Full length article

A pilot randomized clinical trial of an intervention to reduce overdose risk behaviors among emergency department patients at risk for prescription opioid overdose

Amy S.B. Bohnert, a, b, c, d, * Erin E. Bonar a, Rebecca Cunningham c, d, e, f, Mark K. Greenwald g, Laura Thomas a, b, Stephen Chermack a, b, Frederic C. Blow a, b, Maureen Walton a, c

a Department of Psychiatry, University of Michigan Medical School, 4250 Plymouth Rd., Ann Arbor, MI 48109, USA
b VA Center for Clinical Management Research (CCMR), Department of Veterans Affairs Healthcare System, 2800 Plymouth Rd., Bldg. 16, Ann Arbor, MI 48109, USA
c University of Michigan Injury Center, University of Michigan Medical School, 2800 Plymouth Rd., Bldg. 10, Ann Arbor, MI 48109, USA
d Institute for Healthcare Policy and Innovation, University of Michigan, 2800 Plymouth Rd., Bldg. 16, Ann Arbor, MI 48109, USA
e Department of Emergency Medicine, University of Michigan Medical School, 1500 East Medical Center Drive, Ann Arbor, MI 48109, USA
f Department of Health Behavior and Health Education, University of Michigan School of Public Health, 1415 Washington Heights, Ann Arbor, MI 48109, USA
g Department of Psychiatry and Behavioral Neurosciences, and Department of Pharmacy Practice, 3901 Chrysler Service Drive, Suite 2A, Wayne State University, Detroit, MI 48201, USA

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ABSTRACT

Background and aims: Prescription opioid overdose is a significant public health problem. Interventions to prevent overdose risk behaviors among high-risk patients are lacking. This study examined the impact of a motivational intervention to reduce opioid misuse and overdose risk behaviors.

Methods: This study was a pilot randomized controlled trial set in a single emergency department (ED) in which, 204 adult, English-speaking patients seeking care who reported prescription opioid misuse during the prior 3 months were recruited. Patients were randomized to either the intervention, a 30-minute motivational interviewing-based session delivered by a therapist plus educational enhanced usual care (EUC), or EUC alone. Participants completed self-reported surveys at baseline and 6 months post-baseline (87% retention rate) to measure the primary outcomes of overdose risk behaviors and the secondary outcome of non-medical opioid use.

Findings: Participants in the intervention condition reported significantly lower levels of overdose risk behaviors (incidence rate ratio [IRR] = 0.72, 95% CI: 0.59–0.87; 40.5% reduction in mean vs. 14.7%) and lower levels of non-medical opioid use (IRR = 0.81, 95% CI: 0.70–0.92; 50.0% reduction in mean vs. 39.5%) at follow-up compared to the EUC condition.

Conclusions: This study represents the first clinical trial of a behavioral intervention to reduce overdose risk. Results indicate that this single motivational enhancement session reduced prescription opioid overdose risk behaviors, including opioid misuse, among adult patients in the ED.

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1. Introduction

Starting in the 1990s, opioids were increasingly prescribed to treat pain in the U.S., particularly for chronic non-cancer pain (Paulozzi et al., 2011). An unintended consequence of these efforts to reduce pain-related suffering has been an alarming increase in opioid-related addiction and overdoses (Compton and Volkow, 2006; Office of National Drug Control Policy, 2011). Specifically, the rate of prescription opioid overdose deaths in the U.S. increased 293% between 1999 and 2009 (Calcaterra et al., 2013), and opioid-related emergency department (ED) visits nearly tripled from 2004 to 2011 (Substance Abuse and Mental Health Services Administration (SAMHSA), 2013). Additionally, the non-medical use of prescription opioids (NMUPO) is a problem associated with opioid prescribing that has an important role in overdose risk, with
NMUPO commonly found in investigations of opioid overdose fatalities (Hall et al., 2008).

Non-fatal overdose is more common than fatal overdose, with an estimated 23 non-fatal overdoses for every fatality (Centers for Disease Control and Prevention (CDC), 2014). Non-fatal prescription opioid overdose is associated with substantial morbidity, such as pulmonary impairment and neurological damage from prolonged hypoxia (Warner-Smith et al., 2001). People who have experienced a non-fatal overdose are at heightened risk for future overdose (Coffin et al., 2007). In addition to NMUPO, a number of specific behaviors have been found to increase risk, such as combining different substances, injecting, using alone, and consuming more than usual amounts of a given substance (Coffin et al., 2007; Cone et al., 2004; Gutierrez-Cebollada et al., 1994; Park et al., 2015; Paulozzi et al., 2012; Strang et al., 2008). Reducing these behaviors is an important target of overdose prevention interventions.

