PERSONS WHO INJECT DRUGS’ PERSPECTIVES ON THE RISKS AND BENEFITS OF PARTICIPATION IN A MOBILE HEALTH STUDY OF POLYDRUG USE

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Outline: A tale of three cities

Building a research line in empirical ethics centering on how vulnerable populations experience research:

1. **The Urban Women’s Health Study**: Diary studies of sexual behavior may improve female sex workers’ mental health

2. **RETI Fellowship Study**: Persons who inject drugs’ perspectives on the risks and benefits of participation in a mobile health study of polydrug use

3. **Current Study**: Piloting a naloxone intervention in an emergency response community to reduce opioid overdoses in Philadelphia
URBAN WOMEN’S HEALTH STUDY

Diary Studies of Sexual Behavior May Improve Female Sex Workers’ Mental Health
ACKNOWLEDGEMENTS

Participants

Collaborators
- Jayleen K.L. Gunn, MA, MPH
- Karla D. Wagner, PhD
- Jessica J. Cho
- Sarah E. Wiehe, MD MPH

Community Partners
- Bell Flower Clinic
- Indianapolis Community Court
- Step-Up Inc.
- The Bethlehem House

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- Center for Urban Health, Indiana University Purdue University Indianapolis (IUPUI)
- Division of Global Public Health, University of California San Diego (NIDA T32DA023356-06)
THE BACK STORY...

- While conducting a daily diary study of sexual behavior, female sex workers (FSWs) indicated that participation was beneficial.
  - Increased self-reflection about life choices
  - Provided outlet to discuss taboo topics
  - Improved social support

- Thus, we decided to assess whether their mental health improved at exit compared to baseline.
GOAL & OBJECTIVES

Goal: Ascertain whether participation in a 4-study of FSW’s sexual lives was associated with improvements in mental health.

Objectives:

1. Compare FSW mental health scores pre/post-participation
2. Examine individual characteristics associated with observed changes in mental health
HYPOTHESES

1. Compared to baseline, participants would experience improvements in mental health

2. Individual characteristics would moderate these effects
BACKGROUND

- FSWs experience high rates of morbidity including anxiety, depression, low self-esteem and post-traumatic stress.

- Psychological impacts of selling sex may be linked to sexual and drug-seeking behaviors.

- Thus, mental health conditions among FSW may help to perpetuate disease disparity.
PARENT STUDY

- **Inclusion criteria:**
  - English-speaking women ≥18 years old
  - Sex exchange for drugs or money within 90 days
  - Likely to sell or trade sex in next month
  - Able to safely keep and charge a phone

- **Recruitment:**
  - Venues
  - Targeted outreach
  - Incentivized peer referral
PARENT STUDY

• Delivered via cell phone twice daily
• 4-hour completion window
• Each diary assessed
  • Individual factors
  • Sexual interactions
    • Interpersonal
    • Behavioral
    • Environmental
  • Daily activities
PARENT STUDY

- Utilized diary data and open-ended questions to assess context of sexual events

- Exemplar items:
  - I’d like to walk through your interaction with “X”. Tell me a little bit about where you met up; where to have sex; about that location, etc…
CURRENT STUDY: Procedures

- Baseline and exit computer assisted self-interview (CASI) & assessing mental health
- Qualitative exit interview assessing the participation experience
MEASURES (Independent variables)

- Demographics
- Childhood sexual abuse
- Social support
- Commercial sex history, lifetime
- Substance use, 90 days
- Criminal history, lifetime
MEASURES (Outcome variables)

• Self-esteem
  • 10-item Rosenberg Self-Esteem Scale ($\alpha=.87$)

• Bodily Connection
  • 20-item scale assessing body awareness ($\alpha=.83$) & body dissociation ($\alpha=.78$)

• Depression
  • 9-item Patient Health Questionnaire ($\alpha=.89$)

• Anxiety
  • 6-item Brief Symptom Inventory-Anxiety ($\alpha=.80$)
ANALYSIS

- Measures were stratified to group participants into meaningful clusters
  - **Social support** scores in the bottom quartile (≤2.6 out of 7) were considered low
  - **Self-esteem** scores of ≥ 24 (of 37) were considered high
  - **Depression** scores of ≥ 15 (of 27) were considered moderate to severe based on pre-established scale cutoffs
  - **Anxiety scores** of ≥ 13 (of 24) were considered high
ANALYSIS

