year of publication, country, study design, intervention(s), funding source, and whether the authors reported the trial registry number. A second author (KT) verified all data points. Disagreements were settled by consensus or by consulting the senior author (MB).

Data Analysis

We calculated agreement for inclusion using the kappa statistic with 95% confidence interval using the GraphPad kappa calculator (http://graphpad.com/quickcalcs/kappa2/). We used SPSS version 24 to conduct Fisher's exact tests and t-tests comparing unpublished and published study characteristics, and to construct a Kaplan–Meier survival curve for publication status (with an "event" defined as publication) and reported the median survival time with 95% confidence interval. We present descriptive statistics using frequencies and percentages, as appropriate. We also conducted a sensitivity analysis using a cut-off of 24 months since completion, per the upper limit of the WHO's recommendations for making study results available. We conducted an exploratory multivariable binary logistic regression to determine if country, study design, and funding source were associated with publication.

RESULTS

Search Results

We identified 274 study records in clinicaltrials.gov (**Figure 2**). We excluded 59 of these studies because they did not relate to intimate partner violence and 106 because they were not yet completed. Four studies were withdrawn, suspended, or terminated, and 22 had been completed less than 18 months prior to the registry search. Thus, there were 83

relevant clinicaltrials.gov records for which we sought matching publications. Inter-observer agreement for inclusion was almost perfect (kappa=0.97, 95% CI: 0.93 to 1.00).

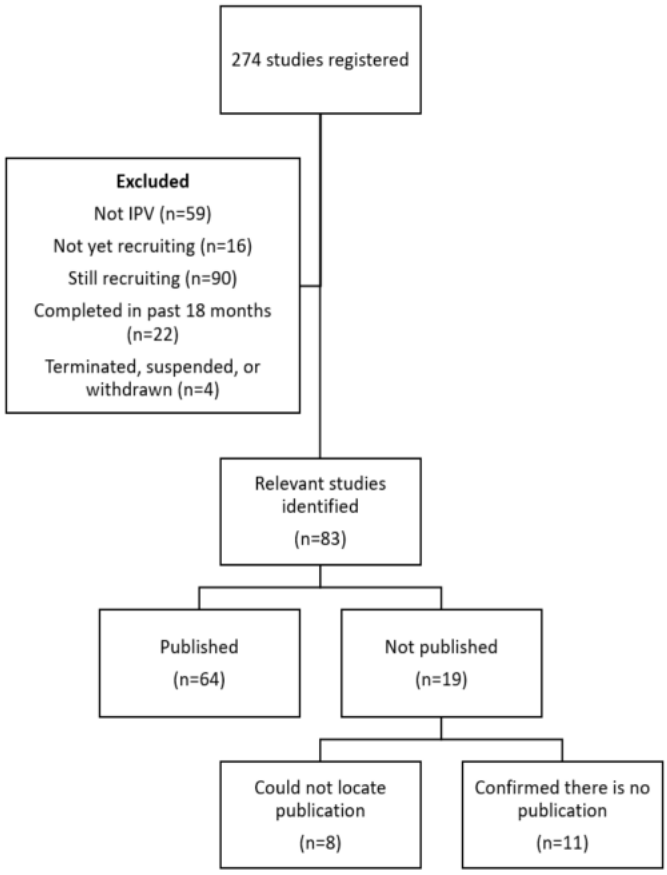

Figure 2: Study flow diagram

Published Registered Studies

Of the 83 studies for which we sought full text publications, we were able to locate 64 (77.1%). Of the remaining 19, authors of 11 studies confirmed that there is no publication, and we were unable to contact the PI or a locate publication for 8 studies. Reasons given by authors for not having a published paper included that the publication is still in preparation or review, the results were uninteresting (i.e. negative), the study had methodological flaws, and the study was part of a PhD dissertation and was never published. Median time to publication was 32.0 months (95% CI 21.8 to 42.2 months) (**Figure 3**). Using a cut-off of 24 months since study completion, 60/77 studies were published (77.9%).

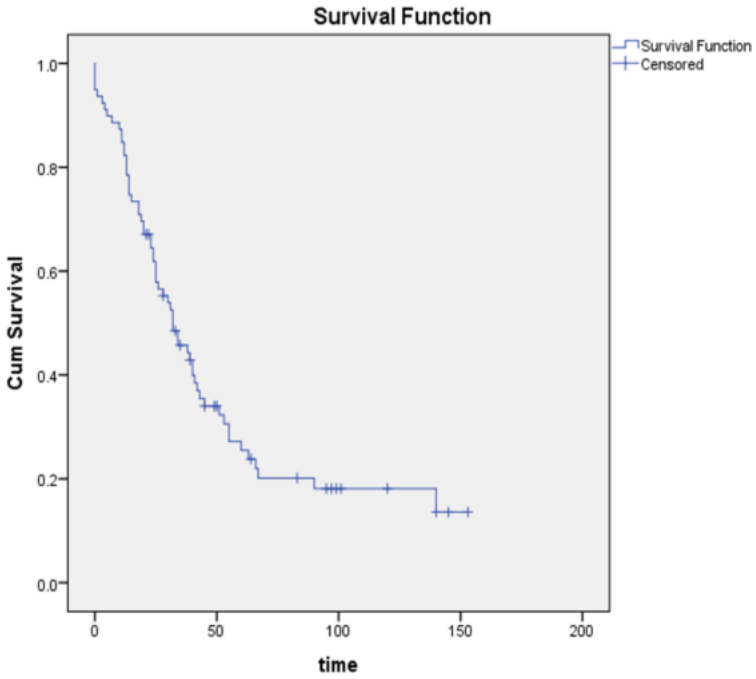

Figure 3: Kaplan-Meier survival curve for time to publication

Study Characteristics

Study characteristics for published and unpublished studies are shown in **Table 1**. Most studies were from the United States (52/83, 62.7%) and were randomized controlled trials (RCTs) (66/83; 79.5%).

Table 1**:** Study Characteristics

Study Characteristic	**Published Studies N=64**	**Unpublished Studies N=19**
Study Design		
RCT	52	14
Non-RCT	12	5
Country		
USA	43	9
Other	21	10
Funding Type		
Government	43	11
Foundation/Association	7	0
Industry	1	0
Unclear/Not Reported	13	8
Results Reported in Registry		
Yes	4	0
No	60	19
NCT Number Reported in Publication		
Yes	38	
No	26	

Few studies (4/83; 4.8%) had posted their results to clinicaltrials.gov. Interestingly, only 38 of the 64 published studies (59.4%) reported their clinicaltrials.gov registration number in the published paper despite that reporting the registration number is required by CONSORT guidelines. We did not find any evidence that study design (RCT vs non-RCT; OR: 1.67, 95% CI: 0.48 to 5.86) or country (USA vs non-USA; OR: 2.23, 95% CI: 0.77 to 6.50) or funding source (Government/Non-Profit/Industry vs Unreported; OR: 2.817, 95% CI: 0.92 to 8.64) were associated with publication, however with a small sample size these results should be interpreted with caution.

DISCUSSION

Clinicaltrials.gov and other trial registries are important tools to aid in transparency of conducting and reporting clinical research and reducing bias associated with non-publication. Since IPV interventions and associated trials are a growing area of interest for clinicians and knowledge users, it is important to critically evaluate the quality of this body of literature in order to make informed decisions. This systematic review of clinicaltrials.gov records found that nearly 1 in 4 IPV-related studies are not published at 18 months or longer after being reported as completed on clinicaltrials.gov. The non-publication rate was nearly the same (22.1%) when using a cut-off of 24 months instead of 18 months. There was no evidence that study design, country, or funding source are

predictive of publication, but this finding should be interpreted with caution due to small numbers.

Publication bias is a well-documented phenomenon that arises when negative studies are not published, and only positive studies are available to users of medical literature and systematic reviewers[62]. The effect is that interventions appear to be more effective than they actually are, thereby misleading clinicians and others seeking to apply results to clinical practice[62]. According to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group, publication bias is a critical problem that leads to reduced confidence in estimates of treatment effects[63]. Failure to publish a study, whether by the investigators' decision or by an editor's decision, can result in publication bias. Some of the investigators contacted for the current review stated that they did not publish their study because they perceived that the study was not impactful (i.e. negative results), indicating the presence of publication bias. The most common reason for non-publication given by authors was that the paper was still in review at a journal. Although negative trials have similar[64] or better[65] methodological quality compared to positive trials, it often takes significantly longer for negative trials to be published compared to positive trials[66]. However, there is evidence that much of the decision not to publish negative trials is made by the author as opposed to journal editors in top medical journals[67] so authors must be aware of the consequences of publication bias and make all reasonable efforts to publish studies regardless of perceived impact or statistical significance.

Although there are other methods of making results of trials available, publication of study results in a peer-reviewed journal is the classic method of disseminating results to those who can use the knowledge in practice and in future research. Many other methods of dissemination are not publicly available except to a very select group of people (e.g. conference presentations; internal policy documents). Additionally, the full peer-reviewed publication usually contains the most comprehensive description of the study, allowing for proper critical appraisal and inclusion in knowledge syntheses. Since effective knowledge translation and exchange should be an important goal of health research, by failing to publish studies, research funding is not used to its fullest potential. At least 11 of the 19 non-published studies investigated in the current review were funded by foundations, government, or industry. Peer-reviewed journal publication can lead to other forms of knowledge dissemination such as dissemination through social networks, layperson media reporting, and use in a systematic review or other method of knowledge synthesis[68]. Literature users who are interested in the status of unpublished registered studies could search for a trial or research group website to determine the status of the trial.

Only four studies (all published) posted their results to clinicaltrials.gov. This rate is lower than previous literature on reporting results in clincialtrials.gov which showed that 22% of trials where it was mandatory to report results did so, and 10% of trials where it was not mandatory to report results[69]. Although Section 801 of the Food and Drug Administration Amendments Act (FDAAA) mandates posting results only for regulated drug and device

trials in the USA[14], and many IPV studies do not test drug or device interventions, the ICMJE highly recommends posting trial results[12]. The clinicaltrials.gov registry is available to members of the general public and to clinicians who do not have access to medical journals through an academic institution, including those in low and middle income countries (LMICs). The Declaration of Helsinki states that "Researchers have a duty to make publicly available the results of their research on human subjects... Negative and inconclusive as well as positive results should be published or otherwise made publicly available"[70]. Many funding agencies such as the United States National Institutes of Health (NIH) and Canadian Institutes of Health Research (CIHR) encourage making research results widely available. For example, CIHR's open access policy states "Only when research findings are widely available, enabling open scrutiny, will this evidence be translated into policies, technologies, health-related standards and practices, and new avenues of research that will benefit the health of Canadians and others"[71]. The clinicaltrials.gov results database and other similar registries are one tool to aid in making human research results widely available. The World Health Organization specifically states that key outcomes for all trials should be made publicly available within 12 months of study completion[13]. The vast majority of registered IPV studies, both published and unpublished, did not adhere to this recommendation.

The WHO's recommendations for trial registration also stipulate that the trial's registration number is to be included on all publications of registered studies[13]. The purpose of this recommendation is to allow evidence users to be able to easily link a publication with the trial registry record. This linkage allows evidence users to determine if there is a risk of reporting bias in a study. One type of reporting bias occurs when researchers collect data for several outcomes but only report those that make the intervention look good. Readers can go back to the clinicaltrials.gov entry to see what the original outcomes (and other protocol items) were and compare that to what was reported in the publication. This transparency is important to identify and/or prevent reporting bias. Nearly half of the published IPV studies did not follow the WHO's recommendation, which is consistent with previous literature[72]. Future IPV studies should report the trial registration number in all publications of registered studies, including related substudies.

Previous studies have reported very low publication rates in other fields. Ross et al.[73] randomly sampled 10% of all trials in a trials registry and found a publication rate of less than half. Similarly, with conference presentations, only 49% of poster and podium presentations in orthopaedic surgery were published 5 years after presentation at the American Academy of Orthopaedic Surgeons, and 64% after presentation at the Orthopaedic Trauma Association[74,75]. It is also possible that other factors affect publication rate. For example, Hakala et al[76] found that "stalled drugs" (i.e. drugs that reached late stage testing but were discontinued) had a publication rate of only 37% compared with licensed drugs that had a publication rate of 75%. It is unclear whether there is a real difference between IPV research and other fields with respect to publication rates, or if comparisons with other similar reviews are limited by differing methodologies.

A strength of this review is our exhaustive attempts to locate published studies using multiple techniques and multiple attempts to contact study investigators. Previous similar studies[56,60] rarely attempted to contact investigators. This study has a few limitations as well. It is possible that some of the eight studies for which we were unable to locate a publication were actually published. However, the systematic and thorough design of this review with comprehensive searching, double-checking, and contact with investigators attempts to minimize this possibility. Current recommendations for systematic reviews suggest searching Medline, Embase, and the Cochrane Register at minimum[77]. We exceeded this minimum recommendation in our search strategy, enhancing the strength of our conclusions. It is also a possibility that some of the eight studies that we were unable to locate were published in grey literature or journals that are not indexed in major databases, but our conclusions would remain the same, since such publications would not be easily accessible by a general user of medical literature.

We were unable to determine the association between industry funding and non-publication due to small numbers. Future research could investigate the impact of industry funding on IPV studies. We were unable to determine whether statistical significance (i.e. a positive versus negative trial) was related to non-publication because it is not possible to determine the statistical significance of unpublished studies, so we cannot make comparisons between published and unpublished studies. We did not examine the quality of the literature because the primary outcome was non-publication. It is not possible to evaluate the quality of studies that are not published. Additionally, we were able to gather only limited data on reasons why studies are not published in IPV-related research as it was outside the scope of this study, however it warrants further research. There may be reasons unique to IPV research why studies are not published. For example, members of the current study team experienced rejection of a publication when we attempted to publish in a specialized surgery journal because the editor did not believe that IPV is a surgeon's issue.

CONCLUSIONS

Approximately 1 in 4 registered IPV studies are not published following completion, which means that clinicians, researchers, and other evidence users should consider whether publication bias might affect their interpretation of the IPV literature. Publication bias in IPV literature could lead to an over-estimation of the effectiveness of IPV interventions which could mislead clinicians and policymakers. Additionally, the non-publication of completed IPV studies indicates that research funding is wasted. Further research is warranted to understand reasons for non-publication of IPV research and methods to improve publication rates. Investigators of completed studies as well as journal editors should be aware of the consequences of publication bias.

DECLARATIONS

Ethics approval and consent to participate – Not applicable
Consent for publication – Not applicable
Availability of data and material - The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests - The authors declare that they have no competing interests
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Authors' contributions – KM and MB designed the study. KM, KT, and PS collected data. All authors analysed and/or interpreted data. KM drafted the manuscript. All authors made significant revisions and approved the final manuscript.
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Chapter 4: Published intimate partner violence studies often differ from their trial registration record

Kim Madden , Kerry Tai, Zak Ali , Patricia Schneider, Mahip Singh, Michelle Ghert, Mohit Bhandari . Published Intimate Partner Violence Studies Often Differ from their Trial Registration Record.

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Published Intimate Partner Violence Studies Often Differ from their Trial Registration Record

Introduction: Registering study protocols in a trial registry is important for methodologic transparency and reducing selective reporting bias. The objective of this investigation was to determine whether published studies of intimate partner violence (IPV) that had been registered matched the registration record on key study design elements.

Methods: We systematically searched three trial registries to identify registered IPV studies and the published literature for the associated publication. Two authors independently determined for each study whether key study elements in the registry matched those in the published paper.

Results: We included 66 studies published between 2006 and 2017. Nearly half (29/66, 44%) were registered after study completion. Many (26/66, 39%) had discrepancies regarding the primary outcome, and nearly two-thirds (42/66, 64%) had discrepancies in secondary outcomes. Discrepancies in study design were less frequent (13/66, 20%), but large changes in sample size (26/66, 39%) and discrepancies in funding source (28/66, 42%) were frequently observed.

Conclusions: Trial registries are important tools for research transparency and identifying and preventing outcome switching and selective outcome reporting bias. Published IPV studies often differ from their records in trial registries. Researchers should pay close attention to the accuracy of trial registry records.

INTRODUCTION

Intimate partner violence (IPV) is a social issue that adversely affects women's health worldwide[46]. The most frequent forms of IPV include physical, sexual, and emotional abuse, and/or controlling behavior by an intimate partner[13]. Affecting 30% of women globally, it is the most frequent form of violence against women[78,79] and often results in several major health implications, including gastrointestinal distress and psychosomatic problems[80], post-traumatic stress disorder (PTSD), depression, and self-harm[49], musculoskeletal injuries[32], and death[50]. An estimated 38% of female homicides are committed by an intimate partner[79]. Given that IPV is a preventable health problem that continues to affect so many individuals, it deserves more attention. Fortunately, a growing number of studies have been conducted in clinical settings aimed at reducing the incidence and improving the identification and management of IPV.

As the number of IPV studies increases, it is becoming more important to ensure their methodological rigor, because evidence-based medicine relies on high-quality data to inform practice. Our previous systematic review demonstrated that publication bias may affect the interpretation of IPV literature as approximately 1 in 4 IPV studies are not published within 18 months following trial completion[81]. However, bias can also arise within a study; often many outcomes are measured, and the results can be presented in multiple ways when information is selectively disclosed. Selective outcome reporting bias is defined as the discriminate reporting of a subset of the original variables in the final publication, and it is often based on the significance and direction of the results[82]. Selective outcome reporting bias acts in addition to the selective publication of studies (i.e., publication bias) and can have widespread implications that may distort the body of evidence available, such as an increase in the prevalence of spurious results and the overestimation of treatment effects[82]. Ultimately, such bias limits the usefulness of evidence and undermines the development of evidence-based clinical practice guidelines.

To prevent the selective publication of outcomes that show positive or exciting results, all measured outcomes should be identified *a priori*[70]. To ensure sufficient reporting, substantial efforts have been made in guidelines for study reporting. The Consolidated Standards of Reporting Trials (CONSORT) Statement recommended that both primary and secondary outcomes be specified prior to the commencement of enrolment, and that any changes after the start of the study be clearly documented and justified[23]. Furthermore, the World Health Organization (WHO) subsequently published a list of 20 items that ought to be reported, at minimum, prior to the start of the trial[13]. One key approach to increasing the transparency of outcome reporting, and thereby reducing the risk of selective outcome reporting bias, is to ensure that the details of a study are documented in a publicly accessible trial registry.

The use of such registries has been embraced by several international regulatory organizations and publishing groups to promote transparency. Since 2004, the International Committee of Medical Journal Editors (ICMJE) has made trial registration a mandatory

prerequisite for publication in its member journals[83]. Even the Declaration of Helsinki, a guiding statement of ethical principles regarding human biomedical experimentation first developed in 1964 by the World Medical Association (WMA), has stated that trial registration is necessary. While the declaration was only recently amended to include the compulsory registration of all research studies involving human subjects "in a publicly accessible database before recruitment of the first subject"[70], prior versions contained preventative measures for selective outcome reporting, such as the stipulation that "[n]egative as well as positive results should be published or otherwise publicly available"[84]. More recently, alltrials.net has called for the transparent registration and reporting of all clinical trials, past, present, and future. The organization's website debunks common misconceptions about registering and reporting trials and calls for researchers to sign a petition to improve the reporting regulations. The culmination of these requirements has had a drastic effect on trial registration; ClinicalTrials.gov, the largest clinical trial registry, has seen a dramatic increase in the number of new registrations since the implementation of these rules[7]. The International Committee of Medical Journal Editors (ICJME) and alltrails.net try to raise awareness of trial registration and encourage researchers to register their trials. However, a perception exists that registering a study is not part of the scientific process but is merely an administrative hurdle, so the task is often not completed with careful attention[85].

Despite the efforts by journals and regulatory bodies, bias persists as selective outcome reporting has been recently reported in various medical specialties[10,86–88]. For example, previous studies have found that only 10% of surgical trials are prospectively registered[89], and over 50% of properly registered orthopaedic trials still contain inconsistent primary outcomes[90]. However, while the extent of selective outcome reporting has been examined in other areas of medicine, it has yet to be documented in IPV research. Therefore, an evaluation of selective reporting is necessary to further evaluate the quality of evidence in IPV studies.

In this study, we sought to describe the key methodological characteristics of registered IPV trials and compare the registry record to the published paper. To do so, we systematically reviewed completed IPV studies registered on three publicly available trial databases and assessed three attributes – the timing of study registration, any changes made to critical elements of the study design between the time of trial registration and the final publication, and any differences between the registered and reported funding source of the trial.

METHODS

Identification of Registry Records

We performed a search of the three largest English-language registries, clinicaltrials.gov, the Netherlands Trial Registry (NTR), and Current Controlled Trials (ISRCTN) on September 12, 2017 using the terms "spouse abuse" OR "domestic violence" OR "partner violence" OR "partner abuse". Two authors (KM and KT) independently reviewed all identified registry records for possibly eligible studies. We included studies of any design for which the date of completion was at least 18 months prior to the search date to allow

sufficient time for publication. We included all published results as long as they reported a primary outcome (i.e., not just feasibility), including preliminary findings. We excluded studies if they focused only on child abuse, or if the title, outcomes, interventions, and conditions did not mention intimate partner violence or a related term such as domestic violence. We had no date restrictions, although it was rare to register non-drug trials before 2006. Non-interventional studies are not required to be registered; however, investigators are permitted to register them for transparency. We chose to include non-interventional studies in this review for completeness.

