

A group intervention to reduce intimate partner violence among female drug users. Results from a randomized controlled pilot trial in a community substance abuse center

Intervención grupal para reducir la violencia de género entre consumidoras de drogas. Resultados de un estudio piloto en un centro comunitario de tratamiento de adicciones

JUDIT TIRADO-MUÑOZ*, GAIL GILCHRIST*,***, EVA LLIGOÑA**, LOUISA GILBERT****, MARTA TORRENS *,**

*Addiction Research Group, IMIM-Institut Hospital del Mar d'Investigacions Mèdiques; Universitat Autònoma de Barcelona, Barcelona, Spain

** Institute of Neuropsychiatry and Addictions, Parc de Salut Mar, Barcelona, Spain

*** National Addiction Centre, Institute of Psychiatry, King's College, London, UK

**** Social Intervention Group, Columbia University, New York, NY, USA

Abstract

Background: A greater proportion of drug dependent women are victims of intimate partner violence (IPV) than women in the general population; however, few interventions have been developed to reduce IPV among drug dependent women. **Methods:** An adapted version of the *Women's Wellness Treatment*, to address IPV and depressive symptoms, was piloted in a randomized controlled trial conducted in outpatient treatment program in Barcelona, Spain among 14 women receiving outpatient treatment for a drug use disorder who screened positive for IPV in the previous month. Participants were randomly assigned to receive the 10 session cognitive behavioral therapy (IPaViT-CBT) group intervention or treatment as usual. The frequency of IPV, depressive symptoms, substance use, quality of life and health status were assessed at baseline and 1, 3 and 12 months post intervention. Intention to treat analysis was performed. **Results:** Moderate effects for the intervention were found in reducing psychological maltreatment, increasing assertiveness of IPV and reducing aggressiveness in the partner relationship, and in reducing the frequency of drinking up to 3 months post intervention. The intervention did not significantly reduce the likelihood of any IPV, depressive symptoms, quality of life or self-reported health status, up to 12-months post intervention.

Conclusion: This pilot trial suggests some initial support for the 10-session CBT group intervention among IPV victims who received treatment for drug use. Study findings indicate that it is feasible to deliver the intervention in a community substance abuse center. An adequately powered trial is required to replicate these results.

Keywords: intimate partner violence; substance abuse; females; cognitive behavioral therapy; group intervention; randomized controlled trial.

Resumen

Antecedentes: Las mujeres usuarias de drogas son víctimas de violencia de género en mayor proporción que las mujeres en población general; sin embargo, pocas intervenciones se han desarrollado para reducir la violencia de género entre mujeres usuarias de drogas. **Métodos:** Una versión adaptada de la intervención "*Women's Wellness Treatment*" para reducir violencia de género y síntomas depresivos, ha sido evaluada mediante un ensayo clínico piloto en un centro de tratamiento ambulatorio en Barcelona, España. Catorce mujeres que recibían tratamiento ambulatorio para un trastorno por consumo de sustancias y que declararon ser víctimas de violencia en el mes anterior fueron incluidas en el ensayo clínico. Las participantes fueron asignados al azar para recibir 10 sesiones grupales de terapia cognitivo-conductual (IPaViT-CBT) o tratamiento habitual. La frecuencia de violencia, síntomas depresivos, consumo de sustancias, calidad de vida y estado de salud fueron evaluados al inicio del estudio y 1, 3 y 12 meses después de la intervención. Se realizó análisis por intención de tratar. **Resultados:** Se encontraron efectos moderados de la intervención en la reducción de maltrato psicológico, aumento de la asertividad y la reducción de la agresividad en la relación de pareja, y reducción en la frecuencia de consumo de alcohol hasta 3 meses después de la intervención. La intervención no redujo significativamente la probabilidad de ser víctima de cualquier tipo de violencia de género, los síntomas depresivos, calidad de vida o el estado de salud auto-referido, hasta 12 meses después de la intervención. **Conclusiones:** Los resultados de este estudio piloto indican que es factible realizar una intervención de 10 sesiones grupales de TCC entre las víctimas de violencia de género que reciben tratamiento por uso de sustancias en un centro comunitario de tratamiento de adicciones. Se requiere un ensayo clínico más robusto para replicar estos resultados.

Palabras clave: violencia de género; abuso de sustancias, mujeres, terapia cognitivo-conductual, intervención grupal, ensayo aleatorizado controlado.