- T-tests and Wilcoxon signed-rank tests (for non-normally distributed variables) to compare outcome variables at baseline and exit

- Tests were repeated, for each stratum of each hypothesized effect modifier, to compare scores on outcome variables at the beginning and end of the study
  - E.g., stratum = hi versus low social support
### RESULTS: Cohort characteristics (N=24)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latina ethnicity</td>
<td>11.5%</td>
</tr>
<tr>
<td>Homeless</td>
<td>23.1%</td>
</tr>
<tr>
<td>Frequency of sex work in last 90 days</td>
<td></td>
</tr>
<tr>
<td>Only a few times</td>
<td>19.2%</td>
</tr>
<tr>
<td>1-3 times per month</td>
<td>19.2%</td>
</tr>
<tr>
<td>1-5 times per week</td>
<td>42.3%</td>
</tr>
<tr>
<td>Everyday</td>
<td>19.2%</td>
</tr>
<tr>
<td>Alcohol use in last 90 days</td>
<td>92.3%</td>
</tr>
<tr>
<td>Any illicit drug use in last 90 days</td>
<td>88.5%</td>
</tr>
<tr>
<td>No. lifetime drug/alcohol arrests</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>42.3%</td>
</tr>
<tr>
<td>1</td>
<td>15.4%</td>
</tr>
<tr>
<td>2-5</td>
<td>26.9%</td>
</tr>
<tr>
<td>6 or more</td>
<td>15.4%</td>
</tr>
<tr>
<td>History of sexual abuse &lt; 13 years old</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>58%</td>
</tr>
</tbody>
</table>
RESULTS: Change in MH scores over time

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre Mean (SD)</th>
<th>Post Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-esteem</td>
<td>27 (5.14)</td>
<td>31 (5.34)</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Body dissociation</td>
<td>1.60 (0.70)</td>
<td>1.28 (0.68)</td>
<td>p=0.01</td>
</tr>
<tr>
<td>Depression</td>
<td>8.96 (6.69)</td>
<td>7.54 (7.05)</td>
<td>N/S</td>
</tr>
<tr>
<td>Anxiety</td>
<td>11.08 (4.05)</td>
<td>9.83 (4.88)</td>
<td>N/S</td>
</tr>
<tr>
<td>Body awareness</td>
<td>2.18 (0.63)</td>
<td>2.15 (0.82)</td>
<td>N/S</td>
</tr>
</tbody>
</table>
# RESULTS

<table>
<thead>
<tr>
<th></th>
<th>Self-esteem</th>
<th></th>
<th></th>
<th>Body-dissociation</th>
<th></th>
<th></th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Pre-mean (SD)</td>
<td>Post-mean (SD)</td>
<td></td>
<td>Pre-mean (SD)</td>
<td>Post-mean (SD)</td>
<td></td>
</tr>
<tr>
<td><strong>N</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 12th grade</td>
<td>9</td>
<td>25.9 (3.5)</td>
<td>30.7 (5.3)</td>
<td><em>&lt;0.01</em></td>
<td>1.4 (0.7)</td>
<td>1.3 (0.6)</td>
<td>0.23</td>
</tr>
<tr>
<td>High school</td>
<td>8</td>
<td>25.1 (5.7)</td>
<td>30.2 (5.6)</td>
<td><em>0.00</em></td>
<td>1.6 (0.7)</td>
<td>1.3 (0.7)</td>
<td><em>0.03</em></td>
</tr>
<tr>
<td>Some college</td>
<td>7</td>
<td>30.6 (5.1)</td>
<td>32.6 (5.6)</td>
<td>0.16</td>
<td>1.8 (0.7)</td>
<td>1.3 (0.8)</td>
<td><em>0.04</em></td>
</tr>
<tr>
<td>High total social support</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>7</td>
<td>23.6 (3.1)</td>
<td>27.4 (4.0)</td>
<td><em>0.05</em></td>
<td>2.0 (0.7)</td>
<td>1.6 (0.7)</td>
<td>0.12</td>
</tr>
<tr>
<td>No</td>
<td>17</td>
<td>28.4 (5.2)</td>
<td>32.6 (5.2)</td>
<td><em>&lt;0.01</em></td>
<td>1.4 (0.7)</td>
<td>1.1 (0.6)</td>
<td><em>0.01</em></td>
</tr>
<tr>
<td>Sexual abuse before the age of 13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>14</td>
<td>26.5 (5.5)</td>
<td>31.1 (5.1)</td>
<td><em>&lt;0.01</em></td>
<td>1.6 (0.7)</td>
<td>1.5</td>
<td>0.11</td>
</tr>
<tr>
<td>No</td>
<td>10</td>
<td>27.7 (4.8)</td>
<td>31.1 (6.0)</td>
<td><em>0.05</em></td>
<td>1.6 (0.7)</td>
<td>1.0</td>
<td><em>0.01</em></td>
</tr>
<tr>
<td>Age at first trick</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;18 years</td>
<td>10</td>
<td>29.1 (4.7)</td>
<td>31.4 (6.5)</td>
<td>0.10</td>
<td>1.7 (0.7)</td>
<td>1.3 (0.8)</td>
<td><em>0.03</em></td>
</tr>
<tr>
<td>≥18 years</td>
<td>14</td>
<td>25.5 (5.1)</td>
<td>31.0 (4.6)</td>
<td><em>&lt;0.01</em></td>
<td>1.5 (0.7)</td>
<td>1.2 (0.6)</td>
<td><em>0.04</em></td>
</tr>
</tbody>
</table>
RESULTS: Participation Experience