The ED is a critical setting to address the public health problem of prescription opioid overdose. In 2010, an estimated 51% of ED visits by adults nationally were for a painful condition, and 31% of all ED visits resulted in an opioid being prescribed. ED physicians write a substantial proportion of opioid prescriptions, particularly to those under age 40 (Cantrill et al., 2012). ED patients are also more likely to be engaged in risky substance use than the general community (Cherpitel, 2003; Cunningham et al., 2003). Thus, clinical encounters in the ED could provide an opportunity to intervene with patients who are at increased risk for opioid overdose. To date, there have been no published ED-based trials to address overdose risk.

To address this gap, we developed a 30-minute, therapist-delivered and tailored intervention for the ED setting. The intervention was primarily informed by motivational interviewing (MI) strategies (Miller and Rollnick, 2013; Miller and Rose, 2009) due to the demonstrated utility of MI in promoting changes in health-related behaviors, including substance use (Miller and Rollnick, 2013). We conducted a pilot randomized controlled trial that compared the intervention to enhanced usual care (EUC) only. The present study tests the hypothesis that the motivational intervention results in reduced self-reported overdose risk behaviors during the six months following randomization compared to EUC alone.

2. Material and methods

2.1. Setting

Recruitment occurred in the ED at the University of Michigan Medical Center (UMMC) between April, 2013 and March, 2014. Standard care for opioid safety in this ED is that all patients leaving with opioids or a prescription receive instructions to not operate machinery and avoid alcohol use. The study received approval from the institutional review board at the University of Michigan.

2.2. Recruitment and participants

Fig. 1 displays the flow of participants through the study. Research staff approached patients aged 18–60 while waiting for care in private rooms and recruited them to participate in a brief (~5 min) computerized screening survey, before which participants provided informed consent. Pen-and-paper surveys were used in 170 screenings due to unavailability of computers. This age range was selected because the vast majority of fatal overdoses in the U.S. occur within this group (Bohnert et al., 2010). Participants were compensated with a token gift valuing $1.00 (e.g., decks of cards, puzzle books). Exclusion criteria for screening were: (1) presenting in the ED for suicidality or sexual assault (based on the medical record), (2) inability to speak or read English, (3) active psychosis (4) unstable medically (i.e., level one trauma), (5) altered mental status or cognition suggesting an inability to give consent, and, (6) inability to provide any contact information for follow-up.

The primary eligibility criterion for the trial determined by screening survey was self-reported NMUPO in the prior three months on any of 8 items from the Current Opioid Misuse Measure (COMM; Butler et al., 2007). Individuals with a prior non-fatal overdose (due to any substance and broadly defined; see Section 2.7.4) were oversampled. Eligible participants were consented for the trial and completed a computerized baseline survey, for which they were compensated $20. Computerized randomization was stratified by overdose history and thus was unknown to both participant and research staff until the completion of all assessments (clinical staff were continuously blind to assignment). In total, 205 individuals were eligible and randomized; one randomized participant was excluded from analysis due to dying (for reasons unrelated to the study) during the follow-up period, resulting in a sample size of 204. In some cases patients had completed their ED visit before they had received all study protocols. Research staff successfully completed protocols with seven participants in the community.

2.3. Trial design

This study used a two-group parallel trial design with 1:1 allocation. The study was initially designed to include only individuals with a prior overdose in addition to past three month NMUPO. Due to challenges in recruiting with this strategy, we modified the criteria to allow individuals with NMUPO, regardless of prior overdose, to participate. Sample size for this pilot trial was selected to provide sufficient information on study protocols, intervention acceptability, clinical meaningfulness, and effect sizes for a future trial.

2.4. Intervention and control conditions

The two conditions of this study were the motivational intervention plus enhanced usual care (EUC) and EUC only. Standard care was not altered.

