

A Pilot Intervention Trial among drug involved, abused women in MMTPs

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Stage 1 of Intervention Research – NIDA definition

- Establish safety of intervention (i.e. no adverse events)
- Demonstrate feasibility of implementing all phases of the study (i.e. recruitment, randomization, attendance, retention, cost-efficiency)
- Obtain preliminary effects of intervention on study outcomes

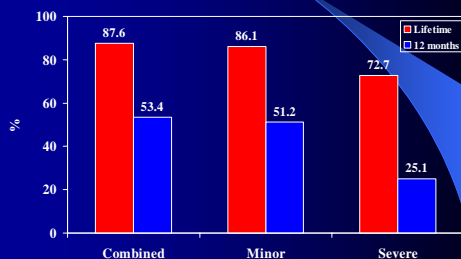
Stage 1: Steps of intervention research for WWP

- STEP 1 – Conducting background research to inform intervention study
- STEP 2 - Defining broad parameters and developing governing structure for study
- STEP 3 - Developing all study protocols (pre-pilot phase)
- STEP 4 - Pilot Stage 1b intervention trial

Step 1: Conducting Survey Research for WHP

- High prevalence of IPV among women in drug treatment – Studies have found between 60 - 87% of women in drug treatment report IPV
- Key Findings from Women’s Health Project (WHP), a 3 year NIDA funded study to examine the relationships among IPV, drug use, and HIV risk using qualitative and quantitative data
- Prevalence and longitudinal data on random sample of 416 women in methadone maintenance treatment programs in NYC who were assessed at baseline, 6 and 12 months

Prevalence of Physical/Sexual IPV among MMTP sample



Step 1: WHP longitudinal survey:

- Women who report frequent use of crack/cocaine at 6 months were 4.4 times (CI=2.1,9.1) more likely to experience physical or sexual IPV at 12 month FU than women who did not use illicit drugs at 6 months; similar results were found for frequent marijuana use at 6 ms and IPV at 12 months (OR = 4.5; 95% CI = [2.4, 8.4])
- Women who reported IPV at 6 months were 2.7 times [CI=1.1, 6.5] more likely to report regular heroin use at 12 months than women without IPV

Step 1: Linking Drugs and IPV

- Disputes over spending limited resources on drugs and splitting drugs increases likelihood of IPV
- Partners' verbal abuse and ridiculing behavior often focuses on putting women down for their drug use
- Partners would attempt to control women's efforts to get into or stay in treatment
- Use of drugs to self-medicate against the emotional and physical pain from IPV

Step 1: Linking drug use and sexual IPV

- Increased partner expectancies/demands for sex or for certain degrading sexual acts, if male and/or female partner is under the influence of drugs, particularly if male partner has provided drugs
- Fear of IPV prevented women from requesting that their partners use condoms
- Partners may pressure or force women to trade sex to supply them with drugs

Step 1 – Treatment Implications from WHP research

- Findings indicate that IPV is a serious public health problem among women in MMTPs - High prevalence of recent, severe IPV is particularly disconcerting
- Longitudinal findings confirm relationships between IPV and use of crack/cocaine, marijuana and heroin
- Qualitative findings highlight multiple contexts in which drug-related activities may be linked with IPV
- Failure to address IPV among women in MMTPs may jeopardize their safety as well as their recovery

Step 2 : Eliciting Feedback from Experts

- No integrated treatment models which address drug abuse and IPV have been empirically tested, although effective case management models exist
- Need to consider secondary IPV outcomes
- Advantages of peer group support vs. individual
- Need a referral protocol for addressing trauma
- Need to be careful about language and labeling abused women may not identify as abused
- May need to move slower with HIV prevention

Step 2: Eliciting Feedback from MMTP providers – focus groups

- MMTPs have a limited capacity to provide basic IPV services due to high counselor/patient ratio and lack of training
- Need service linkages and enhanced referrals for IPV related services
- Need to consider all potential threats to confidentiality and safety of participants in study

