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A Randomized Clinical Trial of an Emergency Department-Based Peer Recovery Support Intervention to Increase Treatment Uptake and Reduce Recurrent Overdose among Individuals at High Risk for Opioid Overdose: Study Protocol

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ABSTRACT

Introduction: Effective approaches to increase engagement in treatment for opioid use disorder (OUD) and reduce the risk of recurrent overdose and death following emergency department (ED) presentation for opioid overdose remain unknown. As such, we aim to compare the effectiveness of behavioral interventions delivered in the ED by certified peer recovery support specialists relative to those delivered by licensed clinical social workers (LCSWs) in promoting OUD treatment uptake and reducing recurrent ED visits for opioid overdose.

Methods and Analysis: Adult ED patients who are at high risk for opioid overdose (i.e., are being treated for an opioid overdose or identified by the treating physician as having OUD) (n = 650) will be recruited from two emergency departments in a single health care system in Providence, Rhode Island into a two-arm randomized trial with 18 months of follow-up post-randomization. Eligible participants will be randomly assigned (1:1) in the ED to receive a behavioral intervention from a certified peer recovery support specialist or a behavioral intervention from an LCSW. The primary outcomes are engagement in formal OUD treatment within 30 days of the initial ED visit and recurrent ED visits for opioid overdose within 18 months of the initial ED visit, as measured through statewide administrative records.

Ethics and Dissemination: Given the strong interest in peer-based recovery interventions for opioid overdose survivors, the results of this trial have the potential to change clinical practice for treating patients at high risk for opioid overdose who present to EDs.

Trial Registration: NCT03684681 (ClinicalTrials.gov)

KEYWORDS

Opioid Overdose; Emergency Department; Peer Support; Recovery; Randomized Trial

STRENGTHS AND LIMITATIONS

- This study represents the first randomized controlled trial to assess the impact of a peer recovery support intervention on uptake of OUD treatment and recurrent ED presentation for opioid-involved overdose.
- This study leverages a statewide comprehensive data sharing infrastructure to use administrative records to characterize the primary outcomes (e.g., OUD treatment enrollment, recurrent ED presentation), thus overcoming biases associated with self-reported outcomes and loss to follow-up in previous studies.
- Although the administrative databases used to characterize the primary outcomes are meant to be representative, they are by no means comprehensive (i.e., individuals who enroll in OUD treatment programs or who present to EDs in other states will not be captured in these resources).

INTRODUCTION

Deaths attributable to accidental drug overdose, particularly those involving opioids, have reached epidemic levels in the United States (US) (1-4). In the past two decades, US overdose mortality rates have more than doubled, from 6.2 per 100,000 persons in 2000 to 21.7 per 100,000 persons in 2017 (2, 3). There have been 700,000 opioid overdose deaths between 2000 to 2015 in the US (5), and the crisis that is expected to worsen under current trends (6). Since 2013, the opioid overdose epidemic has been marked by significant increases in deaths involving powerful synthetic opioids (e.g., fentanyl) (3). The burden of the drug overdose epidemic is greatly elevated in New England, where fentanyl has been present in the illicit drug supply since as early as 2012 (7-10). Rhode Island has one of the highest drug overdose rates in the nation (3), and in 2014 reported the third and fourth highest rate of opioid-related emergency department (ED) visits and inpatient hospital stays, respectively (11).

In addition to increases in fatal opioid overdoses, EDs have had substantial increases in visits for non-fatal opioid overdoses (12-14). About 120,000 ED visits were reported for suspected non-fatal opioid overdoses between July 2016 and September 2017 in sixteen states participating in the Enhanced State Opioid Overdose Surveillance, representing a 35% increase over this period (15). As such, the ED serves as a critical intervention site for providing services to people at high risk of opioid overdose and those with opioid use disorder (OUD). In the year after presenting to the ED for a drug overdose, a person is at heightened risk for death (16, 17). In a nested case-control study in New York, the odds of death due to prescription drug overdose were 4.9 times higher for those with two ED visits, 16.6 times higher for those with three ED visits, and 48.2 times higher for those with four or more visits relative to one ED visit or less in the year preceding death (16). Thus, the ED is both a critical and timely place for intervention and the reason for the ED visit itself (i.e., overdose) can be used as an opportunity to identify patients at highest risk of fatal drug overdose and deliver interventions (18).

The most effective means to promote engagement in substance use disorder (SUD) treatment and reduce the risk of recurrent overdose and death following presentation to an ED for opioid overdose remains unknown. One of the only randomized studies of overdose education combined with a brief behavioral intervention for high-risk adults recruited from an ED setting did not result in reduced recurrent overdose, subsequent ED visits, or hospitalizations compared to usual care (19). It is possible, however, that these types of interventions may be more effective if delivered by people with lived experiences with SUD and recovery. Peer-based interventions are an effective component of care across non-clinical settings and in other aspects of health care for other conditions (20), but little is known about their effectiveness in improving outcomes for persons at high risk for opioid overdose. In response to Rhode Island's overdose

crisis, individuals in long-term recovery with specialized training in SUD management, known as certified peer recovery support specialists, have been deployed in EDs since 2014 (21). The goal of their work is to help patients navigate obstacles to recovery through problem-solving, goal setting, avoiding relapse triggers, and planning and obtaining services. Despite the promise of and significant national interest in this approach (22), no studies have rigorously evaluated whether peer-based behavioral interventions delivered in the ED result in improved outcomes for patients at high risk of opioid overdose.

We aim to test the effectiveness of behavioral interventions delivered in the ED by certified peer recovery support specialists relative to those delivered by licensed clinical social workers (LCSWs). We hypothesize that, because certified peer recovery support specialists are able to draw from their own lived experiences with SUD and recovery, patients who are randomly assigned to receive a behavioral intervention from a peer recovery support specialist, as compared to receiving an intervention from an LCSW, will be: (1) more likely to engage in formal SUD treatment within 30 days following the initial visit, and (2) less likely to experience a recurrent ED visit for an opioid overdose during the succeeding 18 months.

METHODS

Trial Design

The trial utilizes a parallel design where patients at high risk for opioid overdose who present to the ED are randomly assigned 1:1 to receive a behavioral intervention from a certified peer recovery support specialist or an LCSW. All protocols have been approved by the institutional review boards at the Lifespan health system representing the two clinical sites (Approval Number: 212418). The privacy of all trial participants is protected by a Certificate of Confidentiality issued by the National Institutes of Health.

Participants

Rhode Island is home to over one million residents. Since 2000, the state has experienced a high burden of opioid overdose. According to the 2016–2017 cycle of the National Survey on Drug Use and Health, 4.7% of Rhode Islanders used heroin or misused a prescription opioid in the past year (23). Between 2013 and 2017, the age-adjusted rate of death due to opioid overdose increased by 44.2%, from 18.1 to 26.1 per 100,000 persons, with these increases largely driven by synthetic opioids other than methadone (16.8% of opioid overdose deaths in 2013 versus 72.6% in 2017) (24).

Participants will be recruited from two EDs—Level 1 and Level 2 trauma centers—located in the state's capital of Providence. Together, these two EDs receive over 175,000 adult visits each year. Between 2017

and 2018, the two EDs reported a total of 1,446 visits for suspected opioid overdoses, representing 45% of all ED visits for suspected opioid overdose reported to the Rhode Island Department of Health (n = 3,239).

A consecutive sample of ED patients will be assessed for eligibility by one of eleven full-time research assistants employed in the two EDs who can recruit participants 24 hours per day, seven days per week. Potential participants will be identified by the research assistants by screening electronic medical records (EMRs) or by referral from treating providers in the ED. Potential participants will be considered eligible if they are 18 years of age or older and speak English. To be eligible, participants must also be in the ED because they are: (1) being treated for an opioid overdose; (2) receiving treatment related to OUD (e.g., infectious complication, withdrawal); or (3) self-report an opioid overdose within the previous 12 months. The presence of an opioid overdose will be determined by the treating physician and is generally defined as (1) the presence of decreased levels of consciousness or respiratory depression and (2) occurring after the consumption of opioids or resolving after the administration of naloxone. Potential participants will be deemed ineligible if they are critically ill or injured, have previously enrolled in the trial, are in police custody or incarcerated, pregnant, or live outside of Rhode Island. Patients who are critically ill or injured will be eligible for screening and enrollment once cleared to participate by their treating physician.

Patient and Public Involvement

No patient involved.

Interventions

Current Standard of Care

The current standard of care following an ED visit for an opioid overdose at the study sites is to receive a behavioral intervention delivered by a certified peer recovery support specialist or an LCSW. Whether a patient is evaluated by a social worker or a peer recovery support specialist can depend on the time of day, staff availability, and preferences or views of the provider or patient. In the trial, patients will be randomly assigned to receive a behavioral intervention in the ED delivered by (1) a staff LCSW, or (2) a certified peer recovery support specialist trained by the Anchor Recovery Community Center (Figure 1).

Behavioral Intervention Delivered by Certified Peer Recovery Support Specialists

The Anchor Recovery Community Center is Rhode Island's first community-based peer recovery center (21). It is designed as an access point for those with SUD, providing services such as job counseling, health and wellness activities, and individualized long-term peer recovery coaching (21). Through one of its outreach programs, known as AnchorED, the Anchor Recovery Community Center has deployed certified

peer recovery support specialists to EDs across Rhode Island since 2014 (21). As part of AnchorED, certified peer recovery support specialists arrive in the ED within 30 minutes of consultation, assess individuals for readiness to seek treatment, provide linkage to treatment, and educate patients on overdose prevention and response (21). Peer recovery specialists call every day for ten days in an attempt to make contact following discharge from the ED. Once contact is made, peer recovery specialists and their clients make plans for regular contact and follow-up.

To become a certified peer recovery support specialist, applicants must be in recovery for at least two years, undergo a 45-hour training program at Anchor Recovery Community Center based on the Connecticut Community for Addiction Recovery curriculum, and accrue 500 hours of supervised work experience providing peer recovery support services (21). All peer recovery support specialists obtain certification from the International Certification and Reciprocity Consortium (21). The certification program focuses on advocacy, wellness and recovery, motivational interviewing techniques, mentoring and education, and ethics as well as additional training on the provision of trauma-informed care and the transtheoretical model of behavior change. In addition to employing motivational interviewing techniques, peer recovery support specialists support individuals' self-efficacy and prevent relapse by addressing social, environmental, and personal factors, such as awareness and avoidance of relapse triggers, polysubstance use, stigma associated with SUD and their treatment, knowledge of treatment services (including the use of medications for OUD treatment), and addressing financial and transportation barriers to treatment (21). Certified peer recovery support specialists are uniquely positioned to deliver behavioral interventions to individuals who have experienced overdose as they couple their training with lived experiences of SUD and recovery (21).

Behavioral Intervention Delivered via Licensed Clinical Social Workers

There are 35 full and part-time LCSW on staff in the Department of Social Work between the two study sites. Staff social workers arrive in the ED within 30 minutes of consultation. Staff social workers are trained and available to deliver interventions to patients presenting with an opioid overdose and/or with OUD in the ED. As LCSWs, these individuals are capable of delivering a variety of interviewing and intervention techniques that are rooted in social work theory and practice models. Social work practice models are strategies that the social worker can incorporate into their interventions to help people meet their goals (e.g., task-centered practice, cognitive behavioral therapy, crisis intervention model). Although the intervention delivered by LCSWs and their associated theoretical underpinnings are similar in some respects to those associated with those delivered by certified peer recovery support specialists, the social worker intervention is intended to be a single session with referral to SUD treatment.