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Send correspondence to:

Marta Torrens MD, PhD. Addiction Unit. Institute of Neuropsychiatry and Addictions, Parc de Salut Mar, Passeig Marítim, 25-29, 08003 Barcelona, Spain. E-mail: mtorrens@parcdesalutmar.cat

Intimate partner violence (IPV) is a growing public health concern. The World Health Organisation (WHO) estimate that one-third of women globally have been victims of IPV at least once in their lifetime (World Health Organization, 2013). Rates of physical and sexual IPV victimization are even higher among women with a substance use disorder (SUD) (Cohen & Hien, 2006; El-Bassel, Gilbert, Witte, Wu, & Chang, 2011; El-Bassel, Gilbert, Wu, Go, & Hill, 2005; Miller, Downs, & Testa, 1993) ranging from 40-70% among women in substance abuse treatment programs (Gilbert et al., 2006; Gilchrist, Blazquez, & Torrens, 2011; Wagner et al., 2009). IPV victimization is strongly associated with mental health problems (Campbell, 2002; Howard et al., 2010; Trevillion, Oram, Feder, & Howard, 2012), with recent evidence confirming that around 20% of women who experienced IPV in the past year, developing a new onset psychiatric disorder (Okuda et al., 2011). The high rate of IPV among female substance users has adverse consequences on physical, mental and reproductive health. Among female drug users, IPV is associated with mental health problems including depression (Connelly, Hazen, Baker-Ericzen, Landsverk, & Horwitz, 2013; Gilchrist, Blazquez, & Torrens, 2012; Illangasekare, Burke, McDonnell, & Gielen, 2013), borderline personality disorder (Gilchrist, Blazquez, & Torrens, 2012) and Post-Traumatic Stress Disorder (PTSD) (Cohen, Field, Campbell, & Hien, 2013; Kaysen et al., 2007; Najavits, Sonn, Walsh, & Weiss, 2004; Peters, Khondkaryan, & Sullivan, 2012). Those drug dependent women with depression are more than twice as likely to experience IPV (OR= 2.42), and over three times as likely (OR= 3.05) for those drug dependent women with a borderline personality disorder (Gilchrist, Blazquez, & Torrens, 2012). Women who met criteria for PTSD and SUD, were more than twice as likely to experience IPV (OR= 2.7) (Cohen, Field, Campbell, & Hien, 2013). A recent general population study in Chile found that the prevalence of being a victim of assault, aggression or sexual violence was greater among men and women with higher monthly alcohol consumption or who binge drink (six or more drinks on one occasion at least once in the month) compared to those who did not report these consumption patterns (Castillo-Carniglia, Pizarro, Luengo, & Soto-Brandt, 2014). In addition, IPV results in increasing or maintaining substance abuse (El-Bassel, Gilbert, Wu, Go, & Hill, 2005; McKinney, Caetano, Rodriguez, & Okoro, 2010; Testa, Livingston, & Hoffman, 2007) and more physical ill health and health care utilization (Liebschutz, Mulvey, & Samet, 1997). Drug dependent women who experience IPV may engage in risky sex and drug taking practices, potentially due to the negative influence of the perpetrator (Wagner et al., 2009) which may put them at increased risk for bloodborne viruses, sexually acquired infections and unwanted pregnancy (Bourgois, Prince, & Moss, 2004; Campbell et al., 2008; El-Bassel, Gilbert, Witte, Wu, & Chang, 2011; Singer, 1996). As such, interventions need to consider female drug users' relationships with their partners (Hearn, O'Sulli-

van, El-Bassel, & Gilbert, 2005) and address all aspects of their lives including substance use disorders, psychiatric comorbidity and sexual and injecting risk behaviours. Previous systematic reviews identified interventions addressing trauma and substance abuse simultaneously (Najavits, 2009) and SUD among women survivors of IPV (Fowler & Faulkner, 2011). A more recent systematic review of RCT interventions to reduce IPV among women (Tirado-Muñoz, Gilchrist, Farré, Hegarty, & Torrens, 2014), identified only one RCT intervention targeted at female drug abusers where the outcome assessed was IPV, the Women's Wellness Treatment (WWT) (Gilbert et al., 2006). Other interventions addressing substance use, PTSD symptoms and IPV were identified such as ATRIUM (Addiction and trauma recovery integration model) (Miller & Guidry, 2001), TREM (Trauma Recovery and Empowerment Model) (Harris, 1998). Seeking Safety (SS: A treatment manual for PTSD and Substance Abuse) (Najavits, 2002) and TRIAD (more focused on teaching interpersonal skills) (Fearday, Clark, & Edington, 2001). Seeking Safety is clearly the most studied PTSD-SUDs intervention. Finally, WWT was the intervention which most focused on the purpose of this research in terms of primary outcome and intensity of intervention.

The purpose of this pilot trial was (1) to adapt the WWT manualized group intervention to address IPV and depressive symptoms among females receiving drug treatment; (2) to conduct a pilot randomized controlled trial to assess the feasibility and initial efficacy of the CBT intervention on reducing IPV compared to treatment as usual at 1,3 and 12 months post intervention.

Methods

Study design and sample description

The clinical trial was conducted from March 2011 to June 2012 at an outpatient community drug treatment centre in Barcelona (Spain). Ethical approval was granted by the Institute's Human Research Ethics Committee of IMIM-Institut Hospital del Mar d'Investigacions Mèdiques; Parc de Salut Mar de Barcelona.

