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Substance use disorder telehealth treatment in the emergency department/inpatient unit with peer support workers

Submission date
10/10/2023

Recruitment status
No longer recruiting

Registration date
16/10/2023

Overall study status
Completed

Last Edited
25/07/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In 2020, New Mexico had the highest alcohol-related death and the 11th-highest drug overdose rate in the USA. Toward the long-term goal of addressing this public health problem, the study team are implementing and evaluating an integrated multi-level intervention designed to identify adults at risk of substance use disorder (SUD) and encourage linkage to and retention in treatment. The study plans to expand on previous research related to the implementation of treatment strategies for patients presenting at EDs and admitted to medical inpatient units wherein there is a significant window of opportunity to link patients with follow-up behavioral and clinical service for alcohol and/or drug misuse.

Who can participate?
Patients aged 18 years old and over accessing the ED or medical inpatient services at Sandoval Regional Medical Center (SRMC)

What does the study involve?
The study will use a Type 1 hybrid implementation design with a non-randomized approach to enrol patients who screen positive for unhealthy use of alcohol, prescription medications (used nonmedically), and illicit drugs.

Four approaches will be implemented:
1. Equipping the emergency department (ED) and medical inpatient units of a safety-net hospital with a method to screen individuals at risk of a SUD
2. Motivational interviewing (MI)
3. Seeking Safety (SS), a trauma-specific treatment for PTSD and SUD
4. Pharmacotherapy for SUD

Peer support workers (PSWs) are responsible for screening, MI to increase engagement in screening and treatment, and delivery of SS.

Pharmacotherapy is provided by addiction clinical specialists. All treatment is provided post-discharge via telehealth to increase access to care.

Participants are identified through (1) a review of electronic health records for individuals with a chief or secondary complaint or mental health condition relating to alcohol and/or other drug use, (2) referrals from clinical staff, and (3) screening in the ED and medical inpatient units. Feasibility will be measured through various process data. The primary outcomes that will inform our assessment of effectiveness will be changes in: (i) post-traumatic stress disorder symptom severity; and (ii) substance use.

What are the possible benefits and risks of participating?
It is not known if patients will get any benefit from participating in this study. However, by participating in this study, the information learned may help others with SUD. Potential risks include being asked to share information about the services they receive that may be unpleasant or mildly stressful. Despite our best efforts to protect patient information, there is inevitably a small risk of loss of privacy and/or confidentiality.

Where is the study run from?
The University of New Mexico (UNM) (USA)

When is the study starting and how long is it expected to run for?
May 2022 to September 2024

Who is funding the study?
The Substance Abuse and Mental Health Services Administration (SAMHSA - 1H79FG000817-01) (USA)

Who is the main contact?
Justine Saavedra (Program Manager), jlsaavedra@salud.unm.edu

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1H79FG000817-01

Study information

Scientific Title
Peer support model to address substance use disorders treatment engagement in rural communities

Study objectives
By the end of the project period, participants enrolled in the SRMC TH-SUD treatment will demonstrate a decreasing trend in PTSD symptom severity and substance use.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/10/2022, The University of New Mexico Health Sciences Office of Research Human Research Protections Program (1 University of New Mexico, MSC08 4560, Albuquerque, 87131, United States of America; +1 (505) 272-1129; hsc-hrpo@salud.unm.edu), ref: 22-305

Study design
Single-center non-randomized Type 1 hybrid implementation design study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, Internet/virtual, Telephone

Study type(s)
Quality of life, Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Substance use disorder

Interventions
The purpose of this single-centre project is to evaluate the effectiveness of the Sandoval Regional Medical Center (SRMC) Telehealth Substance Use Disorder Treatment (hereafter referred to as SRMC TH-SUD treatment), among individuals who are admitted to the emergency department (ED) or medical inpatient units at the University of New Mexico's (UNM) SRMC using a Type 1 hybrid implementation design with a non-randomized approach.

Participants are recruited through the ED after screening positive for at-risk substance use disorder. The intervention includes Seeking Safety (SS), Medication for Addiction Treatment (MAT), Motivational Interviewing (MI) and psychosocial support. Peer support workers (PSWs) provide SS and MI and Addiction Specialists provide MAT. The intervention is provided via telehealth and is time-unlimited.

The study's primary outcome includes:
Post-traumatic Symptom Checklist – Civilian Version (PCL-C): The PCL-C is a valid, reliable and sensitive tool to monitor PTSD symptom change as a result of services. The checklist consists of 17 self-report items that can be used with any population and can be completed within approximately 5-10 minutes. To be completed at baseline and every 60 days thereafter.
Secondary outcomes include:
Barriers Questionnaire (one for Alcohol and one for Drugs): The Barriers Questionnaire was developed to ask people about the reasons why they had not previously sought treatment for either their alcohol use or their drug use. Both instruments contain 50 items rated on a 4-point Likert-type scale with response options ranging from no, not at all to very important.
Craving Scale: The Craving Scale is a 3-item measure of craving related to the participant's drug of choice (e.g., cocaine, alcohol, opioids, etc.). The items are measured on a 10-point Likert-type scale ranging from 0 – 10
Motivation for Change (one for Alcohol and one for Drugs): The Motivation to Change Questionnaire was developed as a brief screening measure of motivation for change. The questionnaire includes 12 items measured on a 10-point Likert-type scale ranging from definitely not to definitely.
Questionnaire about the Process of Recovery (QPR): The QPR is a 15-question self-report survey that measures aspects of recovery related to mental health and well-being. The survey takes approximately 5-10 minutes to complete. The QPR tool has been found to be a reliable and valid measure of recovery in serious mental illness.
RAND 36-Item Short Form Health Survey (SF-36): The SF-36 is a set of 36 generic, coherent and