Participant Assessments

While the primary outcomes assessments will rely on the use of administrative data (see below), we will also collect patient-reported assessments at baseline and follow-up. Baseline assessments will be administered by a research assistant in the ED to collect information about sociodemographic characteristics, medical history, medication use, substance use patterns, prior substance use treatment engagement, recovery capital (25), treatment readiness (26), opinions about medications for OUD treatment (27), perceived stigma towards people who use drugs (28), symptoms of pain (29), opioid withdrawal (30), and depression (31) using established instruments. Follow-up assessments will be conducted at 30 days, three months, and six months post-discharge, respectively. All data collection instruments will be designed using Research Electronic Data Capture (REDCap) software and administered using a tablet computer connected to the wireless network at the two study sites. All follow-up assessments will be conducted via telephone by a research assistant, and all responses will be directly entered into REDCap.

Outcomes

Primary Outcomes

The two primary outcomes of the trial are (1) engagement with a formal SUD treatment program within 30 days of the initial ED visit, and (2) recurrent ED visit(s) for a suspected opioid overdose over 18 months. Both endpoints will be assessed via statewide administrative databases as outlined below. All records will be linked deterministically to participant data using identifiable information in a secure, Health Insurance Portability and Accountability Act (HIPAA)-compliant computing environment.

The first primary outcome of the trial is treatment engagement, defined as admission to a formal, publicly licensed SUD treatment program within 30 days of the initial ED visit. The Rhode Island Department of Behavioral Health, Developmental Disabilities, and Hospitals (BHDDH) maintains the Behavioral Health Online Database (BHOLD), a state database containing information on all admission and discharge events of clients of all licensed behavioral healthcare organizations in the state (32). BHOLD is a comprehensive database on all licensed treatment programs, including inpatient detoxification programs, day treatment programs, residential treatment programs, intensive outpatient programs, and opioid treatment programs (32). In addition to this resource, records from the prescription drug monitoring program (PDMP) maintained by the Rhode Island Department of Health will be used to supplement BHOLD to identify patients who initiate buprenorphine in office-based settings (33).

The second primary outcome of the trial is recurrent visits to the ED for a suspected opioid overdose, defined as receipt of treatment in an ED in Rhode Island for an opioid overdose within the 18 months

following the initial ED visit at the two sites. The Rhode Island Quality Institute maintains CurrentCare, a health information exchange that provides a unified data system for EMRs for all major health systems in Rhode Island, allowing us to identify repeat visits for suspected opioid overdoses at all twelve EDs in the state (34). Opioid overdoses will be defined according to the Centers for Disease Control and Prevention (CDC) guidelines for all opioid poisonings and utilize International Classification of Disease (ICD) codes (35, 36). The Rhode Island Department of Health mandates that all suspected overdoses presenting to a hospital be reported to the department within 48 hours. This data source, referred to as the 48-hour overdose surveillance system (37), will be used to supplement the EMRs in CurrentCare.

Sample Size

Based on preliminary assessments from the study sites, we are assuming that 7% of participants assigned to receive a behavioral intervention from an LCSW will enroll in a formal SUD treatment program within 30 days of their ED visit. Given this assumption for a sample size of 650 participants, we have at least 80% power to detect a two-fold increase in treatment engagement among participants assigned to receive a behavioral intervention from a peer recovery specialist. This two-fold increase was identified by community stakeholders as an appropriate benchmark for this outcome. Based on a recent medical record review from one of the study sites and estimates from other studies (19, 38), we are assuming that 15% of participants who receive a behavioral intervention from an LCSW will experience a subsequent repeat ED visit for opioid overdose. Given this assumption and our sample, we have at least 80% power to detect a 50% relative reduction in the risk of recurrent ED visits for opioid overdose within 18 months following the initial visit among those assigned to receive a behavioral intervention from a peer recovery specialist.

Randomization

Participants will be randomly assigned 1:1 to receive either a behavioral intervention delivered by a certified peer recovery support specialist or by an LCSW. Participants will be stratified during randomization based on age and gender (39). Allocations will be randomly assigned using the REDCap randomization feature based on a random permutation method with block sizes between 4 and 8 (39). The randomization schedule will be maintained by a data manager not involved with participant recruitment or the final study analyses.

Blinding

Participants and providers cannot be blinded to their intervention assignment. However, research assistants who are responsible for the follow-up assessments and investigators and analysts performing the study analyses will be blinded to arm allocation.

Statistical Methods

We will use an intention-to-treat (ITT) approach in all analyses to estimate the average treatment effect. A sensitivity analysis will be conducted using a per-protocol approach with a sample restricted to those who complete their interventions. We will first assess the success of randomization by comparing key pre-intervention characteristics (e.g., sociodemographic characteristics, substance use patterns, prior engagement in formal SUD treatment) across the two arms using one-way analyses of variance (ANOVA) for continuous variables and χ^2 tests of independence of categorical variables. Should any differences in pre-intervention characteristics be detected between the two arms, we will include these variables as covariates in the primary outcomes analyses. Given our use of administrative data sources to characterize the primary outcomes, we anticipate minimal missingness in our final dataset, but missing covariate data will be handled using two-stage chained equations.

For the two primary outcomes (engagement in formal SUD treatment within 30 days of the initial ED visit and occurrence of a subsequent ED visit for opioid overdose within 18 months of the initial ED visit), we will first compare the proportions of patients with each of these outcomes in the two arms using χ^2 tests of independence. Second, we will fit separate logistic regression models for each of the outcomes to identify the independent effect of the intervention on the outcome, adjusting for pre-intervention characteristics.

DISCUSSION

The AnchorED program of Anchor Recovery Community Center, which deploys certified peer recovery support specialists to EDs across Rhode Island to deliver behavioral interventions to individuals who have experienced an opioid overdose, is the first statewide program of its kind in the nation (21). Despite a lack of evidence to demonstrate the effectiveness of this program and improved long-term outcomes for patients, several other jurisdictions in the US have created or are initiating programs based on the AnchorED model (22). Given the intense interest in peer recovery models, the results of this trial have a strong potential to fundamentally change clinical practice paradigms for treating patients at high risk for opioid overdose who present to EDs across the nation.

The current study benefits from support from a unique policy environment in Rhode Island. In 2015, Governor Gina Raimondo signed an executive order to establish the Rhode Island Overdose Prevention and Intervention Task Force, which charged experts to develop a strategic plan to guide efforts to tackle the state's overdose crisis (40). An important outcome of this plan was a comprehensive data sharing infrastructure between key state agencies (including the Rhode Island Departments of Health and Behavioral Healthcare, Developmental Disabilities, and Hospitals) and academic researchers (41). These

data sharing agreements offer unprecedented access to population-based data on overdose morbidity and mortality (41). As a result, the trial investigators can create a large database linking participant data with multiple administrative databases to ascertain our primary and secondary outcomes. The ability to conduct these robust data linkages is an important methodological innovation that overcomes biases associated with self-reported outcomes and loss to follow-up in previous studies.

The results of this trial will need to be considered in light of some caveats. Although Good Samaritan laws are present in many jurisdictions across the US, including Rhode Island, to protect individuals from criminal prosecutions (42), many people do not call emergency medical services in the event of an overdose (43). It is possible that the intervention may increase participants' self-efficacy and willingness to engage with emergency medical services in the event of an overdose. As a result, those receiving the peer recovery intervention might be more likely to present to the ED in the event of an overdose. Should the intervention reduce the overall rate of non-fatal overdose but increase the proportion of non-fatal overdoses that are treated in the ED, the findings related to the impact of the intervention on recurrent ED visits may be null or counterintuitive. Although the administrative databases used to characterize the primary outcomes are meant to be representative, they are by no means comprehensive. Individuals who enroll in SUD treatment programs or who present to EDs in other states will not be captured in these resources. To address these limitations, we will conduct follow-up surveys to capture treatment enrollment and experiences of opioid overdose via phone interviews.

This trial represents the first systematic evaluation of behavioral interventions delivered by certified peer recovery support specialists in the ED to individuals at high risk for opioid overdose. Should the trial be successful, its findings have the potential to establish the evidence base for peer recovery support services as an effective intervention and provide support for the large-scale implementation of these services in EDs. Amidst a national crisis, peer recovery support interventions could be an effective means for improving SUD treatment engagement and reducing rates of fatal and non-fatal overdose.

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Authors' Contributions:

WCG led the manuscript preparation. The research was conceived by FLB and BDLM. All authors provided feedback on several drafts of the study protocol and this manuscript. WCG, BDLM, EAS, MGB, DD, KJL, LM, RCM, TN, GAO, SER, JYL, and FLB read and approved of the final manuscript.

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Figure 1. Intervention arms in a randomized clinical trial of an emergency department-based peer recovery support intervention to increase treatment uptake and reduce recurrent overdose among individuals at high risk for opioid overdose

	Certified Peer Recovery Specialist		Licensed Clinical Social Worker
1	Enrollment Visit in Emergency Department • Intervention based on motivational interviewing plus lived experience of peer recovery specialist • Navigate barriers to treatment, provide referrals	1	Brief Intervention in Emergency Department • Intervention based on motivational interviewing plus other clinical skills • Provide referrals as needed
2	Community-Based Follow-Up Visit (<48 hours) • Navigate barriers to treatment and recovery • Ongoing peer support • Ongoing overdose prevention education		
3	Retention in Peer Recovery Support (≥90 days) • Promote retention in treatment • Ongoing peer support • Ongoing overdose prevention education		

Figure 1

BMJ Open

A Randomized Clinical Trial of an Emergency Department-Based Peer Recovery Support Intervention to Increase Treatment Uptake and Reduce Recurrent Overdose among Individuals at High Risk for Opioid Overdose: Study Protocol for the Navigator Trial

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A Randomized Clinical Trial of an Emergency Department-Based Peer Recovery Support Intervention to Increase Treatment Uptake and Reduce Recurrent Overdose among Individuals at High Risk for Opioid Overdose: Study Protocol for the Navigator Trial

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ABSTRACT

Introduction: Effective approaches to increase engagement in treatment for opioid use disorder (OUD) and reduce the risk of recurrent overdose and death following emergency department (ED) presentation for opioid overdose remain unknown. As such, we aim to compare the effectiveness of behavioral interventions delivered in the ED by certified peer recovery support specialists relative to those delivered by licensed clinical social workers (LCSWs) in promoting OUD treatment uptake and reducing recurrent ED visits for opioid overdose.

Methods and Analysis: Adult ED patients who are at high risk for opioid overdose (i.e., are being treated for an opioid overdose or identified by the treating physician as having OUD) (n = 650) will be recruited from two emergency departments in a single health care system in Providence, Rhode Island into a two-arm randomized trial with 18 months of follow-up post-randomization. Eligible participants will be randomly assigned (1:1) in the ED to receive a behavioral intervention from a certified peer recovery support specialist or a behavioral intervention from an LCSW. The primary outcomes are engagement in formal OUD treatment within 30 days of the initial ED visit and recurrent ED visits for opioid overdose within 18 months of the initial ED visit, as measured through statewide administrative records.

Ethics and Dissemination: This protocol was approved by the Rhode Island Hospital institutional review board (Approval Number: 212418). Data will be presented at national and international conferences and published in peer-reviewed journals.