Participants were recruited from the waiting rooms of two outpatient drug treatment centres in Barcelona. Potential participants were approached by the researcher in the waiting room who discussed the objectives of the study, and gave them an information leaflet. If they agreed to participate, they were screened to determine whether they met the study's inclusion criteria. Female drug abusers were eligible for the study if they a) were aged 18 or older; b) were currently receiving substance abuse treatment in a outpatient drug treatment center; c) were currently in a relationship with a male partner and d) reported IPV in the past month using an adapted version of the Composite Abuse Scale (Hegarty, Sheehan, & Sconfeld, 1999) and the Psychological Maltreatment of Women Inventory (Tolman, 1999) e) could

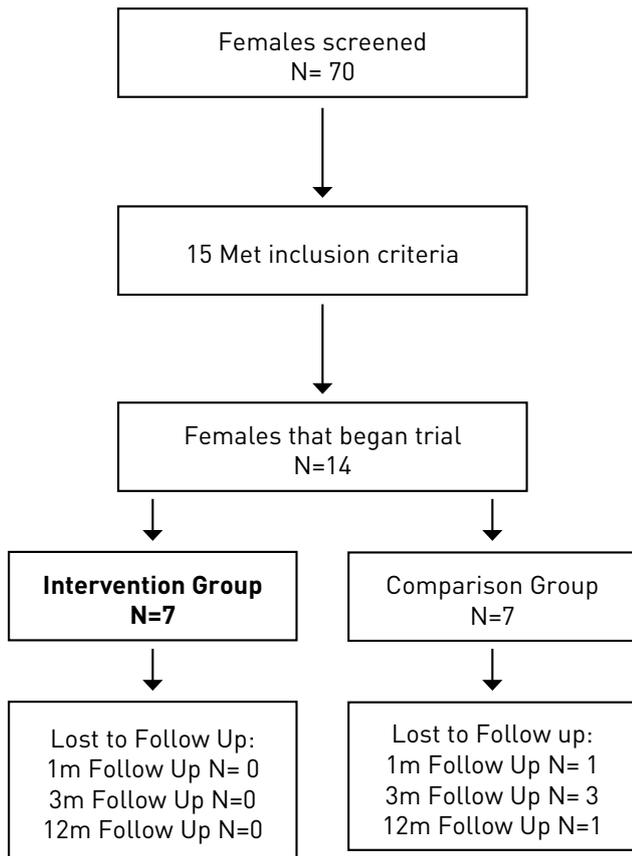


Figure 1. Study Flowchart

communicate in Spanish. Seventy female drug abusers were screened, 15 were eligible to participate and 14 agreed to participate. None of the participants received financial incentive to respond the follow-up assessments. Of the 14 participants who began the trial following randomisation, three were lost to follow up - one moved away from Barcelona, one was receiving inpatient treatment, and one was incarcerated (Figure 1).

Intervention: Process of adaptation

A systematic review of RCT interventions to reduce IPV among females (Tirado-Muñoz, Gilchrist, Farré, Hegarty, & Torrens, 2014), identified only one RCT intervention targeted at female substance users, the Women's Wellness Treatment (WWT) (Gilbert et al., 2006). With the authors' consent, the WWT intervention was translated into Spanish and adapted to meet the needs of female drug abusers and the drug abuse treatment system in Spain. The original WWT intervention had 11 2-hour group sessions plus 1 individual session, aimed to promote relationship safety and to reduce drug use. Based on previous experience of delivering group interventions and retaining participants in Spain, we decided to reduce the number of sessions from 12 to 10 and address negative mood given the high prevalence of depression among women in drug treatment (Torrens, Gilchrist, & Domingo-Salvany, 2011). Therefore, a new ses-

sion on addressing negative mood was included, which was adapted with the authors' permission from the Behavioural Therapy for Depression in Drug Dependence (BTDD) Manual (Carpenter, Aharonovich, Smith, Iguchi, & Nunes, 2006). This session presented and discussed the model of depression and highlights the importance of life satisfaction, through encouraging women to introduce pleasant activities into their lives, and assists them to develop a pleasant activities list. Women in the trial were offered the chance to participate (free of charge) in classes of their choice at a local community centre (e.g., yoga, dance, cooking, computing etc.) in an attempt to facilitate pleasant activities and in turn reduce negative mood. Due to the high prevalence of hepatitis C among females who inject drugs (Gilchrist, Blazquez, & Torrens, 2011) we adapted the original session on HIV to also include education on hepatitis C transmission.

The adaptation phase was undertaken by the research team in Spain, in consultation with the original authors of both manualized therapies (Carpenter, Aharonovich, Smith, Iguchi, & Nunes, 2006; Gilbert et al., 2006). The final intervention "IPaViT-CBT" (Intimate Partner Violence Therapy-Cognitive Behavioral Therapy) consisted of 10 weekly 2 hour group sessions. The following 10 sessions were administered in a group format:

- Session 1 Preparing for the journey: Enhancing motivation for wellness
- Session 2 Building relationship safety (group session)
- Session 3 Identifying triggers for drug use and relationship conflict
- Session 4 Healing from psychological IPV
- Session 5 Dealing with physical IPV: reconstructing anger
- Session 6 Recovering from trauma: Identifying PTSD triggers
- Session 7 Managing negative mood
- Session 8 Setting sexual boundaries: Negotiation skills
- Session 9 Avoiding dangerous sexual liaisons: Identifying triggers for HIV/ HCV risk and Identifying strategies for reducing HIV/ HCV risk.
- Session 10 On the road to recovery and safety: Celebrating successes.