2.4.1. Motivational intervention. Specific intervention content was based on MI (Miller and Rollnick, 2013), an evidence-based strategy for reducing risky behaviors by enhancing self-efficacy and motivation (Hettema et al., 2005; Resnicow and Rollnick, 2011; Zahradnik et al., 2009). MI is delivered from a non-judgmental, empathic, and encouraging stance, with a focus on supporting the participant’s autonomy to decide if, when, and how to make changes. It employs a relational foundation in which clinicians approach patients with acceptance, collaboration, evocation, and compassion. Technical skills (open questions, affirmations, strategic reflection, summarizing) are used to respond to statements that favor change (i.e., change talk) and statements that defend the status quo (sustain talk), in order to move participants through four processes: engaging, evoking, focusing, and planning for change. Educational components of MI interventions use an “elicit–provide–elicit” strategy. In this approach, the counselor asks questions to determine the need for new information (e.g., “What are some things you think increase risk for overdose?”), provides new information in a neutral manner after affirming the patient’s knowledge, and then asks the participant’s perspective on this new information (e.g., “What does this mean to you?”) (Resnicow and Rollnick, 2011). The Supplementary Material lists the specific intervention components.

The intervention included content on peer outreach, which emphasized ways to discuss overdose risk reduction with others at risk for overdose. This peer outreach focus has been used in HIV risk behavior interventions, and studies indicate that participants
are more likely to change their own drug risk behavior in outreach interventions compared to when the intervention focuses on the individual participant’s behavior only (Booth et al., 2011). Additionally, public health interventions have trained participants to respond when witnessing an overdose, including administration of naloxone (Albert et al., 2011; Walley et al., 2013). The intervention included content on response to a witnessed overdose and included information on naloxone distribution locations, but naloxone was not distributed in this study.

Two Master’s-level therapists with prior training and experience in MI delivered the intervention. The therapists received approximately 1.5 additional days of general MI training and 2 days of training in delivering the specific intervention content using MI. The sessions were aided by a computer guide to enhance fidelity and to provide therapists in a busy clinical setting with decision support. The guide provided visual aids when appropriate and prompts for the therapist to elicit responses to open-ended questions. Therapists received weekly supervision from licensed clinicians to review intervention audio-recordings. A clinical supervisor rated adherence on a randomly selected 10% sample of sessions using the recordings. Using a scale of 0 (not covered) to 7 (mastery) for 10 components, the average adherence ratings were between 4.8 and 5.5, with 4 representing “Solid” adherence; no ratings were below 4.

2.4.2. Enhanced usual care (EUC). Both conditions received EUC, in which therapists provided two brochures: (1) an overdose prevention and response brochure, and (2) a resource brochure. The overdose prevention and response brochure included a definition of overdose, signs and symptoms, risk factors, and bystander response to overdose. The resource brochure contained information on drug, mental health and alcohol treatment, mutual help groups, local resources for obtaining naloxone, free health clinics in the area, and a suicide prevention hotline. The therapists briefly reviewed the brochure sections using a didactic style and without any tailoring to specific concerns or risk factors.

2.5. Follow-up

Follow-up assessments occurred six months after recruitment and participants were compensated $30. The majority of participants completed the follow-up online; in 36 cases, follow-up was completed in person via pen-and-paper based on participant preference. Follow-up staff members were blind to randomization. Because relatively few participants were lost to follow-up (n = 26) or had missing data on any outcome variable (n = 24), we combined these groups to examine the potential impact of loss of data on analyses. Exclusion from outcome analyses was not associated with baseline level of any outcome, age, gender, or prior overdose history.
2.6. Measures

2.6.1. Primary outcomes. All items used to assess outcomes are listed in Table 1.

2.6.1.1. Overdose risk behavior. To our knowledge, no measure of overdose risk behaviors had been published at the time recruitment began in 2013. In collaboration with other study teams conducting concurrent trials on overdose prevention (Ps: Phillip Coffin and Caleb Banta-Green), we developed a measure of overdose risk behaviors based on established associations with overdose (Coffin et al., 2007; Cone et al., 2004; Gutierrez-Cebollada et al., 1994; Park et al., 2015; Paulozzi et al., 2012; Strang et al., 2008). Frequency of each behavior was assessed for the prior six months at both baseline and follow-up. Item responses were summed, with higher levels indicating a greater frequency and number of overdose risk behaviors. The Cronbach’s alpha for these items was 0.82 and 0.79 at baseline and follow-up, respectively. At baseline, the total overdose risk behavior score was associated with the number of prior overdoses (b from a linear regression = 0.10, p < 0.001).

2.6.1.2. Behavioral intentions. Based on structure of readiness rulers used in MI (Resnicow and Rollnick, 2011), we developed three items to assess intentions to reduce overdose risk. There was a strong “ceiling” effect, and items were reverse coded to enable use of appropriate modeling strategies (see Section 2.8). Consequently, higher scores indicate lower intention to avoid overdose risk.