Trial Registration: NCT03684681 (ClinicalTrials.gov)

KEYWORDS

Opioid Overdose; Emergency Department; Peer Support; Recovery; Randomized Trial

STRENGTHS AND LIMITATIONS

- This study represents the first randomized controlled trial to assess the impact of a peer recovery support intervention on uptake of OUD treatment and recurrent ED presentation for opioid-involved overdose.
- This study leverages a statewide comprehensive data sharing infrastructure to use administrative records to characterize the primary outcomes (e.g., OUD treatment enrollment, recurrent ED presentation), thus overcoming biases associated with self-reported outcomes and loss to follow-up in previous studies.
- Although the administrative databases used to characterize the primary outcomes are meant to be representative, they are by no means comprehensive (i.e., individuals who enroll in OUD treatment programs or who present to EDs in other states will not be captured in these resources).

INTRODUCTION

Background and Rationale

Deaths attributable to accidental drug overdose, particularly those involving opioids, have reached epidemic levels in the United States (US) (1-4). In the past two decades, US overdose mortality rates have more than doubled, from 6.2 per 100,000 persons in 2000 to 21.7 per 100,000 persons in 2017 (2, 3). There have been 700,000 opioid overdose deaths between 2000 to 2015 in the US (5), and the crisis that is expected to worsen under current trends (6). Since 2013, the opioid overdose epidemic has been marked by significant increases in deaths involving powerful synthetic opioids (e.g., fentanyl) (3). The burden of the drug overdose epidemic is greatly elevated in New England, where fentanyl has been present in the illicit drug supply since as early as 2012 (7-10). Rhode Island has one of the highest drug overdose rates in the nation (3), and in 2014 reported the third and fourth highest rate of opioid-related emergency department (ED) visits and inpatient hospital stays, respectively (11).

In addition to increases in fatal opioid overdoses, EDs have had substantial increases in visits for non-fatal opioid overdoses (12-14). About 120,000 ED visits were reported for suspected non-fatal opioid overdoses between July 2016 and September 2017 in sixteen states participating in the Enhanced State Opioid Overdose Surveillance, representing a 35% increase over this period (15). As such, the ED serves as a critical intervention site for providing services to people at high risk of opioid overdose and those with opioid use disorder (OUD). In the year after presenting to the ED for a drug overdose, a person is at heightened risk for death (16, 17). In a nested case-control study in New York, the odds of death due to prescription drug overdose were 4.9 times higher for those with two ED visits, 16.6 times higher for those with three ED visits, and 48.2 times higher for those with four or more visits relative to one ED visit or less in the year preceding death (16). Thus, the ED is both a critical and timely place for intervention and the reason for the ED visit itself (i.e., overdose) can be used as an opportunity to identify patients at highest risk of fatal drug overdose and deliver interventions (18).

The most effective means to promote engagement in substance use disorder (SUD) treatment and reduce the risk of recurrent overdose and death following presentation to an ED for opioid overdose remains unknown. One of the only randomized studies of overdose education combined with a brief motivational interviewing-based intervention delivered in the ED by licensed mental health counselors resulted in reductions in overdose risk behaviors among individuals presenting to the ED and reporting non-medical prescription opioid use (Bohnert et al., 2016). However, a trial deploying a similar intervention did not reduce overdose rates or prevent subsequent ED visits or hospitalizations compared to usual care (19). It is possible, however, that these types of interventions may be more effective if delivered by people with lived

experiences with SUD and recovery. Peer-based interventions are an effective component of care across non-clinical settings and in other aspects of health care for other conditions (20). A recent systematic review by Ramchand and colleagues (2017) found that group-based interventions that use peers as educators commonly improve knowledge, attitudes, beliefs, and perceptions and improve connectedness and engagement with health promotion activities (20). Further, a recent systematic review of peer recovery support services in care for substance use disorder found that existing randomized controlled trials have been subject to several limitations, particularly poorly defined and non-manualized roles for peers, and, as such, there remains a need for more rigorous evaluation to determine the efficacy, effectiveness, and cost-effectiveness of peer recovery support services (21). However, little is known about their effectiveness in improving outcomes for persons at high risk for opioid overdose. In response to Rhode Island's overdose crisis, individuals in long-term recovery with specialized training in SUD management, known as certified peer recovery support specialists, have been deployed in EDs since 2014 (22). The goal of their work is to help patients navigate obstacles to recovery through problem-solving, goal setting, avoiding relapse triggers, and planning and obtaining services. Despite the promise of and significant national interest in this approach (23), no studies have rigorously evaluated whether peer-based behavioral interventions delivered in the ED result in improved outcomes for patients at high risk of opioid overdose.

Objectives

We aim to test the effectiveness of behavioral interventions delivered in the ED by certified peer recovery support specialists in improving outcomes for patients at high risk of opioid overdose relative to those delivered by licensed clinical social workers (LCSWs). We hypothesize that, because certified peer recovery support specialists are able to draw from their own lived experiences with SUD and recovery, patients who are randomly assigned to receive a behavioral intervention from a peer recovery support specialist, as compared to receiving an intervention from an LCSW, will be: (1) more likely to engage in formal SUD treatment within 30 days following the initial visit, and (2) less likely to experience a recurrent ED visit for an opioid overdose during the succeeding 18 months.

Trial Design

The trial utilizes a parallel design where patients at high risk for opioid overdose who present to the ED are randomly assigned 1:1 to receive a behavioral intervention from a certified peer recovery support specialist or an LCSW.

METHODS: PARTICIPANTS, INTERVENTIONS, OUTCOMES

Study Setting

Rhode Island is home to over one million residents. Since 2000, the state has experienced a high burden of opioid overdose. According to the 2016–2017 cycle of the National Survey on Drug Use and Health, 4.7% of Rhode Islanders used heroin or misused a prescription opioid in the past year (24). Between 2013 and 2017, the age-adjusted rate of death due to opioid overdose increased by 44.2%, from 18.1 to 26.1 per 100,000 persons, with these increases largely driven by synthetic opioids other than methadone (16.8% of opioid overdose deaths in 2013 versus 72.6% in 2017) (25).

Eligibility Criteria

To be eligible, participants must also be in the ED because they are: (1) being treated for an opioid overdose; (2) receiving treatment related to OUD (e.g., infectious complication, withdrawal); or (3) self-report an opioid overdose within the previous 12 months. The presence of an opioid overdose will be determined by the treating physician and is generally defined as (1) the presence of decreased levels of consciousness or respiratory depression and (2) occurring after the consumption of opioids or resolving after the administration of naloxone. Potential participants will be deemed ineligible if they are critically ill or injured, have previously enrolled in the trial, are in police custody or incarcerated, pregnant, or live outside of Rhode Island. Patients who are critically ill or injured will be eligible for screening and enrollment once cleared to participate by their treating physician.

Patient and Public Involvement

No patient involved.

Interventions

Current Standard of Care

The current standard of care following an ED visit for an opioid overdose at the study sites is to receive a behavioral intervention delivered by a certified peer recovery support specialist or an LCSW. Whether a patient is evaluated by a social worker or a peer recovery support specialist can depend on the time of day, staff availability, and preferences or views of the provider or patient. In the trial, patients will be randomly assigned to receive a behavioral intervention in the ED delivered by (1) a staff LCSW, or (2) a certified peer recovery support specialist trained by the Anchor Recovery Community Center (Figure 1).

Behavioral Intervention Delivered by Certified Peer Recovery Support Specialists

The Anchor Recovery Community Center is Rhode Island's first community-based peer recovery center (22). It is designed as an access point for those with SUD, providing services such as job counseling, health and wellness activities, and individualized long-term peer recovery coaching (22). Through one of its

outreach programs, known as AnchorED, the Anchor Recovery Community Center has deployed certified peer recovery support specialists to EDs across Rhode Island since 2014 (22). As part of AnchorED, certified peer recovery support specialists arrive in the ED within 30 minutes of consultation, assess individuals for readiness to seek treatment, provide linkage to treatment, and educate patients on overdose prevention and response (22). Peer recovery specialists call every day for ten days in an attempt to make contact following discharge from the ED. Once contact is made, peer recovery specialists and their clients make plans for regular contact and follow-up.

To become a certified peer recovery support specialist, applicants must be in recovery for at least two years, undergo a 45-hour training program at Anchor Recovery Community Center based on the Connecticut Community for Addiction Recovery curriculum, and accrue 500 hours of supervised work experience providing peer recovery support services (22). All peer recovery support specialists obtain certification from the International Certification and Reciprocity Consortium (22). The certification program focuses on advocacy, wellness and recovery, motivational interviewing techniques, mentoring and education, and ethics as well as additional training on the provision of trauma-informed care and the transtheoretical model of behavior change. In addition to employing motivational interviewing techniques, peer recovery support specialists support individuals' self-efficacy and prevent relapse by addressing social, environmental, and personal factors, such as awareness and avoidance of relapse triggers, polysubstance use, stigma associated with SUD and their treatment, knowledge of treatment services (including the use of medications for OUD treatment), and addressing financial and transportation barriers to treatment (22). Certified peer recovery support specialists are uniquely positioned to deliver behavioral interventions to individuals who have experienced overdose as they couple their training with lived experiences of SUD and recovery (22).

Behavioral Intervention Delivered via Licensed Clinical Social Workers

There are 35 full and part-time LCSW on staff in the Department of Social Work between the two study sites. Staff social workers arrive in the ED within 30 minutes of consultation. Staff social workers are trained and available to deliver interventions to patients presenting with an opioid overdose and/or with OUD in the ED. As LCSWs, these individuals are capable of delivering a variety of interviewing and intervention techniques that are rooted in social work theory and practice models. Social work practice models are strategies that the social worker can incorporate into their interventions to help people meet their goals (e.g., task-centered practice, cognitive behavioral therapy, crisis intervention model). Although the intervention delivered by LCSWs and their associated theoretical underpinnings are similar in some respects to those associated with those delivered by certified peer recovery support specialists, the social worker intervention is intended to be a single session with referral to SUD treatment.

Outcomes

Primary Outcomes

The two primary outcomes of the trial are (1) engagement with a formal SUD treatment program within 30 days of the initial ED visit, and (2) recurrent ED visit(s) for a suspected opioid overdose over 18 months. Both endpoints will be assessed via statewide administrative databases as outlined below. All records will be linked deterministically to participant data using identifiable information in a secure, Health Insurance Portability and Accountability Act (HIPAA)-compliant computing environment.

The first primary outcome of the trial is treatment engagement, defined as admission to a formal, publicly licensed SUD treatment program within 30 days of the initial ED visit. The Rhode Island Department of Behavioral Health, Developmental Disabilities, and Hospitals (BHDDH) maintains the Behavioral Health Online Database (BHOLD), a state database containing information on all admission and discharge events of clients of all licensed behavioral healthcare organizations in the state (26). BHOLD is a comprehensive database on all licensed treatment programs, including inpatient detoxification programs, day treatment programs, residential treatment programs, intensive outpatient programs, and opioid treatment programs (26). Records in BHOLD include individuals who receive methadone or buprenorphine from a licensed opioid treatment program. In addition to this data resource, records from the prescription drug monitoring program (PDMP) maintained by the Rhode Island Department of Health will be used to supplement BHOLD to identify patients who initiate buprenorphine in office-based settings (27).

The second primary outcome of the trial is recurrent visits to the ED for a suspected opioid overdose, defined as receipt of treatment in an ED in Rhode Island for an opioid overdose within the 18 months following the initial ED visit at the two sites. The Rhode Island Quality Institute maintains CurrentCare, a health information exchange that provides a unified data system for EMRs for all major health systems in Rhode Island, allowing us to identify repeat visits for suspected opioid overdoses at all twelve EDs in the state (28). Opioid overdoses will be defined according to the Centers for Disease Control and Prevention (CDC) guidelines for all opioid poisonings and utilize International Classification of Disease (ICD) codes (29, 30). The Rhode Island Department of Health mandates that all suspected overdoses presenting to a hospital be reported to the department within 48 hours. This data source, referred to as the 48-hour overdose surveillance system (31), will be used to supplement the EMRs in CurrentCare.