The format of the intervention across sessions consisted of a sequence of 5 steps. Each session started with: (1) an inspirational opening (quote from a female artist or writer) which served to inspire and motivate participants in their recovery, and tied into the context of the session; (2) a recovery and relationship check-in was completed for each participant thereafter to detect and discuss any incident occurring between sessions related to participants' drug use or relationship conflicts, identifying triggers that would help women generate safety plans and provides new skills to reduce IPV; (3) raising awareness, through discussion, about the relationship between drug-related behaviours and different forms of IPV; (4) skills building and group discussion; and (5) a check-in of the participants' outstanding needs/

problems and how to address these. At the end of each session, participants were encouraged to practice 'homework' exercises between sessions (e.g. positive self talk, behavioural activation). The final intervention "*IPaViT-CBT*" was a manualized small-group, cognitive behavioural intervention, designed to reduce IPV and improve depressive symptoms in female drug users. A formal cultural adaptation and translation of WWT to adapt the intervention content activities to the target population was conducted taking into account the following aspects: 1) language: some concepts or words that could not be literally translated were replaced in order to make more sense to participants; and 2) resources: Some exercises, quotes and resources information were replaced to be more culturally meaningful to the target population.

Intervention conditions

The 14 participants were randomly assigned to receive either the experimental or control condition. Participants were assigned a random number generated using SPSS from 1-14. Numbers 1 to 7 were assigned to (a) the treatment condition (10 session *IPaViT-CBT* group intervention) and numbers 8 to 14 were assigned to (b) control condition. Due to the nature of the study, blinding of the participants was not feasible. Assessors were not blinded to the study condition. A pre-experimental evaluation was not conducted; the researcher (JT) was responsible for collecting baseline and follow-up data from participants in both the intervention and control conditions.

Women randomized to the intervention condition received 10 2-hour sessions over 5 weeks. The intervention was delivered in outpatient drug treatment settings by a clinical psychologist. The professional providing the *IPaViT-CBT* intervention in the experimental condition was a clinical psychologist (ELL) with over 30 years' experience working with drug users, including the delivery of CBT in groups. The intervention was manualized, therefore, instructions were contained in the manual. However, JT met with the clinical psychologist to discuss the delivery of the manualized therapy before each session was delivered. A researcher (JT) attended each session to check the fidelity of the intervention delivered against the manual. To increase participation, participants in the treatment group received text reminders 24 hours before each session, a financial incentive for attending each session and had their travel costs reimbursed as the integrated intervention was in addition to their treatment as usual for their drug use. Participants assigned to the intervention group continued to receive all treatment as usual services. The control and intervention groups did not receive any financial incentives, text reminders (sms) or reimbursement of travel costs to attend treatment as usual at the community drugs treatment center.

The control condition received treatment as usual provided by the outpatient drug treatment centre. Treatment as

usual consisted of fortnightly monitoring of their substance use and psychiatric comorbidity by relevant professionals (psychiatrists, psychologists, and social workers) and monitoring medication if it was prescribed. Treatment as usual included motivational interviewing, relapse prevention and counselling. While addressing IPV was not part of usual treatment, if participants in the control group disclosed IPV during a routine visit with a professional, the usual referral/treatment pathways were followed to ensure the participant was not in immediate danger. At recruitment potential participants were informed that they would be randomized to receive either the integrated intervention or to treatment as usual, and that if the intervention significantly reduced IPV, those randomized to the control group would be offered the intervention in the future. This was explained to participants prior to their consenting to be randomized.

Different therapists delivered the control and intervention conditions. Women in both the intervention and control groups received treatment as usual for their drug use.

Outcome measures

All participants completed a one to one interviewer-administered assessment at baseline in a private room of the centres involved in the study. Follow up interviews were completed in a private room or by telephone if the participant was unable to attend in person.

Sociodemographics variables

Data on age, education, employment status, marital status, health status and partner characteristics were collected.

Intimate partner violence

Two instruments were used to measure IPV - the Composite Abuse Scale (CAS) (Hegarty, Sheehan, & Sconfeld, 1999) and the Psychological Maltreatment of Women Inventory (PMWI) (Tolman, 1999). In addition, the Spouse Specific Assertion/Aggression Scale (SSAAS) (O'Leary & Curley, 1986) assessed assertiveness and aggression in intimate relationships.