Identification of Publications

Two authors independently attempted to locate each publication to match the trial record in AMED (Allied and Complementary Medicine Database), Embase, Global Health, Healthstar, Medline, and PsycInfo using the Ovid search interface, plus Google Scholar. We also attempted on up to three occasions to contact the Principal Investigator listed on the trial registry record for publications that could not be located and for publications for which we were unsure about their match to the registry record.

Data Collection

Author pairs (KM and either KT or ZA) independently abstracted every registry record and corresponding papers in duplicate for the following information: timing of registration, primary outcome, secondary/other outcomes, study design, sample size, and source of funding. Any discrepancies between the registry and paper were noted. Disagreements were settled by discussion toward consensus or by consulting a senior author (MB). We classified types of discrepancies for primary and secondary outcomes as follows: 1) no discrepancy; 2) registered outcome was omitted in the publication; 3) in the publication, used an unregistered outcome instead of the reported outcome; 4) primary outcome became a secondary outcome (or the reverse); and 5) the timing of outcome assessment differed.

Data Analysis

The primary analysis was descriptive. We present descriptive statistics using frequencies and percent, as appropriate. We also calculated percent change in sample size between the registry record and the publication.

RESULTS

Study Characteristics

Our search of clinicaltrials.gov and ISRCTN revealed 289 possibly eligible studies. After excluding ineligible studies (204) and those with no published paper (19), we included a total of 66 studies from clinicaltrials.gov and ISRCTN (**Appendix 1**). We found no relevant studies in NTR. A total of 43 eligible studies (65%) were from the United States, four from Canada, three each from Uganda, South Africa, China, and Cote d'Ivoire, and one each from the Netherlands, the United Kingdom, Egypt, Ecuador, Mexico, Austria, and

Belgium. Most studies were randomized controlled trials or cluster randomized controlled trials (55/66; 83%).

Timing of Registration

Only 24% (16/66) of studies were registered before the first participant was enrolled; 26% (17/66) were registered after the first participant was enrolled but before study completion. Nearly half (29/66, 44%) were registered after study completion. Four studies (6%) did not have enough information to assess the timing of registration. (**Table 2**).

Table 2: Registered Versus Published Major Study Elements

Comparison of Registered Versus Published Elements (N=35)		**n (%)**
Timing of Registration	Registered before the first patient was enrolled	16 (24.2)
	Registered after start of trial but before completion	17 (25.8)
	Registered after completion	29 (43.9)
	Unable to assess – not reported	4 (6.1)
Primary Outcome	Registered same as published	37 (56.1)
	Registered NOT the same as published	26 (39.4)
	Registered 1° outcome was omitted in the publication	*9 (13.6)*
	Reported an unregistered outcome	*6 (9.1)*
	Registered 1° outcome was published as a 2° outcome	*3 (4.5)*
	Published 1° outcome was registered as a 2° outcome	*4 (6.1)*
	The timing of assessment differed	*4 (6.1)*
	Unable to assess – not reported	3 (4.5)
Secondary Outcome(s)	Registered same as published	19 (28.8)
	Registered NOT the same as published	42 (63.6)
	Registered 2° outcome was omitted in the publication	*13 (19.7)*
	A new 2° outcome was introduced in the publication	*23 (34.8)*
	Reported an unregistered outcome	*5 (7.6)*
	The timing of assessment differed	*1 (1.5)*
	Unable to assess – not reported	5 (7.6)
Study Design	No major discrepancies in the design	51 (77.3)
	Discrepancies in the design	13 (19.7)
	Unable to assess – not reported	2 (3.0)
Sample Size	No major changes to the sample size (≤10% change)	36 (54.5)
	Sample size changed by >10%	26 (39.4)
	Decreased by >10%	*15 (22.7)*
	Increased by > 10%	*11 (16.7)*
	Unable to assess – not reported	4 (6.1)
Funding Source	No major discrepancies in the funding	30 (45.5)
	Discrepancies in the funding	28 (42.4)
	New industry funder	*1 (1.5)*
	New non-industry funder	*26 (39.4)*
	Registered non-industry funder not reported in paper	*1 (1.5)*
	Unable to assess – not reported	8 (12.1)

Discrepancies in Primary and Secondary Outcomes

More than half of the studies (37/66, 56.1%) had no discrepancies in primary outcomes between the registry and published paper, and just over one quarter had no discrepancies in secondary outcomes (19/66, 28.8%) (**Table 2**). Of the 39.4% of studies (26/66) with discrepancies in primary outcome, the most frequent discrepancy was that a registered primary outcome was omitted from the paper (9 papers). Other discrepancies included new primary outcomes being introduced in the paper, switching an unregistered outcome for the primary outcome, and switching primary and secondary outcomes. Of the 63.6% (42/66) of studies with secondary outcome discrepancies, the most frequent discrepancy was introducing an unregistered secondary outcome in the paper (23 papers). Insufficient information was available either in the publication or the registry to assess three studies (4.5%) for primary outcomes and 5 studies (7.6%) for secondary outcomes.

Discrepancies in Study Design

Over three quarters of studies (51/66, 77.3%) had no discrepancies in study design. For the 13 studies that had discrepancies (19.7%), seven studies (10.6%) differed on who would be blinded, and six studies (9.0%) differed on the description of the study type (e.g., factorial and cluster designs were described differently in the paper and in the registry). Two additional studies did not have enough information to assess discrepancies in study design (**Table 2**).

Discrepancies in Sample Size

Two-fifths of studies (26/66, 39.4%) had a published sample size that differed by at least 10% from the registered value (**Table 2**). Fifteen of these studies had a lower sample size, and eleven had a higher sample size compared to the registered value (**Table 2; Table 3**). The sample size discrepancies ranged from -99% to +852% (**Table 3**). None of these changes were explained in the papers or registries (e.g., with a power analysis or feasibility considerations). Insufficient information was available either in the publication or the registry to assess four studies (6.1%).

Table 3: Sample Size Discrepancies in Registered and Published IPV Studies

Study	Registered Sample Size	Published Sample Size	Change (%)	Direction of change (if >10%)
Abramsky 2016	800	1583	783 (97.9)	Increase
Ahmad 2009	280	314	34 (12.1)	Increase
Aupperle 2013	41	14	27 (65.9)	Decrease
Bair-Merritt 2006	500	499	1 (0.2)	--
Bass 2013	1000	405	595 (59.5)	Decrease
Becker 2010	1,521	1,521	0	--
Braithwaite 2014	104	104	0	--
Brothers 2016	43	43	0	--
Buller 2016	2580	2357	8.6	--
Calderon 2008	410	63	347 (84.6)	Decrease
Carter 2016	409	409	0	--
Choo 2015	40	40	0	--
Coker 2007	1,200	3,664	2,464 (205.3)	Increase
Creinin 2007	1,128	1,128	0	--
Doherty 2015	600	580	20 (3.3)	--
Feder 2011	48	48	0	--
George 2011	104	60	44 (42.3)	Decrease
Gilbert 2015	209	191	18 (8.6)	--
Gillum 2009	40	41	1 (2.5)	--
Gupta 2013	981	1,198	217 (22.1)	Increase
Gupta 2017	959	950	9 (0.9)	
Haberland 2015	500	698	198 (39.6)	Increase
Hossain 2014	601	616	15 (2.3)	--
Houry 2008	NR	2,134	Unable to assess	--
Houry 2006	569	569	0	--
Jaindl 2016	351,000	1,366	-349,634 (99.6)	Decrease
Jewkes 2008	2,801	2,776	25 (0.9)	--
Johnson 2011	60	70	10 (16.7)	Increase
Kiely 2010	1,750	1,044	706 (40.3)	Decrease
Klevens 2012	2,700	2,700	0	--
Kornfeld 2012	173	173	0	--
Kraanen 2013	100	52	48 (48.0)	Decrease
Levesque 2016	3,901	3,901	0	--
MacMillan 2009	5,681	6,743	1,062 (18.7)	Increase
MacMillan 2006	2,000	2,461	461 (23.1)	Increase
Meffert 2011	NR	22	Unable to assess	--
Miller 2016	3,687	3,687	0	--
Miller 2015	1,012	1,062	50	--
Miller 2012	2,006	2,006	0	--
Mittal 2017	120	55	65 (54.2)	Decrease
Murphy 2017	60	42	18 (30.0)	Decrease
Muzny 2014	213	163	50 (23.5)	Decrease

Myers 2015	50	40	10 (20.0)	Decrease
Padala 2006	20	20	0	--
Post 2015	72	72	0	--
Pronyk 2006	2,700	3,038	338 (12.5)	Increase
Rhodes 2016	600	600	0	--
Rothman 2016	36	NR	Unable to assess	--
Rothman 2008	630	266	364 (57.8)	Decrease
Saftlas 2013	305	306	1 (0.3)	--
Salazar 2014	743	743	0	--
Sharps 2013	239	239	0	--
Stover 2015	20	18	2 (10.0)	--
Stuart 2016	253	252	1 (0.3)	--
Sullivan 2013	216	82	134 (62.0)	Decrease
Taft 2016	135	135	0	--
Tiwari 2015	600	539	61 (10.2)	Decrease
Tiwari 2010a	200	200	0	--
Tiwari 2010b	250	200	50 (20.0)	Decrease
van Parys 2014	199	1894	1695 (851.8)	Increase
Waagman 2014	11,451	11,448	3 (0.03)	--
Weir 2008	530	530	0	--
Wolfe 2009	1,507	1,722	215 (14.3)	Increase
Zlotnick 2010	60	54	6 (10.0)	--

NR = Not Reported

Discrepancies in Funding Source

More than two in five studies (28/66, 42.4%) had at least one discrepancy in funding source. Twenty-six of the 28 studies with discrepancies involved a new non-industry funder in the paper that was not in the registry. In one case, a registered non-industry funder was not reported in the paper, and in one case a new industry funder was reported in the paper (**Table 2**). Insufficient information was available in either the publication or registry to assess eight studies (6%).

DISCUSSION

The IPV field relies on high-quality clinical studies to provide the best evidence for IPV treatment and prevention programs. However, a number of biases can cause a distortion of the body of evidence for a particular intervention. We evaluated a prevalent source of bias - selective outcome reporting bias - in this review. We found that key methodologic characteristics of these IPV studies differed between the trial registry record and the published paper. Nearly 40% of the included studies differed in primary outcomes, 60% in secondary outcomes, 40% in sample size (>10% discrepancy) and 40% in funding. Discrepancies in study design were relatively less frequent (20%). Additionally, fewer than one quarter of studies (24%) were registered before recruitment began. These findings are in line with previous research in other areas of medicine. Specifically, multiple studies have previously found discrepancies in outcomes, study design, and sample size[61,91–93].

Research plans change over time due to feasibility, scientific, administrative, and other reasons; this is expected and often acceptable. However, issues can arise when research plans are changed without adequate transparency and explanation. For example, selective outcome reporting has been identified as an issue in many areas of medicine because it tends to overestimate effects of interventions or associations[82]. Selective outcome reporting arises when outcome measures for interventions are only partially reported or outcomes are switched partway through a study; often the negative outcomes remain unreported, and the results seem more positive than they actually are. Authors may choose to report only statistically significant findings and leave out non-significant results if they are perceived to be uninteresting or do not fit the desired story, which makes the body of evidence have more statistically significant results than it should. Additionally, selective outcome reporting can lead to misleading systematic reviews of otherwise very high-quality evidence. If negative (i.e., non-statistically significant) results for a particular outcome are left out of a trial report, it will not be possible for systematic review authors to include that negative result in a systematic review, thereby skewing the pooled results to be systematically more positive[82,94]. Selective outcome reporting is of particular concern when conducting meta-analyses because important negative findings are omitted from pooled estimates, systematically inflating treatment and association effects[94].

Prospective trial registration (i.e., registering a trial before enrollment begins) is an important tool to combat selective outcome reporting. By prospectively registering a trial, investigators of the trial declare key elements of the study at the time of registration. This allows evidence users (readers of literature, clinicians, policy makers) to compare the (ideally) prospectively registered trial record to the published details and determine if any major changes were made that can affect the report of the results[95]. Another important tool to improve transparency of the research is to publish a study protocol, which contains a detailed description of the methodology planned for the study. While it is increasingly common to publish study protocols for trials, it is not required by journals and is not as frequent as it could be. A limitation of using prospective trial registration and publishing trial protocols is that most evidence users, especially busy clinicians, are unlikely to take the time to go to the registry record or published protocol to compare methodology. Therefore, it falls to authors to state explicitly any changes made to the elements of the study design and the reason for the change, and for peer reviewers and journal editors to be aware of the issue of selective outcome reporting and attempt to prevent it.

Discrepancies in sample size between the pre-determined value and the actual published value are important mainly because of the issues caused by stopping a trial early. Stopping a trial early (i.e., having fewer trial participants than originally planned) can happen for several reasons, including feasibility issues, futility, apparent harm of one treatment arm, and apparent benefits of one treatment arm. Each of these issues is important for different reasons and must be clearly explained in a published paper. Trials stopped early for benefit consistently show overestimated treatment effects[30,96]. Stopping a trial early for futility is also problematic because if the stopped trial had been completed as planned, it could contribute more to future meta-analyses on the topic[96]. Trials can also be stopped early by data monitoring committees or other regulatory bodies because of disproportionate harm to

one of the groups. Any harm resulting from an intervention is an important finding and should be clearly explained in any published report on the study. Trials with smaller than planned sample sizes due to feasibility issues should also be reported and clearly explained so other investigators are aware of the challenges and can plan future trials accordingly. These biases and quality issues are also likely to affect non-interventional studies in similar ways.

Although it may not be as obvious, trials with larger than planned sample sizes should also have clear explanations for the increase in sample size. The reasons for the increase in sample size could be methodologically important. For example, if the investigators discovered that the assumptions of the original sample size calculation were incorrect and re-calculated a new larger sample size during the trial, then that is an important change that needs to be reported and explained for transparency. An example of a trial in which this situation occurred was the FLOW trial[97]. The investigators originally planned to include 2280 patients in the trial, but discovered at a planned interim analysis that the event rate was lower than anticipated. This prompted a re-calculation of the sample size, and the investigators enrolled 2551 patients based on the revised estimate. The situation was clearly explained in the published paper so that readers could see the reason for the difference in sample sizes between what was originally planned and what was actually implemented in the final paper.

It is important to register and report sources of funding so that readers can evaluate the potential impact of conflicts of interest on the study results. Studies with certain sources of funding, particularly industry funding, have been shown to have more favorable conclusions and better efficacy results compared to non-industry funded studies[1]. While few IPV studies are industry-funded, source of funding is still important to register and report for transparency because non-profit organizations and associations may have a conflict of interest or a preference for a particular result as well. For example, if an IPV screening program developed by a non-profit organization is being tested in an intervention study, the developers of the program may have an interest in the program being shown to be successful. Discrepancies in registered and reported finding sources are therefore important even in the IPV field.

Strengths and Limitations

This study was strengthened by its systematic design and the use of two authors working independently in duplicate to minimize errors in data extraction. Our search was systematic and thorough and included three major trial registries and many of the major publication databases. We also contacted authors to obtain published papers. It is possible that IPV studies have been registered in other trial registries, but we believe we have captured a large proportion of the target studies and their published papers. In addition to trial registries, sometimes investigators also publish trial protocols to give a more detailed description of the trial methodology. We did not evaluate published protocols compared to published papers because they are relatively rare in the IPV field. Although, this could be an area of future research as protocol papers become more common in the IPV field. Ideally, we would have liked to provide an analysis of whether outcome switching leads to more

reporting of statistically significant findings, most of the primary outcomes in the included studies were descriptive (i.e., no associated statistical significance), and, therefore. this was impossible. The majority of the registered primary outcomes could have been analyzed in such a way that gave a statistical significance if they had been reported in the paper. This may indicate that the outcomes that were not reported were not statistically significant, meaning that the possibility of reporting bias is still a concern in IPV studies. It would be ideal to also assess discrepancies in eligibility criteria in this review; however, according to the World Health Organization, only key eligibility criteria are required to be registered. They are therefore not usually included in the registry except for sex/gender and approximate age (e.g., adults, children). These two items are unlikely to be discrepant for this review as we only included studies of adult IPV, and many IPV studies include only women. Finally, because non-interventional studies are not required to be registered, though strongly recommended for transparency purposes, those that are registered are likely a minority of such studies and thus may not be a representative or unbiased sample.

CONCLUSIONS

Published IPV studies often differ from their record in clinical trials registries. Clinical trial registries are important tools for transparency of research and to identify and prevent outcome switching and selective outcome reporting bias, as well as to identify major changes in study design. Investigators should pay close attention to the accuracy of their own clinical trial registry records. Literature users should be aware that selective outcome reporting may be an issue in the IPV literature and interpret results with caution if the published paper does not match the trial registry in important ways, or if no publicly available registry record exists. Journal editors and peer reviewers should also be aware of these issues and encourage authors to be more transparent in study reporting. Meta-analysis authors should be aware of how selective outcome reporting and major unexplained changes in study design can affect pooled results of treatment effects and associations. The results of this study show that the IPV literature is vulnerable to outcome switching and selective outcome reporting bias.

Chapter 5: A systematic review of quality of reporting in registered intimate partner violence studies: Where can we improve?

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Unpublished

ABSTRACT

Introduction: Quality of reporting is paramount when presenting clinical findings in published research to ensure that we have the highest quality of evidence on this important topic. Poorly reported clinical findings can result in a number of potential pitfalls, including confusion of the methodology used or selective reporting of study results. High quality reporting is a key aspect of research transparency. The CONSORT checklist is a tool that aims to standardize the way in which randomized trials are reported in the literature to ensure transparency. Other checklists for other study designs have also been developed for the same purpose, including STROBE for observational studies, PRISMA for systematic reviews, and others. The use of these reporting guidelines and checklists may aid in the appropriate reporting of research, which is of increased importance in highly complex fields like intimate partner violence.

Objectives: The primary objective of this systematic review is to assess the reporting quality of published IPV studies using the CONSORT and STROBE checklists.

Methods: We performed a systematic review of the three largest English-language study registries, clinicaltrials.gov, the Netherlands Trial Registry (NTR), and Current Controlled Trials (ISRCTN) for intimate partner violence related studies. Of the completed studies, we sought full text publications and used the CONSORT, CONSORT pilot extension, or STROBE checklist to assess the quality of reporting.

Results: Of the 42 randomized controlled trials, the mean score on the CONSORT checklist was 63.5% (23.5/37 items, SD 4.7 items). There were also 12 pilot trials in this systematic review, which scored a mean of 49.3% (19.7/40 items; SD 3.3 items) on the CONSORT extension for pilot trials. We included 12 observational studies which scored a mean of 56.1% (18.5/33 items; SD: 4.1 items).

Conclusions: In this systematic review of IPV studies we identified that there is an opportunity to improve reporting quality and transparency by encouraging adherence to reporting guidelines such as CONSORT and STROBE. Additionally, there should be a particular focus on ensuring that pilot studies report pilot-specific items, specifically rationale for a pilot design, criteria for feasibility success, and feasibility objectives. Journal editing staff, peer reviewers, and authors all have a responsibility to ensure commitment to high quality reporting to ensure transparency in IPV studies.

INTRODUCTION

Intimate partner violence (IPV) refers to behaviour by an intimate partner or ex-partner that causes physical, sexual or psychological harm, including physical aggression, sexual coercion, psychological abuse, and controlling behaviours[46]. IPV is a human rights violation that disproportionately affects women and is pervasive worldwide. More than one third of female homicides globally are perpetrated by an intimate partner[80], and is a prevalent source of non-fatal injury to women[36]. To address the need for health care professionals to assist victims of abuse, multiple IPV screening, identification, advocacy, and assistance programs have been developed and implemented across different clinical settings. A variety of research methodologies and outcome measures have been used to evaluate each program's effectiveness. The results of these studies are often inconclusive and frequently conflicting, resulting in a high level of clinical uncertainty and controversy regarding the merits of IPV screening and assistance programs[38–40]. Because of the clinical importance of IPV, controversies in the field, and the need for high quality evidence to resolve these controversies, it is important to focus on the quality of research including reporting quality.

Quality of reporting is paramount when presenting clinical findings in published research to ensure that we have the highest quality of evidence on this important topic. Poorly reported clinical findings can result in a number of potential pitfalls, including confusion of the methodology used or selective reporting of study results[23,98]. High quality reporting is a key aspect of research transparency. Studies that are inadequately reported may also score poorly on risk of bias assessments due to lack of clarity in the published manuscript[99]. The Consolidated Standards of Reporting (CONSORT) checklist is a tool that aims to standardize the way in which randomized trials are reported in the literature to ensure transparency[23]. Other checklists for other study designs have also been developed for the same purpose, including Strengthening Reporting of Observational Studies in Epidemiology (STROBE) for observational studies[100,101], Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) for systematic reviews[102,103], and others. The use of these reporting guidelines and checklists may aid in the appropriate reporting of research, which is of increased importance in fields that have controversies and complex methodological issues, such as intimate partner violence.

The primary objective of this systematic review is to assess the reporting quality of published IPV studies. Our overarching goal is to determine which aspects of reporting are commonly deficient so that we can make recommendations to improve the transparency and clarity of IPV research in the future.

METHODS

This is a secondary report of a previously published systematic review[81,104] (reported in Chapters 3 and 4). The methods are briefly described below.