Step 2 – Designing an integrated intervention: AIMS

- Reducing drug use
- Establishing relationship safety
 - reduce all types of types of IPV
 - increase safety planning
 - avoid unwanted sex
 - avoid unprotected sex
- Reducing psychological distress & PTSD symptoms

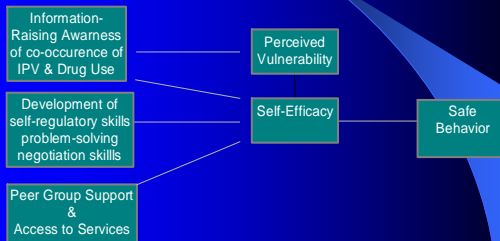
Step 2 – Define parameters of intervention

- Identify target population and establish rationale for eligibility inclusion criteria:
 1. Experience of physical, sexual or severe psychological IPV by an intimate partner in past 3 months
 2. Report illicit drug use in past 3 months
 3. No severe psychiatric/cognitive impairment

Step 2: Intervention design

- Intervention design is guided by social cognitive and empowerment theories and WHP findings on the co-occurrence of drug use and IPV
- Overarching aim of intervention is to increase women's self-efficacy for protective behaviors and for avoiding drug use as well as to develop social support for behavior change

Step 2: Integrated theoretical model of behavioral change



Step 2: Intervention Components

- Raising awareness of reciprocal connections between drug-related activities and IPV
- Eliciting intrinsic motivation to reduce drug use and increase relationship safety using BMI
- Skills Building:
 - Self regulation skills
 - Problem-solving skills
 - Safety planning skills
 - Negotiation and Communication skills
 - Help-seeking and social support enhancement

Step 2 – Define parameters of intervention

- Focus on relapse prevention and establishing relationship safety, identify and make referrals for addressing deeper layers of trauma
- 12 two hour intervention sessions – one individual session, 11 group sessions led by co-facilitators with professional clinical training
- Intervention format: structured, manualized

Step 2: Developing a community advisory board

- Recruit service providers and local experts from fields of substance abuse and IPV services for Community Advisory Board (CAB)
- Role of CAB: to ensure relevance of intervention and to consult on all aspects of study - feasibility issues, ethical issues, research design, measurement, facilitator training, measurement

Step 3: Define goals of pilot trial

- Primary goals of pilot trial
 1. Demonstrate feasibility and safety of WWP
 2. Demonstrate acceptability
 3. Demonstrate a preliminary effect size on drug use and IPV outcomes
- Determine size of pilot and selection of comparison group

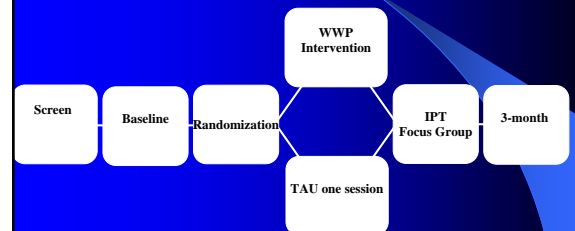
Step 3: Measurement protocol

- Design measurement – background, mediating, moderating and outcome measures
- Outcome measures on drug use, and IPV as measured by revised conflict tactics scale and Tolman's psychological abuse scale. Secondary outcomes – psychological distress and PTSD symptoms and HIV risk behavior
- Mediating variables – self-regulatory skills, problem-solving, negotiation/communication skills, social support, utilization of services

Step 3 – Intervention & QA protocols

- Production of intervention manual - specifying objectives, content and intervention techniques for each session – over 300 pages
- Selection, training and supervision of facilitators
- Design QA Protocol
- Design Process Measures

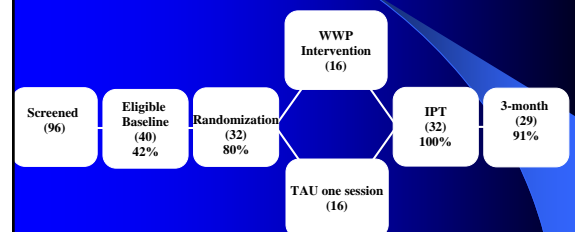
Step 3: Finalize Study Design



Step 3: Getting IRB approval

- Submit IRB applications and consent forms to Beth Israel MMTP and Columbia
- Define potential adverse events, develop a data safety monitoring plan, detailing safeguards to minimize likelihood of events
- Compensation: participants receive \$25 per intervention session (including transportation) and \$30 per assessment