Any IPV in the past month and 12 months was assessed using the 30-item CAS to identify the type of abuse experienced (severe combined (sexual and physical abuse); physical abuse only; physical abuse and emotional abuse and/or harassment; emotional abuse and/or harassment). Good internal reliability (Cronbach's alpha > 0.85) was found for these 4 factors and the corrected item-total correlations were high (> 0.5) (Hegarty, Bush, & Sheehan, 2005). Each item requires a response to the frequency of occurrence in the previous 12 months: "never", "only once", "several times", "monthly", "weekly" or "daily". An accepted cut-off score of ≥ 7 was used to indicate any IPV.

The Psychological Maltreatment of Women Inventory (PMWI) measured psychological abuse in the past month and 12 months (Tolman, 1989). The PMWI has 58 items

that assess the frequency of emotional/verbal abuse and dominance/isolation from 1 “never” to 5 “very frequently”. The dominance/isolation subscale includes “items related to rigid observance of traditional sex roles, demands for subservience, and isolation from resources” and the emotional/verbal abuse subscale includes “withholding emotional resources, behaviour that could degrade women and verbal abuse”. The PMWI was also shown to have good reliability and validity in a sample of primarily white and African American women (Cronbach’s alpha = 0.88) (Tolman, 1999)

Abusive relationships show lower levels of spouse-specific assertion in comparison with non-abusive relationships (O’Leary & Curley, 1986). SSAAS measured the degree of similarity or difference that the respondent felt towards each of 29 statements about assertiveness and aggression in their relationship, ranging from; -3 (extremely unlike me) to +3 (extremely like me).

The CAS, PMWI and SASS were not available in Spanish. Therefore, these instruments were forward translated from English to Spanish by a native Spanish speaker familiar with the research area, and these Spanish versions were back translated to English by a native English speaker. These back translated English versions were sent to the original authors of each instrument for approval. The Spanish version of the CAS, PMWI and SASS were thereafter, approved by the original authors.

Depression

The Spanish version of the Beck Depression Inventory (BDI-II) assessed depressive symptoms in the last week (Bonicatto, Dew, & Soria, 1998). BDI-II (Beck, Steer, & Garbin, 1988) has 21 items that measure the severity of depression where each answer is scored 0 (absence of symptoms) to 3 (more presence of symptoms). The BDI-II has a high internal reliability (Cronbach’s alpha = 0.88) (Bonicatto, Dew, & Soria, 1998). Participants with depression (Score of 19-63, indicating moderate to severe depression) were referred to a psychologist/psychiatrist at the outpatient drug treatment centre.

Quality of Life and Health Status

Quality of life and health perception were measured by a visual analogue scale ranking from 0 (lowest quality of life/health) to 100 (highest quality of life/health). Good (0.87) test re-test reliability correlation has been reported (Boer et al., 2004)

Substance use

Finally, the frequency and amount of alcohol, heroin, cocaine, cannabis and benzodiazepine use in the past week were recorded using a substance use consumption table designed by the Spanish research team based on the Time Line Follow-back (Sobell & Sobell, 1992). The test-retest re-

liability ranges from $r = +0.79$ to $+0.98$ (Sobell, Maisto, Sobell, & Cooper, 1979).

All instruments were re-administered by the researcher 1, 3, and 12 months post intervention. IPV in the past month was assessed using the CAS and PMWI at all follow up points. Any IPV in the past 12 months was also assessed using the CAS at 12 month follow up. Depressive symptoms in the last week were assessed using the BDI at all follow up points.

Fidelity

Participants in the intervention arm of the trial completed an evaluation form at the end of each of the 10 group sessions to determine whether the content and information gained in each session met the objectives of each session with responses ranging from 1 (strongly disagree) to 5 (totally agree). Furthermore, 3 questions were asked at the end of each session about: 1) how comfortable the participant felt during the session, ranging from 1 (very uncomfortable) to 5 (very comfortable); 2) the skill/ability of the therapist, ranging from 1 (excellent) to 5 (poor) and 3) their satisfaction with the session, ranging from 1 (not at all satisfied) to 5 (very satisfied).

Analysis

Categorical variables were calculated as frequencies and percentages, and continuous variables as means and standard deviations. Intention to treat analyses was conducted to avoid loss to follow-up using baseline scores or last follow up scores. Fisher’s exact tests were used to compare differences in outcomes between groups for categorical variables, and Mann-Whitney tests were used to compare differences in outcomes between groups for continuous variables. Pre-post differences between baseline and follow ups were calculated. It was not possible to control for baseline outcome indicators due to the small sample size. For the purpose of this study, a 5% or lower p-value is considered statistically significant. We hypothesized that participants who received the WWT would be more likely to reduce IPV and depression symptoms compared to TAU participants. Differential attrition by treatment group was found. All those lost to follow up were allocated to the control condition. Intention to treat analysis was conducted.

Results

Attendance and Retention

Participation in the group intervention was variable (average 5 sessions attended, range 0-9 sessions).