Study Inclusion

We performed a search of the three largest English-language registries, clinicaltrials.gov, the Netherlands Trial Registry (NTR), and Current Controlled Trials (ISRCTN) on September 12, 2017 using the terms "spouse abuse" OR "domestic violence" OR "partner violence" OR "partner abuse". Two authors (KM and KT) independently reviewed all identified registry records for possibly eligible studies. We included studies of any design for which the date of completion was at least 18 months prior to the search date to allow sufficient time for publication. We included all published results as long as they reported a primary outcome (i.e., not just feasibility or baseline characteristics), including preliminary findings. We excluded studies if they focused only on child abuse, or if the title, outcomes, interventions, and conditions did not mention intimate partner violence or a related term such as domestic violence. We had no date restrictions, although it was rare to register non-drug trials before 2006. Non-interventional studies are not required to be registered; however, investigators are permitted to register them for transparency. We chose to include non-interventional studies in this review for completeness.

Identification of Publications

Two authors independently attempted to locate each publication to match the trial record in AMED (Allied and Complementary Medicine Database), Embase, Global Health, Healthstar, Medline, and PsycInfo using the Ovid search interface, plus Google Scholar. We also attempted on up to three occasions to contact the Principal Investigator listed on the trial registry record for publications that could not be located and for publications for which we were unsure about their match to the registry record.

Assessment of Reporting Completeness

Two authors independently completed the CONSORT checklist for randomized controlled trials (RCTs), or the STROBE checklist for observational studies, and conflicts were resolved through discussion or consulting a third reviewer. The CONSORT checklist includes 37 items addressing completeness of reporting of the title/abstract, background/objectives, design, participants, interventions, outcomes, randomization and blinding considerations, sample size and statistical considerations, recruitment and retention, and discussion items. For pilot RCTs, we used the CONSORT extension for pilot and feasibility studies which has language that is adapted for pilot studies including feasibility objectives/outcomes, feasibility success criteria, and rationale for a why pilot trial is needed[105,106]. The STROBE checklist is a 33 item list that is similar to CONSORT but tailored for observational studies. For example, randomization and blinding don't apply to observational studies so those items are removed, there is more emphasis on controlling confounding, and the wording is tailored to the three major types of observational studies: cohort studies, case-control studies, and cross-sectional studies. We gave 1 point for complete reporting of the item, 0.5 points for reporting with weaknesses, and 0 points for items that were not reported.

Data Analysis
The analyses are descriptive. We present frequency data (proportions and percentages) to describe the percentage of studies that fully reported, partially reported, and did not report each checklist item. We also report the mean and standard deviation of reported items for each study.

RESULTS

Literature Search Results
Our search of clinicaltrials.gov and ISRCTN revealed 289 possibly eligible studies. We found no relevant studies in NTR. 204 of these studies were ineligible because they were unrelated to IPV or they were still ongoing. We excluded 19 registered studies because they had no associated published paper. We included a total of 66 studies from clinicaltrials.gov and ISRCTN (**Appendix 1**). 42 studies (63.6%) were definitive randomized trials, 12 (18.2%) were pilot/feasibility trials, and 12 (18.2%) were observational studies. Of the 42 definitive randomized trials, 20 (47.6%) were 2 group parallel trials, 5 (11.9%) were 3 or 4 group parallel trials, 12 (28.6%) were cluster randomized trials, 1 (2.4%) was a parallel trial embedded in a mixed methods study, and 4 (9.5%) were unclear in their study design.

Reporting Completeness – Definitive Trials
For the 42 definitive randomized controlled trials, the mean number of correctly reported items was 23.5 (SD: 4.7; 95% CI: 22.0 to 25.0) out of 37 items (63.5%). The only item that was reported fully in each study was the scientific background. Other items that were generally well-reported included interventions, interpretation consistent with results, settings and locations, numbers randomized and receiving interventions, and limitations. The lowest scoring items in terms of reporting were changes in methods, changes in outcomes, harms, and where the protocol can be accessed (**Table 4**).

Table 4: Quality of Reporting for Definitive Randomized Trials (CONSORT)

CONSORT Item n=42 trials	Fully Reported n (%)	Partially Reported n (%)	Not Reported n (%)
Identified as randomized trial in title	30 (71.4)	2 (4.8)	10 (23.8)
Structured abstract	36 (85.7)	6 (14.3)	0 (0)
Scientific background and rationale	42 (100)	0 (0)	0 (0)
Specific objectives	37 (88.1)	1 (2.4)	4 (9.5)
Description of design	17 (40.5)	14 (33.3)	11 (26.2)
Changes to methods	4 (9.5)	0 (0)	38 (90.5)
Eligibility criteria	38 (90.5)	1 (2.4)	3 (7.1)
Settings and locations	38 (90.5)	3 (7.1)	1 (2.4)
Intervention description	40 (95.2)	1 (2.4)	1 (2.4)
Primary and secondary outcomes	38 (90.5)	1 (2.4)	3 (7.1)
Changes to outcomes or measurements	0 (0)	0 (0)	42 (100)
Rationale for sample size	19 (45.2)	2 (4.8)	21 (50.0)

Interim analysis and stopping guidelines	2 (4.8)	1 (2.4)	39 (92.9)
Methods to generate randomization sequence	22 (52.4)	1 (2.4)	19 (45.2)
Type of randomization	18 (42.9)	1 (2.4)	23 (54.8)
Mechanism to implement randomization	17 (40.5)	1 (2.4)	24 (57.1)
Who was responsible for randomization/enrollment steps	13 (31.0)	1 (2.4)	28 (66.7)
Who was blinded	12 (28.6)	4 (9.5)	26 (61.9)
Similarity of interventions	5 (11.9)	0 (0)	37 (88.1)
Statistical methods for primary and secondary outcomes	39 (92.9)	1 (2.4)	2 (4.8)
Additional analysis methods (subgroups, adjusted etc.)	30 (71.4)	0 (0)	12 (28.6)
Participant flow	39 (92.9)	1 (2.4)	22 (52.4)
Losses and exclusions	33 (78.6)	4 (9.5)	5 (11.9)
Recruitment and follow-up dates	35 (83.3)	1 (2.4)	6 (14.3)
Why trial stopped	5 (11.9)	3 (7.1)	34 (81.0)
Baseline demographics	37 (88.1)	1 (2.4)	4 (9.5)
Denominator for each outcome	30 (71.4)	4 (9.5)	8 (19.0)
Results and uncertainty (e.g. 95% CI) for each outcome	34 (81.0)	8 (19.0)	0 (0)
Present absolute and relative risks	8 (19.0)	2 (4.8)	32 (76.2)
Results of other analyses (subgroups, adjusted etc.)	36 (85.7)	0 (0)	6 (14.3)
Harms	5 (11.9)	2 (4.8)	35 (83.3)
Limitations	38 (90.5)	2 (4.8)	2 (4.8)
Generalizability	36 (85.7)	4 (9.5)	2 (4.8)
Interpretation consistent with results	41 (97.6)	1 (2.4)	0 (0)
Registration number	31 (73.8)	0 (0)	11 (26.2)
Where protocol can be accessed	5 (11.9)	0 (0)	37 (88.1)
Funders	38 (90.5)	0 (0)	4 (9.5)

Reporting Completeness – Pilot/Feasibility Trials

For the 12 pilot trials, the mean number of correctly reported items was 19.7 (SD: 3.3; 95% CI: 17.6 to 23.8) of 40 (49.3%). Two items were reported fully in each study: settings/locations, and interventions for each group. Other items that were generally well-reported included identifying the study as a pilot in the title and reporting limitations. The lowest scoring items were description of pilot design including allocation ratio, changes after trial commencement, criteria to judge to proceed to definitive trial, rationale for sample size, interim analyses and stopping guidelines, blinding, why the trials was stopped, harms, registration number, and where the protocol can be accessed (**Table 5**).

Table 5: Quality of Reporting for Pilot Randomized Trials (CONSORT)

CONSORT Item – Pilot extension n=12 pilot trials	**Fully Reported n (%)**	**Partially Reported n (%)**	**Not Reported n (%)**
Identified as pilot trial in title	10 (83.3)	2 (16.7)	0 (0)
Structured abstract	3 (25.0)	9 (75.0)	0 (0)
Scientific background and rationale for pilot	0 (0)	12 (100)	0 (0)
Specific objectives for pilot	4 (33.3)	5 (41.7)	3 (25.0)
Description of pilot design	5 (41.7)	0 (0)	7 (58.3)
Changes to methods	1 (8.3)	0 (0)	11 (91.7)

Eligibility criteria	10 (83.3)	0 (0)	2 (16.7)
Settings and locations	12 (100)	0 (0)	0 (0)
How participants identified and consented	10 (83.3)	0 (0)	2 (16.7)
Intervention description	12 (100)	0 (0)	0 (0)
Measurement of all outcomes	3 (25.0)	9 (75.0)	0 (0)
Changes to outcomes or measurements	0 (0)	0 (0)	12 (100)
Criteria for whether/how to proceed to definitive trial	0 (0)	0 (0)	12 (100)
Rationale for sample size	0 (0)	0 (0)	12 (100)
Interim analysis and stopping guidelines	0 (0)	0 (0)	12 (100)
Methods to generate randomization sequence	5 (41.7)	0 (0)	7 (58.3)
Type of randomization	3 (25.0)	1 (8.3)	8 (66.7)
Mechanism to implement randomization	4 (33.3)	1 (8.3)	7 (58.3)
Who was responsible for randomization/enrollment steps	1 (8.3)	3 (25.0)	8 (66.7)
Who was blinded	1 (8.3)	0 (0)	11 (91.2)
Similarity of interventions	0 (0)	0 (0)	12 (100)
Statistical methods	9 (75.0)	3 (25.0)	0 (0)
Participant flow	10 (83.3)	1 (8.3)	1 (8.3)
Losses and exclusions	10 (83.3)	1 (8.3)	1 (8.3)
Recruitment and follow-up dates	6 (50.0)	1 (8.3)	5 (41.7)
Why trial stopped	0 (0)	0 (0)	12 (100)
Baseline demographics	9 (75.0)	1 (8.3)	2 (16.7)
Denominator for each outcome	11 (91.2)	0 (0)	1 (8.3)
Results and uncertainty (e.g. 95% CI) for each outcome	6 (50.0)	6 (50.0)	0 (0)
Results of other analyses	8 (66.7)	1 (8.3)	3 (25.0)
Harms	2 (16.7)	0 (0)	10 (83.3)
Unintended consequences	1 (8.3)	0 (0)	11 (91.2)
Limitations and feasibility uncertainty	11 (91.2)	0 (0)	1 (8.3)
Generalizability	9 (75.0)	0 (0)	3 (25.0)
Interpretation consistent with results	10 (83.3)	2 (16.7)	0 (0)
Progression to definitive	4 (33.3)	1 (8.3)	7 (58.3)
Registration number	2 (16.7)	0 (0)	10 (83.3)
Where protocol can be accessed	1 (8.3)	0 (0)	11 (91.2)
Funders and role	0 (0)	11 (91.2)	1 (8.3)
Ethical approval	8 (66.7)	1 (8.3)	3 (25.0)

Reporting Completeness – Observational Studies

For the 12 observational studies, the mean number of correctly reported items was 18.5 (SD: 4.1; 95% CI: 15.9 to 21.1) of 33 (56.1%). The only item that was reported fully in each study was numbers of outcome and exposure events. Other items that were generally well-reported included summarizing the results in the discussion, discussing the limitations of the study, explaining the scientific background and rationale, and describing the statistical methods. The lowest scoring items in terms of reporting were indicating the design in the title, explaining how loss to follow-up was addressed, and reporting both relative and absolute risks (**Table 6**).

Table 6: Quality of Reporting for Observational Studies (STROBE)

STROBE Item n=12 observational studies	Fully Reported n (%)	Partially Reported n (%)	Not Reported n (%)	Not applicable n (%)
Study design in title	3 (25.0)	0 (0)	9 (75.0)	
Informative and balanced abstract	7 (58.3)	5 (41.7)	0 (0)	
Scientific background and rationale	9 (75.0)	3 (25.0)	0 (0)	
Specific objectives	8 (66.7)	4 (33.3)	0 (0)	
Key elements of study design early in paper	8 (66.7)	2 (16.7)	2 (16.7)	
Setting, locations, dates	7 (58.3)	4 (33.3)	1 (8.3)	
Eligibility criteria	7 (58.3)	2 (16.7)	3 (25.0)	
Define outcomes, exposures, predictors, confounders	7 (58.3)	5 (41.7)	0 (0)	
Sources of data an measurement methods	7 (58.3)	5 (41.7)	0 (0)	
Describe efforts to address bias	6 (50.0)	1 (8.3)	5 (41.7)	
Explain sample size	2 (16.7)	1 (8.3)	9 (75.0)	
How quantitative variables were handled	7 (58.3)	5 (41.7)	0 (0)	
Statistical methods	9 (75.0)	3 (25.0)	0 (0)	
Methods for subgroups and interactions	5 (41.7)	0 (0)	7 (58.3)	
How missing data addressed	0 (0)	1 (8.3)	11 (91.7)	
How loss to follow-up addressed	0 (0)	0 (0)	6 (50.0)	6 (50.0)
Sensitivity analysis methods	0 (0)	0 (0)	12 (100)	
Numbers of participants at each stage	5 (41.7)	7 (58.3)	0 (0)	
Reasons for non-participation	3 (25.0)	2 (16.7)	7 (58.3)	
Flow diagram	2 (16.7)	1 (8.3)	9 (75.0)	
Participant characteristics	10	0 (0)	2 (16.7)	
Numbers of participants with missing data	1 (8.3)	1 (8.3)	10 (83.3)	
Summarize follow-up time	6 (50.0)	0 (0)	0 (0)	6 (50.0)
Report numbers of outcome/exposure events	12 (100)	0 (0)	0 (0)	
Unadjusted estimates and precision	8 (66.7)	2 (16.7)	2 (16.7)	
Category boundaries for continuous variables that were categorized	5 (41.7)	0 (0)	0 (0)	7 (58.3)
Relative risk and absolute risk	0 (0)	0 (0)	12 (100.0)	
Other analyses	8 (66.7)	1 (8.3)	3 (25.0)	
Summarize key results	11 (91.7)	1 (8.3)	0 (0)	
Limitations	11 (91.7)	0 (0)	1 (8.3)	
Cautious overall interpretation	8 (66.7)	3 (25.0)	1 (8.3)	
Generalizability	3 (25.0)	7 (58.3)	2 (16.7)	
Source of funding and role of funders	3 (25.0)	4 (33.3)	5 (41.7)	

DISCUSSION

In this systematic review of 66 IPV studies, we found that reporting guidelines were followed well in some cases but not very well in other cases. Of the 42 randomized controlled trials, the mean score on the CONSORT checklist[23] was 63.5% (23.5/37 items, SD 4.7 items). There were also 12 pilot trials in this systematic review, which scored a mean of 49.3% (19.7/40 items; SD 3.3 items) on the CONSORT extension for pilot trials[106]. We included 12 observational studies which scored a mean of 56.1% (18.5/33 items; SD: 4.1 items). In each of the three study types, limitations were well-explained. In interventional studies, the settings/locations, and interventions for each group were well-described in most trials. The scientific background was also done well in definitive trials and observational studies. However, this section did not score highly in pilot trials because the pilot extension also requires an explanation for why a pilot is needed, and that was generally not well-reported. The items that were generally poorly reported were changes that occurred after study commencement, where the protocol can be accessed, and harms of interventions for interventional studies. In addition, the pilot-specific items were generally not well-reported, including rationale for a pilot design, criteria for feasibility success, and feasibility objectives.

There have been numerous previous studies that have assessed adherence to the CONSORT statement and checklist, including acupuncture[107], prosthodontics[108], nursing[109], cardiology[110], and many others. These studies consistently demonstrate suboptimal reporting in nearly every field, but we are unaware of any similar studies in the IPV field. There have also been studies of adherence to STROBE, including general medicine[111], occupational medicine[112], influenza[113] and others which show a similar trend of suboptimal reporting. There have not been many studies to date assessing the quality of pilot trial reporting using the CONSORT pilot extension. However, a study of pilot cluster RCTs showed similar results to the current study, particularly that there is a lack of emphasis on feasibility-specific items[114]. Additionally, previous studies focusing on harms of interventions have found similar results, particularly that harms are poorly reported in published trials[115,116].

These findings that study reporting is generally poor, which is consistent across specialties and study designs, suggests that further emphasis needs to be placed on adherence to reporting guidelines. Even though many journals and the International Committee of Medical Journal Editors (ICMJE) endorse reporting guidelines, authors still do not adhere to the guidelines. Poor reporting is still an issue even when authors are required to complete and submit a CONSORT checklist (or other checklist depending on study design) with their manuscript[117]. It has been suggested that editorial assistants should be responsible to ensuring compliance with reporting guidelines[117] and we suggest that peer reviewers should be trained to ensure that all items are reported. Another study showed that CONSORT adherence was improved when a dental journal required the use of specific subheadings that follow CONSORT requirements[118]. This could be implemented in other specialties to enhance reporting quality, but would require individual journals to agree to the change, and it would require subheadings to be tailored for other study designs.

Although we followed a systematic process to complete this review, with duplicate reviewers and attempts to limit errors, there are some limitations. We focused only on studies that were registered in clinicaltrials.gov or ISRCTN and were subsequently published. Studies that were not registered, particularly non-randomized studies, were likely left out and may be different than included studies in important ways. Additionally, some items are subjective to rate; particularly the ones that could be judged "partially reported". We attempted to limit this effect by requiring data extractors to train with the lead author prior to completing data extraction assignments, and having two independent assessors.

Conclusion

In this systematic review of IPV studies we identified that there is an opportunity to improve reporting quality and transparency by encouraging adherence to reporting guidelines such as CONSORT and STROBE. Additionally, there should be a particular focus on ensuring that pilot studies report pilot-specific items, specifically rationale for a pilot design, criteria for feasibility success, and feasibility objectives. Journal editing staff, peer reviewers, and authors all have a responsibility to ensure commitment to high quality reporting to ensure transparency in IPV studies.

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Declaration of Conflicting Interests

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Chapter 6: Knowledge dissemination of intimate partner violence intervention studies measured using alternative metrics

Kim Madden, Nathan Evaniew, Taryn Scott, Elaina Domazetoska, Pritnek Dosanjh, Chuan Silvia Li, Lehana Thabane, Mohit Bhandari, Sheila Sprague. Knowledge Dissemination of Intimate Partner Violence Intervention Studies Measured Using Alternative Metrics: Results from a Scoping Review.

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Knowledge Dissemination of Intimate Partner Violence Intervention Studies Measured Using Alternative Metrics: Results From a Scoping Review

Alternative metrics measure the number of online mentions that an academic paper receives, including mentions in social media and online news outlets. It is important to monitor and measure dispersion of intimate partner violence (IPV) victim intervention research so that we can improve our knowledge translation and exchange (KTE) processes improving utilization of study findings. The objective of this study is to describe the dissemination of published IPV victim intervention studies and to explore which study characteristics are associated with a greater number of alternative metric mentions and conventional citations. As part of a larger scoping review, we conducted a literature search to identify IPV intervention studies. Outcomes included number of alternative metric mentions and conventional citations. Fifty-nine studies were included in this study. The median number of alternative metric mentions was six, and the median number of conventional citations was two. Forty-one percent of the studies (24/59) had no alternative metric mentions, and 27% (16/59) had no conventional citations. Longer time since publication was significantly associated with a greater number of mentions and citations, as were systematic reviews and randomized controlled trial designs. The majority of IPV studies receive little to no online attention or citations in academic journals, indicating a need for the field to focus on implementing strong knowledge dissemination plans. The papers receiving the most alternative metric mentions and conventional citations were also the more rigorous study designs, indicating a need to focus on study quality. We recommend using alternative metrics in conjunction with conventional metrics to evaluate the full dissemination of IPV research.

INTRODUCTION

As with many fields, the volume of intimate partner violence (IPV) intervention literature is steadily growing. With that growth comes a need to effectively disseminate the findings of these IPV intervention studies to maximize uptake and use of that information by clinicians, researchers, advocacy organizations, policymakers, and other stakeholders. Despite the growing number of IPV intervention studies, few clinical settings have policies guiding management of patients who have experienced IPV[119]. This could indicate that knowledge translation and exchange (KTE) strategies are lacking in IPV victim intervention research. It is important to monitor and measure impact of IPV victim intervention research so that we can improve our KTE processes, thereby improving utilization of study findings, improving efficiency of research funding, and in the long term, improving the lives of women who have experienced IPV.

One commonly used measure of knowledge dissemination is the number of citations that a published paper receives. This measure is limited as there can be a long delay between publication of a paper and that paper being cited by another paper because of the time lag between article submission and publication[120]. In addition, conventional citation metrics are typically determined solely through academic mentions (e.g., peer-reviewed journal citations) and does not capture the growing role of non-academic means of knowledge dissemination including social media (e.g., Facebook, Twitter, Reddit), scientific and lay media (e.g., online newspapers and science blogs), and online forums[121] (e.g., Mendeley, PubPeer, Publons). Alternative metrics, which measure the number of online mentions that an academic paper receives and represent rapidly growing and novel approach to measure how widely an article is disseminated[121,122].

KTE is also known as knowledge translation, knowledge to action, knowledge transfer, implementation science, innovation diffusion, and many more terms[123]. A widely used description of KTE is a cyclical process that starts with knowledge creation, moves to identifying the problem, adapting knowledge to local contexts, assessing barriers to knowledge use, designing and implementing interventions based on the knowledge, monitoring knowledge use, evaluating the intervention, and sustaining the interventions, and then cycles back to creation of more knowledge[124]. It is well-documented that many researchers stop at knowledge creation and their innovations fail to translate to useful policies or practices[125]. Some granting agencies such as the Canadian Institutes of Health Research[126] emphasize the need to have a KTE plan that goes beyond traditional dissemination (i.e., publishing in an academic journal and/or presenting at conferences), and they have begun to require a written plan for how the knowledge will be disseminated to maximize the impact of their funding. KTE plans will vary greatly for different studies or bodies of literature. An example KTE plan for IPV victim intervention studies could include publication in a high-impact journal, presentation at a relevant conference, a press release, meeting with stakeholder and policy groups to develop a plan of implementation, educating clinicians on victim interventions, and involving patients and health care advocacy groups. The plan should also involve a process for evaluating knowledge dissemination/uptake/usage and sustaining a change in practice[124].