2.6.1.3. Overdose knowledge. Two aspects of overdose knowledge were assessed: (1) symptoms and (2) risk factors. Items to assess knowledge of overdose symptoms were adapted from an existing checklist measure (Strang et al., 2008). The measure was changed by dropping an intentionally incorrect item of “fitting” because the prior study was specific to heroin and seizures could be caused by non-opioid overdoses. The total number of symptoms correctly identified was summed and was roughly normally distributed and standardized for analysis. A similar checklist assessment of knowledge of risk factors for overdose was also developed based on risk factors described by Warner-Smith et al. (2001). Due to the strong “ceiling” effect of many participants identifying a high number of risk factors correctly, this sum was also reverse coded to enable use of appropriate modeling strategies, and thus higher scores indicated more incorrect answers.

2.6.2. Secondary outcome.

2.6.2.1. Non-Medical prescription opioid use. Selected items from the Current Opioid Misuse Measure (COMM; Butler et al., 2007)] assessed NMUPO. The original COMM has good test-retest reliability among patients receiving opioids for pain (Butler et al., 2007). Given that assessment in the ED setting must be brief to be feasible, we elected to use a shortened version of the COMM in this study. Our prior work with individuals with substance use disorders (Ashrafioun et al., 2015) indicated that the COMM items can assess NMUPO in those without pain as well. We selected eight items (see Table 1) in the domain of opioid misuse specifically, rather than negative psychological states generally, based on our prior factor analyses (Ashrafioun et al., 2015). At baseline, these items were assessed for the past three months to assess proximal behavior to the ED visit to determine eligibility, and at follow-up they were assessed to cover the entire six months. The Cronbach’s alpha for the COMM items was 0.89 at both baseline and follow-up in this sample.

2.6.3. Other measures. A number of other measures were collected at baseline to characterize the sample. A modified version of the Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST; WHO ASSIST Working Group, 2002) was used to measure use of specific substances and severity of opioid use problems. Participants also self-reported demographic characteristics, pain treatment history, substance use treatment and counseling history, and prior ED visits. Prior overdose history was assessed with this query: “The following questions are about experiences with taking too much drugs or medications/pills, and/or drinking too much alcohol. This is sometimes called ‘poisoning,’ ‘passing out,’ ‘nodding out,’ ‘blackout,’ or an overdose or ‘OD.’ How many times in your life has this kind of situation happened to you?” This was intended to maximize sensitivity given that many patients do not identify with the term “overdose.”

2.7. Statistical methods

All continuous and categorical measures were evaluated for their distributional characteristics. Analyses to examine differences between intervention and EUC participants used t-tests, Fisher’s exact tests, and χ² tests as appropriate. Poisson regression modeling was used for outcomes that followed a Poisson distribution, which was true for all outcomes except overdose symptom knowledge, which was normally distributed. Thus, a linear regression was used for this outcome. Unlike the summary scores used for other measures, behavioral intentions were analyzed separately based on prior studies (e.g., Bertholet et al., 2012). The independent variable of interest was an indicator for group (intervention coded as “1,” EUC as “0”). The baseline level of the outcome measures was included as a covariate in each model. Statistical significance was set at a two-sided p < 0.05 for all testing. All analyses of outcomes used an intent-to-treat framework and used all available observations.

3. Results

In total, 2,250 ED patients completed the screening survey (see Fig. 1). Of the 204 participants in the trial, 178 (87%) completed the six month assessment. Six participants randomized to the intervention did not receive the assigned protocols; of those 6, 5 (83%) completed the six month follow-up. Participants with a prior history of overdose who were randomized to EUC only were more likely to be lost to follow-up (24%) compared to all other study groups (all 8% or less).

Table 2 reports the sample characteristics. In terms of opiate (heroin or opioid) use, the sample largely reported prescription opioid use only, with only 33 reporting lifetime heroin use. Roughly half of the sample (48%) had levels of prescription opioid involvement considered moderate or high risk. The intervention and EUC only groups significantly differed in the proportion that reported their race as “other” (10 vs. 2%) and the proportion that reported alcohol during the prior three months (53 vs. 69%). Of the 75% who had experienced at least one overdose, 5% reported that their most recent overdose was a suicide attempt, 70% reported that it was accidental, 12% reported that they “didn’t want to die but did not care about the risks either” and 13% reported being unsure.