Sample Size

Based on preliminary assessments from the study sites, we are assuming that 7% of participants assigned to receive a behavioral intervention from an LCSW will enroll in a formal SUD treatment program within 30 days of their ED visit. Given this assumption for a sample size of 650 participants, we have at least 80% power to detect a two-fold increase in treatment engagement among participants assigned to receive a behavioral intervention from a peer recovery specialist (Effect Size: 0.07; 95% CI: 0.02–0.12). This two-fold increase was identified by community stakeholders as an appropriate benchmark for this outcome. Based on a recent medical record review from one of the study sites and estimates from other studies (19, 32), we are assuming that 15% of participants who receive a behavioral intervention from an LCSW will experience a subsequent repeat ED visit for opioid overdose. Given this assumption and our sample, we have at least 80% power to detect a 50% relative reduction in the risk of recurrent ED visits for opioid overdose within 18 months following the initial visit among those assigned to receive a behavioral intervention from a peer recovery specialist (Effect Size: 0.075; 95% CI: 0.02–0.13).

Recruitment

Participants will be recruited from two EDs—Level 1 and Level 2 trauma centers—located in the state's capital of Providence. Together, these two EDs receive over 175,000 adult visits each year. Between 2017 and 2018, the two EDs reported a total of 1,446 visits for suspected opioid overdoses, representing 45% of all ED visits for suspected opioid overdose reported to the Rhode Island Department of Health (n = 3,239). A consecutive sample of ED patients will be assessed for eligibility by one of eleven full-time research assistants employed in the two EDs who can recruit participants 24 hours per day, seven days per week. Potential participants will be identified by the research assistants by screening electronic medical records (EMRs) or by referral from treating providers in the ED. Potential participants will be considered eligible if they are 18 years of age or older and speak English. Given the specificity of the pool of LCSWs and certified peer recovery support specialists to the ED, recruitment will occur in the ED only.

METHODS: ASSIGNMENT OF INTERENTIONS

Allocation

Participants will be randomly assigned 1:1 within each study site to receive either a behavioral intervention delivered by a certified peer recovery support specialist or by an LCSW. Allocations will be randomly assigned using the REDCap randomization feature. The randomization schedule will be maintained by a data manager not involved with participant recruitment or the final study analyses.

Blinding (Masking)

Participants and providers cannot be blinded to their intervention assignment. However, research assistants who are responsible for the follow-up assessments and investigators and analysts performing the study analyses will be blinded to arm allocation.

METHODS: DATA COLLECTION, MANAGEMENT, ANALYSIS

Data Collection Methods

While the primary outcomes assessments will rely on the use of administrative data (see below), we will also collect patient-reported assessments at baseline and follow-up. Baseline assessments will be administered by a research assistant in the ED to collect information about sociodemographic characteristics, medical history, medication use, substance use patterns, prior substance use treatment engagement, recovery capital (33), treatment readiness (34), opinions about medications for OUD treatment (35), perceived stigma towards people who use drugs (36), symptoms of pain (37), opioid withdrawal (38), and depression (39) using established instruments. Follow-up assessments will be conducted at 30 days, three months, and six months post-discharge, respectively.

Data Management

All data collection instruments will be designed using Research Electronic Data Capture (REDCap) software and administered using a tablet computer connected to the wireless network at the two study sites. All follow-up assessments will be conducted via telephone by a research assistant, and all responses will be directly entered into REDCap.

Statistical Methods

We will use an intention-to-treat (ITT) approach in all analyses to estimate the average treatment effect. A sensitivity analysis will be conducted using a per-protocol approach with a sample restricted to those who complete their interventions. For the two primary outcomes (engagement in formal SUD treatment within 30 days of the initial ED visit and occurrence of a subsequent ED visit for opioid overdose within 18 months of the initial ED visit), we will use separate logistic regression models with indicators for treatment allocation and study site, as well as term representing the interaction of treatment allocation with study site. Second, we will conduct subgroup analyses to understand potential heterogeneity of treatment effects by age and gender.

METHODS: MONITORING

Data Monitoring

A single data safety monitoring board (DSMB) will be convened and include members external to the research team and funding source and without potential conflicts of interest. The DSMB will be notified within 24 hours of any serious adverse event in which the relationship to the study is possible. The DSMB will convene at the earliest possible time (no more than 30 days from time of notification) to discuss this adverse event. Further, the DSMB will meet on a quarterly basis with the study coordinator and co-principal investigators to review protocol adherence and adverse events.

Harms

An adverse event is considered any physical or clinical change experienced by the patient, including the onset of new symptoms or the exacerbation of pre-existing conditions. Adverse events assessment will be performed at each follow-up assessment at 30 days, three months, and six months post-discharge.

ETHICS AND DISSEMINATION

Research Ethics Approval

All protocols have been approved by the institutional review boards at the Lifespan health system representing the two clinical sites (Approval Number: 212418).

Protocol Amendments

Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the patient, or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment.

Consent

Training research assistants will introduce and discuss the trial with potential participants. These potential participants will then be able to have an informed discussion with the research assistant about their potential participation. Following this discussion research assistants will obtain written informed consent.

Confidentiality

The privacy of all trial participants is protected by a Certificate of Confidentiality issued by the National Institutes of Health. Unique identification numbers will be assigned to participants. All data forms and interviews will be coded with this number rather than with a name. All paper forms will be stored in locked file cabinets. Informed consent documents will be stored separately, as they contain identifying information. Upon completion of the study, identifying information will be destroyed.

Access to Data

The institutional review boards at the Lifespan health system representing the two clinical sites will have access to anonymized data at their discretion. However, no third-party investigators will have access to study data prior to synthesis and dissemination.

Dissemination Policy

The study has been registered on ClinicalTrials.gov. A summary of the trial's results will be published there when available. Results will be published at national scientific meetings and the final results will be submitted for publication in peer-reviewed journals.

DISCUSSION

The AnchorED program of Anchor Recovery Community Center, which deploys certified peer recovery support specialists to EDs across Rhode Island to deliver behavioral interventions to individuals who have experienced an opioid overdose, is the first statewide program of its kind in the nation (22). Despite a lack of evidence to demonstrate the effectiveness of this program and improved long-term outcomes for patients, several other jurisdictions in the US have created or are initiating programs based on the AnchorED model (23). Given the intense interest in peer recovery models, the results of this trial have a strong potential to fundamentally change clinical practice paradigms for treating patients at high risk for opioid overdose who present to EDs across the nation.

The current study benefits from support from a unique policy environment in Rhode Island. In 2015, Governor Gina Raimondo signed an executive order to establish the Rhode Island Overdose Prevention and Intervention Task Force, which charged experts to develop a strategic plan to guide efforts to tackle the state's overdose crisis (40). An important outcome of this plan was a comprehensive data sharing infrastructure between key state agencies (including the Rhode Island Departments of Health and Behavioral Healthcare, Developmental Disabilities, and Hospitals) and academic researchers (41). These data sharing agreements offer unprecedented access to population-based data on overdose morbidity and mortality (41). As a result, the trial investigators can create a large database linking participant data with multiple administrative databases to ascertain our primary and secondary outcomes. The ability to conduct these robust data linkages is an important methodological innovation that overcomes biases associated with self-reported outcomes and loss to follow-up in previous studies.

The results of this trial will need to be considered in light of some caveats. Although Good Samaritan laws are present in many jurisdictions across the US, including Rhode Island, to protect individuals from criminal

prosecutions (42), many people do not call emergency medical services in the event of an overdose (43). It is possible that the intervention may increase participants' self-efficacy and willingness to engage with emergency medical services in the event of an overdose. As a result, those receiving the peer recovery intervention might be more likely to present to the ED in the event of an overdose. Should the intervention reduce the overall rate of non-fatal overdose but increase the proportion of non-fatal overdoses that are treated in the ED, the findings related to the impact of the intervention on recurrent ED visits may be null or counterintuitive. Although the administrative databases used to characterize the primary outcomes are meant to be representative, they are by no means comprehensive. Individuals who enroll in SUD treatment programs or who present to EDs in other states will not be captured in these resources. To address these limitations, we will conduct follow-up surveys to capture treatment enrollment and experiences of opioid overdose via phone interviews.

This trial represents the first systematic evaluation of behavioral interventions delivered by certified peer recovery support specialists in the ED to individuals at high risk for opioid overdose. Should the trial be successful, its findings have the potential to establish the evidence base for peer recovery support services as an effective intervention and provide support for the large-scale implementation of these services in EDs. Amidst a national crisis, peer recovery support interventions could be an effective means for improving SUD treatment engagement and reducing rates of fatal and non-fatal overdose.

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Authors' Contributions:

WCG led the manuscript preparation. The research was conceived by FLB and BDLM. All authors provided feedback on several drafts of the study protocol and this manuscript. WCG, BDLM, EAS, MGB, DD, KJL, LM, RCM, TN, GAO, SER, JLY, and FLB read and approved of the final manuscript.

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The authors declare no competing interests.

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Figure 1. Intervention arms in a randomized clinical trial of an emergency department-based peer recovery support intervention to increase treatment uptake and reduce recurrent overdose among individuals at high risk for opioid overdose

	Certified Peer Recovery Specialist		Licensed Clinical Social Worker
1	Enrollment Visit in Emergency Department • Intervention based on motivational interviewing plus lived experience of peer recovery specialist • Navigate barriers to treatment, provide referrals	1	Brief Intervention in Emergency Department • Intervention based on motivational interviewing plus other clinical skills • Provide referrals as needed
2	Community-Based Follow-Up Visit (<48 hours) • Navigate barriers to treatment and recovery • Ongoing peer support • Ongoing overdose prevention education		
3	Retention in Peer Recovery Support (≥90 days) • Promote retention in treatment • Ongoing peer support • Ongoing overdose prevention education		

Figure 1

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

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*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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A Randomized Clinical Trial of an Emergency Department-Based Peer Recovery Support Intervention to Increase Treatment Uptake and Reduce Recurrent Overdose among Individuals at High Risk for Opioid Overdose: Study Protocol for the Navigator Trial

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A Randomized Clinical Trial of an Emergency Department-Based Peer Recovery Support Intervention to Increase Treatment Uptake and Reduce Recurrent Overdose among Individuals at High Risk for Opioid Overdose: Study Protocol for the Navigator Trial

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ABSTRACT

Introduction: Effective approaches to increase engagement in treatment for opioid use disorder (OUD) and reduce the risk of recurrent overdose and death following emergency department (ED) presentation for opioid overdose remain unknown. As such, we aim to compare the effectiveness of behavioral interventions delivered in the ED by certified peer recovery support specialists relative to those delivered by licensed clinical social workers (LCSWs) in promoting OUD treatment uptake and reducing recurrent ED visits for opioid overdose.

Methods and Analysis: Adult ED patients who are at high risk for opioid overdose (i.e., are being treated for an opioid overdose or identified by the treating physician as having OUD) (n = 650) will be recruited from two emergency departments in a single health care system in Providence, Rhode Island into a two-arm randomized trial with 18 months of follow-up post-randomization. Eligible participants will be randomly assigned (1:1) in the ED to receive a behavioral intervention from a certified peer recovery support specialist or a behavioral intervention from an LCSW. The primary outcomes are engagement in formal OUD treatment within 30 days of the initial ED visit and recurrent ED visits for opioid overdose within 18 months of the initial ED visit, as measured through statewide administrative records.