Some previous research has been completed on KTE in the IPV field including the importance of research networks[127] and education of health care professionals and other stakeholders[128]. However, there have been no studies assessing how IPV victim intervention research is disseminated online and cited in peer-reviewed journals, and no studies focusing on alternative metrics in the IPV field.

Objectives

The primary objective of this study is to describe the dissemination of published IPV intervention studies using alternative metrics compared with conventional citation metrics. As a secondary objective, we aim to explore which study characteristics are associated with a greater number of alternative metric mentions and number of conventional citations.

Method

This review of the literature is a sub-study of a recent scoping review that included all published studies investigating IPV victim interventions in health care settings. The full methodology of the scoping review is reported elsewhere[129].

Literature Search

As part of the scoping review, we developed a comprehensive search strategy, in consultation with a health sciences librarian, to search the following electronic databases: MEDLINE, Embase, Cumulative Index of Nursing and Allied Health Literature (CINAHL), Cochrane Database of Systematic Reviews (CDSR), Proquest, and Web of Science. We performed the literature searches in July 2015 and did not use any language or date restrictions. Reviewers screened articles for eligibility in duplicate using Distiller SR software (systematic-review.ca).

Eligibility Criteria

For the current study, we included studies that met the following inclusion criteria: (a) published in English, (b) focus on IPV, (c) evaluate the effectiveness of an IPV program (i.e., identification, assistance, or health care provider education programs focusing on female victims) in a health care setting, (d) the population is adult participants, and (e) published between 2011 and 2015. We only included studies published in 2011 and after because alternative metric data were not available prior to 2011.

Primary Outcome: Alternative Metric Mentions

We collected alternative metric data from Altmetric LLP (http://www.altmetric.com/), which is a leading alternative metric company in academic research[122,130]. The Altmetric index is a weighted score given to individual journal articles based on a proprietary algorithm combining online mentions of an academic article, including social media, online science and mainstream news, blogs, and other academic and lay online sources. The Altmetric index is increasingly being used by academic journals to summarize and highlight non-conventional citations of academic publications[122]. We used Altmetric's

package for R (rAltmetric; freely available) to retrieve all alternative metric mentions including overall number of alternative metric mentions and number of alternative metric mentions per source.

Secondary Outcome: Conventional Metrics

We collected number of conventional citations (i.e., citations in academic journals) using Thomson Reuters Web of Science citation reports for each study. To avoid entry errors, this was completed in duplicate.

Study, Journal, and Author Characteristics

We collected the following for each included article: month and year of publication, study design, study topic (IPV assistance, IPV education, or IPV identification), journal impact factor (IF), and h-index of first and last authors. We defined the study topics as follows: (a) IPV identification studies (also known as screening studies) aim to screen or identify victims of IPV but not provide clinical intervention, (b) IPV assistance programs pair identification of victims with an intervention that aims to improve health or social outcomes (e.g., referral to services, counseling, etc.), and (c) IPV education studies evaluate an education intervention for health care professionals to assist victims of IPV[129]. The h-index is a widely used measure of an author's impact defined as having *h* publications cited *h* times or more[131]. For example, an author with an h-index of 15 would have 15 publications cited at least 15 times. Impact factor, however, is a journal-level metric, which measures the average number of citations that a journal has over a set period of time (e.g., past 5 years for a 5-year IF)[132]. We collected h-indices using Thomson Reuters Web of Science. We obtained journal impact factors from Journal Citation Reports in the Thomson Reuters Institute for Scientific Information (ISI) Web of Knowledge. To avoid entry errors, we completed data extraction in duplicate.

Statistical Analysis

We present study characteristics as counts with percentages for frequency data, and as medians with first and third quartiles for continuous data. To explore associations between study characteristics and number of alternative metric mentions and conventional citations, we conducted multivariable negative binomial regression analyses. We used negative binomial regression because the dependent variables are discrete count data. Before the study began, we hypothesized that time since publication (in months), journal impact factor, study design (randomized controlled trial [RCT] vs. systematic review vs. other designs), number of conventional citations, and h-index of the last author would be significantly associated with having more alternative metric mentions. Similarly, we hypothesized that time since publication (in months), journal impact factor, study design (RCT vs. systematic review vs. other designs), number of alternative metric mentions, and h-index of the last author would be significantly associated with having more conventional citations. We based these hypotheses on a previous study of alternative metrics in orthopedic surgery trials[120]. We also conducted a sensitivity analysis removing one predictor from the model if there was evidence of multicollinearity. We present regression analyses with the β

coefficient, 95% confidence interval (95% CI), and *p* value for each characteristic. There was very little missing information so we did not impute for missing data. All analyses were conducted using SPSS Version 23.

RESULTS

Study Characteristics

Of 187 studies from the scoping review considered for this study, we excluded 126 because they were published before 2011 and we excluded two because they focus on perpetrator interventions as opposed to victim interventions. Therefore, 59 studies met our eligibility criteria and were included in this study (**Figure 4**). We included 22 (37%) IPV assistance program studies, 19 (32%) IPV education studies, and 18 (31%) IPV identification studies. The most common study designs were qualitative/mixed methods (14/59, 24%), RCTs (12/59, 20%), and pre-test/post-test studies (11/50, 19%). The median journal impact factor was 1.84 (quartiles: 0.95-2.89). The median h-index of the last author (nine; quartiles: 3-17) was higher than that of the first author (four; quartiles: 2-10). Full study characteristics can be found in **Table 7**.

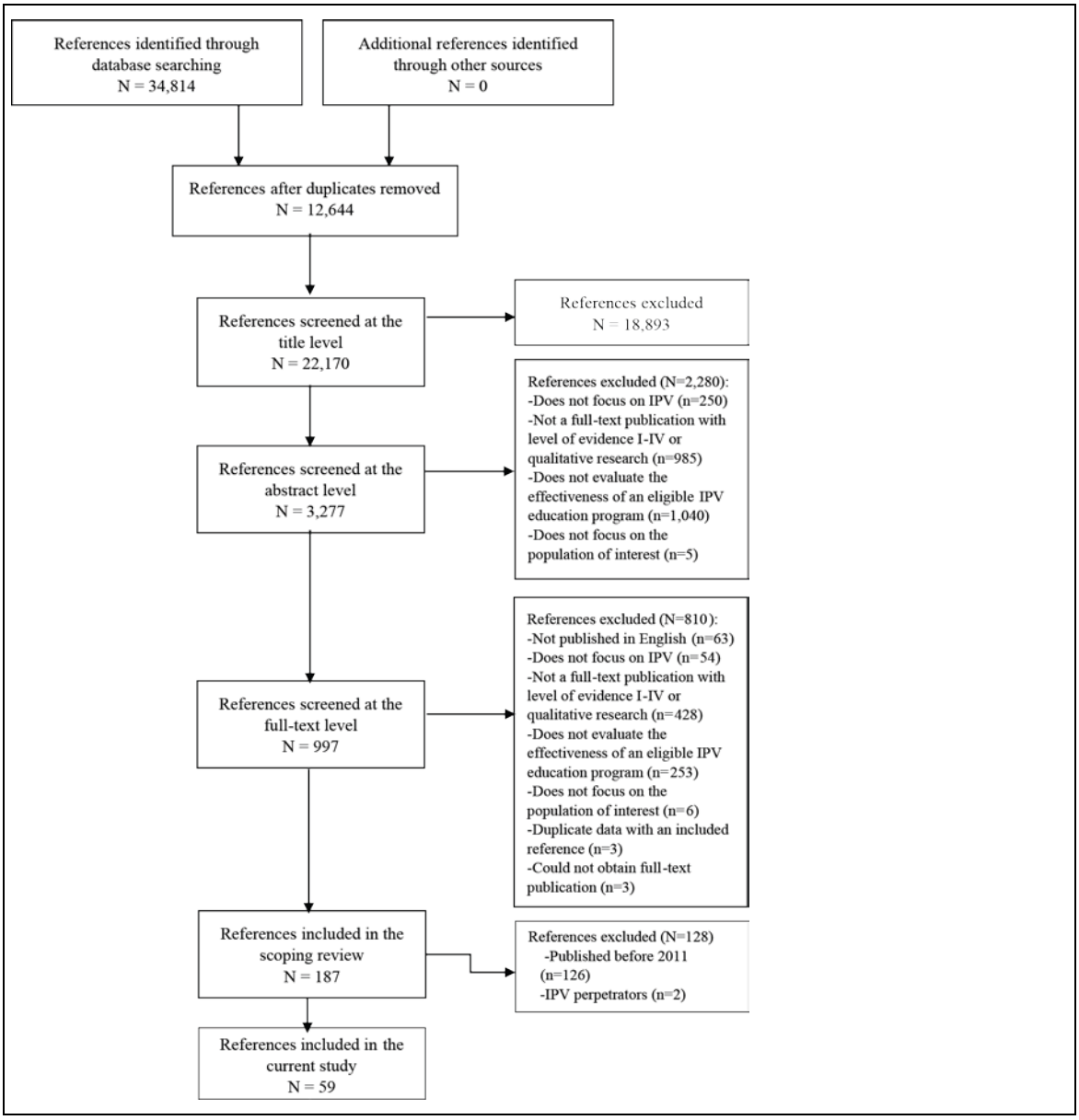

Figure 4. Study flow diagram.
Note. IPV = intimate partner violence.

Table 7. Characteristics of Included Studies.

Study Characteristics	**Number of Studies (%)**
Year	
2011	14 (23.7)
2012	10 (16.9)
2013	10 (16.9)
2014	15 (25.4)
2015	10 (16.9)
Study design	
Randomized controlled trial	12 (20.3)
Systematic review	7 (11.9)
Pre-test/post-test or quasi-experimental	11 (18.6)
Cohort	6 (10.2)
Cross-sectional	7 (11.9)
Qualitative or mixed methods	14 (23.7)
Other	2 (3.4)
Study topic	
IPV assistance program	22 (37.3)
IPV education program	19 (32.2)
IPV identification program	18 (30.5)
Journal and Author Characteristics	Median (First and Third Quartiles)
Journal impact factor	1.84 (0.95-2.89)
H-index first author	4 (2-10)
H-index last author	9 (3-17)
Outcomes	Median (First and Third Quartiles)
Conventional citations	2 (0-9)
Alternative metric mentions	6 (0-23)

Note. IPV = intimate partner violence.

Number of Citations

The 59 included studies had a total of 544 conventional citations and 1,108 alternative metric mentions (**Figure 5**). The median number of alternative metric mentions was nine (quartiles: 0-23), and the median number of conventional citations was two (quartiles: 0-9). Twenty-four of 59 studies (41%) had no alternative metric mentions, and 16 of 59 studies (27%) had no conventional citations. Alternative metric mentions were primarily driven by Mendeley (63%) and Twitter (33%) with Facebook, news outlets, and blogs making up the majority of the remaining sources (**Figure 6**).

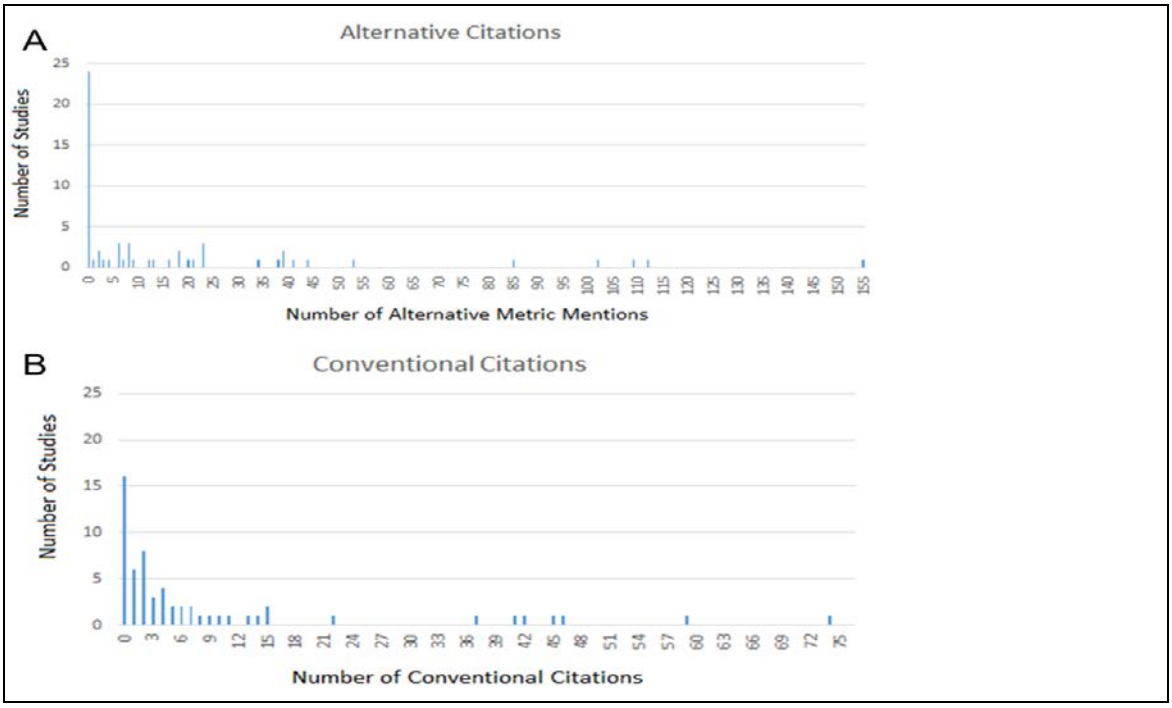

Figure 5**.** Alternative (A) and conventional (B) citations frequency distributions.

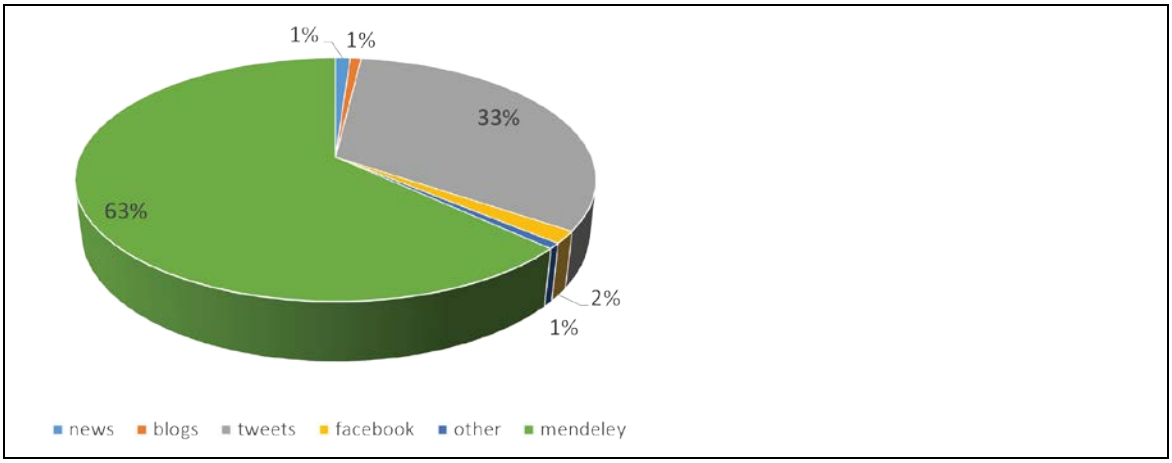

Figure 6. Proportion of alternative metric mentions by source.
Note. May not add to 100% due to rounding error.

Factors Associated With Alternative Metric Mentions

In the multivariable analysis, systematic reviews (β = 1.91, 95% CI = [0.90, 2.92]) and RCTs (β = 1.32, 95% CI = [0.26, 2.38]) had a significantly higher number of alternative metric mentions, as did papers published a longer time ago (β = 0.03, 95% CI = [0.01, 0.05]; **Table 8**). However, impact factor, conventional citations, and h-index of the last author were not significantly associated (**Table 8**). Because of high correlation between

two of our study characteristics (h-index and impact factor), we conducted a sensitivity analysis removing h-index of the last author, but it did not affect any of the model parameters greatly so we decided to include both h-index and impact factor in the model.

Table 8. Multivariable Negative Binomial Regression of Study Characteristics on Number of Alternative Metric Mentions.

Characteristic	**β Coefficient**	**95% CI**	***p* Value**
Time since publication (months)	0.03	[0.01, 0.05]	.015
Impact factor	0.06	[–0.01, 0.12]	.094
Study design			
Systematic review	1.91	[0.90, 2.92]	<.001
RCT	1.32	[.26, 2.38]	.015
Other	REF		
Conventional citations	–0.03	[–0.08, 0.03]	.327
H-index last author	0.01	[–0.03, 0.04]	.602

Note. Omnibus test: $p < .001$. CI = confidence interval; RCT = randomized controlled trial; REF = reference category.

Factors Associated With Conventional Citations

Similar to the alternative metric mentions analysis, systematic reviews (β = 1.91, 95% CI = [0.80, 3.02]) and RCTs (β = 1.17, 95% CI = [0.13, 2.22]) had a significantly higher number of alternative metric mentions, as did papers published a longer time ago (β = 0.05, 95% CI = [0.03, 0.08]; **Table 9**). However, impact factor, alternative metric mentions, and h-index of the last author were not significantly associated (**Table 9**).

Table 9. Multivariable Negative Binomial Regression of Study Characteristics on Number of Conventional Citations.

Characteristic	**β Coefficient**	**95% CI**	***p* Value**
Time since publication (months)	0.05	[0.03, 0.08]	<.001
Impact factor	0.04	[–0.01, 0.09]	.104
Study design			
Systematic review	1.91	[0.80, 3.02]	.001
RCT	1.17	[0.13, 2.22]	.028
Other	REF		
Alternative metric mentions	0.01	[–0.01, 0.02]	.326
H-index last author	–0.03	[–0.7, 0.01]	.069

Note. Omnibus test: $p < .001$. CI = confidence interval; RCT = randomized controlled trial; REF = reference category.

DISCUSSION

In this study, we found that increasingly rigorous study designs (systematic reviews and RCTs) received more alternative metric mentions and conventional citations than other

study designs. In addition, longer time since publication was also associated with studies having more alternative metric mentions and conventional citations, which is plausible because it takes time for citations to build up. IPV intervention studies have more alternative metric mentions than conventional citations, indicating the growing importance of online news and social media in distributing academic findings. Despite this, a large proportion of IPV intervention studies have no alternative and/or conventional citations, stressing the importance of having a good KTE plan and focusing on improving the quality of IPV literature.

Traditionally, a researcher's impact has been evaluated based largely on the quality of the journals in which he or she published (i.e., the journal's impact factor). However, there have been criticisms of using a journal-level metric such as impact factor to determine an individual paper's impact[133]. Number of citations in peer-reviewed journals has also been used to measure an individual paper's impact, but this ignores the impact that a paper has on the community and potential stakeholders[134]. It has been suggested that alternative metrics be used in addition to conventional metrics to give a more complete picture of a paper's impact[120,133,134]. However, some academics disagree, believing that alternative metrics contribute to the problem of quantity over quality[135]. The results of the current study and Evaniew's[120] study show that alternative metric mentions are associated with higher level of evidence studies and lower risk of bias, respectively, indicating that alternative metrics are valid indicators of higher quality studies. There is even some evidence that alternative metric mentions can predict future conventional citations, which is important because they have the advantage of accumulating faster than conventional citations[120,136]. We therefore recommend using alternative metrics in addition to conventional metrics to evaluate impact of research, which is in line with the San Francisco Declaration on Research Assessment (DORA) initiative to standardize how research impact is assessed[137].

Few previous studies have described patterns of alternative metric mentions among academic studies. Evaniew et al.[120] explored the impact of orthopedic surgery trials and found a similar pattern. However, in our study, we found a higher median number of alternative metric mentions compared with that of orthopedic trials (six vs. two, respectively). The median number of conventional citations was more similar (two vs. three, respectively). It is arguable that IPV studies are very relevant and interesting to the public compared with many orthopedic papers in which interest may be more specialized to clinicians. This could account for the large difference in alternative metric mentions. Alternatively, this difference could be due to varying patterns of online dissemination between fields. Dinsmore et al.[134] described the number of Twitter mentions of Wellcome Trust-funded papers published in *PLOS* and found that there are a large number of studies with no Twitter mentions and very few that have a high number of Twitter mentions. This is similar to what we found in the current study. It is concerning that such a large percentage of the IPV literature receives no online mentions and/or no conventional citations. It is possible that some of the literature is of insufficient quality to be of use in practice or policy. For example, Sprague et al.[138] found that many IPV studies use inappropriate or sub-

optimal outcome measures when evaluating IPV interventions. It is also a possibility that high-quality studies are not being promoted as widely as they could because of insufficient emphasis on KTE plans. The relationship between study quality and alternative citation patterns is an area for future investigation and could indicate that the IPV field needs to focus on generating high-quality literature. We also hypothesize that public interest in the topic or the "virality" (as with viral videos and online memes) of the content matter can drive online activity, which is another area for future exploration.