Sociodemographics

The sociodemographic characteristics of the participants are shown in table 1. The mean age of 14 substance abusers women was 40 years (SD = 8.8). At baseline the majority of participants were unemployed or receiving a disability pen-

Table 1
Sociodemographic Characteristics of Participants (n=14)

Variables	Intervention (n=7)	Comparison (n=7)
Age Total		40 [8.81]
Mean (SD)	42.0 (5.56)	39.8 (11.61)
Living with		
Alone	1	1
Partner	5	6
Employment		
Employed	2	1
Unemployed	2	2
Disability benefit/other	0	2
Housewife	1	2
Heterosexual	7	7
Injecting		
Never	5	7
More than once a week	2	0
Sex trading		
Never	4	5
Yes in the past	2	2
Yes in the last month	1	0
Length of current relationship		
6- 12 months	3	2
13-60 months	1	2
+ 5 years	3	3
Current partner		
Problems with alcohol	5	5
Problems with drugs	1	2
Health status		
HIV +	2	0
HCV +	1	2

sion or benefit. Only 2 women had injected drugs in their lifetime and were allocated to the intervention group. In both groups, women had been previously involved in prostitution during their lifetime. The length of their current intimate relationships was variable however; most participants reported that their current male partner had problems with alcohol. Regarding baseline outcome variables, the intervention and control groups were comparable on almost all characteristics with the exception of self-perceived health status and responses in SSAAS scale. At baseline, all 14 participants reported any IPV (cut-off score of ≥ 7) but those allocated to the intervention group described slightly more psychological maltreatment than those allocated to the control group. Baseline differences in the outcomes variables could not be statistically controlled due to the small sample size.

IPV outcomes

Composite Abuse Scale (CAS). Table 2 presents the percentage of participants at each follow up point by treatment condition who reported experiencing any incident of IPV. We present data for those participants who remained in a relationship with their partners. All women reported any IPV (CAS score equal or more than seven) at baseline. In the intervention group, participants reported a 60% decrease in experiencing any IPV (physical, emotional or harassment)

from baseline to 1-month (n= 2 women reported IPV) and 3-month (n=2 women reported IPV) post intervention and an 80% decrease at 12 months post intervention, only one woman reported IPV in the previous month. In the control group, the percentage of participants who reported any IPV also decreased but to a lesser extent, from 100% at baseline to 71% at 1 and 83% at 3 months post intervention, decreasing at 12 months post intervention to 60% of participants reporting experiencing any IPV.

No statistical significance was found between groups, despite this, the intervention group showed a tendency for greater reductions in IPV victimization at all follow up points post intervention when compared to the control group. However, the sample size may not have been large enough to detect differences.

Psychological Maltreatment of Women Inventory (PMWI).

Psychological maltreatment and assertiveness scores are reported in table 2. Again, we present data only for those women who remained in a relationship with their partner. The isolation/dominance subscale of the PMWI reduced from baseline (Mean: 17.20; SD: 6.14) to 12 months post intervention (Mean: 12.00; SD: 5.61) for those allocated to the intervention group. For those participants randomized to the control group, the mean isolation/dominance subscale score also reduced from baseline (Mean: 13.85; SD: 5.39) to 12 months post intervention (Mean: 8.60; SD: 2.07). Significance differences were found between groups at 1 (p=0.048) and 3-months (p=0.030) follow up. The mean score on the emotional/verbal subscale of the PMWI reduced from baseline (Mean: 21.40; SD: 8.64) to 12 months post intervention (Mean: 11.60; SD: 1.67) for those allocated to the intervention group. The mean emotional/verbal subscale score also reduced for participants in the control group from baseline (Mean: 18.28; SD: 5.49) to 12 months post intervention (Mean: 12.80; SD: 4.76). No statistical differences between groups were found.

Spouse Specific Assertion/Aggression Scale (SSAAS). In the intervention group, the mean aggression scores reduced from baseline (Mean: -8.40; SD: 6.10) to 12 months post intervention (Mean: -12.60; SD: 5.12). For participants randomized to the control group, the mean aggression scores increased from baseline (Mean: -6.42; SD: 13.62) to 12 months post intervention (Mean: -3.60; SD: 14.80). Those participants receiving the intervention showed greater decreases in aggressiveness during the relationship than those receiving treatment as usual. A statistical difference was found between groups at 1-month (p= 0.030) post intervention. In the intervention group, the mean assertiveness score increased from baseline (Mean: -3.80; SD: 16.39) to 12 months post intervention (Mean: 17.00; SD: 15.41) in the expected direction. For participants randomized to the control group, the mean assertiveness mean score also increased from baseline (Mean: 7.71; SD: 21.76) to 12 months post intervention (Mean: 16.60; SD: 7.14). All participants showed increases in assertiveness during the follow up points. A sig-

Table 2
Mean study instrument Scores for both groups (IPV, Assertiveness)