- “I had fun because I had somebody to talk to about the things that I did that I never could talk about with my family-- they didn’t know what I did. When you try to talk to another girl [FSW], they don’t really give you much encouragement.”
  - Jordan, White, 42 years

- “…This helped me to see that I’m better than that you know, and I’ve been takin’ steps to change that since I’ve been in this group [study] …it’s like you make me feel comfortable and you make me believe that what we’re sitting here doing is for a good cause and, I mean, mostly, the biggest thing is you actually listen.”
  - Body Talk, Black, 51 years
LIMITATIONS

- Small sample size (N=24) limits power to test for differences
- Unable to identify mechanism of change in this study
- Relatively short duration study
  - Unknown whether effects are lasting
  - Unknown if the improvements are by-product of surveillance (i.e., assessment reactivity or Hawthorne effect)
  - Unknown impact of compensation for participation
SUMMARY

1. Mental health among this sample of FSW was poor but improved over time.

2. Findings suggest that for particularly vulnerable FSWs, participation in HIV prevention studies may confer unanticipated benefits including improved mental health outcomes.

3. Could have implication for HIV prevention given the link between mental health and subsequently, risk behaviors.
RETI FELLOWSHIP STUDY

Persons who inject drugs’ perspectives on the risks and benefits of participation in a mobile health study of polydrug use
Acknowledgements

Participants

Collaborators

• Dr. Janie Simmons
• Dr. Richard Garfein
• Dr. Richard Armenta
• Marisa Felsher, DrPH(c)
• Megan Reed, DrPH(c)

Funding

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• NIDA T32 DA023356 (Strathdee)
• NIDA 1R01 DA031074 (Garfein)
Mobile Health (mHealth) Research

• mHealth research leverages the capabilities of mobile devices to monitor behavior and deliver health care

• The harms and benefits of using mHealth approaches have yet to be systematically assessed

• Best-practice guidelines are not yet available; such guidelines are particularly salient for research with vulnerable populations
Potential Risks in mHealth

• Theft of devices

• Stigmatization

• Participant burden
  o Behavioral assessments 2-5 times per day\textsuperscript{1}
  o Either pre-specified or random times\textsuperscript{1,2}

• Fairly generous compensation structures\textsuperscript{2-5}
Potential Benefits in mHealth

- Research has documented unanticipated benefits of participation in diary and interview studies
  - Increased self-awareness, empowerment, and ability to manage emotional reactions
  - May effect cognitive processes
  - Participants may begin to assess predictors, consequences and correlates of their behaviors
Study purpose

To explore participant perspectives on the potential risks and benefits associated with participation in a hypothetical mHealth study of polydrug use.
Methods: Scenario