Ethics and Dissemination: This protocol was approved by the Rhode Island Hospital institutional review board (Approval Number: 212418). Data will be presented at national and international conferences and published in peer-reviewed journals.

Trial Registration: NCT03684681 (ClinicalTrials.gov)

KEYWORDS

Opioid Overdose; Emergency Department; Peer Support; Recovery; Randomized Trial

STRENGTHS AND LIMITATIONS

- This study represents the first randomized controlled trial to assess the impact of a peer recovery support intervention on uptake of OUD treatment and recurrent ED presentation for opioid-involved overdose.
- This study leverages a statewide comprehensive data sharing infrastructure to use administrative records to characterize the primary outcomes (e.g., OUD treatment enrollment, recurrent ED presentation), thus overcoming biases associated with self-reported outcomes and loss to follow-up in previous studies.
- Although the administrative databases used to characterize the primary outcomes are meant to be representative, they are by no means comprehensive (i.e., individuals who enroll in OUD treatment programs or who present to EDs in other states will not be captured in these resources).

INTRODUCTION

Background and Rationale

Deaths attributable to accidental drug overdose, particularly those involving opioids, have reached epidemic levels in the United States (US) (1-4). In the past two decades, US overdose mortality rates have more than doubled, from 6.2 per 100,000 persons in 2000 to 21.7 per 100,000 persons in 2017 (2, 3). There have been 700,000 opioid overdose deaths between 2000 to 2015 in the US (5), and the crisis is expected to worsen under current trends (6). Since 2013, the opioid overdose epidemic has been marked by significant increases in deaths involving powerful synthetic opioids (e.g., fentanyl) (3). The burden of the drug overdose epidemic is greatly elevated in New England, where fentanyl has been present in the illicit drug supply since as early as 2012 (7-10). Rhode Island has one of the highest drug overdose rates in the nation (3), and in 2014 reported the third and fourth highest rate of opioid-related emergency department (ED) visits and inpatient hospital stays, respectively (11).

In addition to increases in fatal opioid overdoses, EDs have had substantial increases in visits for non-fatal opioid overdoses (12-14). About 120,000 ED visits were reported for suspected non-fatal opioid overdoses between July 2016 and September 2017 in sixteen states participating in the Enhanced State Opioid Overdose Surveillance, representing a 35% increase over this period (15). As such, the ED serves as a critical intervention site for providing services to people at high risk of opioid overdose and those with opioid use disorder (OUD). In the year after presenting to the ED for a drug overdose, a person is at heightened risk for death (16, 17). In a nested case-control study in New York, the odds of death due to prescription drug overdose were 4.9 times higher for those with two ED visits, 16.6 times higher for those with three ED visits, and 48.2 times higher for those with four or more visits relative to one ED visit or less in the year preceding death (16). Thus, the ED is both a critical and timely place for intervention and the reason for the ED visit itself (i.e., overdose) can be used as an opportunity to identify patients at highest risk of fatal drug overdose and deliver interventions (18).

The most effective means to promote engagement in substance use disorder (SUD) treatment and reduce the risk of recurrent overdose and death following presentation to an ED for opioid overdose remains unknown. One of the only randomized studies of overdose education combined with a brief motivational interviewing-based intervention delivered in the ED by licensed mental health counselors resulted in reductions in overdose risk behaviors among individuals presenting to the ED and reporting non-medical prescription opioid use (Bohnert et al., 2016). However, a trial deploying a similar intervention did not reduce overdose rates or prevent subsequent ED visits or hospitalizations compared to usual care (19). It is possible, however, that these types of interventions may be more effective if delivered by people with lived

experiences with SUD and recovery. Peer-based interventions are an effective component of care across non-clinical settings and in other aspects of health care for other conditions (20). A recent systematic review by Ramchand and colleagues (2017) found that group-based interventions that use peers as educators commonly improve knowledge, attitudes, beliefs, and perceptions and improve connectedness and engagement with health promotion activities (20). Further, a recent systematic review of peer recovery support services in care for substance use disorder found that existing randomized controlled trials have been subject to several limitations, particularly poorly defined and non-manualized roles for peers, and, as such, there remains a need for more rigorous evaluation to determine the efficacy, effectiveness, and cost-effectiveness of peer recovery support services (21). However, little is known about their effectiveness in improving outcomes for persons at high risk for opioid overdose. In response to Rhode Island's overdose crisis, individuals in long-term recovery with specialized training in SUD management, known as certified peer recovery support specialists, have been deployed in EDs since 2014 (22). The goal of their work is to help patients navigate obstacles to recovery through problem-solving, goal setting, avoiding relapse triggers, and planning and obtaining services. Despite the promise of and significant national interest in this approach (23), no studies have rigorously evaluated whether peer-based behavioral interventions delivered in the ED result in improved outcomes for patients at high risk of opioid overdose.

Objectives

We aim to test the effectiveness of behavioral interventions delivered in the ED by certified peer recovery support specialists in improving outcomes for patients at high risk of opioid overdose relative to those delivered by licensed clinical social workers (LCSWs). We hypothesize that, because certified peer recovery support specialists are able to draw from their own lived experiences with SUD and recovery, patients who are randomly assigned to receive a behavioral intervention from a peer recovery support specialist, as compared to receiving an intervention from an LCSW, will be: (1) more likely to engage in formal SUD treatment within 30 days following the initial visit, and (2) less likely to experience a recurrent ED visit for an opioid overdose during the succeeding 18 months.

Trial Design

The trial utilizes a parallel design where patients at high risk for opioid overdose who present to the ED are randomly assigned 1:1 to receive a behavioral intervention from a certified peer recovery support specialist or an LCSW.

METHODS: PARTICIPANTS, INTERVENTIONS, OUTCOMES

Study Setting

Rhode Island is home to over one million residents. Since 2000, the state has experienced a high burden of opioid overdose. According to the 2016–2017 cycle of the National Survey on Drug Use and Health, 4.7% of Rhode Islanders used heroin or misused a prescription opioid in the past year (24). Between 2013 and 2017, the age-adjusted rate of death due to opioid overdose increased by 44.2%, from 18.1 to 26.1 per 100,000 persons, with these increases largely driven by synthetic opioids other than methadone (16.8% of opioid overdose deaths in 2013 versus 72.6% in 2017) (25).

Eligibility Criteria

To be eligible, participants must also be in the ED because they are: (1) being treated for an opioid overdose; (2) receiving treatment related to OUD (e.g., infectious complication, withdrawal); or (3) self-report an opioid overdose within the previous 12 months. The presence of an opioid overdose will be determined by the treating physician and is generally defined as (1) the presence of decreased levels of consciousness or respiratory depression and (2) occurring after the consumption of opioids or resolving after the administration of naloxone. Potential participants will be deemed ineligible if they are critically ill or injured, have previously enrolled in the trial, are in police custody or incarcerated, pregnant, or live outside of Rhode Island. Patients who are critically ill or injured will be eligible for screening and enrollment once cleared to participate by their treating physician.

Patient and Public Involvement

No patient involved.

Interventions

Current Standard of Care

The current standard of care following an ED visit for an opioid overdose at the study sites is to receive a behavioral intervention delivered by a certified peer recovery support specialist or an LCSW. Whether a patient is evaluated by a social worker or a peer recovery support specialist can depend on the time of day, staff availability, and preferences or views of the provider or patient. In the trial, patients will be randomly assigned to receive a behavioral intervention in the ED delivered by (1) a staff LCSW, or (2) a certified peer recovery support specialist trained by the Anchor Recovery Community Center (Figure 1).

Behavioral Intervention Delivered by Certified Peer Recovery Support Specialists

The Anchor Recovery Community Center is Rhode Island's first community-based peer recovery center (22). It is designed as an access point for those with SUD, providing services such as job counseling, health and wellness activities, and individualized long-term peer recovery coaching (22). Through one of its outreach programs, known as AnchorED, the Anchor Recovery Community Center has deployed certified peer recovery support specialists to EDs across Rhode Island since 2014 (22). As part of AnchorED, certified peer recovery support specialists arrive in the ED within 30 minutes of consultation, assess individuals for readiness to seek treatment, provide linkage to treatment, and educate patients on overdose prevention and response (22). Peer recovery specialists call every day for ten days in an attempt to make contact following discharge from the ED. Once contact is made, peer recovery specialists and their clients make plans for regular contact and follow-up. There are 30 peer recovery support specialists available to deliver these interventions between the two study sites.

To become a certified peer recovery support specialist, applicants must be in recovery for at least two years, undergo a 45-hour training program at Anchor Recovery Community Center based on the Connecticut Community for Addiction Recovery curriculum, and accrue 500 hours of supervised work experience providing peer recovery support services (22). All peer recovery support specialists obtain certification from the International Certification and Reciprocity Consortium (22). The certification program focuses on advocacy, wellness and recovery, motivational interviewing techniques, mentoring and education, and ethics as well as additional training on the provision of trauma-informed care and the transtheoretical model of behavior change. In addition to employing motivational interviewing techniques, peer recovery support specialists support individuals' self-efficacy and prevent relapse by addressing social, environmental, and personal factors, such as awareness and avoidance of relapse triggers, polysubstance use, stigma associated with SUD and their treatment, knowledge of treatment services (including the use of medications for OUD treatment), and addressing financial and transportation barriers to treatment (22). Certified peer recovery support specialists are uniquely positioned to deliver behavioral interventions to individuals who have experienced overdose as they couple their training with lived experiences of SUD and recovery (22).

Behavioral Intervention Delivered via Licensed Clinical Social Workers

There are 35 full and part-time LCSW on staff in the Department of Social Work between the two study sites. Staff social workers arrive in the ED within 30 minutes of consultation. Staff social workers are trained and available to deliver interventions to patients presenting with an opioid overdose and/or with OUD in the ED. As LCSWs, these individuals are capable of delivering a variety of interviewing and intervention techniques that are rooted in social work theory and practice models. Social work practice

models are strategies that the social worker can incorporate into their interventions to help people meet their goals (e.g., task-centered practice, cognitive behavioral therapy, crisis intervention model). Although the intervention delivered by LCSWs and their associated theoretical underpinnings are similar in some respects to those associated with those delivered by certified peer recovery support specialists, the social worker intervention is intended to be a single session with referral to SUD treatment.

Outcomes

Primary Outcomes

The two primary outcomes of the trial are (1) engagement with a formal SUD treatment program within 30 days of the initial ED visit, and (2) recurrent ED visit(s) for a suspected opioid overdose over 18 months. Both endpoints will be assessed via statewide administrative databases as outlined below. All records will be linked deterministically to participant data using identifiable information in a secure, Health Insurance Portability and Accountability Act (HIPAA)-compliant computing environment.

The first primary outcome of the trial is treatment engagement, defined as admission to a formal, publicly licensed SUD treatment program within 30 days of the initial ED visit. The Rhode Island Department of Behavioral Health, Developmental Disabilities, and Hospitals (BHDDH) maintains the Behavioral Health Online Database (BHOLD), a state database containing information on all admission and discharge events of clients of all licensed behavioral healthcare organizations in the state (26). BHOLD is a comprehensive database on all licensed treatment programs, including inpatient detoxification programs, day treatment programs, residential treatment programs, intensive outpatient programs, and opioid treatment programs (26). Records in BHOLD include individuals who receive methadone or buprenorphine from a licensed opioid treatment program. In addition to this data resource, records from the prescription drug monitoring program (PDMP) maintained by the Rhode Island Department of Health will be used to supplement BHOLD to identify patients who initiate buprenorphine in office-based settings (27).