We hypothesized that impact factor would be significantly associated with number of alternative metric mentions, but the association was not significant in the multivariable analysis. We observed that almost all of the papers published in low impact factor journals that received a large number of alternative metric mentions were RCTs or systematic reviews. This observation warrants further investigation, but we hypothesize that study design is especially important in the IPV field, because IPV intervention RCT findings tend to be controversial and lead to conflicting guideline recommendations[38,39,53]. It is also possible that we were unable to find a significant association due to lack of power, given that our multivariable analysis was exploratory in nature.

Strengths of this study include a systematic and thorough search of the literature and that our findings converge with previous research in other fields. Our study is limited to studies published in English only and may not be applicable to studies published in other languages. Our study is also limited in that neither conventional citation metrics nor alternative metric mentions account for type of attention. It is possible that certain studies gain more attention not because of high quality, but because of controversial findings, leading to negative media attention. Our findings are limited to online citations indexed by Altmetric LLP, which is linked to a paper's DOI or PMID. It could be possible that Altmetric's algorithm could have missed some online citations, but Altmetric is currently the industry leader in providing online article-level metrics to high-impact journals[122,130]. In addition, a larger number of included studies would be ideal to better explore factors associated with number of citations and mentions.

The majority of IPV studies receive very little to no online attention, indicating a need for the field to focus on implementing strong KTE plans to maximize research dissemination. We also recommend using alternative metrics in conjunction with conventional metrics to evaluate the full dissemination of IPV research to academic and non-academic stakeholders. Future research should focus on methods of disseminating IPV studies while maintaining high standards of methodological quality to improve efficiency of IPV research with the aim of improving life for as many women who have experienced IPV as possible.

Author Contributions

K.M. and N.E. designed the study. S.S., L.T., and M.B. refined the study design. K.M., E.D., T.S., C.S.L., and P.D. collected study data. K.M. drafted the manuscript, and all authors critically revised the manuscript. All authors reviewed and approved the manuscript.

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PART C: PUTTING TRANSPARENCY PRINCIPLES INTO ACTION

Chapter 7: Prospective evaluation of intimate partner violence in surgical injury clinics (PRAISE-2): Feasibility of Recruitment and Baseline Characteristics of the Participants

Kim Madden, Saraniya Pathmananthan, Sheila Sprague, Brad Petrisor, Diane Heels-Ansdell, Michelle Ghert, Elisa AM Hackenberg, Lehana Thabane, Mohit Bhandari; PRAISE-2 Investigators. Prospective Abuse and Intimate Partner Violence Surgical Evaluation (PRAISE-2 Pilot): Baseline Characteristics and Feasibility of a Pilot Prospective Cohort Study

Unpublished

Prospective Abuse and Intimate Partner Violence Surgical Evaluation (PRAISE-2 Pilot): Feasibility of Recruitment and Baseline Characteristics of the Participants

Background: Violence against women is an emerging topic of interest in orthopaedic studies that has been globally recognized as a public health problem. A previous study, PRAISE, evaluated the cross-sectional prevalence of intimate partner violence (IPV) in orthopaedics, but longitudinal information on IPV in orthopaedics is lacking. Previous studies in other fields have described potential health problems associated with IPV, however, information is lacking on orthopaedic-specific outcomes. We believe that orthopaedic surgeons would be more likely to ask their patients about IPV and take the time to educate themselves about IPV if we have better information about how IPV affects outcomes that are of interest to orthopaedic surgeons.

Objectives: We aim to provide valuable feasibility information on processes to recruit and retain orthopaedic patients in longitudinal IPV research. We also aim to describe baseline characteristics of participants including IPV status.

Methods: The current study is a report of the baseline characteristics and preliminary feasibility of the ongoing PRAISE-2 multicentre pilot prospective cohort study. PRAISE-2 follows adult women with orthopaedic injuries for 12 months. We asked patients to disclose whether they had experienced abuse. We are currently following patients for 12 months to determine the associations between IPV and orthopaedic outcomes.

Results: We successfully recruited 252 women with orthopaedic injuries from 6 sites. Two women were excluded leaving 250 for analysis. The mean age of participants was 53.4 years (SD 16.6). Most participants were currently in a relationship (153/250; 61.2%) with many of those being married (111/153; 72.5%). Most participants were either employed full time (97/250; 38.8%) or retired (61/250; 24.4%). Many participants had children (66.0%) or comorbidities (58.8%). At baseline, 8.4% (95% CI: 5.3% to 12.6%) of women disclosed IPV in the past 12 months and 32.4% (95% CI: 26.6% to 38.6%) disclosed IPV in their lifetime. Follow-up is currently ongoing.

Conclusions: We have demonstrated preliminary feasibility of the PRAISE-2 pilot study after recruiting 250 women. The PRAISE-2 pilot study has the potential to provide valuable feasibility information and preliminary estimates for future longitudinal IPV study planning.

BACKGROUND

Violence against women is a topic of interest in orthopaedic studies that has been globally recognized as a public health problem[139]. Its consequences can result from immediate to long-term physical, sexual, and psychological harm and in some severe cases, death[140]. Intimate partner violence (IPV) is one of the many violations to women's rights[79]. IPV is any self-reported physical, sexual or psychological abuse by a current or former intimate partner[79]. Although women and men can be victims, the body of literature focuses mostly on women in heterosexual relationships as victims[141]. According to the World Health Organization (WHO), 1 in 3 women worldwide have been physically or sexually assaulted by an intimate partner or sexually by a non-intimate partner[140].

In North America, IPV is one of the most common causes of non-fatal injuries to women[142]. A study analyzing the injuries from 218 physically abused women had identified musculoskeletal injuries to be the second most common result of IPV[36]. These injuries included sprains, fractures, and dislocations[36]. Furthermore, PRAISE, a cross-sectional survey study that evaluated the prevalence of IPV in orthopaedics, reported one in six women with musculoskeletal injuries disclosed experiencing IPV within the past year, and one in three women disclosed IPV in their lifetime[32]. From the respondents who reported IPV in the past year, fractures were the most commonly reported type of injury[32].

Multiple studies have investigated injury characteristics of abused women, however, if IPV is not properly addressed it could escalate to intimate partner homicide[44]. Victims of IPV tend to not seek help from IPV-specialized services or the police and due to the sensitive topic, they often seek informal support from family and friends[143]. Globally, 38% of murdered women were killed by an intimate partner[140]. Other studies have found that 45% of women that were murdered by their intimate partner had received medical treatment for IPV-related injuries two years before their death[37]. Multiple health professional organizations have argued that HCPs should play a role in identifying and assisting IPV victims[144,145]. The Canadian Orthopaedic Association (COA) recommends that surgeons receive training on responding to IPV victims[44]. Especially since fracture clinics often require follow-up visits to assess recovery, these orthopaedic settings are ideal locations for HCPs to create safe and trusting relationships that may encourage IPV disclosure over time[44].

Partner violence does not only harm one's physical, sexual and emotional health, but it could also impair one's independence, productivity, and capacity to care for themselves and loved ones, as well as their overall health and quality of life[141]. Previous studies have described potential health problems associated with IPV, including sexual and reproductive health issues (e.g. HIV and abortions), as well as perinatal and maternal complications (e.g. low birth rate)[79]. However, information is lacking on injury-related complications and outcomes of interest to orthopaedic surgeons. We believe that orthopaedic surgeons would be more likely to ask their patients about IPV and take the time to educate themselves about IPV if we have better information about how IPV affects outcomes that are of interest to orthopaedic surgeons. We also aim to provide valuable feasibility information on processes

to recruit and retain orthopaedic patients in longitudinal IPV research. Additionally, because measuring consequences of IPV has been a major challenge in previous studies[138], we aim to test and refine our data collection strategies and outcome measures for future longitudinal IPV studies.

Objectives

Overall PRAISE-2 Pilot Objectives

The primary objective of the PRAISE-2 pilot study is to determine the feasibility of a multi-national prospective cohort study. Specifically, we will: 1) assess our ability to recruit women across clinical sites; 2) evaluate adherence to study visit windows; 3) assess our ability to follow participants and collect data for 12 months; 4) assess our ability to collect data on our chosen clinical outcomes, including questionnaire completion; and 5) identify areas for improvement for future studies. Clinical objectives in this pilot study are exploratory. The clinical objectives of the PRAISE-2 study include determining: 1) how a history of IPV affects injury-related complications; 2) how a history of IPV affects return to pre-injury function; 3) incident cases of IPV after a musculoskeletal injury if the injury was not the result of IPV; 4) how a history of IPV affects health care and support service use after a musculoskeletal injury; 5) how a history of IPV affects health-related quality of life after a musculoskeletal injury; 6) how patterns of IPV change over time after a musculoskeletal injury; and 7) how abused women's stage of change (i.e. readiness to make changes to move toward a life free from violence) changes over time after a musculoskeletal injury.

Objectives of the Current Study

For this report, we focus on the following objectives: 1) assess our ability to recruit 250 participants; 2) describe baseline characteristics including IPV disclosure at baseline.

METHODS

This is a pilot prospective cohort study. This study was registered with clinicaltrials.gov (NCT02529267) on 20 August 2015, which was before the first patient was enrolled. The current study is a report of the baseline characteristics of the ongoing PRAISE-2 multicentre pilot prospective cohort study. The full PRAISE-2 pilot protocol is available from *Pilot and Feasibility Studies*[146] and the full Statistical Analysis Plan is available from *PeerJ Preprint*[147]. A brief summary of the methods is below.

Eligibility Criteria

The inclusion criteria are: 1) adult females (at least 16 or 18 years of age depending on local ethics requirements); 2) patients presenting to participating fracture clinics within 6 weeks of their injury; and 3) patients presenting with a fracture or dislocation which is being managed with either surgical or non-surgical treatment. Patients were excluded if they were: 1) unwilling to or unable to provide consent; 2) unable to complete the study questionnaires in a private location; 3) unwilling or unable to follow the study protocol or their attending surgeon had concerns about their ability or willingness to follow study protocols; and 4) do not speak and write in English or the dominant language of the local

clinic. Due to the sensitive nature of the topic, only patients who can consent for themselves were considered for participation.

Patient Screening and Enrolment
All adult female patients were screened for eligibility by a female research coordinator when they attended a standard of care visit at the fracture clinic (or local equivalent clinic). Patients completed the screening, consent, and questionnaire process in a private location for safety and confidentiality reasons. All participants provided written informed consent before completing study questionnaires.

Study Follow Up
Participants in the PRAISE-2 pilot study complete the questionnaires at baseline (0-6 weeks post-injury), and at 1, 3, 6, and 12 months after the baseline assessment. The current report focuses on the baseline visit only.

Study Outcomes
Primary (Feasibility) Outcome
The primary outcome of the pilot study is feasibility. For this study we focus on feasibility of recruitment. Originally, our feasibility goal was based on recruiting 50 participants at each of 5 sites (total 250 participants) in 12 months or less after their training call/visit. However, due to staffing issues at one site we decided to add an additional site to split the 50 participant target.

Secondary (Clinical) Outcomes
The clinical outcomes of the PRAISE-2 pilot study include injury-related complications; return to pre-injury function; new IPV disclosures; utilization and associated costs of health, legal, and social support services; changes in abuse severity/frequency and type of abuse; health-related quality of life; and stage of change. For this report we focus on baseline characteristics including a description of demographic and injury characteristics, IPV disclosure at baseline, baseline stage of change, functional status, and support service use.

Measurement of Secondary (Clinical) Outcomes

Return to pre-injury function - We used the Return to Function Questionnaire (RTF) which is a four question tool that was used in a recently completed large FDA-regulated fracture trial[2].

Use and Associated Costs of Health, Legal, and Social Support Services - Women's access to and use of health and support services were measured by directly asking participants to self-report if they have accessed health care services, or other services directly and indirectly related to IPV like legal services, social workers, and online IPV resources.

Changes in Abuse Type and Severity/Frequency – We used the direct method of screening that was used in the PRAISE study[32], which categorizes types of violence as physical, emotional, and/or sexual abuse. We recorded type of IPV experienced at baseline.

Health-Related Quality of Life - Participants' quality of life was measured using the EuroQol-5 Dimensions (EQ-5D), a widely used and well-validated quality of life tool[148]. We report the mean Visual Analog Scale (VAS) score with 95% confidence interval (95% CI) as well as the mean function index with 95% CI. The VAS is a patient-reported scale of 1 (low) to 100 (high) where patients are asked to report their state of health today. The function index consists of five questions on mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each item has five response options. The overall index ranges from 0 (death) to 1 (full health) and was calculated using the methods described in the EQ-5D-5L User Guide and index value calculator[149,150].

Stage of Change - Participants completed the Domestic Violence Survivor Assessment (DVSA) Short Form questionnaire to determine their stage of change. The stages of change are based on the transtheoretical model of health behavior change applied specifically to survivors of abuse[151]. The stages of change are 1) Pre-contemplation: committed to continuing the relationship, change is not contemplated; 2) Contemplation: committed but questioning/contemplating change; 3) Preparation: considering change/exploring options to end abuse; 4) Action: victim breaks away from abusive relationship or partner stops being abusive, and 5) Maintenance: establishment of a new life apart or together. The DVSA is well-used in IPV research and counselling, and has been determined to be feasible to administer, reliable, and sensitive to change[152]. The original scoring method involves taking the mean of the stages (i.e. pre-contemplation = 1; contemplation = 2; preparation = 3; action = 4; maintenance = 5). However, upon consultation with a researcher and a social worker, both trained at the MSW level, we also report a revised method of scoring. For some items, we found that respondents could easily mix up the pre-contemplation and maintenance response options if they deny that violence is a problem in their life. We therefore report a revised stage of change where we believed, based on the context of the participant's other answers, that she had marked an inconsistent pre-contemplation or maintenance stage. This is discussed further in the discussion section.

Study Location and Clinical Sites

The study is coordinated at McMaster University's Centre for Evidence-Based Orthopaedics in Hamilton Ontario Canada. The Centre for Evidence-Based Orthopaedics has focused on large international orthopaedic trauma trials and some of the only large observational studies on IPV in orthopaedics to date, for example, the original PRAISE study[32] and the POSITIVE study[34]. The clinical sites involved in patient recruitment for the PRAISE-2 pilot study include three sites in Canada, and one site in each of the Netherlands, Spain, and Finland. These include the Hamilton General Hospital in Hamilton Ontario, St. Michael's Hospital in Toronto Ontario, Foothills Medical Centre in Calgary Alberta, Deventer Hospital in Deventer, University Hospital Vall d'Hebron in Barcelona,

and Helsinki University Hospital in Helsinki. All recruiting sites have previously worked with the Centre for Evidence-Based Orthopaedics.

IPV Disclosure
We identified women who have experienced IPV in the past year and in their lifetime using the method from the original PRAISE study[32,153]. Briefly, participants completed three direct questions from the Woman Abuse Screening Tool (WAST)[154] that have been shown to be more sensitive in an orthopaedic population than other screening methods[153] and are able to elicit disclosure estimates similar to or higher than in other medical specialties. If a participant answered affirmatively to any of the direct screening questions, she was classified as having experienced IPV.

Baseline Questionnaires
While participants were waiting for their appointment with their surgeon, they completed six questionnaires at baseline which took 10-20 minutes to complete. These questionnaires included a demographics form, IPV disclosure questionnaire, return to function questionnaire, EQ-5D, stages of change, and support services use. Attending surgeons or their delegate completed an injury/treatment form and information on any in-hospital adverse events, if applicable, at baseline.

Data Analysis
We report baseline, injury, and treatment characteristics descriptively by IPV status and for all participants. We report categorical variables as frequencies and percentages, and continuous data as means and standard deviations (SD) and minimum and maximum values, if appropriate.

We did not exclude participants with incomplete data. Because one of our feasibility objectives is to determine the feasibility of our data collection strategies, we report numbers of missing answers. We did not impute for missing data in this pilot study. Descriptive analyses were conducted using SPSS version 25 and inter-rater agreement statistics were analyzed using STATA version 13.

Differences from Protocol
We made some changes from the protocol[146] for feasibility reasons. We had originally planned to include five sites, each recruiting 50 participants. We decided to add a sixth site in Finland to split the target of 50 participants with the site in Spain due to personnel availability. Additionally, we allowed one site to recruit patients up to 12 weeks post-injury whose injury had not yet fully healed. This is because the site standard of care is to follow up with injured patients in clinic for the first time at 7-12 weeks post-injury.

RESULTS

Feasibility – Recruitment

We screened 587 patients for inclusion from six clinical sites in four countries between September 2015 and April 2018. We enrolled 252 participants, 61 patients were missed, and 274 were excluded. Reasons for exclusion can be found in **Figure 7**. The most common reason for exclusion was that the patient presented to clinic more than 6 weeks after her injury. Two additional participants were withdrawn immediately after enrollment because the site discovered they did not have an eligible injury, leaving 250 participants for analysis.

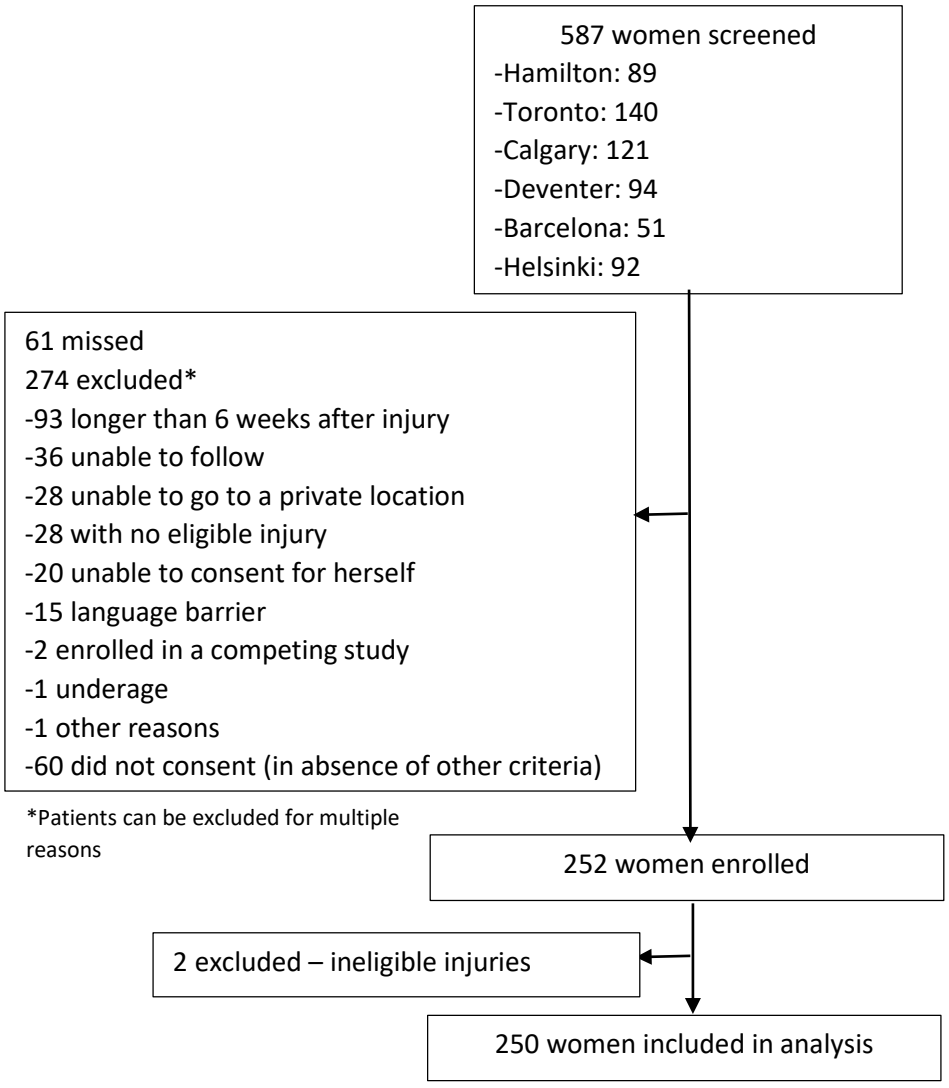

Figure 7: Study flow diagram

Table 10 shows the target and actual number of patients enrolled at each site, as well as the target and actual time spent enrolling. Four of six sites met their goal enrollment time; two of these enrolled substantially faster than their goal. Two sites took slightly longer than expected to reach their target.

Table 10: Enrollment targets and actual enrollment by site

Site	Target	Enrolled	Time to Reach Target – Goal**	Time to Reach Target - Actual
Site A	55 (originally 50)*	55	13 months	13 months
Site B	50	50	12 months	2 months
Site C	50	50	12 months	2 months
Site D	50	50	12 months	15 months
Site E	25	26	6 months	4 months
Site F	20 (originally 25)*	21	5 months	8 months

*The original target of Site A was 50 and Site F was 25 but targets were revised due to staffing limitations. Site A recruited an additional 5 participants to compensate.

**The goal enrollment time is based on the feasibility criterion of 50 participants per site recruited in 12 months. This goal has been adjusted for sites with a target that is less than 50.

Patient Demographic Characteristics

The mean age of participants was 53.4 years (SD 16.6). The youngest participant was 18 and the oldest was 89. Most participants were white (92.8%). Most participants were currently in a relationship (153/250; 61.2%) with many of those being married (111/153; 72.5%). Most participants were either employed full time (97/250; 38.8%) or retired (61/250; 24.4%). Many participants had children (66.0%) or comorbidities (58.8%) (**Table 11**).

