Author's response to reviews

Title: The comparative effectiveness of Integrated treatment for Substance abuse and Partner violence (I-StoP) and substance abuse treatment alone: A randomized controlled trial

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Author's response to reviews: see over
Dear editor,

Herby we send you the revised version of the manuscript “The comparative effectiveness of Integrated treatment for Substance abuse and Partner violence (I-StoP) and substance abuse treatment alone: A randomized controlled trial”. In response to the previous version of the manuscript, you made the following comment:

“Based on the two peer reviews of this paper, we would be willing to examine a revision. I am concerned about power. Can the authors demonstrate that they had sufficient power to detect differences between groups? Low power could explain the null findings. Given the concerns about the paper, while we would consider a revision, we cannot promise acceptance of the paper. Authors will need to demonstrate rigorously that the paper has sufficient evidence in order to draw substantial conclusions about their research.”

We agree that power might be an issue. However, based on Cohen’s (1992) article, we argue that to demonstrate a large difference between 2 groups using 1-sided testing for a power of .80, 20 participants per condition were needed. Also, we argue that to be clinically meaningful, the difference between the 2 conditions should be large. To give an example: if a sample is large enough, the difference between perpetrating 3 acts of physical IPV in 8 weeks may statistically differ from perpetrating 4 acts of physical IPV in 8 weeks. However, the question is whether this difference is also clinically relevant. We argue that this is not the case and therefore, we consider it necessary that the difference between the two conditions should be large.

When running ITT analyses, over 20 participants per condition were included and thus a large difference between conditions would have been detected. Power for the completers sample was indeed on the low side (i.e., less than 20 participants per condition were included). However, apart from power considerations, it is important to note that treatment of the combination of IPV and substance abuse is a relative young and difficult topic of research, on which much information is still lacking. Although the main limitation of this study lies in the substantial number of dropouts and consequent relatively low power, the additional value of this study compared to previous research is that it included individual treatments (instead of group treatments), different types of substances (instead of only alcohol) and both male and female patients. The major finding is that - independent of pretreatment severity of IPV - the frequency of IPV had dropped to about zero in both treatment conditions for the patients who finished the treatment. Future studies should therefore focus on variables that predict and prevent dropout.

In addition, we adapted the manuscript according to the reviewers’ comments.
Reviewer 1

1. The abstract states that "no successful treatments for perpetrators of intimate partner violence are available, possibly due to neglecting individual differences between IPV perpetrators" and then substance use disorders are described as a potential factor. However, in the introduction, it is noted that IPV perpetration has been reduced following treatment for substance abuse. Please re-write that portion of the abstract to more accurately reflect the current state of the substance use-IPV treatment literature.

We agree with the reviewer that it is not accurate to report that there are no effective treatments, and changed the abstract accordingly. We now report that it has been demonstrated that successfully treating alcohol dependence in alcohol dependent IPV perpetrators led to reductions in IPV perpetration.

2. It seems that the prevalence of IPV was lower than expected in the current sample/study. In the methods, it would be helpful to provide more description of the inclusion and exclusion criteria. Was there an evidence-based rationale for requiring participants to have perpetrated 7 or more acts of IPV? What does "being able to follow outpatient treatment" entail? Why were individuals who were diagnosed with crack cocaine dependence excluded if cocaine was a focus of the current study? Did being excluded for receiving treatment for other mental health problems mean lifetime treatment or current treatment? (p 7)

We expanded the participants-section of the method (p. 7 and 8). We now report why we chose to include patients who committed at least 7 acts of physical IPV (i.e., including patients who were involved in a pattern of IPV perpetration in an enduring relationship). Further, we only included patients who were triaged to outpatient treatment, because inpatients followed more extensive treatment programs including additional social skills training and emotion regulation treatment, which were (partially) overlapping with I-StoP.

Patients diagnosed with crack cocaine abuse or dependence were excluded because in the majority of cases, these patients need a more intensive treatment and are thus triaged to inpatient treatment. Also, in fact, none of the participants were excluded solely because of crack cocaine or heroin use disorders. Patients who were currently receiving other treatment were excluded.

3. Retention was a significant problem in the current study. In the discussion on page 22, it is noted that dropouts and completers did not differ with respect to pretreatment IPV perpetration, verbal IPV perpetration, inflicted injuries, days of abstinence, and substance use Z-scores. Did they differ in pretreatment psychopathology?

We ran additional analyses; dropouts and completers did not differ regarding being diagnosed with an alcohol use disorder, a cannabis use disorder, a cocaine use disorder, other substance use disorders, panic disorder, social phobia, OCD, PTSD, and GAD. However, dropouts were more often diagnosed with a major depressive episode than completers ($X^2 (1) = 4.45; p = .04$). We added this to the discussion section (p.22). In addition, we added that targeting depressive symptoms might prevent dropout, as suggested by Kirchner et al. (2002) (p. 23).

4. On page 23, the authors cite as a reason for delay in treatment that “patients were doing so well they did not feel the need to come to the institution every week.” In these cases, were therapists in agreement that patients were doing so well they could skip treatment or could this actually be avoidance behavior on the part of the patient?

This happened indeed in agreement with the therapist; we added this on page 24.
5. On page 25, the authors refer to this sample as "representative" of patients entering substance abuse treatment. I would refrain from using this descriptor as of the 1799 patients who completed the J-IPV, only 52 were randomized to treatment and only 19 completed; further, many were excluded from participation for reasons that are not uncommon to substance abuse treatment clientele (e.g., seeking treatment for other mental health problems, being diagnosed as heroin or crack cocaine dependent).