The second primary outcome of the trial is recurrent visits to the ED for a suspected opioid overdose, defined as any presentation to an ED in Rhode Island for an opioid overdose within the 18 months following the initial ED visit at the two sites. The Rhode Island Quality Institute maintains CurrentCare, a health information exchange that provides a unified data system for EMRs for all major health systems in Rhode Island, allowing us to identify repeat visits for suspected opioid overdoses at all twelve EDs in the state (28). Opioid overdoses will be defined according to the Centers for Disease Control and Prevention (CDC) guidelines for all opioid poisonings and utilize International Classification of Disease (ICD) codes (29, 30). The Rhode Island Department of Health mandates that all suspected overdoses presenting to a hospital be

reported to the department within 48 hours. This data source, referred to as the 48-hour overdose surveillance system (31), will be used to supplement the EMRs in CurrentCare.

Sample Size

Based on preliminary assessments from the study sites, we are assuming that 7% of participants assigned to receive a behavioral intervention from an LCSW will enroll in a formal SUD treatment program within 30 days of their ED visit. Given this assumption for a sample size of 650 participants, we have at least 80% power to detect a two-fold increase in treatment engagement among participants assigned to receive a behavioral intervention from a peer recovery specialist (Effect Size: 0.07; 95% CI: 0.02–0.12). This two-fold increase was identified by community stakeholders as an appropriate benchmark for this outcome. Based on a recent medical record review from one of the study sites and estimates from other studies (19, 32), we are assuming that 15% of participants who receive a behavioral intervention from an LCSW will experience a subsequent repeat ED visit for opioid overdose. Given this assumption and our sample, we have at least 80% power to detect a 50% relative reduction in the risk of recurrent ED visits for opioid overdose within 18 months following the initial visit among those assigned to receive a behavioral intervention from a peer recovery specialist (Effect Size: 0.075; 95% CI: 0.02–0.13).

Recruitment

Participants will be recruited from two EDs—Level 1 and Level 2 trauma centers—located in the state's capital of Providence. Together, these two EDs receive over 175,000 adult visits each year. Between 2017 and 2018, the two EDs reported a total of 1,446 visits for suspected opioid overdoses, representing 45% of all ED visits for suspected opioid overdose reported to the Rhode Island Department of Health (n = 3,239). A consecutive sample of ED patients will be assessed for eligibility by one of eleven full-time research assistants employed in the two EDs who can recruit participants 24 hours per day, seven days per week. Potential participants will be identified by the research assistants by screening electronic medical records (EMRs) or by referral from treating providers in the ED. Potential participants will be considered eligible if they are 18 years of age or older and speak English. Given the specificity of the pool of LCSWs and certified peer recovery support specialists to the ED, recruitment will occur in the ED only.

METHODS: ASSIGNMENT OF INTERENTIONS

Allocation

Participants will be randomly assigned 1:1 within each study site to receive either a behavioral intervention delivered by a certified peer recovery support specialist or by an LCSW. Allocations will be randomly

assigned using the REDCap randomization feature. The randomization schedule will be maintained by a data manager not involved with participant recruitment or the final study analyses.

Blinding (Masking)

Participants and providers cannot be blinded to their intervention assignment. However, research assistants who are responsible for the follow-up assessments and investigators and analysts performing the study analyses will be blinded to arm allocation.

METHODS: DATA COLLECTION, MANAGEMENT, ANALYSIS

Data Collection Methods

The primary outcomes assessments will rely on the use of administrative data (see below).

Data Management

All data collection instruments will be designed using Research Electronic Data Capture (REDCap) software and administered using a tablet computer connected to the wireless network at the two study sites. All follow-up assessments will be conducted via telephone by a research assistant, and all responses will be directly entered into REDCap.

Statistical Methods

We will use an intention-to-treat (ITT) approach in all analyses to estimate the average treatment effect. For the two primary outcomes (engagement in formal SUD treatment within 30 days of the initial ED visit and occurrence of a subsequent ED visit for opioid overdose within 18 months of the initial ED visit), we will use separate logistic regression models with indicators for treatment allocation. Analyses with binary outcomes were selected based on input from community stakeholders. In exploratory analyses, we will use survival methods (e.g., Cox proportional hazards models) to assess the impact of treatment on the time to events for both outcomes (i.e., days from discharge to enrollment in formal SUD treatment and days from discharge to first recurrent ED visit for opioid overdose). In addition, on an exploratory basis, we will conduct moderation analyses to understand potential heterogeneity of treatment effects by age and gender. Given the multicenter design of the trial, the effect of treatment site will be quantified by the intraclass correlation coefficient (ICC), representing the variance due to the between-center variability (33). Should the ICC suggest that a large portion of the variance is explained by between-center variability, we will control for treatment site using a generalized estimating equations (GEE) approach to estimate population-average treatment effects across the two sites.

METHODS: MONITORING

Data Monitoring

A single data safety monitoring board (DSMB) will be convened and include members external to the research team and funding source and without potential conflicts of interest. The DSMB will be notified within 24 hours of any serious adverse event in which the relationship to the study is possible. The DSMB will convene at the earliest possible time (no more than 30 days from time of notification) to discuss this adverse event. Further, the DSMB will meet on a quarterly basis with the study coordinator and co-principal investigators to review protocol adherence and adverse events.

Harms

An adverse event is considered any physical or clinical change experienced by the patient, including the onset of new symptoms or the exacerbation of pre-existing conditions.

ETHICS AND DISSEMINATION

Research Ethics Approval

All protocols have been approved by the institutional review boards at the Lifespan health system representing the two clinical sites (Approval Number: 212418).

Protocol Amendments

Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the patient, or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment.

Consent

Training research assistants will introduce and discuss the trial with potential participants. These potential participants will then be able to have an informed discussion with the research assistant about their potential participation. Following this discussion research assistants will obtain written informed consent.

Confidentiality

The privacy of all trial participants is protected by a Certificate of Confidentiality issued by the National Institutes of Health. Unique identification numbers will be assigned to participants. All data forms and interviews will be coded with this number rather than with a name. All paper forms will be stored in locked file cabinets. Informed consent documents will be stored separately, as they contain identifying information. Upon completion of the study, identifying information will be destroyed.

Access to Data

The institutional review boards at the Lifespan health system representing the two clinical sites will have access to anonymized data at their discretion. However, no third-party investigators will have access to study data prior to synthesis and dissemination.

Dissemination Policy

The study has been registered on ClinicalTrials.gov. A summary of the trial's results will be published there when available. Results will be published at national scientific meetings and the final results will be submitted for publication in peer-reviewed journals.

DISCUSSION

The AnchorED program of Anchor Recovery Community Center, which deploys certified peer recovery support specialists to EDs across Rhode Island to deliver behavioral interventions to individuals who have experienced an opioid overdose, is the first statewide program of its kind in the nation (22). Despite a lack of evidence to demonstrate the effectiveness of this program and improved long-term outcomes for patients, several other jurisdictions in the US have created or are initiating programs based on the AnchorED model (23). Given the intense interest in peer recovery models, the results of this trial have a strong potential to fundamentally change clinical practice paradigms for treating patients at high risk for opioid overdose who present to EDs across the nation.

The current study benefits from support from a unique policy environment in Rhode Island. In 2015, Governor Gina Raimondo signed an executive order to establish the Rhode Island Overdose Prevention and Intervention Task Force, which charged experts to develop a strategic plan to guide efforts to tackle the state's overdose crisis (34). An important outcome of this plan was a comprehensive data sharing infrastructure between key state agencies (including the Rhode Island Departments of Health and Behavioral Healthcare, Developmental Disabilities, and Hospitals) and academic researchers (35). These data sharing agreements offer unprecedented access to population-based data on overdose morbidity and mortality (35). As a result, the trial investigators can create a large database linking participant data with multiple administrative databases to ascertain our primary and secondary outcomes. The ability to conduct these robust data linkages is an important methodological innovation that overcomes biases associated with self-reported outcomes and loss to follow-up in previous studies.

The results of this trial will need to be considered in light of some caveats. Although Good Samaritan laws are present in many jurisdictions across the US, including Rhode Island, to protect individuals from criminal prosecutions (36), many people do not call emergency medical services in the event of an overdose (37). It is possible that the intervention may increase participants' self-efficacy and willingness to engage with emergency medical services in the event of an overdose. As a result, those receiving the peer recovery intervention might be more likely to present to the ED in the event of an overdose. Should the intervention reduce the overall rate of non-fatal overdose but increase the proportion of non-fatal overdoses that are treated in the ED, the findings related to the impact of the intervention on recurrent ED visits may be null or counterintuitive. Although the administrative databases used to characterize the primary outcomes are meant to be representative, they are by no means comprehensive. Individuals who enroll in SUD treatment programs or who present to EDs in other states will not be captured in these resources. Given the pragmatic nature of the trial, fidelity monitoring and process checking are not being conducted, thus limiting potential understanding of what components of the intervention were performed should they be deemed efficacious.

This trial represents the first systematic evaluation of behavioral interventions delivered by certified peer recovery support specialists in the ED to individuals at high risk for opioid overdose. Should the trial be successful, its findings have the potential to establish the evidence base for peer recovery support services as an effective intervention and provide support for the large-scale implementation of these services in EDs. Amidst a national crisis, peer recovery support interventions could be an effective means for improving SUD treatment engagement and reducing rates of fatal and non-fatal overdose.

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Authors' Contributions:

WCG led the manuscript preparation. The research was conceived by FLB and BDLM. All authors provided feedback on several drafts of the study protocol and this manuscript. WCG, BDLM, EAS, MGB, DD, KJL, LM, RCM, TN, GAO, SER, JLY, and FLB read and approved of the final manuscript.

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Declarations of Competing Interest:

The authors declare no competing interests.

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Figure 1. Intervention arms in a randomized clinical trial of an emergency department-based peer recovery support intervention to increase treatment uptake and reduce recurrent overdose among individuals at high risk for opioid overdose

	Certified Peer Recovery Specialist		Licensed Clinical Social Worker
1	Enrollment Visit in Emergency Department • Intervention based on motivational interviewing plus lived experience of peer recovery specialist • Navigate barriers to treatment, provide referrals	1	Brief Intervention in Emergency Department • Intervention based on motivational interviewing plus other clinical skills • Provide referrals as needed
2	Community-Based Follow-Up Visit (<48 hours) • Navigate barriers to treatment and recovery • Ongoing peer support • Ongoing overdose prevention education		
3	Retention in Peer Recovery Support (≥90 days) • Promote retention in treatment • Ongoing peer support • Ongoing overdose prevention education		

Figure 1

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

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	2b	Not Applicable
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	31c	Not Applicable
Appendices		
Informed consent materials	32	Not Applicable
Biological specimens	33	Not Applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

A Randomized Clinical Trial of an Emergency Department-Based Peer Recovery Support Intervention to Increase Treatment Uptake and Reduce Recurrent Overdose among Individuals at High Risk for Opioid Overdose: Study Protocol for the Navigator Trial

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A Randomized Clinical Trial of an Emergency Department-Based Peer Recovery Support Intervention to Increase Treatment Uptake and Reduce Recurrent Overdose among Individuals at High Risk for Opioid Overdose: Study Protocol for the Navigator Trial

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ABSTRACT

Introduction: Effective approaches to increase engagement in treatment for opioid use disorder (OUD) and reduce the risk of recurrent overdose and death following emergency department (ED) presentation for opioid overdose remain unknown. As such, we aim to compare the effectiveness of behavioral interventions delivered in the ED by certified peer recovery support specialists relative to those delivered by licensed clinical social workers (LCSWs) in promoting OUD treatment uptake and reducing recurrent ED visits for opioid overdose.