Table 11: Baseline demographic characteristics by IPV status

Characteristic	**All participants (n=250)**	**IPV past 12 months**		**IPV lifetime**	
		No * (n=221)	**Yes* (n=21)**	**No* (n=163)**	**Yes* (n=81)**
Country					
-Canada	155 (62.0%)	131 (59.3%)	17 (81.0%)	93 (57.1%)	58 (71.6%)
-Netherlands	50 (20.0%)	49 (22.2%)	1 (4.8%)	44 (27.0%)	6 (7.4%)
-Spain	21 (8.4%)	20 (9.0%)	1 (4.8%)	13 (8.0%)	8 (9.9%)
-Finland	24 (9.6%)	21 (9.5%)	2 (9.5%)	13 (8.0%)	9 (11.1%)
Age (years)					
-mean years (SD)	53.4 (16.6)	54.1 (16.2)	50.0 (19.0)	54.5 (16.4)	51.6 (16.5)
-minimum	18	18	20	18	20
-maximum	89	89	78	89	89
Ethnicity					
-White	232 (92.8%)	205 (92.8%)	19 (90.5%)	152 (93.3%)	74 (91.4%)
-Asian	8 (3.2%)	7 (3.2%)	1 (4.8%)	7 (4.3%)	1 (1.2%)
-Latina	5 (2.0%)	4 (1.8%)	1 (4.8%)	2 1.2(%)	3 (3.7%)
-Black	2 (0.8%)	2 (0.9%)	0 (0%)	1 (0.6%)	1 (1.2%)
-Middle Eastern	1 (0.4%)	1 (0.5%)	0 (0%)	1 (0.6%)	0 (0%)
-missing	2 (0.8%)	2 (0.9%)	0 (0%)	0 (0%)	2 (2.5%)
Relationship status					
-Married	111 (44.4%)	99 (44.8%)	11 (52.4%)	86 (52.8%)	24 (29.6%)
-Single	43 (17.2%)	36 (16.3%)	4 (19.0%)	23 (14.1%)	19 (23.5%)
-In a relationship	27 (10.8%)	23 (10.4%)	3 (14.3%)	19 (11.7%)	8 (9.9%)
-Divorced	19 (7.6%)	18 (8.1%)	1 (4.8%)	7 (4.3%)	12 (14.8%)
-Widowed	19 (7.6%)	18 (8.1%)	0 (0%)	16 (9.8%)	2 (2.5%)
-Common law	15 (6.0%)	12 (5.4%)	1 (4.8%)	6 (3.7%)	8 (9.9%)
-Separated	6 (2.4%)	6 (2.7%)	0 (0%)	3 (1.8%)	3 (3.7%)
-missing	10 (4.0%)	9 (4.1%)	0 (0%)	3 (1.8%)	5 (6.2%)
Relationship type					
-Opposite-sex	144 (57.6%)	127 (57.5%)	13 (61.9%)	106 (65.0%)	36 (44.4%)
-Same-sex	9 (3.6%)	7 (3.2%)	2 (9.5%)	5 (3.1%)	4 (4.9%)
-No relationship	87 (34.8%)	78 (35.3%)	0 (0%)	49 (30.1%)	36 (44.4%)
-missing	10 (4.0%)	9 (4.1%)	6 (28.6%)	3 (1.8%)	5 (6.2%)
Employment					
-Employed full-time	97 (38.8%)	86 (38.9%)	5 (23.8%)	63 (38.7%)	31 (38.3%)
-Employed part-time	39 (15.6%)	35 (15.8%)	4 (19.0%)	28 (17.2%)	11 (13.6%)
-Retired	61 (24.4%)	55 (24.9%)	5 (23.8%)	40 (24.5%)	20 (24.7%)
-Student	16 (6.4%)	13 (5.9%)	3 (14.3%)	12 (7.4%)	4 (4.9%)
-Unemployed	11 (4.4%)	10 (4.5%)	1 (4.8%)	7 (4.3%)	4 (4.9%)
-Disability	10 (4.0%)	8 (3.6%)	1 (4.8%)	5 (3.1%)	5 (6.2%)
-Homemaker	4 (1.6%)	3 (1.4%)	1 (4.8%)	3 (1.8%)	1 (1.2%)
-missing	12 (4.8%)	11 (5.0%)	0 (0%)	5 (3.1%)	5 (6.2%)
Education					
-High school	21 (8.4%)	19 (8.6%)	2 (9.5%)	13 (8.0%)	8 (9.9%)
incomplete	47 (18.8%)	41 (18.6%)	5 (23.8%)	27 (16.6%)	19 (23.5%)

-High school complete	87 (34.8%)	72 (32.6%)	11 (52.4%)	54 (33.1%)	31 (38.3%)
-College	52 (20.8%)	50 (22.6%)	1 (4.8%)	37 (22.7%)	15 (18.5%)
-University	29 (11.6%)	26 (11.8%)	1 (4.8%)	25 (15.3%)	3 (3.7%)
-Advanced degree	14 (5.6%)	13 (5.9%)	1 (4.8%)	7 (4.3%)	5 (6.2%)
-missing					
Income (Canadian $)					
-Less than $20,000	25 (10.0%)	21 (9.5%)	3 (14.3%)	11 (6.7%)	14 (17.3%)
-$20,000-40,000	44 (17.6%)	40 (18.1%)	3 (14.3%)	25 (15.3%)	18 (22.2%)
-$40,000-60,000	50 (20.0%)	45 (20.4%)	3 (14.3%)	40 (24.5%)	9 (11.1%)
-$60,000-80,000	23 (9.2%)	21 (9.5%)	2 (9.5%)	17 (10.4%)	6 (7.4%)
-$80,000-100,000	25 (10.0%)	22 (10.0%)	2 (9.5%)	15 (9.2%)	10 (12.3%)
-More than $100,000	35 (14.0%)	34 (15.4%)	0 (0%)	30 (18.4%)	4 (4.9%)
-missing	48 (19.2%)	38 (17.2%)	8 (38.1%)	25 (15.3%)	20 (24.7%)
Children					
-0	72 (28.8%)	62 (28.1%)	6 (28.6%)	50 (30.7%)	20 (24.7%)
-1	27 (10.8%)	26 (11.8%)	1 (4.8%)	19 (11.7%)	8 (9.9%)
-2	84 (33.6%)	71 (32.6%)	8 (38.1%)	52 (31.9%)	30 (37.0%)
-3	39 (15.6%)	36 (16.3%)	3 (14.3%)	29 (17.8%)	10 (12.3%)
-4	11 (4.4%)	10 (4.5%)	1 (4.8%)	5 (3.1%)	6 (7.4%)
-More than 4	4 (1.6%)	3 (1.4%)	1 (4.8%)	2 (1.2%)	2 (2.5%)
-missing	13 (5.2%)	12 (5.4%)	1 (4.8%)	6 (3.7%)	5 (6.2%)
Comorbidities					
-None	99 (39.6%)	88 (39.8%)	5 (23.8%)	71 (43.6%)	23 (28.4%)
-Any	147 (58.8%)	129 (58.4%)	16 (76.2%)	91 (55.8%)	55 (67.9%)
-missing	4 (1.6%)	4 (1.8%)	0 (0%)	1 (0.6%)	3 (3.7%)

*Excludes participants for whom IPV status is missing
IPV – intimate partner violence
SD – standard deviation

Injury and Treatment Characteristics

The most common mechanism of injury was a fall (80.8%). 19.6% of patients were hospitalized after their injury, and very few required an ICU stay (1.6%). 11.2% of patients had more than one orthopaedic injury. Most patients had closed fractures as their most severe injury (96.0%). There were no participants with open fractures. Most injuries were of the upper extremity (56.8%), followed by the lower extremity (36.4%). 28.4% of patients had surgical treatment while the remaining 71.6% had non-surgical treatment. The mean injury severity score (ISS) was 5.4 (SD 3.6) (**Table 12**).

Table 12: Injury and treatment characteristics by IPV status

Characteristic	All participants (n=250)	IPV past 12 months		IPV lifetime	
		No* (n=221)	Yes* (n=21)	No* (n=163)	Yes* (n=81)
Mechanism of injury					
-Fall	202 (80.8%)	179 (82.0%)	17 (81.0%)	126 (77.3%)	71 (87.7%)
-Motor vehicle accident	18 (7.2%)	16 (7.2%)	2 (9.5%)	14 (8.6%)	4 (4.9%)
-Twist	12 (4.8%)	9 (4.1%)	1 (4.8%)	7 (4.3%)	4 (4.9%)
-Struck by/against object	9 (3.6%)	8 (3.6%)	1 (4.8%)	8 (4.9%)	1 (1.2%)
-Sports injury	5 (2.0%)	5 (2.3%)	0 (0%)	5 (3.1%)	0 (0%)
-Overextension	2 (0.8%)	2 (0.9%)	0 (0%)	1 (0.6%)	1 (1.2%)
-Overuse	1 (0.4%)	1 (0.5%)	0 (0%)	1 (0.6%)	0 (0%)
-Crush	1 (0.4%)	1 (0.5%)	0 (0%)	1 (0.6%)	0 (0%)
-missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Nights in hospital					
-0	201 (81.4%)	178 (80.5%)	16 (76.2%)	129 (79.1%)	67 (82.7%)
-1-2	18 (7.2%)	16 (7.2%)	2 (9.5%)	12 (7.4%)	5 (6.2%)
-3-7	21 (8.4%)	19 (8.6%)	1 (4.8%)	15 (9.2%)	6 (7.4%)
-more than 7	10 (4.0%)	8 (3.6%)	2 (9.5%)	7 (4.3%)	3 (3.7%)
-missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Nights in intensive care					
-0	246 (98.4%)	218 (98.6%)	20 (95.2%)	160 (98.2%)	80 (98.8%)
-1-2	1 (0.4%)	1 (0.5%)	0 (%)	1 (0.6%)	0 (0%)
-3-5	3 (1.2%)	2 (0.9%)	1 (4.8%)	2 (1.2%)	1 (1.2%)
-missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Number of orthopaedic injuries					
-1	222 (88.8%)	196 (88.7%)	19 (90.5%)	143 (87.7%)	75 (92.6%)
-2	23 (9.2%)	21 (9.5%)	1 (4.8%)	16 (9.8%)	5 (6.2%)
-3 or 4	5 (2.0%)	4 (1.8%)	1 (4.8%)	4 (2.5%)	1 (1.2%)
-missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Most severe injury type					
-Closed fracture	240 (96.0%)	211 (95.5%)	21 (100%)	157 (96.3%)	77 (95.1%)
-Open fracture	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
-Dislocation	5 (2.0%)	5 (2.3%)	0 (0%)	3 1.8(%)	2 (2.5%)
-Fracture/dislocation	4 (1.6%)	4 (1.8%)	0 (0%)	3 (1.8%)	1 (1.2%)
-missing	1 (0.4%)	1 (0.5%)	0 (0%)	0 (0%)	0 (0%)
Most severe injury location					
-Upper extremity	142 (56.8%)	127 (57.5%)	14 (66.7%)	93 (57.1%)	47 (58.0%)
-Lower extremity	91 (36.4%)	78 (35.3%)	6 (28.6%)	60 (36.8%)	28 (34.6%)
-Spine	9 (3.6%)	9 (4.1%)	0 (%)	6 (3.7%)	2 (2.5%)
-Pelvis	2 (0.8%)	1 (0.5%)	1 (4.8%)	1 (0.6%)	1 (1.2%)
-missing	6 (2.4%)	6 (2.7%)	0 (0%)	3 (1.8%)	3 (3.7%)

Treatment type -Surgical -Non-surgical -missing	 71 (28.4%) 179 (71.6%) 0 (0%)	 59 (26.7%) 162 (73.3%) 0 (0%)	 8 (38.1%) 13 (61.9%) 0 (0%)	 47 (28.8%) 116 (71.2%) 0 (0%)	 23 (28.4%) 58 (71.6%) 0 (0%)
Mean injury severity score (SD)	5.4 (3.6)	5.2 (3.2)	6.1 (6.8)	5.3 (3.2)	5.3 (4.3)

*Excludes participants for whom IPV status is missing
IPV – intimate partner violence
SD – standard deviation

Baseline IPV Status

The prevalence of IPV in the past year was 8.4% (95% CI: 5.3% to 12.6%) and the lifetime prevalence of IPV was 32.4% (95% CI: 26.6% to 38.6%). The most common form of IPV was emotional abuse, but it was also common for emotional and physical abuse to co-occur in lifetime IPV (**Table 13**).

Table 13: IPV prevalence and type

Type of IPV	**Past 12 months (n=250)**	**Lifetime (n=250)**
No IPV	221 (88.4%) 95% CI: 83.8% to 92.1%	163 (65.2%) 95% CI: 58.9% to 71.1%
Any IPV	21 (8.4%) 95% CI: 5.3% to 12.6%	81 (32.4%) 26.6% to 38.6%
Emotional + physical + sexual	1 (0.4%)	15 (6.0%)
Emotional + physical	0 (0%)	21 (8.4%)
Emotional + sexual	1 (0.4%)	3 (1.2%)
Emotional only	18 (7.2%)	40 (16.0%)
Physical only	0 (0%)	2 (0.8%)
Sexual only	1 (0.4%)	0 (0%)
Missing	8 (3.2%)	6 (2.4%)

IPV – intimate partner violence
CI – confidence interval

Baseline Stage of Change

Six participants identified that their current relationship has been abusive at some point and completed the stage of change form. **Table 14** shows the stages of change for each participant for each of the two methods of scoring. Using the original method of scoring, two participants were in the contemplation stage, two were in preparation, and two were in action. When using the revised scoring approach, three of the six participants were categorized differently; they were all reclassified as being in the maintenance stage.

Table 14: Stage of change by scoring method

Participant	Original Scoring	Revised Scoring
1	Action	Action
2	Contemplation	Contemplation
3	Action	Maintenance
4	Preparation	Maintenance
5	Preparation	Maintenance
6	Contemplation	Contemplation

Order of stages: precontemplation, contemplation, preparation, action, maintenance.

Baseline Functional Status

EQ-5D

The mean EQ-5D VAS score was 70.7 (95% CI: 68.6 to 72.8; 100 is highest state of health) and the mean function index was 0.62 (95% CI: 0.59 to 0.64; 1 is highest function). The mean VAS for the IPV group was 2.0 points worse for IPV in the past 12 months and 5.6 points worse for lifetime IPV, but the confidence intervals overlap substantially. Similarly, the mean function index for the IPV group was 0.01 points worse for both IPV in the past 12 months and lifetime IPV, but again the confidence intervals overlap substantially (**Table 15**). For reference, the minimal clinically important difference (MCID) for the EQ-5D VAS is between 8.6 and 10.8, and for the function index it is 0.05 to 0.1[155,156].

Table 15: Baseline EQ-5D visual analog scale (VAS) and mean function index by IPV status

	All participants (n=250)	IPV past 12 months		IPV lifetime	
		No* (n=220)	Yes* (n=21)	No* (n=162)	Yes* (n=81)
Mean VAS (95% CI)	70.7 (68.6 to 72.8)	71.1 (69.0 to 73.2)	69.1 (59.3 to 78.9)	72.6 (70.3 to 74.9)	67.0 (62.8 to 71.3)
Mean function index (95% CI)	0.62 (0.59 to 0.64)	0.62 (0.60 to 0.64)	0.61 (0.58 to 0.64)	0.62 (0.59 to 0.65)	0.61 (0.58 to 0.63)

VAS – visual analog scale
CA – confidence interval
IPV – intimate partner violence

Return to Function

Participants most commonly prioritized return to home duties (36.8%), closely followed by return to leisure (36.0%). Of the 165 participants who were working at the time of their injury, only 40 (24.2%) had returned to all of their work duties. Very few participants had returned to all of their leisure (13/250; 5.2%) or home duties (22/250; 8.8%) (**Table 16**).

Table 16: Return to function by IPV status

RTF Question	All participants (n=250)	IPV past 12 months		IPV lifetime	
		No * (n=221)	Yes* (n=21)	No* (n=163)	No * (n=81)
Most important domain	66 (26.4%)	56 (25.3%)	7 (33.3%)	38 (23.3%)	26 (32.1%)
-Work	90 (36.0%)	81 (36.7%)	6 (28.6%)	65 (39.9%)	23 (28.4%)
-Leisure	92 (36.8%)	83 (37.6%)	8 (38.1%)	59 (36.2%)	32 (39.5%)
-Home duties	2 (0.8%)	1 (0.5%)	0 (0%)	1 (0.6%)	0 (0%)
-missing					
Return to work					
-None	80 (32.0%)	71 (32.1%)	8 (38.1%)	45 (27.6%)	33 (40.7%)
-Some	30 (12.0%)	24 (10.9%)	4 (19.0%)	20 (12.3%)	9 (11.1%)
-Most	15 (6.0%)	14 (6.3%)	1 (4.8%)	11 (6.7%)	4 (4.9%)
-All with restrictions	33 (13.2%)	30 (13.6%)	1 (4.8%)	20 12.3(%)	13 (16.0%)
-All no restrictions	7 (2.8%)	7 (3.2%)	0 (0%)	7 (4.3%)	0 (0%)
-N/A not working	85 (34.0%)	75 (33.9%)	7 (33.3%)	60 (36.8%)	22 (27.2%)
Return to leisure					
-None	127 (50.8%)	114 (51.6%)	9 (42.9%)	83 (50.9%)	41 (50.6%)
-Some	89 (35.6%)	80 (36.2%)	6 (28.6%)	62 (38.0%)	25 (30.9%)
-Most	20 (8.0%)	15 (6.8%)	5 (23.8%)	9 (5.5%)	11 (13.6%)
-All with restrictions	1 (0.4%)	1 (0.5%)	0 (0%)	1 (0.6%)	0 (0%)
-All no restrictions	12 (4.8%)	11 (5.0%)	1 (4.8%)	8 (4.9%)	4 (4.9%)
-missing	1 (0.4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Return to home duties					
-None	68 (27.2%)	62 (28.1%)	5 (23.8%)	45 (27.6%)	23 (28.4%)
-Some	134 (53.6%)	117 (52.9%)	12 (57.1%)	87 (53.4%)	43 (53.1%)
-Most	25 (10.0%)	23 (10.4%)	1 (4.8%)	16 (9.8%)	8 (9.9%)
-All with restrictions	17 (6.8%)	14 (6.3%)	3 (14.3%)	11 (6.7%)	6 (7.4%)
-All no restrictions	5 (2.0%)	5 (2.3%)	0 (0%)	4 (2.5%)	1 (1.2%)
-missing	1 (0.4%)	0 (%)	0 (0%)	0 (0%)	0 (00%)

*Excludes participants for whom IPV status is missing
IPV – intimate partner violence
RTF – return to function
N/A – not applicable

Baseline Service Use

In the 3 months before enrollment, most participants had visited a primary care physician (66.7%) or the emergency department (94.0%). Over one quarter (26.6%) of participants had seen a specialist physician other than their treating orthopaedic surgeon. Many participants had used physiotherapist or rehabilitation services (19.4%). Some participants had used mental health services (5.6%) or visited a social worker (4.0%). One participant also called the police for a domestic situation (0.4%). Only one of the participants used any IPV-specific services like women's shelters, support groups, IPV websites, IPV

helplines, or IPV brochures/print materials. Additionally, six participants (2.4%) reported that they referred a friend or family member to IPV-specific services in the last 3 months (**Table 17**).

Table 17: Health care and support service use in the past 3 months by IPV status

Service	**All participants (n=250)**	**IPV past 12 months**		**IPV lifetime**	
		No* (n=221)	**Yes* (n=21)**	**No* (n=163)**	**Yes* (n=81)**
Primary care physician/ nurse practitioner	164 (66.7%)	144 (65.8%)	17 (81.0%)	106 (65.8%)	57 (70.4%)
Emergency department	233 (94.0%)	211 (95.5%)	17 (81.0%)	156 (95.7%)	74 (91.4%)
Specialist physician (other than orthopaedics)	66 (26.6%)	56 (25.3%)	9 (42.9%)	44 (27.0%)	21 (25.9%)
Physiotherapy	48 (19.4%)	41 (18.6%)	5 (23.8%)	33 (20.2%)	14 (17.3%)
Mental health services	14 (5.6%)	9 (4.1%)	4 (19.0%)	4 (2.5%)	10 (12.3%)
Family lawyer	7 (2.8%)	5 (2.3%)	2 (9.5%)	2 (1.2%)	5 (6.2%)
Police for domestic situation	1 (0.4%)	0 (0%)	1 (4.8%)	0 (0%)	1 (1.2%)
Social worker	10 (4.0%)	8 (3.6%)	2 (9.5%)	5 (3.1%)	4 (5.0%)
IPV-specific services*	1 (0.4%)	1 (0.5%)	0 (0%)	1 (0.6%)	0 (0%)
Refer a friend to IPV-specific services	6 (2.4%)	4 (1.8%)	2 (9.5%)	1 (0.6%)	5 (6.2%)

*IPV-specific services include women's shelters, support groups, IPV websites, IPV helplines, and IPV brochures/print materials
IPV – intimate partner violence

DISCUSSION

This is a report of the baseline characteristics and preliminary feasibility of the PRAISE-2 pilot prospective cohort study. We successfully enrolled 250 women in this pilot study and follow-up is ongoing. Six clinical sites in Canada, the Netherlands, Spain, and Finland enrolled female patients and asked them to disclose whether they have experienced IPV in the past year and in their lifetime.