In terms of between-group differences in baseline levels of the outcomes, intervention participants had a higher frequency of overdose risk behaviors at baseline compared to EUC only, with a mean level of 3.8 in the intervention group and 3.3 in the EUC group, (incidence rate ratio [IRR] = 1.16 in a Poisson regression model), although this was short of statistical significance (p = 0.05). This group difference was attenuated when restricted to those with six month outcome data (IRR = 1.10, p = 0.22). Baseline level of the two overdose knowledge summary scores and COMM score did not differ between groups; intervention participants had lower levels of...
Table 1
Outcome measures.

Overdose Risk Behavior Items

1. How often have you used opioid pain medications when nobody else was around?
2. How often have you used opioid pain medications in a place where you don’t usually use them?
3. How often do you drink alcohol within 2 h before or after using opioid pain medications?
4. How often did you take sedatives (such as Xanax) within 2 h before or after using opioid pain medications?
5. How often did you use heroin within 2 h before or after using opioid pain medications?
6. How often did you use uppers (such as crack, cocaine, crystal/meth) within 2 h before or after using opioid pain medications?
7. How often have you increased the amount of opioid pain medications you used to more than you usually use?
8. How often have you snorted any drugs?
9. How often have you injected any drugs?

Behavioral Intentions

1. If you receive an opioid prescription, how likely is it that you would use prescription opioids as prescribed by a medical professional?
2. How likely is it that you will reduce or avoid using alcohol, drugs, and/or medications (recreationally)?
3. How likely is it that you will avoid combining alcohol, drugs, and/or medications?

Overdose Knowledge

Risk Factors: For each item, please check “Yes” for the items that you believe can lead to an overdose or “No” if you believe it cannot cause an overdose. (1) Taking more alcohol, drugs, and/or medications than usual; (2) Taking less alcohol, drugs, or medications than usual; (3) Having an illness; (4) Drug impurities; (5) Drugs, alcohol and/or medications stronger than expected; (6) Injecting drugs; (7) Using drugs at a young age; (8) Combining drugs; (9) Combining different medications; (10) Drinking alcohol with drugs and/or medications; (11) Combining drugs and medications; (12) Low tolerance; (13) Emotional problems or life difficulties; (14) Suicide attempt.

Symptoms: For each item below, please check “Yes” for the items that you believe to be a symptom of an overdose or “No” if you believe it is not a symptom of overdose: (1) Shallow breathing; (2) Turning blue; (3) Bloodshot eyes; (4) Loss of consciousness; (5) Deep snoring; (6) Pinpoint pupils; (7) Blurred vision.

Current Opioid Misuse Measure Items

1. How often have you had to go to someone other than your prescribing physician to get sufficient pain relief from opioid pain medications? (i.e., another doctor, the Emergency Room, friends, street sources)
2. How often have you taken your opioid pain medications differently from how they are prescribed?
3. How much of your time was spent thinking about opioid pain medications (having enough, taking them, dosing schedule, etc.)?
4. How often have you needed to take opioid pain medications belonging to someone else?
5. How often have you been worried about how you’re handling your opioid pain medications?
6. How often have you had to take more of your opioid pain medication than prescribed?
7. How often have you borrowed opioid pain medication from someone else?
8. How often have you used your opioid pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?

intention to use as prescribed at baseline (IRR = 1.20, p < 0.05) but were not different on the other two measures.

Table 3 reports the result of regression models examining all outcomes. The intervention group reported greater reduction in frequency of overdose risk behaviors (Model 1; IRR = 0.72, p < 0.01). The percent decrease in average overdose risk behavior frequency was 40.5% in intervention participants and 14.7% in EUC only participants among those participants with data at both timepoints. Similarly, the intervention group reported greater reductions in NMUPO (Model 5; IRR = 0.81, p < 0.01) at 6 months follow-up compared to EUC only. Percent decrease in average COMM score was 50.0% in intervention participants and 39.5% in EUC participants among those participants with data at both timepoints. No differences by group were observed for knowledge and intentions outcomes, with the exception that intervention participants reported greater increases in intention to reduce or avoid using substances (Model 2b; p < 0.01).

Adjusting for the two factors associated with group assignment despite randomization (alcohol use and other/missing race) did not change statistical inferences for the models for overdose risk behaviors and COMM scores (<0.07 absolute change in IRR). Including these covariates also had no impact on inference for the models of behavioral intentions or overdose symptom knowledge. For the model of overdose risk factor knowledge, the effect of intervention group became significant (IRR = 1.28, p < 0.05) after adjusting for these variables, indicating that intervention participants had more incorrect answers at follow-up than EUC only participants. Because we oversampled patients with a prior overdose, we conducted sensitivity analyses by re-estimating the models in that group alone; effect sizes (IRRs) were relatively similar for the overdose risk behavior (IRR = 0.65) and COMM outcomes (IRR = 0.74; both p’s < 0.05) but the effect in Model 2b was attenuated (IRR = 0.84, p = 0.07).

