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

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Abstract:

\textbf{Background:} Reporting quality is paramount when presenting clinical findings in published research to ensure that we have the highest quality of evidence. Poorly reported clinical findings can result in a number of potential pitfalls, including confusion of the methodology used or selective reporting of study results. There are guidelines and checklists that aim to standardize the way in which studies are reported in the literature to ensure transparency. The use of these reporting guidelines may aid in the appropriate reporting of research, which is of increased importance in highly complex fields like intimate partner violence (IPV). The primary objective of this systematic review is to assess the reporting quality of published IPV studies using the CONSORT and STROBE checklists.

\textbf{Methods:} We performed a systematic review of three large study registries for IPV studies. Of the completed studies, we sought full text publications and used reporting checklists to assess the quality of reporting.

\textbf{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).

\textbf{Conclusions:} We identified an opportunity to improve reporting quality by encouraging adherence to reporting guidelines. There should be a particular focus on ensuring that pilot studies report pilot-specific items. All researchers have a responsibility to ensure commitment to high quality reporting to ensure transparency in IPV studies.

Introduction

Intimate partner violence (IPV) refers to behavior by an intimate partner or ex-partner that causes physical, sexual or psychological harm, including physical aggression, sexual coercion, psychological abuse, and controlling behaviors.\textsuperscript{1} IPV is a human rights violation that affects men and women of all walks of life and is pervasive worldwide. More than one third of female homicides globally are perpetrated by an intimate partner,\textsuperscript{2} and IPV is a prevalent source of non-fatal injury to women.\textsuperscript{3} 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.4-6 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.7,8 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.9 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.7 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,10,11 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) for systematic reviews,12,13 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 analysis of a previously published systematic review14,15 which answers a different research question than the original review. The methods are 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 reviewers independently reviewed all identified registry records for possibly eligible studies. We included registry records for studies of any design for which the date of completion was at least 18 months prior to the search date. We chose a cut-off of 18 months to allow sufficient lag time between reporting the study is complete and publication. We excluded registry records 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 uncommon 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 study records in this review for completeness.

Identification of Publications

Two authors independently attempted to locate each publication to match the included trial records. We searched AMED (Allied and Complementary Medicine Database), Embase, Global Health, Healthstar, Cinahl, Medline, and PsycInfo using the Ovid search interface, plus Google Scholar for the matching publications. 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 publications for which it was unclear if they matched the registry record. We included all published studies as long as they reported a primary outcome (i.e., not just feasibility or baseline characteristics), including preliminary findings. In case of disagreement between the two reviewers, a senior author broke the tie.

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 more senior 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 con-
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 why a pilot trial is needed.\textsuperscript{16,17} The STROBE checklist is a 33 item list that is similar to CONSORT but tailored for observational studies. For example, randomization and blinding do not 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 awarded 1 point for complete reporting of the item, 0.5 points for reporting with weaknesses, and 0 points for items that were not reported. In case of disagreement between the two reviewers, a senior author broke the tie.

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 (Figure 1; 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 loca-
tions, 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 1).

**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-

| CONSORT Item                                      | 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)                  | 33 (88.3)         |
| 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)           |
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, methodological 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 2).

**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

| CONSORT Item – Pilot Randomized Trials (CONSORT Pilot) | 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 exclusations                                | 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)          |
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 3).

Table 3: Quality of Reporting for Observational Studies (STROBE).

| STROBE Item                                      | 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 and 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 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;
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 reporting guidelines) with their manuscript. Some items are subjective to rate; particularly that harms are poorly reported properly in a study, the intervention may be adopted into clinical practice without critical information about possible drawbacks. If there are unreported conflicts of interest, such as industry influence, clinicians could adopt an intervention into practice without knowledge of the industry bias and the ramifications thereof. Additionally, poor reporting makes it difficult for systematic review and clinical practice guideline authors to make appropriate decisions regarding the available literature. It is possible that otherwise good studies could be discarded due to poor reporting, and will fail to make an impact in the field. All of these drawbacks of poor reporting make it more difficult for clinicians to implement evidence-based interventions or programs, which can negatively affect the victims of IPV in two ways: failure to implement a high-quality intervention/program; or implementing a harmful or ineffective intervention/program.

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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