In this study, 8.4% of women disclosed IPV in the past 12 months and 32.4% disclosed IPV in their lifetime. In the original PRAISE study of 2,945 orthopaedic patients, 16.0% (95% CI: 14.7-17.4%) of participants disclosed IPV in the past year and 34.6% (95% CI: 32.8-36.5%) in their lifetime. The current study's disclosure estimate is lower than the original PRAISE study despite a similar population and similar methodology (albeit PRAISE-2 is much smaller). However, given that PRAISE was an anonymous one-time questionnaire, and PRAISE-2 is not anonymous, a lower disclosure estimate should be expected in PRAISE-2. A recent longitudinal IPV study in maternal health found that between 6.1% and 10.3% of participants disclosed IPV depending on the questionnaire that they used[157]. Our results are similar. However, it is possible that some selection bias

occurred during recruitment. One of the site coordinators gave feedback that she believed patients were declining the study if they had fewer problems and a better quality of life. Also, patients who were acutely intoxicated, could not be separated from a partner, and certain vulnerable populations had to be excluded from the study. It is possible that IPV is more common among these women. The information about disclosures gained from the current study will provide valuable information for planning future longitudinal IPV studies. We also believe that asking the same participant more than once over the course of her recovery can build trust and elicit disclosures. In the PRAISE-2 study we ask participants five times over a 12-month period, so it is probable that the cumulative IPV disclosure estimate will increase by the 12-month follow-up visit.

The most common reason for exclusion in this study was that the patient presented to the clinic more than 6 weeks after her injury. One site's standard practice was to see patients in the fracture clinic for the first time at 7-12 weeks after their injury. Enrollment was therefore a challenge at this site. The rationale for implementing the 6-week limit was so we could follow the patient through her recovery and very few eligible orthopaedic injuries are expected to be healed before 6 weeks. We decided to allow the site to enroll patients up to 12 weeks after their injury as long as the patient's injury had not healed yet. The site was able to recruit patients much more efficiently after this change was implemented. Any planning for the definitive study should take this situation into consideration and possibly revise the relevant eligibility criterion. However, the limitation is that it will be more difficult to follow the participants' orthopaedic outcomes if they are recruited later in their recovery period. Another major reason for exclusion was that there was no private location available. This situation is difficult to prevent in a busy hospital setting, but any future studies should address the availability of a private location during site screening and again at site training.

Four of six sites were able to meet their enrollment time target; and two of these sites were substantially quicker. Of the two sites that did not meet their enrollment time target, one site had a major unforeseen change in site personnel that required them to stop enrollment for a period of time and the other site could only recruit a few days a month due to staffing issues. It is unlikely that any changes to the protocol could have prevented this situation. The recommendation for future studies would be to remove the enrollment target per site to allow faster enrolling sites to recruit more patients.

This is a pilot study that is not sufficiently powered to detect differences between groups for all of the clinical outcomes. We therefore cannot provide definitive conclusions on the relationship between IPV and orthopaedic outcomes. One of the limitations of this study is a lack of ethnic diversity. 92.8% of the participants were white, with very few participants from other ethnic backgrounds. Future studies should attempt to include sites in locations with greater diversity to achieve better representation. Additionally, there were no open fractures and very few participants with severe injuries, which may indicate that some potential participants were missed during screening/recruitment. Another limitation is the possibility that the stages of change form does not adequately disambiguate pre-

contemplation from maintenance stages. The main reason for this issue was likely that some of the responses for pre-contemplation and maintenance are too similar when they are not ascertained in the context of a clinical interview. The pre-contemplation stage is characterized by the respondent denying that abuse is enough of a problem in her life to consider change at this time. The maintenance stage is characterized by establishing a life free from abuse. In both of these situations, violence is perceived as not being an issue at that point in her life. These two situations are both conceptually different, but they are difficult to distinguish with a self-report written questionnaire. Since the initiation of this study, our local social workers have stopped using the DVSA self-report form and began to use an interview-focused approach to determine their clients' stage of change. The recommendation for future studies would be to further refine the approach to assessing stage of change prior to using it in research to better disambiguate the pre-contemplation and maintenance stages.

Conclusions

In this pilot prospective cohort study, we were successful in recruiting 250 women with orthopaedic injuries from 4 countries. Follow-up is currently ongoing. In this study, 8.4% of women disclosed IPV in the past 12 months and 32.4% disclosed IPV in their lifetime. We will follow participants for 12 months to determine changes in IPV patterns and associations with orthopaedic outcomes. The PRAISE-2 pilot study has the potential to provide valuable feasibility information and preliminary estimates for future longitudinal IPV study planning.

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Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

All writing committee members contributed to study design. KM drafted the manuscript and all writing committee members contributed substantially to revising the drafts. All writing committee members read and approved the final manuscript.

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Chapter 8: Prospective evaluation of intimate partner violence in surgical injury clinics (PRAISE-2): Statistical analysis plan for a pilot prospective cohort study

Kim Madden, Diane Heels-Ansdell, Sheila Sprague, Michelle Ghert, Herman Johal, Mohit Bhandari, Lehana Thabane; PRAISE-2 Investigators. Prospective Evaluation of Intimate Partner Violence in Surgical Injury Clinics (PRAISE-2): Statistical Analysis Plan for a Pilot Prospective Cohort Study

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Prospective Abuse and Intimate Partner Violence Surgical Evaluation (PRAISE-2 Pilot): Statistical Analysis Plan for a Pilot Prospective Cohort Study

BACKGROUND AND OBJECTIVES

Intimate partner violence (IPV) is a prevalent social issue that affects the health and well-being of women globally. In orthopaedics, the prevalence of women who have experienced abuse in the past year is as high as 1 in 6[32]. Additionally, this prevalence is higher than the prevalence in some other specialties, and is second only to addiction recovery clinics[32,158]. Orthopaedic surgeons now recognize that they have an opportunity to identify and assist women in abusive relationships in hopes of preventing further abuse[44,45]. In order for surgeons to be as effective as possible in assisting and advocating for women who have experienced abuse, we need more information on how IPV experiences are associated with musculoskeletal outcomes.

PRAISE-2 is a multi-centre pilot prospective cohort study of 250 women with musculoskeletal injuries to determine how IPV experiences affect injury-related outcomes, and how patterns of IPV change over a 12-month period of time following a musculoskeletal injury. The PRAISE-2 pilot study aims to evaluate the feasibility of a larger multi-national prospective cohort study of women presenting to fracture clinics with musculoskeletal injuries, and to obtain preliminary estimates of change in type/severity of IPV and cases of new abuse among injured women.

Both the feasibility and clinical information gained from this pilot study will be instrumental in informing future observational and interventional IPV studies.

STUDY METHODS

Study Design

This study is a pilot multicentre prospective cohort study to primarily assess feasibility of our recruitment, retention and data collection strategies, and to collect preliminary data on orthopaedic outcomes after experiencing IPV, as well as changes in IPV patterns following an injury. The protocol is registered on clinicaltrials.gov (NCT02529267) and the full detailed protocol is published with *Pilot and Feasibility Studies*[146].

Sample Size

Based on the statistic that 1 in 50 women present to fracture clinics because of an IPV-related injury[32], we aim to recruit 50 women at each of 5 sites (250 total). We determined *a priori* that the study will be feasible if loss to follow-up is less than 15% and adherence to study windows is 75% or greater. We believe that our loss to follow-up will be about 10%, therefore using the confidence interval approach suggested by Thabane et al.[159] we require 214 patients to achieve a 5% margin of error (which will generate a confidence interval that excludes 15%). We believe that the adherence to study windows will be over 80%, therefore we require 214 patients to achieve a 6% margin of error (which will generate a confidence interval that excludes 75%). Therefore, 250 participants will be sufficient to assess our feasibility outcomes.

Timing of Outcome Assessments
We will follow patients for 12 months after their injury and measure all study outcomes at 1 month, 3 months, 6 months, and 12 months post-injury. Investigators have 6 weeks to enroll a participant after her injury, so the 1-month visit is optional for participants whose injury occurred between 4 and 6 weeks before enrollment. Acceptable visit windows are defined as 0-6 weeks post-injury for baseline, 2-6 weeks for the 1-month visit, 11-15 weeks for the 3-month visit, 24-28 weeks for the 6-month visit, and 48-56 weeks for the 12-month visit.

STUDY POPULATION
Included participants will be adult females presenting to participating fracture clinics for a fracture and/or dislocation requiring orthopaedic care. Patients must be able and willing to provide written consent and they must be able to complete the questionnaires in a private location. We will collect and report the number of patients who are excluded or withdraw from the study, as well as their reasons for doing so in a CONSORT-type participant flow diagram. We will also summarize key baseline demographic and injury characteristics.

STATISTICAL PRINCIPLES
All secondary (clinical) analyses are exploratory as this is a pilot study which is insufficiently powered to definitively answer the secondary research questions. We will therefore not present p values when making comparisons. All confidence intervals that are reported will be 95% confidence intervals. We do not intend to make any adjustments for multiplicity, and we do not plan to impute for missing data in this pilot study. We do not plan to conduct any subgroup analyses.

ANALYSES
Primary Analyses
Primary Outcome
The primary outcome of the pilot study is feasibility. This includes four major components of feasibility:

1. Number of patients recruited at each site during a 12-month period
2. Percentage of missed and out of window visits
3. Percentage of included patients followed at 12 months for the primary and secondary
   outcomes
4. The percentage of case report forms, including patient questionnaires, completed at 12 months.

Analysis Plan – Primary
The primary analysis will be descriptive. We will report recruitment, missed visits, out of window visits, participant completion data, and completed form data as counts and percentages with 95% confidence intervals (**Tables 18 and 19**).

Based on the primary analyses, we will report whether the feasibility criteria have been met, and recommend modifications to the protocol for any planned definitive studies, if needed.

2.4 Feasibility Criteria

We have set the following criteria for feasibility:

1. Recruitment – Each site should recruit 50 participants in 12 months or less
2. Adherence to visit windows – 75% of visits within defined windows
3. Participant retention – Loss to follow-up should remain under 15%
4. Data completeness - Questionnaire completion should remain over 80%

Table 18: Feasibility outcomes

Site	# Recruited in 12 Months	Time to Reach Target*	Missed Visits/Total Visits (%; 95% CI)	Out of Window Visits/Total Visits (%; 95% CI	Completed Participants/Total Participants (%; 95% CI
Hamilton					
Toronto					
Calgary					
Deventer					
Barcelona					
Helsinki					

*Target at each site is 50 participants except Barcelona and Helsinki (25 each)

Table 19: Percentage (and 95% CI) of completed forms at each visit

Form/ Questionnaire	Baseline	1 Month*	3 Month	6 Month	12 Month
Demographics					
IPV Status					
Return to Function					
EQ-5D					
Support Service Use					
Stages of Change					
Complications/SAEs					

*The 1-month visit is optional for participants whose injury occurred between 4 and 6 weeks before enrollment

Secondary Analyses

PRAISE-2 Secondary Outcomes

Secondary outcomes for the pilot study are the planned clinical outcomes of the definitive study including:

1. Injury-related complications
2. Return to pre-injury function

3. Incident cases of IPV
4. Utilization and associated costs of health, legal, and social support services
5. Changes in abuse severity and type of abuse
6. Health-related quality of life (EQ-5D)
7. Stage of change (Domestic Violence Survivor Assessment)

Secondary Analyses
When referring to comparisons across groups by IPV status, the groups will be determined using the PRAISE method[32]. A participant will be considered to have disclosed IPV if she answers positively to at least one of the three direct screening questions.

Injury-related complications
We will present the percentage of patients with injury-related complications descriptively (**Table 20**) by group (experienced IPV versus not). We will compare across groups using binary logistic regression. The dependent variable will be whether the participant experienced one or more injury-related complications (binary). Independent variables will include past 12 month IPV status (binary), age (continuous), type of injury (open fracture, closed fracture, dislocation), location of injury (upper extremity, lower extremity, other), and location (Canada vs. Europe). We will report odds ratios with 95% CIs (**Table 21**).

Table 20: Injury-related complications by IPV status

Complication Type	**Past 12 months**		**Lifetime**	
	IPV	**No IPV**	**IPV**	**No IPV**
Complication 1				
Complication 2				
Complication 3				
…				

Table 21: Binary logistic regression of selected demographic characteristics on injury-related complications

Factor	Odds ratio	95% CI
IPV in past 12 months		
Age (10-year increments)		
Type of injury Open fracture Closed fracture Dislocation		
Location of injury Upper extremity Lower extremity Other		
Location Canada Europe		

Return to pre-injury function

We will report the cumulative percentage of patients achieving return to pre-injury level of function in each group at baseline, 1 month, 3 months, 6 months, and 12 months with 95% CI (**Table 22)**. Return to function will be defined as the participant reporting "I have returned to all of my responsibilities" for at least two of return to work, return to leisure, and return to home responsibilities. We will compare across groups using binary logistic regression. The dependent variable will be whether the participant achieved return to function by 12 months (binary). Independent variables will include past 12 month IPV status (binary), age (continuous), type of injury (open fracture, closed fracture, dislocation), location of injury (upper extremity, lower extremity, other), and location (Canada vs. Europe). We will report odds ratios with 95% CIs (**Table 23**).

Table 22: Cumulative return to function

Visit	Percentage (and 95% CI) returned to function		
	IPV in past year	No IPV in past year	Total
Baseline			
1 month*			
3 months			
6 months			
12 months			

* The 1-month visit is optional for participants whose injury occurred between 4 and 6 weeks before enrollment

Table 23: Binary logistic regression of selected demographic characteristics on return to function

Factor	Odds ratio	95% CI
IPV in past 12 months		
Age (10-year increments)		
Type of injury Open fracture Closed fracture Dislocation		
Location of injury Upper extremity Lower extremity Other		
Location Canada Europe		

Incident cases of IPV

We will report the incidence of new IPV cases reported within the 12-month study period with 95% CI. The numerator will be the number of new IPV cases and the denominator will be the total population at risk (i.e. total sample size excluding number of non-abused women at baseline).

Utilization and associated costs of health, legal, and social support services

We will report percentages of women using each service per IPV group over 12 months and the median number of times that participants used each service with Quartiles 1 and 3 (Q1-Q3) (**Table 24**). Direct costs will be derived by assigning costs to adjudicated injury-related complications and self-reported utilization of health care services, based on provincial case costing registries and health care provider benefit schedules[160]. All remaining direct costs will be estimated by multiplying self-reported quantities of utilization (e.g., visits to social worker, use of mental health services) by the unit cost of service, based on provincial or national average charges. Indirect costs will be calculated using self-reported annual income and return to function. Costs will be presented as means with 95% CIs, and histograms. Due to the non-normality of cost data, non-parametric bootstrap estimates will be used to present the difference in mean costs between those with and without a history of IPV. Multivariable sensitivity analysis will be conducted by using 95% CI and reported cost ranges for input parameters. All costs will be inflated to 2018 Canadian dollars using the appropriate prices indices. (**Table 25**)

Table 24: Support service use

Support service type	**IPV past 12 months**		**No IPV past 12 months**	
	number using the service (%; 95% CI)	median times (Q1-Q3)	number using the service (%; 95% CI)	median times (Q1-Q3)
Primary care physician				
Emergency department				
Physiotherapist				
…				

Table 25: Economic analyses

Cost Category	**IPV past 12 months**	**No IPV past 12 months**	**Difference in 1-year mean* costs** ($)
	Mean* cost ($)	Mean* cost ($)	
Direct costs			
Injury-related complications			
Utilization of health-care/services			
Indirect costs			
Time off work/loss of income			
Total			

*We will use median cost (and Q1-Q3) if the data are skewed

Changes in abuse severity and type of abuse

We will graphically present the proportion of patients who experienced no abuse, a stable level of abuse, escalating abuse, and de-escalating abuse over 12 months with 95% CI.

Health-related quality of life (EQ-5D)

We will report the mean change in HRQL from baseline to the 1-month, 3-month, 6-month, and 12-month visits by group with 95% CI (**Table 26)**. We will also estimate utility, which will be modelled over the course of 1-year follow-up, using 3, 6 and 12 month EQ-5D scores and standard trapezoidal rules. Utility will be presented as quality adjusted life years (QALYs) for each group, with 95% CI, where 1 represents full health and 0 represents death. The difference between each group will be presented as QALYs lost with 95% CI.

Table 26: Health related quality of life

Visit	Mean HRQL change from baseline (95% CI)		
	IPV in past year	No IPV in past year	Total
1-month*			
3-months			
6-months			
12-months			

* The 1-month visit is optional for participants whose injury occurred between 4 and 6 weeks before enrollment

Stage of change (Domestic Violence Survivor Assessment)

This analysis will only include participants who report that their current relationship is or was abusive. We will report the percentage of participants in each stage of change at each visit (**Table 27**). We will also report the percentage of participants who move forward through the stages of change, move backward, or stay at the same stage at 1-month, 3-months, 6-months, 9-months, and 12-months compared to baseline (**Table 28**).

Table 27: Percentage (95% CI) of participants at each stage of change by visit

Stage of change	Baseline	1 month*	3 months	6 months	12 months
Precontemplation					
Contemplation					
Preparation					
Action					
Maintenance					

* The 1-month visit is optional for participants whose injury occurred between 4 and 6 weeks before enrollment

Table 28: Percentage (95% CI) of participants who moved through the stages of change by visit

Visit	Stayed the same	Moved forward	Moved backward
1 month*			
3 months			
6 months			
12 months			

* The 1-month visit is optional for participants whose injury occurred between 4 and 6 weeks before enrollment

Chapter 9: Discussion and Opportunities in Future IPV Research

Discussion and Opportunities in Future IPV Research

KEY FINDINGS OF THIS THESIS

This thesis explored study quality of IPV literature in three parts and nine chapters. Part A sets the stage with an overview of issues relating to study quality and transparency, followed by a summary of the importance of IPV in society and what health care professionals can do to help their patients who have been abused.

Part B contains four chapters that identify some key issues of study quality in the IPV literature that are related to transparency. In particular, Part B identifies the possibility of publication bias, selective outcome reporting bias, issues with reporting quality, in the IPV literature, and opportunities for knowledge dissemination. We demonstrated that approximately one in four IPV studies that are registered on clinicaltrials.gov are not published at least 18 months after completion. This is important for transparency because publication bias can make an intervention look more effective than it actually is[62] and can leave authors of knowledge synthesis products and knowledge users with little information on which to base decisions. Even in non-interventional studies, failing to publish results can be a waste of resources and can let down participants who dedicated their time and effort to the study. Selective outcome reporting bias can also make interventions appear more effective than they are[95]. By being more transparent with reporting and making protocols and statistical analysis plans available, we can prevent, or at least better identify, selective outcome reporting bias. This thesis identified that IPV trials, pilot studies, and observational studies often do not follow established reporting guidelines, especially for particular items like reporting changes in methodology or outcomes, full reporting of randomization methodology, and pilot-specific items like rationale for conducting a pilot study, feasibility objectives, and criteria for feasibility success. Authors of IPV studies should strive to be as transparent as possible in reporting study methodology and results because a lack of transparency in reporting can cause confusion among readers and difficulty when synthesizing, appraising, and using results from the literature. Part B also identifies that investigators may not be taking full advantage of online sources and social media to disseminate knowledge.

Part C ends this thesis with an original pilot prospective cohort study (PRAISE-2) assessing the relationship between IPV experiences and orthopaedic outcomes. The PRAISE-2 study methodology was informed, in part, by lessons learned from earlier sections in this thesis. In particular, the PRAISE-2 pilot was registered prospectively before beginning to enroll patients, the protocol and statistical analysis plan are publicly available so that any changes in methods can be easily identified, and the PRAISE-2 Investigators can be held accountable to explain any important changes. In Chapter 7, which is the report on baseline characteristics and recruitment feasibility of the PRAISE-2 pilot, we identified and justified changes that we made to the execution of the study after commencement. Additionally, the PRAISE-2 publications made all attempts to follow applicable guidelines for reporting

where they are available, including the protocol (we adapted SPIRIT to suit a non-randomized study)[98], and statistical analysis plan (also adapted for a non-randomized study)[161]. Knowledge dissemination plans have already begun and include publication of the protocol in an open access peer-reviewed journal, publication of the statistical analysis plan on an open-access preprint server, and promotion of these papers on social media. Because of the finding in Chapter 5 that pilot studies often do not put emphasis on key pilot-specific methodology, we ensured that our PRAISE-2 pilot study focuses on feasibility objectives rather than statistical significance (it contains feasibility success criteria which is often overlooked in pilot studies), and we provide a strong rationale for conducting a pilot study.

LIMITATIONS OF THIS THESIS

Beyond the limitations noted in the individual chapters, one of the limitations of this thesis is that it does not comprehensively cover all aspects of research quality and transparency. Instead, it highlights some of the key issues and suggests actions that can be taken immediately to improve research quality through improving transparency. The systematic review that is described in Chapters 3, 4, and 5 is based on IPV studies that were registered in clinicaltrials.gov and ISRCTN. These are the largest English-language trial registries, but they are not comprehensive of all IPV studies. Indeed, it is likely that many IPV studies are not registered; particularly non-interventional ones. Therefore, these three chapters disproportionately focus on randomized trials. It is possible that unregistered studies have important differences. We also focus only on online mentions as a measure of knowledge dissemination. There are other aspects of knowledge dissemination that we did not take into consideration in this thesis, and we only focused on studies that have a published paper. There are likely IPV studies without published papers that have substantial online knowledge translation products that were not studied in this thesis. Despite these limitations, this thesis makes a contribution to the literature by focusing on aspects of methodology that have been previously underappreciated in the IPV field.

RECOMMENDATIONS AND OPPORTUNITIES FOR FUTURE IPV RESEARCH

This thesis demonstrates that there are several opportunities in the IPV field to take advantage of using transparent methodology to improve research quality. Research transparency and quality are highly linked, as is shown in throughout this thesis. **Table 29** summarizes the specific issues that this thesis covers, and adds to the literature by recommending actions that investigators, ethics committees, journals, peer reviewers, and institutions can take to identify potential issues, prevent poor quality research and lack of transparency, and support other members of the IPV research community to improve the quality of the literature.