4. Discussion

The present study is the first trial of a motivational intervention focused on reducing opioid overdose risk behaviors among those with a prior non-fatal opioid overdose and/or who misuse prescription opioids. Analyses indicated that the intervention reduced self-reported behavioral outcomes compared to a control condition. These findings suggest this is a promising strategy for reducing overdose morbidity and mortality.

Self-reported behavioral intentions and knowledge about overdose risk factors and symptoms did not consistently change in response to the intervention. One possible explanation was the “ceiling” effects indicating high levels of knowledge and intention to avoid overdose overall. Additionally, the mechanism of change in our intervention may involve factors other than knowledge and intentions, such as motivation or self-efficacy. Future studies examining this intervention could measure other potential mechanisms of change. In the meantime, we suggest retaining intervention content about psychoeducation for overdose prevention because other settings/samples may not have the same baseline knowledge. Further, we found that reviewing this material using the “elicit-provide-elicit” tool provided an opportunity for collaboration and reinforcing change talk for avoiding overdose, which are thought to be key components of effective MI (Miller and Rollnick, 2013).
Table 2
Baseline Sample Characteristics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall n= 204</th>
<th>Intervention n= 102</th>
<th>EUC only n= 102</th>
<th>p-value *</th>
</tr>
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<tbody>
<tr>
<td>Age (Mean (SD))</td>
<td>36.8 (11.1)</td>
<td>37.5 (11.4)</td>
<td>36.1 (10.9)</td>
<td>0.38</td>
</tr>
<tr>
<td>Gender (%</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female (n)</td>
<td>130 (64)</td>
<td>61 (60)</td>
<td>69 (68)</td>
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<td>Race: White (n)</td>
<td>153 (75)</td>
<td>73 (72)</td>
<td>80 (78)</td>
<td>0.26</td>
</tr>
<tr>
<td>Black (n)</td>
<td>40 (20)</td>
<td>24 (24)</td>
<td>16 (16)</td>
<td>0.16</td>
</tr>
<tr>
<td>Other/Missing (n)</td>
<td>12 (6)</td>
<td>10 (10)</td>
<td>2 (2)</td>
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<td>Education: High School Degree or Less</td>
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<td>27 (26)</td>
<td>24 (24)</td>
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<td>Some College (n)</td>
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<td>46 (45)</td>
<td>45 (44)</td>
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<td>Competed College (n)</td>
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<td>29 (28)</td>
<td>33 (32)</td>
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<tr>
<td>Employment Status: Disabled (n)</td>
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<td>40 (39)</td>
<td>35 (35)</td>
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<tr>
<td>Full- or Part-Time Employment (n)</td>
<td>93 (46)</td>
<td>42 (41)</td>
<td>51 (51)</td>
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<tr>
<td>Unemployed (n)</td>
<td>31 (15)</td>
<td>19 (19)</td>
<td>12 (12)</td>
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</tr>
<tr>
<td>Retired (n)</td>
<td>4 (2)</td>
<td>1 (1)</td>
<td>3 (3)</td>
<td></td>
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<tr>
<td>Prior Overdose (any)</td>
<td>153 (75)</td>
<td>77 (75)</td>
<td>76 (75)</td>
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<tr>
<td>Number of past year ED visits: 0</td>
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<td>12 (12)</td>
<td>13 (13)</td>
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<td>1–2</td>
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<td>6+</td>
<td>46 (23)</td>
<td>21 (21)</td>
<td>25 (25)</td>
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<tr>
<td>Past 3 Month Substance Use</td>
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<tr>
<td>Any Alcohol Use</td>
<td>124 (61)</td>
<td>54 (53)</td>
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<td>21 (21)</td>
<td>30 (29)</td>
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<tr>
<td>Any Marijuana Use</td>
<td>77 (38)</td>
<td>39 (38)</td>
<td>38 (37)</td>
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</tr>
<tr>
<td>Use Frequency: Weekly or Greater</td>
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<td>22 (22)</td>
<td>23 (23)</td>
<td>0.87</td>
</tr>
<tr>
<td>Any Cocaine Use</td>
<td>19 (9)</td>
<td>9 (9)</td>
<td>10 (10)</td>
<td>1.00</td>
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<tr>
<td>Use Frequency: Weekly or Greater</td>
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<td>4 (4)</td>
<td>5 (5)</td>
<td>1.00</td>
</tr>
<tr>
<td>Any Non-Medical Sedative Use</td>
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<td>26 (26)</td>
<td>18 (18)</td>
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<tr>
<td>Use Frequency: Weekly or Greater</td>
<td>18 (9)</td>
<td>9 (9)</td>
<td>9 (9)</td>
<td>1.00</td>
</tr>
<tr>
<td>Chronic Pain Diagnosis, Lifetime</td>
<td>115 (56)</td>
<td>57 (56)</td>
<td>58 (57)</td>
<td>0.89</td>
</tr>
<tr>
<td>Prescribed Opioids in Prior 6 Months, Self-Reported</td>
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<td></td>
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<tr>
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<td>64 (31)</td>
<td>32 (31)</td>
<td>32 (31)</td>
<td>0.13</td>
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<tr>
<td>For Acute Pain Only</td>
<td>37 (18)</td>
<td>19 (19)</td>
<td>18 (18)</td>
<td></td>
</tr>
<tr>
<td>For Chronic Pain Only</td>
<td>38 (19)</td>
<td>13 (13)</td>
<td>25 (25)</td>
<td></td>
</tr>
<tr>
<td>For Acute and Chronic Pain</td>
<td>65 (32)</td>
<td>38 (37)</td>
<td>27 (26)</td>
<td></td>
</tr>
<tr>
<td>Prescription Opioid Involvement, ASSIST</td>
<td>106 (52)</td>
<td>51 (50)</td>
<td>55 (54)</td>
<td>0.85</td>
</tr>
<tr>
<td>Low Risk</td>
<td>106 (52)</td>
<td>51 (50)</td>
<td>55 (54)</td>
<td></td>
</tr>
<tr>
<td>Moderate Risk</td>
<td>80 (39)</td>
<td>42 (41)</td>
<td>38 (37)</td>
<td></td>
</tr>
<tr>
<td>High Risk</td>
<td>18 (9)</td>
<td>9 (9)</td>
<td>9 (9)</td>
<td></td>
</tr>
<tr>
<td>Any prior substance use treatment or counseling</td>
<td>72 (35)</td>
<td>33 (32)</td>
<td>39 (38)</td>
<td>0.37</td>
</tr>
<tr>
<td>Any prior opiate agonist therapy</td>
<td>16 (8)</td>
<td>8 (8)</td>
<td>8 (8)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