We agree with the reviewer and deleted the word “representative”.

6. In general, are the dropout rates observed in this study similar to those found in other studies examining treatment for substance use and IPV? How do the authors think their findings might apply to other settings (e.g., court-mandated substance abuse and IPV treatment)?

Only one other study examined the effectiveness of a combined substance abuse-partner violence treatment (Easton et al., 2007). However, these treatments took place in a group on a weekly basis, patients were allowed to miss sessions, and treatments were running over a shorter period of time, which decreased the chance that patients dropped-out prematurely. Also, patients with drug dependence were excluded. It is therefore difficult to compare the current study to Easton et al.’s (2007) study. Further, it is difficult to predict how patients would behave if they were court-referred to substance abuse treatment or domestic violence treatment. Until now, as far as we know, no comparable study was conducted on patients who were court mandated. A similar study is our own pilot study in an ambulatory forensic setting. In that study, IPV was the primary reason for referral and treatment, with comorbid substance abuse / dependence present. So, the samples in both studies have many in common but may be not completely comparable. The treatment protocols compared in that study were I-Stop versus regular IPV focused treatment. A part of the patients were court mandated and the dropout rates were comparable. We shortly mention this in the discussion (p. 22).

Reviewer 2

1. What is the rationale for selecting those who disclosed 7 or more acts of physical IPV? What are the psychometric characteristics (e.g., validity) of the measure?

As described above (see reviewer 1, comment 2), we chose to include patients who committed at least 7 acts of physical IPV (i.e., we only aimed to include patients who were involved in a pattern of IPV perpetration); we added this to the MS (p. 7). Also, we describe psychometrics of the measures in a more prominent place now in the method section.

2. It would be helpful to present empirical measures of treatment fidelity to demonstrate that conditions were truly different in content.

Unfortunately, no empirical measures of treatment fidelity were conducted. However, primary aim of the 90 minutes supervision sessions that took place once every two weeks was to guarantee treatment fidelity. All ongoing treatments were discussed in detail. Therefore, we are certain that treatments were truly different from one another.

3. Psychometrics are needed on measures, for this sample. I believe all participants were not actually married (p. 12, marital satisfaction).

We ran reliability analyses for this sample on pretreatment measures and found the following results:

Physical IPV perpetration (CTS2): Cronbach’s alpha = .83
Verbal IPV perpetration (CTS2): Cronbach’s alpha = .71
Inflicted injuries (CTS2): Cronbach’s alpha = .55
BSI: Cronbach’s alpha = .97
MMQ: Cronbach’s alpha = .91

Although Cronbach’s alpha for inflicted injuries (a secondary outcome measure) is somewhat low, we argue that reliability is sufficient to warrant use of the chosen instruments.

Further, the reviewer correctly observed that not all patients were married. Therefore, we changed “marital satisfaction” to “relationship satisfaction”. Moreover, it is very common in the Netherlands to live together without being married.

4. p. 12: Were some participants triaged to outpatient and others to inpatient treatment? If so, this is an important characteristic that needs to be considered in analyses. (I see in the discussion that inpatients were excluded; this may be helpful to clarify earlier.)

Only patients were included who were triaged to outpatient treatment (see p. 7, inclusion criterion 4). We added to the method section that we only included patients who were triaged to outpatient treatment, because inpatients followed more extensive treatment programs including additional social skills training and emotion regulation treatment, which were partly overlapping with I-StoP.

5. Shouldn’t ITT analyses include all participants?

Indeed, the strictest interpretation of ITT is that all randomized patients should be analyzed. However, a study that investigated whether studies that used ITT actually analyzed all randomized patients found that only 42% of 100 randomly selected RCTs’ did so (Kruse, Alper, Reust, Stevermer, Shannon, & Williams, 2002). The second most cited reason for excluding patients was that patients had not received any treatment. To clarify this, we adapted figure 1 and specified that in both conditions, 1 participant was not analyzed because of not starting treatment. However, if the reviewer wishes, we could reanalyze the data and include all randomized patients.

6. Only 11 and 8 participants in the two conditions completed 75% of treatment sessions.

We agree with the reviewer that the number of participants that completed treatments was low. We argue that this is a consequence of conducting research in routine clinical practice in which patients referred themselves to substance abuse treatment (and were thus not, for example, court-referred). Also, patients did not receive compensation for participating in the study. Although it is the primary limitation of the study, we think that it is an accurate reflection of what would happen if treatments were implemented in routine clinical care (i.e., the external validity is probably high) (p. 22).

7. Assessment rates at halfway through treatment and completion of treatment were quite low (49% and 39%, respectively).

We agree that assessment rates are low. We reason, though, that this results from doing research in this complex population with patients who are not only diagnosed with substance use disorders but also repeatedly committed IPV against their partner. After dropping out of treatment it was tried in many ways to obtain measures, i.e., by repeatedly phoning patients, and sending questionnaires by mail. Also, dropouts were rewarded with 15 euro’s (approximately 20 US dollars) if they completed questionnaires. However, most participants could either not be reached (because, for example, they changed their phone number) or promised to return the completed questionnaires, but in fact did not do this. We reported on this in the discussion (p. 22).

8. An additional limitation of the study is the lack of follow-up post-treatment.
Again, we agree with the reviewer and added this to the discussion (p. 25). On the other hand, although posttreatment and follow-up results are both relevant, we think that they reflect two different research topics that each have merits in their own. We hope to collect follow up results in the next year.

We hope that, with the adaptations we made, the manuscript is now suitable for publication in BMC Psychiatry.

Sincerely,

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Agnes Scholing
Paul M. G. Emmelkamp