Table 29: Opportunities for improving transparency and quality in future IPV studies

Methodological Issue	**Opportunities and Solutions**
Publication bias	Require that all trials, plus all studies with the potential to change health care decisions, register in a trial registry
	Require registered studies to be reported publicly (e.g. published, results summary reported in registry), regardless of newsworthiness or statistical significance of findings
	Journals and ethics committees should monitor and enforce registration and reporting
Selective outcome reporting/outcome switching	Require that all trials, plus all studies with the potential to change health care decisions, register prospectively and track methodological changes
	Consider publishing full study protocols either on preprint servers or peer-reviewed journals
	Develop a statistical analysis plan in advance, and make it publicly available. When changes are made, track them with rationale
	Journals, institutions, and ethics committees should monitor and enforce prospective registration
Reporting quality	Authors should follow established reporting guidelines where available
	When reporting guidelines are not available for a particular study design, there is an opportunity to develop guidelines
	Journals and peer reviewers enforce reporting standards
Knowledge translation	Investigators should develop a knowledge translation plan in advance (ideally one that goes beyond just publishing in a peer reviewed journal)
	Consider promoting study findings on social media, websites, blogs, training sessions, preprint servers, and other creative KT strategies depending on the study
	Consider a wider audience than just academics. Identify knowledge user groups early and tailor KT strategies to them. Involve patients if possible
	Institutions should support knowledge translation training for investigators, and consider non-traditional KT strategies in promotion and tenure/hiring processes
Pilot studies	Pilot studies should have pre-specified pilot/feasibility objectives, criteria for feasibility success, and sound rationale why a pilot is needed; the emphasis is usually not on statistical significance but on feasibility of the study process
	Ethics committees and peer reviewers should be aware of the characteristics of pilot studies and require investigators to report and justify the pilot objectives and rationale
	Consider publishing the results of a pilot study. Authors should follow specific pilot reporting guidelines, if available
	Institutions should support training specifically for pilot studies

CONCLUSIONS

This thesis highlights several aspects of research methodology in the IPV literature where transparency and study quality intersect including publication bias, selective outcome reporting, reporting quality, and knowledge dissemination. It also suggests actions that can be taken to improve research quality and transparency, and Part C demonstrates the process of following these messages. Key takeaway messages include:

1. Prospective study registration is important for transparency and quality.
2. All studies should be published regardless of how interesting or newsworthy they are.
3. Changes to pre-specified methodology sometimes happen after a study begins, but investigators need to identify and justify these changes.
4. Investigators should consider having a knowledge translation plan that goes beyond traditional peer-reviewed publication. Consider non-academic knowledge users and alternatives to publishing such as preprint, news media, social media, and other study-specific creative knowledge translation.
5. Publish protocols and statistical analysis plans if possible.
6. Follow established reporting guidelines, and consider using specific extensions to guidelines when available (e.g. CONSORT extension for pilot trials).

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Appendix 1. Published Studies Included in Analyses

Reference	Study Design
Abramsky T, Devries KM, Michau L, Nakuti J, Musuya T, Kyegombe N, Watts C. The impact of SASA!, a community mobilization intervention, on women's experiences of intimate partner violence: secondary findings from a cluster randomised trial in Kampala, Uganda. J Epidemiol Community Health 2016;70:818–825	RCT
Ahamd F, Hogg-Johnson S, Stewart DE, Skinner HA, Glazier RH, Levinson W. Computer-Assisted Screening for Intimate Partner Violence and Control: A Randomized Trial. Ann Intern Med. 2009;151:93-102	RCT
Aupperle RL, Allard CB, Simmons AN, Flagan T, Thorp SR, Norman SB, Paulus MP, Stein MB. Neural responses during emotional processing before and after cognitive trauma therapy for battered women. Psychiatry Res. 2013 Oct 30;214(1):48-55.	Non-randomized interventional
Bair-Merritt MH, Feudtner C, Mollen CJ, Winters S, Blackstone M, Fein JA. Screening for intimate partner violence using an audiotape questionnaire: a randomized clinical trial in a pediatric emergency department. Arch Pediatr Adolesc Med. 2006 Mar;160(3):311-6.	RCT
Bass JK, Annan J, McIvor Murray S, Kaysen D, Griffiths S, Cetinoglu T, Wachter K, Murray LK, Bolton PA. Controlled Trial of Psychotherapy for Congolese Survivors of Sexual Violence. N Engl J Med 2013;368:2182-91.	RCT
Becker S, Mlay R, Schwandt HM, Lyamuya E. Comparing couples' and individual voluntary counseling and testing for HIV at antenatal clinics in Tanzania: a randomized trial. AIDS Behav. 2010 Jun;14(3):558-66.	RCT
Braithwaite SR, Fincham FD. Computer-based prevention of intimate partner violence in marriage. Behav Res Ther. 2014 Mar;54:12-21.	RCT
Brothers J, Hotton AL, Hosek SG, Harper GW, Fernandez I. Young Women Living with HIV: Outcomes from a Targeted Secondary Prevention Empowerment Pilot Trial. AIDS Pat Care STD. 2016; 30(5), 229-235	RCT
Buller AM, Hidrobo M, Peterman A, Heise L. The way to a man's heart is through his stomach?: a mixed methods study on causal mechanisms through which cash and in-kind food transfers decreased intimate partner violence. BMC Public Health (2016) 16:488	RCT/mixed methods
Calderón SH, Gilbert P, Jackson R, Kohn MA, Gerbert B. Cueing prenatal providers effects on discussions of intimate partner violence. Am J Prev Med. 2008 Feb;34(2):134-7.	RCT

Carter PM, Walton MA, Zimmerman MA, Chermack ST, Roche JS, Cunningham RM. Efficacy of a Universal Brief Intervention for Violence Among Urban Emergency Department Youth. Acad Emerg Med 2016 23(9) 1061-1070	Non-randomized interventional
Choo EK, Zlotnick C, Strong DR, Squires DD, Tape C, Mello MJ. BSAFER: A Web-based intervention for drug use and intimate partner violence demonstrates feasibility and acceptability among women in the emergency department. Substance Abuse, 37:3, 441-449	RCT
Coker AL, Flerx VC, Smith PH, Whitaker DJ, Fadden MK, Williams M. Partner violence screening in rural health care clinics. Am J Public Health. 2007 Jul;97(7):1319-25.	Observational
Creinin MD, Schreiber CA, Bedmarek P, Lintu H, Wagner MS, Meyn LA. Mifepristone and Misoprostol Administered Simultaneously Versus 24 Hours Apart for Abortion: A Randomized Controlled Trial. Obstet Gynecol 2007 109(4) 885-894	RCT
Doherty IA, Myers B, Zule WA, Minnis AM, Kline TL, Parry CD, El-Bassel N, Weschberg WM. Seek, Test and Disclose: knowledge of HIV testing and serostatus among high-risk couples in a South African township. Sex Transm Infect 2016;92: 5–11.	RCT
Feder G, Davies RA, Baird K, Dunne D, Eldridge S, Griffiths C, Gregory A, Howell A, Johnson M, Ramsay J, Rutterford C, Sharp D. Identification and Referral to Improve Safety (IRIS) of women experiencing domestic violence with a primary care training and support programme: a cluster randomised controlled trial. Lancet. 2011 Nov 19;378(9805):1788-95.	RCT
George DT, Phillips MJ, Lifshitz M, Lionetti TA, Spero DE, Ghassemzedeh N, Doty L, Umhau JC, Rawlings RR. Fluoxetine treatment of alcoholic perpetrators of domestic violence: a 12-week, double-blind, randomized, placebo-controlled intervention study. J Clin Psychiatry. 2011 Jan;72(1):60-5.	RCT
Gilbert L, Shaw SA, Goddard-Eckrich D, Chang M, Rowe J, McCrimmon T, Almonte M, Goodwin S, Epperson M. Project WINGS (Women Initiating New Goals of Safety): A randomized controlled trial of a screening, brief intervention and referral to treatment (SBIRT) service to identify and address intimate partner violence victimisation among substance-using women receiving community supervision. Crim Behav Ment Health 2015 25: 314–329.	RCT
Gillum TL, Sun CJ, Woods AB. Can a health clinic-based intervention increase safety in abused women? Results from a pilot study. J Womens Health (Larchmt). 2009 Aug;18(8):1259-64.	RCT
Gupta J, Falb KL, Lehmann H, Kpebo D, Xuan Z, Hossain M, Zimmerman C, Watts C, Annan J. Gender norms and economic empowerment intervention to reduce intimate partner violence against women in rural Côte d'Ivoire: a randomized controlled pilot study. BMC Int Health Hum Rights. 2013 Nov 1;13:46.	RCT
Gupta J, Falb KL, Ponta O, Xuan Z, Abril Campos P, Arellano Gomez A, Valades J, Cariño G, Diaz Olavarrieta C. A nurse-delivered, clinic-based intervention to address	RCT

intimate partner violence among low-income women in Mexico City: findings from a cluster randomized controlled trial. BMC Medicine (2017) 15:128.	
Haberland N, Ndwiga C, McCarthy K, Makanyengo M, Kosgei R, Choi C, Pulerwitz J, Kalibala S. Addressing intimate partner violence and power in relationships in HIV testing services: Results of an intervention piloted in Nairobi, Kenya. 2016 HIVCore Final Report. Washington, DC: USAID | Project Search: HIVCore.	RCT
Hossain M, Zimmerman C, Kiss L, Abramsky T, Kone D, Bakayoko-Topolska M, Annan J, Lehmann H, Watts C. Working with men to prevent intimate partner violence in a conflict-affected setting: a pilot cluster randomized controlled trial in rural Côte d'Ivoire. BMC Public Health. 2014 Apr 10;14:339.	RCT
Houry D, Kemball R, Rhodes KV, Kaslow NJ. Intimate partner violence and mental health symptoms in African American female ED patients. Am J Emerg Med. 2006 Jul;24(4):444-50.	Observational
Houry D, Kaslow NJ, Kemball RS, McNutt LA, Cerulli C, Straus H, Rosenberg E, Lu C, Rhodes KV. Does screening in the emergency department hurt or help victims of intimate partner violence? Ann Emerg Med. 2008 Apr;51(4):433-42, 442.e1-7	Observational
Jaindl M, Endler G, Marculescu R, Eder S, Heisinger S, Kovar FM. Intimate Partner Violence and a New Screening Score – A Prospective Observation Study Over Eight Years. SAS J. Surg., Volume-2; Issue-6 (Nov-Dec, 2016); p-278-286	Observational
Jewkes R, Nduna M, Levin J, Jama N, Dunkle K, Puren A, Duvvury N. Impact of stepping stones on incidence of HIV and HSV-2 and sexual behaviour in rural South Africa: cluster randomised controlled trial. BMJ. 2008 Aug 7;337:a506.	RCT
Johnson DM, Zlotnick C, Perez S. Cognitive behavioral treatment of PTSD in residents of battered women's shelters: results of a randomized clinical trial. J Consult Clin Psychol. 2011 Aug;79(4):542-51.	RCT
Kiely M, El-Mohandes AAE, El-Khorazaty MN, Gantz MG. An Integrated Intervention to Reduce Intimate Partner Violence in Pregnancy: A Randomized Controlled Trial. Obstet Gynecol 2010;115:273–83).	RCT
Klevens J, Kee R, Trick W, Garcia D, Angulo FR, Jones R, Sadowski LS. Effect of screening for partner violence on women's quality of life: a randomized controlled trial. JAMA. 2012 Aug 15;308(7):681-9.	RCT
Kornfeld BD, Bair-Merritt MH, Frosch E, Solomon BS. Postpartum depression and intimate partner violence in urban mothers: co-occurrence and child healthcare utilization. J Pediatr. 2012 Aug;161(2):348-53.e2.	Observational
Kraanen FL, Vedel E, Scholing A, Emmelkamp PMG. The comparative effectiveness of Integrated treatment for Substance abuse and Partner violence (I-StoP) and substance abuse treatment alone: a randomized controlled trial. BMC Psychiatry 2013, 13:189.	RCT
Levesque DA, Johnson JL, Welch CA, Prochaska JM, Paiva AL. Teen Dating Violence Prevention: Cluster-Randomized Trial of Teen Choices, an Online, Stage-	RCT

Based Program for Healthy, Nonviolent Relationships. Psychol Violence. 2016 July ; 6(3): 421–432.	
MacMillan HL, Wathen CN, Jamieson E, Boyle MH, Shannon HS, Ford-Gilboe M, Worster A, Lent B, Coben JH, Campbell JC, McNutt LA, McMaster Violence Against Women Research Group. Screening for Intimate Partner Violence in Health Care Settings: A Randomized Trial. JAMA. 2009;302(5):493-501.	RCT
MacMillan HL, Wathen CN, Jamieson E, Boyle M, McNutt LA, Worster A, Lent B, Webb M; McMaster Violence Against Women Research Group. Approaches to screening for intimate partner violence in health care settings: a randomized trial. JAMA. 2006 Aug 2;296(5):530-6.	RCT
Meffert SM, Abdo AO, Alla OAA, Elmakki YOM, Metzler TJ, Marmar CR. A Pilot Randomized Controlled Trial of Interpersonal Psychotherapy for Sudanese Refugees in Cairo, Egypt. Psych Trauma: Res Pract Policy 2014;6(3):240–9.	RCT
Miller E, Goldstein S, McCauley HL, Jones KA, Dick RN, Jetton J, Silverman JG, Blackburn S, Monasterio E, James L, Tancredi DJ. A School Health Center Intervention for Abusive Adolescent Relationships: A Cluster RCT. Pediatrics 2015, 135(1), 76-85.	RCT
Miller E. Tancredi DJ, Decker MR, McCauley HL, Jones KA, Anderson H, James L, Silverman JG. A family planning clinic-based intervention to address reproductive coercion: a cluster randomized controlled trial. Contraception 94 (2016) 58–67.	RCT
Miller E, Tancredi DJ, McCauley HL, Decker MR, Virata MC, Anderson HA, Stetkevich N, Brown EW, Moideen F, Silverman JG. "Coaching boys into men": a cluster-randomized controlled trial of a dating violence prevention program. J Adolesc Health. 2012 Nov;51(5):431-8.	RCT
Mittal M, Thevenet-Morrison K, Landau J, Cai X, Gibson L, Schroeder A, Chaize J, Carey MP. An Integrated HIV Risk Reduction Intervention for Women with a History of Intimate Partner Violence: Pilot Test Results. AIDS Behav (2017) 21:2219–2232	RCT
Murphy CM, Eckhardt CI, Clifford JM, Lamotte AD, Meis LA. Individual Versus Group Cognitive-Behavioral Therapy for Partner- Violent Men: A Preliminary Randomized Trial. 2017 [epub]	RCT
Muzny CA, Austin EL, Harbison HS, Hook EW. Sexual Partnership Characteristics of African American Women Who Have Sex With Women; Impact on Sexually Transmitted Infection Risk. Sexually Transmitted Diseases 2014, 41(10) 611-617.	Observational
Myers US Browne KC, Norman SB. Treatment Engagement: Female Survivors of Intimate Partner Violence in Treatment for PTSD and Alcohol Use Disorder. J Dual Diag, 11(3-4), 238–247, 2015.	RCT
Padala PR, Madison J, Monnahan M, Marcil W, Price P, Ramaswamy S, Din AU, Wilson DR, Petty F. Risperidone monotherapy for post-traumatic stress disorder related to sexual assault and domestic abuse in women. Int Clin Psychopharmacol. 2006 Sep;21(5):275-80.	RCT

Post LA, Raile ANW, Zeoli AM, Taylor R, Smith PK, Dziura JD, Biroscak BJ. Domestic Violence Homicide: Validating a Scale to Measure Implicit Collusion with Murder. Health Sci Res. 2015; 2(1): 1-8.	Observational
Pronyk PM, Hargreaves JR, Kim JC, Morison LA, Phetla G, Watts C, Busza J, Porter JD. Effect of a structural intervention for the prevention of intimate-partner violence and HIV in rural South Africa: a cluster randomised trial. Lancet. 2006 Dec 2;368(9551):1973-83.	RCT
Rhodes KV, Rodgers M, Sommers M, Hanlon A, Chittams J, Doyle A, Datner E, Crits-Cristoph P. Brief Motivational Intervention for Intimate Partner Violence and Heavy Drinking in the Emergency Department: A Randomized Clinical Trial. JAMA. 2015;314(5):466-477.	RCT
Rothman EF, Wang N. A feasibility test of a brief motivational interview intervention to reduce dating abuse perpetration in a hospital setting. Psychol Violence. 2016 July ; 6(3): 433–441.	RCT
Rothman EF, Corso PS. Propensity for intimate partner abuse and workplace productivity: why employers should care. Violence Against Women. 2008 Sep;14(9):1054-64.	Observational
Saftlas AF, Harland KK, Wallis AB, Cavanaugh J, Dickey P, Peek-Asa C. Motivational interviewing and intimate partner violence: a randomized trial. Ann Epidemiol. 2014 Feb;24(2):144-50.	RCT
Salazar LF, Vivolo-Kantor A, Hardin J, Berkowitz A. A Web-Based Sexual Violence Bystander Intervention for Male College Students: Randomized Controlled Trial. Med Internet Res 2014;16(9):e203.	RCT
Sharps P, Alhusen JL, Bullock L, Bhandari S, Ghazarian S, Udo IE, Campbell J. Engaging and Retaining Abused Women in Perinatal Home Visitation Programs. Pediatrics 2013;132:S134–S139.	RCT
Stover CS. Fathers for Change for Substance Use and Intimate Partner Violence: Initial Community Pilot. Fam Process 2015 Feb 12. [Epub ahead of print].	RCT
Stuart GL, McGeary J, Shorey RC, Knopik VS. Genetics Moderate Alcohol and Intimate Partner Violence Treatment Outcomes in a Randomized Controlled Trial of Hazardous Drinking Men in Batterer Intervention Programs: A Preliminary Investigation. J Consult Clin Psych. 2016, Vol. 84, No. 7, 592–598.	RCT
Sullivan PS, White D, Rosenberg ES, Barnes J, Jones J, Dasgupta S, O'Hara B, Scales L, Salazar LF, Wingood G, DiClemente R, Wall KM, Hoff C, Gratzer B, Allen S, Stephenson R. Safety and acceptability of couples HIV testing and counseling for US men who have sex with men: a randomized prevention study. J Int Assoc Provid AIDS Care. 2014 Mar-Apr;13(2):135-44.	RCT
Taft CT, Macdonald A, Creech SK, Monson CM, Murphy CM. A Randomized Controlled Clinical Trial of the Strength at Home Men's Program for Partner Violence in Military Veterans. J Clin Psychiatry 2016; 77(9):1168-1175.	RCT

Tiwari AFY, Fong DTY, Wong JTY. Effect of a purpose-built intervention for mental health of mainland Chinese immigrant women who are survivors of intimate partner violence: a randomised controlled trial. Lancet 2015 386(S9).	RCT
Tiwari A, Fong DY, Yuen KH, Yuk H, Pang P, Humphreys J, Bullock L. Effect of an advocacy intervention on mental health in Chinese women survivors of intimate partner violence: a randomized controlled trial. JAMA. 2010 Aug 4;304(5):536-43.	RCT
Tiwari A, Chan KL, Cheung DS, Fong DY, Yan EC, Tang DH. The differential effects of intimate terrorism and situational couple violence on mental health outcomes among abused Chinese women: a mixed-method study. BMC Public Health. 2015 Mar 31;15:314.	Mixed methods
Tollefson DR, Phillips I. A Mind-Body Bridging Treatment Program for Domestic Violence Offenders: Program Overview and Evaluation Results. J Fam Viol (2015) 30:783–794.	RCT
Tsai AC, Kakuhikire B, Perkins JM, Vorechovska D, McDonough AQ, Ogburn EL, Downey JM, Rangsberg DR. Measuring personal beliefs and perceived norms about intimate partner violence: Population-based survey experiment in rural Uganda. 2017 PLoS Med 14(5): e1002303.	RCT
Van Parys AS, Deschepper E, Michielsen K, Temmerman M, Verstraelen H. Prevalence and evolution of intimate partner violence before and during pregnancy: a cross-sectional study. BMC Pregnancy and Childbirth 2014, 14:294.	Survey embedded in RCT
Waagman JA, Gray RH, Campbell JC, Thoma M, Ndyanabo A, Ssekasanvu J, Nalugoda F, Kagaayi J, Nakigozi G, Serwadda D, Brahmbhatt H. Effectiveness of an integrated intimate partner violence and HIV prevention intervention in Rakai, Uganda: analysis of an intervention in an existing cluster randomised cohort. Lancet Glob Health. 2015 Jan;3(1):e23-33.	RCT
Weir BW, O'Brien K, Bard RS, Casciato CJ, Maher JE, Dent CW, Dougherty JA, Stark MJ. Reducing HIV and Partner Violence Risk Among Women with Criminal Justice System Involvement: A Randomized Controlled Trial of Two Motivational Interviewing-based Interventions. AIDS Behav. 2009;13:509–522.	RCT
Wolfe DA, Crooks C, Jaffe P, Chiodo D, Hughes R, Ellis W, Stitt L, Donner A. A school-based program to prevent adolescent dating violence: a cluster randomized trial. Arch Pediatr Adolesc Med. 2009 Aug;163(8):692-9.	RCT
Zlotnick C, Capezza NM, Parker D. An interpersonally based intervention for low-income pregnant women with intimate partner violence: a pilot study. Arch Womens Ment Health. 2011 Feb;14(1):55-65.	RCT

RCT = Randomized controlled trial