EUC: enhanced usual care.

* Fisher’s exact test used when cell sizes <10, otherwise t-test or χ²-test.

** Race categories are not mutually exclusive.

* Queried as “Have you ever been told by a doctor that you have chronic pain?”

There is an emerging body of research on strategies to reduce harms associated with opioid use. These include prescription drug monitoring programs, overdose education and naloxone distribution programs, state legislation, development of clinical guidelines and prescriber education, and public education efforts (Haegerich et al., 2014). Studies of these approaches have largely been observational, with very few trials reported. Additionally, prior studies of overdose prevention have not specifically focused on motivating individuals’ use of behavioral harm reduction strategies. A benefit of the intervention approach in this study is that it has broad application for individuals with elevated risk for overdose. A focus of policy statements addressing opioid overdose risk has been the implementation of naloxone programs (Health and Human Services, 2015; Office of National Drug Control Policy, 2011). These programs seek to distribute an opioid overdose antidote so that bystanders could administer it at witnessed overdoses (Coffin and Sullivan, 2013; Doe-Simkins et al., 2009; Walley et al., 2013). In contrast, this motivational intervention is also appropriate for addressing overdose risk among those who use opioids in a private setting or in combination with drugs that are not treated by naloxone. Future work could examine the benefit of combining this approach with naloxone distribution.