Outcome		Baseline N=14	1 month FU N=12	3 months FU N=11	12 months FU N=10	p-value 1 m	p- value 3 m	p- value 12 m	
Women abused N° [%] CAS ≥ 7	Intervention	7 (100)	2 (40)	2(40)	1(20)	0.558	0.242	0.524	
	Comparison	7 (100)	5 (71)	5 (83)	3 (60)				
Psychological Maltreatment of Women Inventory (PMWI) M (SD)	Isolation/ Dominance	Intervention	17.20 (6.14)	8.80 (1.64)	8.20 (0.83)	12.00 (5.61)	0.048	0.030	0.690
		Comparison	13.85 (5.39)	11.71 (3.81)	12.33 (3.50)	8.60 (2.07)			
	Emotional/ Verbal	Intervention	21.40 (8.64)	11.00 (2.00)	10.60 (1.34)	11.60 (1.67)	0.073	0.126	0.421
		Comparison	18.28 (5.49)	14.85 (4.59)	17.16 (2.31)	12.80 (4.76)			
Spouse Assertiveness Scale (SSAAS) M (SD)	Aggressiveness	Intervention	-8.40 (6.10)	-18.80 (7.32)	-16.80 (7.19)	-12.60 (5.12)	0.030	0.056	0.841
		Comparison	-6.42 (13.62)	-1.00 (12.21)	1.40 (9.44)	-3.60 (14.80)			
	Assertiveness	Intervention	-3.80 (16.39)	26.40 (12.44)	31.40 (14.62)	17.00 (15.41)	0.017	0.056	0.151
		Comparison	7.71 (21.76)	15.33 (11.97)	19.20 (9.65)	16.00 (7.14)			

*Note. For the PMWI and SSAAS the baseline means are frequencies for the past year, the other time periods are mean frequency for the past month.

nificance difference was found between groups at 1-months post intervention ($p=0.017$).

Depression

Depressive symptom outcomes are reported in table 3. Mean BDI scores in the intervention group reduced from baseline (Mean: 22.42; SD: 8.34) to 12 months post intervention (Mean: 14.57; SD: 8.96). In comparison, mean BDI scores also reduced in the control group from baseline (Mean: 23.42; SD: 12.73) to 1 month post intervention (Mean: 17.00; SD: 10.36), and continued decreasing at 12 post intervention (Mean: 12.28; SD: 9.60). No significance difference was found between groups.

Health status and Quality of life

Self-perceived health status and quality of life are reported in table 3. In the intervention group, mean self-perceived health status scores reduced from baseline (Mean: 61.42; SD: 22.45) to 1-month post intervention (Mean: 48.71; SD: 33.78), but increased at 3 (Mean: 76.42; SD: 15.73) and 12-months post intervention (Mean: 62.85; SD: 23.42) compared to baseline. In the control group, the mean scores remained stable across all follow up periods (Baseline mean: 49.01; SD: 21.07) to 12 months post intervention (Mean: 48.57; SD: 25.44). Women randomized to the intervention group reported better self-perceived health

status than women in the control group, but not statistical differences were founded between groups.

Quality of life increased for participants randomized to the intervention group at all follow up points, with the exception of 1 month post intervention, from baseline (Mean: 40.71; SD: 23.52), to 3 months post intervention (Mean: 55.71; SD: 17.18) and to 12 month post intervention (Mean: 59.28; SD: 20.08). The mean score for participants in the control group also increased from baseline (Mean: 42.42; SD: 18.06) to 12 month post intervention (Mean: 54.28; SD: 19.02) but to a lesser extent than for the comparison group. No statistical differences were found between groups for this outcome.

Substance Use

The mean number of days of alcohol consumption reduced from baseline (Mean: 22.28; SD: 40.35) to 1-month post intervention (Mean: 6.42; SD: 12.83) for participants in the intervention group. The mean number of days of alcohol consumption increased for participants allocated to the control group from baseline (Mean: 6.28; SD: 13.79) to one month post intervention (Mean: 10.0; SD: 17.29). A significant difference was found between groups in the alcohol use self-reported ($p=0.035$). No significant difference was found between groups in the number of days of alcohol consumption at the other follow up time points. For other substances, no significance differences were found.

Table 3
Mean study instrument Scores for both groups (Depression, Health Status and Quality of life)

Outcome		Baseline	1 month FU	3 months FU	12 months FU	p-value 1 m	p- value 3 m	p- value 12 m
Depression BDI M (SD)	Intervention	22.42 (8.34)	14.42 (8.16)	11.28 (5.18)	14.57 (8.96)	0.535	0.535	0.620
	Comparison	23.42 (12.73)	17.00 (10.36)	15.28 (10.95)	12.28 (9.60)			
Health Status M (SD)	Intervention	61.42 (22.45)	48.71 (33.78)	76.42 (15.73)	62.85 (23.42)	0.209	0.165	0.805
	Comparison	49.01 (21.07)	55.71 (13.04)	55.00 (23.80)	48.57 (25.44)			
Quality of Life M (SD)	Intervention	40.71 (23.52)	29.78 (27.27)	55.71 (17.18)	59.28 (20.08)	0.209	1	0.620
	Comparison	42.42 (18.06)	49.00 (12.79)	52.85 (19.11)	54.28 (19.02)			

Evaluation of the sessions

An assessment of the quality of the session was completed by participants at the end of each session. Participants reported that the content knowledge acquired during the sessions was high, with a mean score of 4.5 (SD: 0.50) - the maximum score possible was 5. In relation to feeling comfortable during sessions, 83% of participants reported feeling “very comfortable” during the sessions, 90% considered the therapist’s performance was “excellent” and 80% evaluated sessions overall, as “excellent”.