Methods and Analysis: Adult ED patients who are at high risk for opioid overdose (i.e., are being treated for an opioid overdose or identified by the treating physician as having OUD) (n = 650) will be recruited from two emergency departments in a single health care system in Providence, Rhode Island into a two-arm randomized trial with 18 months of follow-up post-randomization. Eligible participants will be randomly assigned (1:1) in the ED to receive a behavioral intervention from a certified peer recovery support specialist or a behavioral intervention from an LCSW. The primary outcomes are engagement in formal OUD treatment within 30 days of the initial ED visit and recurrent ED visits for opioid overdose within 18 months of the initial ED visit, as measured through statewide administrative records.

Ethics and Dissemination: This protocol was approved by the Rhode Island Hospital institutional review board (Approval Number: 212418). Data will be presented at national and international conferences and published in peer-reviewed journals.

Trial Registration: NCT03684681 (ClinicalTrials.gov)

KEYWORDS

Opioid Overdose; Emergency Department; Peer Support; Recovery; Randomized Trial

STRENGTHS AND LIMITATIONS

- This study represents the first randomized controlled trial to assess the impact of a peer recovery support intervention on uptake of OUD treatment and recurrent ED presentation for opioid-involved overdose.
- This study leverages a statewide comprehensive data sharing infrastructure to use administrative records to characterize the primary outcomes (e.g., OUD treatment enrollment, recurrent ED presentation), thus overcoming biases associated with self-reported outcomes and loss to follow-up in previous studies.
- Although the administrative databases used to characterize the primary outcomes are meant to be representative, they are by no means comprehensive (i.e., individuals who enroll in OUD treatment programs or who present to EDs in other states will not be captured in these resources).

INTRODUCTION

Background and Rationale

Deaths attributable to accidental drug overdose, particularly those involving opioids, have reached epidemic levels in the United States (US) (1-4). In the past two decades, US overdose mortality rates have more than tripled, from 6.2 per 100,000 persons in 2000 to 21.7 per 100,000 persons in 2017 (2, 3). There have been 700,000 opioid overdose deaths between 2000 to 2015 in the US (5), and the crisis is expected to worsen under current trends (6). Since 2013, the opioid overdose epidemic has been marked by significant increases in deaths involving powerful synthetic opioids (e.g., fentanyl) (3). The burden of the drug overdose epidemic is greatly elevated in New England, where fentanyl has been present in the illicit drug supply since as early as 2012 (7-10). Rhode Island has one of the highest drug overdose rates in the nation (3), and in 2014 reported the third and fourth highest rate of opioid-related emergency department (ED) visits and inpatient hospital stays, respectively (11).

In addition to increases in fatal opioid overdoses, EDs have had substantial increases in visits for non-fatal opioid overdoses (12-14). About 120,000 ED visits were reported for suspected non-fatal opioid overdoses between July 2016 and September 2017 in sixteen states participating in the Enhanced State Opioid Overdose Surveillance, representing a 35% increase over this period (15). As such, the ED serves as a critical intervention site for providing services to people at high risk of opioid overdose and those with opioid use disorder (OUD). In the year after presenting to the ED for a drug overdose, a person is at heightened risk for death (16, 17). In a nested case-control study in New York, the odds of death due to prescription drug overdose were 4.9 times higher for those with two ED visits, 16.6 times higher for those with three ED visits, and 48.2 times higher for those with four or more visits relative to one ED visit or less in the year preceding death (16). Thus, the ED is both a critical and timely place for intervention and the reason for the ED visit itself (i.e., overdose) can be used as an opportunity to identify patients at highest risk of fatal drug overdose and deliver interventions (18).

The most effective means to promote engagement in substance use disorder (SUD) treatment and reduce the risk of recurrent overdose and death following presentation to an ED for opioid overdose remains unknown. One of the only randomized studies of overdose education combined with a brief motivational interviewing-based intervention delivered in the ED by licensed mental health counselors resulted in reductions in overdose risk behaviors among individuals presenting to the ED and reporting non-medical prescription opioid use (19). However, a trial deploying a similar intervention did not reduce overdose rates or prevent subsequent ED visits or hospitalizations compared to usual care (20). It is possible, however, that these types of interventions may be more effective if delivered by people with lived experiences with

SUD and recovery. Peer-based interventions are an effective component of care across non-clinical settings and in other aspects of health care for other conditions (21). A recent systematic review by Ramchand and colleagues (2017) found that group-based interventions that use peers as educators commonly improve knowledge, attitudes, beliefs, and perceptions and improve connectedness and engagement with health promotion activities (21). Further, a recent systematic review of peer recovery support services in care for substance use disorder found that existing randomized controlled trials have been subject to several limitations, particularly poorly defined and non-manualized roles for peers, and, as such, there remains a need for more rigorous evaluation to determine the efficacy, effectiveness, and cost-effectiveness of peer recovery support services (22). However, little is known about their effectiveness in improving outcomes for persons at high risk for opioid overdose. In response to Rhode Island's overdose crisis, individuals in long-term recovery with specialized training in SUD management, known as certified peer recovery support specialists, have been deployed in EDs since 2014 (23). The goal of their work is to help patients navigate obstacles to recovery through problem-solving, goal setting, avoiding relapse triggers, and planning and obtaining services. Despite the promise of and significant national interest in this approach (24), no studies have rigorously evaluated whether peer-based behavioral interventions delivered in the ED result in improved outcomes for patients at high risk of opioid overdose.

Objectives

We aim to test the effectiveness of behavioral interventions delivered in the ED by certified peer recovery support specialists in improving outcomes for patients at high risk of opioid overdose relative to those delivered by licensed clinical social workers (LCSWs). We hypothesize that, because certified peer recovery support specialists are able to draw from their own lived experiences with SUD and recovery, patients who are randomly assigned to receive a behavioral intervention from a peer recovery support specialist, as compared to receiving an intervention from an LCSW, will be: (1) more likely to engage in formal SUD treatment within 30 days following the initial visit, and (2) less likely to experience a recurrent ED visit for an opioid overdose during the succeeding 18 months.

Trial Design

The trial utilizes a parallel design where patients at high risk for opioid overdose who present to the ED are randomly assigned 1:1 to receive a behavioral intervention from a certified peer recovery support specialist or an LCSW.

METHODS: PARTICIPANTS, INTERVENTIONS, OUTCOMES

Study Setting

Rhode Island is home to over one million residents. Since 2000, the state has experienced a high burden of opioid overdose. According to the 2016–2017 cycle of the National Survey on Drug Use and Health, 4.7% of Rhode Islanders used heroin or misused a prescription opioid in the past year (25). Between 2013 and 2017, the age-adjusted rate of death due to opioid overdose increased by 44.2%, from 18.1 to 26.1 per 100,000 persons, with these increases largely driven by synthetic opioids other than methadone (16.8% of opioid overdose deaths in 2013 versus 72.6% in 2017) (26).

Eligibility Criteria

To be eligible, participants must also be in the ED because they are: (1) being treated for an opioid overdose; (2) receiving treatment related to OUD (e.g., infectious complication of injection drug use, opioid withdrawal); or (3) self-report an opioid overdose within the previous 12 months. The presence of an opioid overdose will be determined by the treating physician and is generally defined as (1) the presence of decreased levels of consciousness or respiratory depression and (2) occurring after the consumption of opioids or resolving after the administration of naloxone. Potential participants will be deemed ineligible if they are critically ill or injured, have previously enrolled in the trial, are in police custody or incarcerated, pregnant, or live outside of Rhode Island. Patients who are critically ill or injured will be eligible for screening and enrollment once cleared to participate by their treating physician.

Patient and Public Involvement

No patient involved.

Interventions

Current Standard of Care

The current standard of care following an ED visit for an opioid overdose at the study sites is to receive a behavioral intervention delivered by a certified peer recovery support specialist or an LCSW. Whether a patient meets with a social worker or a peer recovery support specialist can depend on the time of day, staff availability, and preferences or views of the provider or patient. In the trial, patients will be randomly assigned to receive a behavioral intervention in the ED delivered by (1) a staff LCSW, or (2) a certified peer recovery support specialist trained by the Anchor Recovery Community Center (Figure 1).

Behavioral Intervention Delivered by Certified Peer Recovery Support Specialists

The Anchor Recovery Community Center is Rhode Island's first community-based peer recovery center (23). It is designed as an access point for those with SUD, providing services such as job counseling, health and wellness activities, and individualized long-term peer recovery coaching (23). Through one of its outreach programs, known as AnchorED, the Anchor Recovery Community Center has deployed certified peer recovery support specialists to EDs across Rhode Island since 2014 (23). As part of AnchorED, certified peer recovery support specialists arrive in the ED within 30 minutes of consultation, assess individuals for readiness to seek treatment, provide linkage to treatment, and educate patients on overdose prevention and response (23). Peer recovery specialists call every day for ten days in an attempt to make contact following discharge from the ED. Once contact is made, peer recovery specialists and their clients make plans for regular contact and follow-up. There are 30 peer recovery support specialists available to deliver these interventions between the two study sites.

To become a certified peer recovery support specialist, applicants must be in recovery for at least two years, undergo a 45-hour training program at Anchor Recovery Community Center based on the Connecticut Community for Addiction Recovery curriculum, and accrue 500 hours of supervised work experience providing peer recovery support services (23). All peer recovery support specialists obtain certification from the International Certification and Reciprocity Consortium (23). The certification program focuses on advocacy, wellness and recovery, motivational interviewing techniques, mentoring and education, and ethics as well as additional training on the provision of trauma-informed care and the transtheoretical model of behavior change. In addition to employing motivational interviewing techniques, peer recovery support specialists support individuals' self-efficacy and prevent relapse by addressing social, environmental, and personal factors, such as awareness and avoidance of relapse triggers, polysubstance use, stigma associated with SUD and their treatment, knowledge of treatment services (including the use of medications for OUD treatment), and addressing financial and transportation barriers to treatment (23). Certified peer recovery support specialists are uniquely positioned to deliver behavioral interventions to individuals who have experienced overdose as they couple their training with lived experiences of SUD and recovery (23).

Behavioral Intervention Delivered via Licensed Clinical Social Workers

There are 35 full and part-time LCSW on staff in the Department of Social Work between the two study sites. Staff social workers arrive in the ED within 30 minutes of consultation. Staff social workers are trained and available to deliver interventions to patients presenting with an opioid overdose and/or with OUD in the ED. As LCSWs, these individuals are capable of delivering a variety of interviewing and intervention techniques that are rooted in social work theory and practice models. Social work practice

models are strategies that the social worker can incorporate into their interventions to help people meet their goals (e.g., task-centered practice, cognitive behavioral therapy, crisis intervention model). Although the intervention delivered by LCSWs and their associated theoretical underpinnings are similar in some respects to those associated with those delivered by certified peer recovery support specialists, the social worker intervention is intended to be a single session with referral to SUD treatment.

Outcomes

Primary Outcomes

The two primary outcomes of the trial are (1) engagement with a formal SUD treatment program within 30 days of the initial ED visit, and (2) recurrent ED visit(s) for a suspected opioid overdose over 18 months. Both endpoints will be assessed via statewide administrative databases as outlined below. All records will be linked deterministically to participant data using identifiable information in a secure, Health Insurance Portability and Accountability Act (HIPAA)-compliant computing environment.