easily administered questions to measure quality of life.
Addiction Severity Index (ASI): One section of the ASI will be used to measure drug and alcohol use. Items assess the frequency of drug and alcohol use within the past 60 days.
Substance Abuse Self-Stigma Scale (SASSS): One section of the SASSS will be used to measure self-devaluation as a result of substance use. It includes 8 items measured on a Likert-type scale with response options ranging from “Never or almost never”, “Rarely”, “Sometimes”, “Often” and “Very Often”.
Criminal Justice Involvement: We developed a survey to measure criminal justice involvement in the past 60 days. If the respondent says yes to the various illegal activities asked about then they will be prompted to report the number of times. One of the outcomes of the evaluation is to determine the impact of the intervention on reducing the cost of crime to society. To be able to do this we need details on whether certain crimes were committed because the cost to society varies by crime type.
Service Use: We developed a survey to measure service use in the past 6 months. This survey includes 7 questions that ask about the number of visits to the emergency department and the number of days spent overnight in a hospital or other treatment facility for either mental health, physical health and/or substance use. The survey includes branch logic, to that if a respondent says that he/she hasn’t spent any time in a hospital, then they are not asked the five additional questions about the type of hospital stay.
Client Satisfaction: Client satisfaction will be measured using the Client Satisfaction Questionnaire (CSQ-8) at follow-up interviews only. The CSQ-8 is an 8-item generic and unidimensional instrument that broadly measures current satisfaction with the quality of services, the amount of help, recommendation of the program to friends, and overall general satisfaction. For each of the eight items, participants reported how satisfied they were using a Likert-type scale ranging from 1 (low) to 4 (high). Total scores range from 8 to 32, with higher scores indicating greater satisfaction.

Intervention Type
Behavioural

Primary outcome measure
PTSD symptom change as a result of services measured using the Post-traumatic Symptom Checklist – Civilian Version (PCL-C) at baseline and every 60 days thereafter

Secondary outcome measures
The following secondary outcome measures are completed at baseline and every 60 days thereafter:
1. Reasons why they had not previously sought treatment for either their alcohol use or their drug use measured using the Barriers Questionnaire (one for Alcohol and one for Drugs)
2. Craving related to the participant's drug of choice (e.g., cocaine, alcohol, opioids, etc.) measured using the Craving Scale
3. Motivation for change measured using the Motivation to Change Questionnaire (one for Alcohol and one for Drugs)
4. Aspects of recovery related to mental health and well-being measured using the Questionnaire about the Process of Recovery (QPR)
5. Quality of life measured using the RAND 36-Item Short Form Health Survey (SF-36)
6. The frequency of drug and alcohol use within the past 60 days measured using the Addiction Severity Index (ASI)
7. Self-devaluation as a result of substance use measured using the Substance Abuse Self-Stigma Scale (SASSS)
8. Criminal justice involvement in the past 60 days measured using a bespoke Criminal Justice

Involvement Survey
9. Service use in the past 6 months measured using a bespoke Service Use Survey
10. Client satisfaction will be measured using the Client Satisfaction Questionnaire (CSQ-8) at follow-up interviews only

Overall study start date
01/05/2022

Completion date
29/09/2024

Eligibility

Key inclusion criteria
1. Age 18 years old and over
2. English speaking
3. Have an SUD
4. Accessing the ED or medical inpatient services at SRMC

Participant type(s)
Service user

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
110

Total final enrolment
61

Key exclusion criteria
1. Adults unable to consent
2. Non-English speaking
3. Individuals who are not yet adults (infants, children, teenagers)
4. Prisoners

Date of first enrolment
15/11/2022

Date of final enrolment
19/07/2024

Locations

Countries of recruitment
United States of America

Study participating centre
University of New Mexico (UNM) Sandoval Regional Medical Center
3001 Broadmoor Blvd NE
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Sponsor information

Organisation
University of New Mexico

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Sponsor type
University/education

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ROR
https://ror.org/05fs6jp91

Funder(s)

Funder type
Industry

Funder Name
Substance Abuse and Mental Health Services Administration

Alternative Name(s)

U.S. Substance Abuse and Mental Health Services Administration, The Substance Abuse and Mental Health Services Administration, United States Substance Abuse and Mental Health Services Administration, HHS Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, SAMHSA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are not expected to be made available due to not obtaining consent from participants during the consent process to share raw data beyond the purposes of the main study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		16/05/2024	11/06/2024	Yes	No