Discussion

Although women drug users report high rates of IPV, and depressive symptoms, few studies have tested the effectiveness of CBT interventions to reduce IPV victimization among this population. Some of these studies had short follow ups (Gilbert et al., 2006) that do not allow assessing whether benefits are maintained in long-term. To our knowledge, this feasibility and pilot trial is the first study to assess outcomes for female IPV victims attending substance abuse treatment, 12 months post intervention. This pilot randomized control trial shows encouraging results in terms of feasibility and initial effectiveness of the intervention studied. Twelve months post intervention, participants who received the intervention and remained with their partners showed reductions in the frequency of psychological violence received and improvements in their relationships showing increased assertiveness and reduced aggressiveness in their communication with their partner. A trend for greater reductions in physical IPV has also been detected. Participants randomized to the control group also showed reductions in IPV (physical and psychological). This could be due to the fact that they also received treatment for their drug use which may have resulted in improvements in their partner relationships and therefore improved out-

comes, although improvements were less in this group than in the intervention group. Despite this, significant differences were found between groups for psychological abuse. The *IPaViT-CBT* intervention was more effective than treatment as usual in improving psychological maltreatment such as isolation/dominance at 1 and 3-months post intervention but this was not maintained longer term (12 month follow-up). Also statistical significance was found between groups in assertiveness and aggressiveness in the relationship at 1 month post intervention. These findings suggest that women receiving the *IPaViT-CBT* intervention were more likely to report less psychological abuse and improve their relationships than those in the treatment as usual group at all follow-ups. That may be because the CBT intervention aimed to provide women with the necessary skills to re-evaluate their relationships and this in turn changed the dynamic of psychological abuse. Our findings are consistent with other studies in terms of effectiveness in reducing IPV (Gilbert et al., 2006; Cohen, Field, Campbell, & Hien, 2013). A recent trial of CBT counseling compared to treatment as usual in primary care reported decreases in depressive symptoms among female IPV victims (Hegarty et al., 2013). We did not find that the *IPaViT-CBT* intervention favored the reduction of depressive symptoms compared to usual treatment in female drug users. Participants in both groups showed a reduction in self-reported depressive symptoms and showed an improvement in self-reported quality of life. It is possible therefore, that a single session addressing negative mood was insufficient to address complex depression comorbidity among female drug users. Future trials may need to enhance the intervention to address depressive symptoms. The *IPaViT-CBT* intervention showed a high fidelity and good attendance as well as high participation and retention rates, suggesting that this type of intervention is feasible to implement in community drug treatment centers to address IPV victimization. Moreover, study findings suggest very good ac-

ceptability among participants who indicated a high level of satisfaction with the intervention and their group therapist. Participants also believed they had gained new knowledge.

Around fifteen of women assessed were eligible to participate in that they were victims of IPV in the past month and remained in a relationship with their partner. Future studies may consider lengthening this time period to facilitate recruitment. The main limitation of this study is the small sample size, the interpretation of the findings need to be undertaken with caution. The findings from the current trial can be used to inform the parameters of a future definitive trial of the intervention. One limitation is that outcome data were self-reported. Another limitation was the variable participation of women at the group sessions, despite financial incentives, text reminders (sms) and reimbursement of travel costs. The administration of contingencies based on the principles of operant conditioning, such as the use of vouchers as incentives (Higgins et al., 1994) has been particularly effective in improving the monitoring of treatment and its results among this population (Higgins, Alessi, & Dantona, 2002). As literature has demonstrated, these strategies can be used and seem to be effective. Despite this fact, these variables should be controlled in future RCTs as they have proven influence in outcomes consistently through literature on the topic. Unfortunately, baseline differences were identified after randomization. Baseline differences in the outcomes variables could not be statistically controlled due to the small sample size. Observed baseline differences in alcohol consumption may be impacting on the evolution. However, all participants received treatment for the alcohol use disorder, and the alcohol problem and its evolution were monitored from the community center in both groups.

A future adequately powered trial is required to replicate these results and to draw firm conclusions about the effectiveness of the intervention compared to usual care. The cost effectiveness of the intervention compared to usual care should also be considered in future trials.

Conclusions

The findings from the feasibility and pilot trial suggests some initial support for the 10 session CBT group intervention among IPV victims who received treatment for drug use. This manualized small-group, *IPaViT-CBT* intervention designed to reduce IPV and improve depressive symptoms provides an opportunity when making decisions about how to address IPV victimization among female drug users. An adequately powered trial is required to replicate these results.

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Conflicts of interest

All authors declare that they have no conflicts of interest.

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