The first primary outcome of the trial is treatment engagement, defined as admission to a formal, publicly licensed SUD treatment program within 30 days of the initial ED visit. The Rhode Island Department of Behavioral Health, Developmental Disabilities, and Hospitals maintains the Behavioral Health Online Database (BHOLD), a state database containing information on all admission and discharge events of clients of all licensed behavioral healthcare organizations in the state (27). BHOLD is a comprehensive database on all licensed treatment programs, including inpatient detoxification programs, day treatment programs, residential treatment programs, intensive outpatient programs, and opioid treatment programs (27). Records in BHOLD include individuals who receive methadone or buprenorphine from a licensed opioid treatment program. In addition to this data resource, records from the prescription drug monitoring program (PDMP) maintained by the Rhode Island Department of Health will be used to supplement BHOLD to identify patients who initiate buprenorphine in office-based settings (28).

The second primary outcome of the trial is recurrent visits to the ED for a suspected opioid overdose, defined as any presentation to an ED in Rhode Island for an opioid overdose within the 18 months following the initial ED visit at the two sites. The Rhode Island Quality Institute maintains CurrentCare, a health information exchange that provides a unified data system for electronic medical records (EMRs) for all major health systems in Rhode Island, allowing us to identify repeat visits for suspected opioid overdoses at all twelve EDs in the state (29). Opioid overdoses will be defined according to the Centers for Disease Control and Prevention (CDC) guidelines for all opioid poisonings and utilize *International Statistical Classification of Diseases and Related Health Problems* (ICD) codes (30, 31). The Rhode Island

Department of Health mandates that all suspected overdoses presenting to a hospital be reported to the department within 48 hours. This data source, referred to as the 48-hour overdose surveillance system (32), will be used to supplement the EMRs in CurrentCare.

Sample Size

Based on preliminary assessments from the study sites, we are assuming that 7% of participants assigned to receive a behavioral intervention from an LCSW will enroll in a formal SUD treatment program within 30 days of their ED visit. Given this assumption for a sample size of 650 participants, we have at least 80% power to detect a two-fold increase in treatment engagement among participants assigned to receive a behavioral intervention from a peer recovery specialist (Risk Difference: 0.07; 95% CI: 0.02–0.12). This two-fold increase was identified by community stakeholders as an appropriate benchmark for this outcome. Based on a recent medical record review from one of the study sites and estimates from other studies (20, 33), we are assuming that 15% of participants who receive a behavioral intervention from an LCSW will experience a subsequent repeat ED visit for opioid overdose. Given this assumption and our sample, we have at least 80% power to detect a 50% relative reduction in the risk of recurrent ED visits for opioid overdose within 18 months following the initial visit among those assigned to receive a behavioral intervention from a peer recovery specialist (Risk Difference: 0.075; 95% CI: 0.02–0.13).

Recruitment

Participants will be recruited from two EDs—Level 1 and Level 2 trauma centers—located in the state's capital of Providence. Together, these two EDs receive over 175,000 adult visits each year. Between 2017 and 2018, the two EDs reported a total of 1,446 visits for suspected opioid overdoses, representing 45% of all ED visits for suspected opioid overdose reported to the Rhode Island Department of Health (n = 3,239). A consecutive sample of ED patients will be assessed for eligibility by one of eleven full-time research assistants employed in the two EDs who can recruit participants 24 hours per day, seven days per week. Potential participants will be identified by the research assistants by screening EMRs or by referral from treating providers in the ED. Potential participants will be considered eligible if they are 18 years of age or older and speak English. Given the specificity of the pool of LCSWs and certified peer recovery support specialists to the ED, recruitment will occur in the ED only.

METHODS: ASSIGNMENT OF INTERENTIONS

Allocation

Participants will be randomly assigned 1:1 within each study site to receive either a behavioral intervention delivered by a certified peer recovery support specialist or by an LCSW. Allocations will be randomly

assigned using the REDCap randomization feature. The randomization schedule will be maintained by a data manager not involved with participant recruitment or the final study analyses.

Blinding (Masking)

Participants and providers cannot be blinded to their intervention assignment. However, investigators and analysts performing the study analyses will be blinded to arm allocation.

METHODS: DATA COLLECTION, MANAGEMENT, ANALYSIS

Data Collection Methods

The primary outcomes assessments will rely on the use of administrative data (see below).

Data Management

All data collection instruments will be designed using Research Electronic Data Capture (REDCap) software and administered using a tablet computer connected to the wireless network at the two study sites.

Statistical Methods

We will use an intention-to-treat (ITT) approach in all analyses to estimate the average treatment effect. For the two primary outcomes (engagement in formal SUD treatment within 30 days of the initial ED visit and occurrence of a subsequent ED visit for opioid overdose within 18 months of the initial ED visit), we will use separate logistic regression models with indicators for treatment allocation. Analyses with binary outcomes were selected based on input from community stakeholders. In exploratory analyses, we will use survival methods (e.g., Cox proportional hazards models) to assess the impact of treatment on the time to events for both outcomes (i.e., days from discharge to enrollment in formal SUD treatment and days from discharge to first recurrent ED visit for opioid overdose). In addition, on an exploratory basis, we will conduct moderation analyses to understand potential heterogeneity of treatment effects by age and gender. Given the multicenter design of the trial, the effect of treatment site will be quantified by the intraclass correlation coefficient (ICC), representing the variance due to the between-center variability (34). Should the ICC suggest that a large portion of the variance is explained by between-center variability, we will control for treatment site using a generalized estimating equations (GEE) approach to estimate population-average treatment effects across the two sites.

METHODS: MONITORING

Data Monitoring

A single data safety monitoring board (DSMB) will be convened and include members external to the research team and funding source and without potential conflicts of interest. The DSMB will be notified within 24 hours of any serious adverse event in which the relationship to the study is possible. The DSMB will convene at the earliest possible time (no more than 30 days from time of notification) to discuss this adverse event. Further, the DSMB will meet on a quarterly basis with the study coordinator and co-principal investigators to review protocol adherence and adverse events.

Harms

An adverse event is considered any physical or clinical change experienced by the patient, including the onset of new symptoms or the exacerbation of pre-existing conditions.

ETHICS AND DISSEMINATION

Research Ethics Approval

All protocols have been approved by the institutional review boards at the Lifespan health system representing the two clinical sites (Approval Number: 212418).

Protocol Amendments

Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the patient, or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment.

Consent

Trained research assistants will introduce and discuss the trial with potential participants. These potential participants will then be able to have an informed discussion with the research assistant about their potential participation. Following this discussion research assistants will obtain written informed consent.

Confidentiality

The privacy of all trial participants is protected by a Certificate of Confidentiality issued by the National Institutes of Health (NIH). Unique identification numbers will be assigned to participants. All data forms and interviews will be coded with this number rather than with a name. All paper forms will be stored in locked file cabinets. Informed consent documents will be stored separately, as they contain identifying information. Upon completion of the study, identifying information will be destroyed.

Access to Data

The institutional review boards at the Lifespan health system representing the two clinical sites will have access to anonymized data at their discretion. However, no third-party investigators will have access to study data prior to synthesis and dissemination.

Dissemination Policy

The study has been registered on ClinicalTrials.gov. A summary of the results of the trial will be published there when available. Results will be published at national scientific meetings and the final results will be submitted for publication in peer-reviewed journals.

DISCUSSION

The AnchorED program of Anchor Recovery Community Center, which deploys certified peer recovery support specialists to EDs across Rhode Island to deliver behavioral interventions to individuals who have experienced an opioid overdose, is the first statewide program of its kind in the nation (23). Despite a lack of evidence to demonstrate the effectiveness of this program and improved long-term outcomes for patients, several other jurisdictions in the US have created or are initiating programs based on the AnchorED model (24). Given the intense interest in peer recovery models, the results of this trial have a strong potential to fundamentally change clinical practice paradigms for treating patients at high risk for opioid overdose who present to EDs across the nation.

The current study benefits from support from a unique policy environment in Rhode Island. In 2015, Governor Gina Raimondo signed an executive order to establish the Rhode Island Overdose Prevention and Intervention Task Force, which charged experts to develop a strategic plan to guide efforts to tackle the state's overdose crisis (35). An important outcome of this plan was a comprehensive data sharing infrastructure between key state agencies (including the Rhode Island Departments of Health and Behavioral Healthcare, Developmental Disabilities, and Hospitals) and academic researchers (36). These data sharing agreements offer unprecedented access to population-based data on overdose morbidity and mortality (36). As a result, the trial investigators can create a large database linking participant data with multiple administrative databases to ascertain our primary and secondary outcomes. The ability to conduct these robust data linkages is an important methodological innovation that overcomes biases associated with self-reported outcomes and loss to follow-up in previous studies.

The results of this trial will need to be considered in light of some caveats. Although Good Samaritan laws are present in many jurisdictions across the US, including Rhode Island, to protect individuals from criminal prosecutions (37), many people do not call emergency medical services in the event of an overdose (38). It

is possible that the intervention may increase participants' self-efficacy and willingness to engage with emergency medical services in the event of an overdose. As a result, those receiving the peer recovery intervention might be more likely to present to the ED in the event of an overdose. Should the intervention reduce the overall rate of non-fatal overdose but increase the proportion of non-fatal overdoses that are treated in the ED, the findings related to the impact of the intervention on recurrent ED visits may be null or counterintuitive. Although the administrative databases used to characterize the primary outcomes are meant to be representative, they are by no means comprehensive. Individuals who enroll in SUD treatment programs or who present to EDs in other states will not be captured in these resources. Given the pragmatic nature of the trial, fidelity monitoring and process checking are not being conducted, thus limiting potential understanding of what components of the intervention were performed should they be deemed efficacious.

This trial represents the first systematic evaluation of behavioral interventions delivered by certified peer recovery support specialists in the ED to individuals at high risk for opioid overdose. Should the trial be successful, its findings have the potential to establish the evidence base for peer recovery support services as an effective intervention and provide support for the large-scale implementation of these services in EDs. Amidst a national crisis, peer recovery support interventions could be an effective means for improving SUD treatment engagement and reducing rates of fatal and non-fatal overdose.

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Authors' Contributions:

WCG led the manuscript preparation. The research was conceived by FLB and BDLM. All authors provided feedback on several drafts of the study protocol and this manuscript. WCG, BDLM, EAS, MGB, DD, KJL, LM, RCM, TN, GAO, SER, JLY, and FLB read and approved of the final manuscript.

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Declarations of Competing Interest:

The authors declare no competing interests.

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Figure 1. Intervention arms in a randomized clinical trial of an emergency department-based peer recovery support intervention to increase treatment uptake and reduce recurrent overdose among individuals at high risk for opioid overdose

	Certified Peer Recovery Specialist		Licensed Clinical Social Worker
1	Enrollment Visit in Emergency Department • Intervention based on motivational interviewing plus lived experience of peer recovery specialist • Navigate barriers to treatment, provide referrals	1	Brief Intervention in Emergency Department • Intervention based on motivational interviewing plus other clinical skills • Provide referrals as needed
2	Community-Based Follow-Up Visit (<48 hours) • Navigate barriers to treatment and recovery • Ongoing peer support • Ongoing overdose prevention education		
3	Retention in Peer Recovery Support (≥90 days) • Promote retention in treatment • Ongoing peer support • Ongoing overdose prevention education		

Figure 1

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

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*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.