The ability of motivational brief interventions (particularly in the context of SBIRT) to change drug use has recently come into question after null findings in several trials (Hingson and Compton, 2014). A potential explanation for the discrepancy in findings is that the primary target of the present intervention was to reduce risks associated with use, rather than level of use, and a harm reduction strategy may meet less resistance from patients not seeking treatment. Additionally, there is concern about the potential for dissemination of therapist-delivered motivational interventions, given costs associated with staff time and barriers of standardizing fidelity (O’Donnell et al., 2014). It is possible to obtain reimbursements for SBIRT, and our intervention used a computerized workbook that served as a clinical decision tool for therapist and prompting session content, which is an innovative method for enhancing fidelity. Several EDs across the country have a health behavior specialist present to deliver such interventions (e.g., Bernstein et al., 2009). Nonetheless, the potential for dissemination may be limited in many ED locations by the lack of staff time available, even if reimbursement is possible. An important line of future work is to understand MI effectiveness under alternative modes of delivery that reduce burden on ED staff, such as computerized interventions (Murphy et al., 2013) or interventions that occur as follow-up after the ED visit.
Table 3
Estimates of effect of the intervention on outcomes measured six months later.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Model 1: Overdose Risk Behaviors, n = 172</th>
<th>Model 2a: Behavioral Intention to Use As Prescribed, n = 170</th>
<th>Model 2b: Behavioral Intention to Reduce or Avoid Using, n = 169</th>
<th>Model 2c: Behavioral Intention to Avoid Combining, n = 169</th>
<th>Model 3: Overdose Risk Factor Knowledge, n = 169</th>
<th>Model 4: Overdose Symptom Knowledge, n = 172</th>
<th>Model 5: Non-Medical Opioid Use, n = 163</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IRR</td>
<td>SE</td>
<td>95% CI</td>
<td>IRR</td>
<td>SE</td>
<td>95% CI</td>
<td>IRR</td>
</tr>
<tr>
<td>Intervention Group vs. EUC only</td>
<td>0.72</td>
<td>0.07</td>
<td>0.59, 0.87</td>
<td>1.11</td>
<td>0.10</td>
<td>0.93, 1.33</td>
<td>0.76</td>
</tr>
<tr>
<td>Intervention Group vs. EUC only</td>
<td>1.07</td>
<td>0.01</td>
<td>1.06, 1.08</td>
<td>0.02</td>
<td>1.09, 1.16</td>
<td>0.06</td>
<td>1.04, 1.11</td>
</tr>
<tr>
<td>Intervention Group vs. EUC only</td>
<td>0.72</td>
<td>0.07</td>
<td>0.59, 0.87</td>
<td>1.11</td>
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<td>0.06</td>
<td>1.04, 1.11</td>
</tr>
</tbody>
</table>

Note for interpretation: Outcome and baseline level of the outcome reverse coded in models 2 and 3. Bolded indicates p < 0.05.

4.1. Limitations

This pilot study was not designed to be a definitive trial of brief MI to reduce opioid overdose risk and had a relatively small sample size. The study included only six months of follow-up and was not powered to detect effects on non-fatal overdose and repeat ED visits, which have the potential to strengthen the economic case for delivering this intervention during ED visits. Although these findings are promising, further research is needed to understand the potential impact on key health outcomes across diverse ED settings.

We did not collect urine drug screens or other biometrics of drug use for this study. Standard drug panel testing would not have been useful for validating any of the primary outcomes of the study, and would not differentiate medical and non-medical use of opioids for validating the secondary outcome. Nonetheless, biomarkers have a role as a “bogus pipeline” (Werch et al., 1989) to promote honest self-reporting of substance use, and it is possible that participants in the intervention condition were more likely to underreport NMUPO and concurrent use of other substances at follow-up. However, use of computerized self-administered assessments, detailed assurances of confidentiality, and the fact that follow-up staff members were blinded to condition assignment increases confidence in veracity of self-report (Beck et al., 2014; Harrison, 1997). Additional key limitations are that this study was conducted at a single site and that individuals randomized to the EUC who reported a prior overdose were less likely to complete the six month follow-up assessment compared to other participants; thus, replication is needed.

5. Conclusions

This study provides the first examination of a motivational intervention for reducing prescription opioid overdose risk. This study established the feasibility of this therapist-delivered brief intervention to ED patients and provided evidence of intervention effects on self-reported overdose risk behavior. Although the study has several important limitations, the findings indicate this intervention is a promising strategy to reduce the public health epidemic of opioid overdose, thus warranting further study.

Contributors

Authors Amy Bohnert (study principal investigator), Maureen Walton, Rebecca Cunningham, Mark Greenwald and Frederic Blow conceptualized the study design and were primarily responsible for the conduct of the trial. Authors Stephen Chermack and Erin Bonar provided clinical training and supervision to therapists during the trial. Author Laura Thomas provided project management. Amy Bohnert took primary responsibility for data analysis and for writing and revising all drafts. All other authors provided substantive feedback on all drafts and approved the submitted manuscript.

Conflicts of interest

No conflict declared.

Role of funding

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ClinicalTrials.gov identifier

Safety & Prevention Outcomes Study (SPOS); NCT01894087 (Registered July 2, 2013, prior to the end of data collection).
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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.drugalcdep.2016.03.018.

References