• Participants were informed they would have the opportunity to help researchers design a longitudinal study of polydrug use

• Polydrug use types
  1. Simultaneous
  2. Sequential

• Polydrug use is associated with negative health outcomes including drug overdose
Methods: Recruitment

• Participants were:
  1) ≥ 18 years of age
  2) Reported injecting illicit drugs in the past month
  3) Reported weekly polydrug use

• Recruitment occurred in San Diego, CA (N=18) and Philadelphia, PA (N=20)

• Participant demographics were similar in both cities
  • Mean age 44.5 years, 64% male, 56% white, 56% homeless
Methods: Data Collection & Analysis

• Completed simulations of a cell phone diary
• Interviewed about experiences

“How do you think completing diaries might impact your life?”

“How can you think of any bad [good] things that could happen as a result of answering the questions over time?”

• Qualitative analysis of interview texts for ethical themes
Findings: Potential Benefits

• All participants reported potential indirect benefits associated with participation.

• Many felt repeated behavioral assessments would be a positive influence by encouraging reflection and increasing self-awareness.

• Utilization of expertise and potential to help others.

• Use of phone as economic benefit.
Participant Perspectives on Benefits

Reflexivity

“It would make me reflect on my day-to-day activities...make it more clear as you’re answering the questions where you should be putting in effort to make a change. It’s like putting a mirror in front of you.”

(Steve, 43, San Diego)
Participant Perspectives on Benefits

*Being recognized as an expert*

“[If] you take heed to what I talk about…I’ll feel like, alright, I did something…I’ll feel good about myself…It makes me want to do other things to make me feel good about myself.”

*(Rana, 34, San Diego)*
Participant Perspectives on Benefits

**Altruism**

“If what we’re doing…is going to stop someone from getting on…or help someone get off heroin, let’s do it. I wouldn’t wish this on anyone.”

(Eddie, 65, Philadelphia)
Findings: Potential Risks of Participation

- **Physical** risks arise from carrying a study cell phone
- **Behavioral** and **psychological** risks stem from repeated disclosure of mood state or behavior
- **Social** risks were those that might arise if law enforcement obtained any information about participants
- **Informational** risks arose from unintentional disclosure of drug use or other stigmatized information more broadly
Participant Perspectives on Risks

**Theft & the potential for physical risks**

“It’s hard to keep stuff of value when you’re using drugs, you know what I mean? Some people have it harder than me, when you’re living with vandals you don’t have no security. I know people that wouldn’t sell their stuff and they get their stuff stolen just cause they nod out… [Once,] I fell asleep and when I woke up, I didn’t have my money. I didn’t have this. I didn’t have that.”

(Carlos, 40, Philadelphia)
Participant Perspectives on Risks

Triggers & potential psychological risks

“If a participant is constantly being reminded that they’re in the bottom of the barrel and feeling depressed, constantly having to go over how they feel could make them more anxious and want to commit suicide or overdose.”

(Mike, 40, Philadelphia)
Participant Perspectives on Risks

Mitigating harms

“Say, ‘Listen, you’re gonna have to constantly monitor your mood. I want you to be aware that during the course of what’s going on in your life, if something bad was to occur that would make you have a bad mood or irritated, that you need to be aware you will be constantly reminded of it.”

(Mike, 40, Philadelphia)
Conclusion

• Engagement in mHealth might confer important benefits

• Risks described as unlikely, however, it remains important for researchers to implement reasonable safeguards

• As mHealth becomes more widely used, it will be important to conduct research on harms and benefits
  o Actual harms and benefits could be different than those reported here
CURRENT STUDY
1 R34 DA044758-01 (PI: LANKENAU)

Piloting a naloxone intervention in an emergency response community (ERC) to reduce opioid overdoses in Philadelphia
Next steps: ERC Mobile App Study
Discussion?

Contact:
Alexis Roth
alexisroth@drexel.edu
References


5. Gunn JKL, Roth AM, Center KE, Wiehe SE. The Unanticipated Benefits of Behavioral Assessments and Interviews on Anxiety, Self-Esteem and Depression Among Women Engaging in Transactional Sex. Community Mental Health Journal. 2015; in press.