Step 4: WWP Trial - eligibility, participation, retention



Step 4: WWP pilot sample

Socio-demographics of sample (n=32)

Mean age:	42.2 years (SD=6.6)
Ethnicity:	
Latina	55.8 %
African American	20.5%
White	20.5%
Other	2.9%
High school grad/GED:	54.0%

Step 4: WWP sample characteristics

Type of intimate partner:

common law husband	32.4 %
boyfriend	29.4 %
husband	20.6 %
male lover	8.8 %
female partner	8.8 %

Step 4: IPV characteristics

moderate physical IPV	39%
severe physical IPV	13%
moderate sexual IPV	13%
severe sexual IPV	1%
moderate injury	31%
severe injury	25%
severe psychological	33%

Step 4: WWP pilot trial

- Attendance very high - women in WWP condition attended a mean of 11.5 sessions (min=9 sessions and 50% attended all 12 sessions)
- QA results: 80% or more of the content for each session was sufficiently covered and facilitator competence ratings were 85% or higher for each session
- WWP participants (n=16) attended a focus group two weeks after completing 12 sessions

Step 4: WWP Focus group

- Some women indicated that they had no intention in stopping using drugs, but the group made them think more about not using drugs
- Women felt that the group was too short - not enough time to learn some skills
- Participants indicated that the content of the sessions was relevant, especially the traditional and pop-cultural Latina and African American songs, poems and quotes in opening/closing rituals and relaxation exercises

Step 4: WWP Focus Group Findings

- Women reported that they felt they could share private issues and painful experiences in the group; Holding the groups outside the clinic building was important for confidentiality
- A couple of women were reluctant to share experiences of more severe IPV in group and wanted additional individual sessions
- Women felt that the on-going support from group members had helped them to feel less isolated and made a significant difference for their recovery

Step 4: Pre-post test findings

- Evidence of the preliminary efficacy of WWP from the pilot study was assessed by examining pre post gains and setting a criterion level of 1.96 for the average Reliability Change Index (RCI)
- At IPT, the women assigned to WWP were less likely to use heroin, tranquilizers, and binge drinking than women in TAU (RCI < 1.96); No difference was found for crack/cocaine or marijuana
- Women assigned WWP were more likely to reduce physical, psychological, and injurious IPV

Step 4: Pre-post test findings

- Pilot findings also indicated that the WWP demonstrated promise with respect to:
 1. Reducing psychological distress as assessed using the Brief Symptom Inventory and hyper arousal symptoms of PTSD as assessed by PTSD checklist at IPT
 2. Increasing self regulatory skills, soliciting emotional and social support from others, and solution-focused planning at IPT

WWP: Lessons learned to date

- High rates of eligibility, participation, attendance and retention confirm the feasibility of conducting WWP
- Post intervention focus group data and participant evaluations suggest that the intervention was well received. Financial incentive may be lowered
- QA and process measures indicate high facilitator adherence and competence ratings. Some skills may need to be repeated more frequently
- Combination of group modality and one individual session worked well

WWP: Lessons learned to date

- No adverse events were detected; This pilot trial provided preliminary evidence of safety of WWP
- Pre-post test findings provide preliminary evidence that women assigned to the WWP condition were more likely to improve on primary and secondary outcomes as well as mediating skill variables

Next steps for WWP

- Analyze 3 month FU data to estimate the effects of the WWP on drug use and IPV outcomes
- Review findings with CAB and MMTP collaborators and discuss next steps
- Continue making revisions to WWP manual based on feedback from QA, focus group data, process measures, outcome data and the CAB and MMTP
- Write a grant to test efficacy of WWP in a more rigorous stage 2 randomized clinical trial using a gold standard "relapse prevention" as a comparison condition

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