LIBR #2023-005
12/22/2023

Contingency Management for Problematic Behavior Reduction in the Community

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Sponsor: Laureate Institute for Brain Research

Funded By: Laureate Institute for Brain Research

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A. Study Purpose

This study aims to determine the feasibility and effectiveness of implementing a contingency management program in a small group of mentally ill, homeless individuals with schizophrenia or bipolar disorder and anosognosia (a lack of insight into their mental health) in the City of Tulsa. Tulsa's homeless population grew nearly 7% last year to the highest numbers since the beginning of the COVID-19 pandemic according to Housing Solutions data, an organization that oversees many of the city's efforts to address homelessness. The primary objective of the study is to decrease disruptive or problematic behaviors by homeless individuals in the community through monetary incentives.

Specific Aim: To determine the safety and efficacy of contingency management to decrease the number of disruptive events in the Tulsa community over an 18-month timeframe (e.g. interactions with police, Tulsa Fire Department, Emergency Medical SA, and 911 interventions)

B. Background and Significance

Contingency management (CM) is a behavioral intervention strategy that has demonstrated promising results in various populations. It involves the provision of tangible incentives or rewards to individuals who demonstrate specific behavioral changes, such as adherence to treatment, abstaining from drug use, or engaging in positive life choices. Whereas controversial, the employment of financial incentives to achieve behavioral goals in persons with severe psychiatric disorders has been used previously (Noordraven et al., 2017; Priebe et al., 2010; Rosen et al., 2023).

This study aims to determine the feasibility and effectiveness of implementing a CM program in a small group of homeless individuals with a mental health diagnosis. These individuals will also have the symptom of anosognosia, which is the lack of awareness of their disorder (a term often applied to conditions with structural pathology of the central nervous system, but present also in severe mental health disorders, in which is usually described as lack of insight). This symptom has long been recognized as a major predictor of nonadherence to treatments, poorer psychosocial functioning, aggression, and poorer course of illness overall. The association between anosognosia and treatment noncompliance is particularly strong among patients with chronic psychotic disorders, in whom lack of treatment is a major driver of most other adverse outcomes (e.g., Kim et al. 2020).

The research will be conducted in accordance with the highest ethical standards, ensuring the safety, privacy, and wellbeing of all participants. Data collection will involve multiple sources, including self-report questionnaires, legal records, and housing status updates, allowing for a comprehensive evaluation of the CM program's efficacy in promoting disruptive behavior-free days for homeless individuals in Tulsa.

C. Criteria for Subject Selection

Description and Recruitment of Population:
Fifteen participants (10 completers estimating a very conservative attrition rate of 50%) will be recruited at the Tulsa Day Center (TDC), a private, non-for-profit organization in Tulsa, OK, continuously operating in the city for over 40 years. TDC offers shelter and daytime activities, including medical services, to about 250 homeless people every day. Participants will be pre-selected for participation by TDC staff based on their history of problematic behaviors (Table 1). All participants will be between 18 and 65 years of age, inclusive. TDC staff will collect information from participants regarding their diagnoses, and after initial screening, records will be obtained from clinical records to confirm psychiatric diagnosis. In addition, information regarding disruptive behaviors necessitating intervention will be obtained for the 6 months prior to enrollment to establish a historical baseline of disruptive behaviors against which the efficacy of this study intervention will be compared. Clients with a history of at least one disruptive episode per week in at least 50% of the weeks in the 6-month period will be eligible for enrollment. At this early, feasibility stage, no stratification according to sex, gender, or ethnicity will be made.

Inclusion Criteria:
1. Age 18-65 years old
2. Diagnosis of Schizophrenia Spectrum, Bipolar, or Related Disorders
3. Presence of Anosognosia (SUMD: Minimum combined score of 4 on questions 1) and 2); Recent (at least <6 months) history of disruptive behaviors (at least 1 disruptive behavior per week in >50% of weeks in the 6-month period prior to enrollment)
4. Receive case management services through TDC
5. Ability to comply with study procedures
6. Willingness to participate in contingency management intervention

Exclusion Criteria:
Based on assessment by the client's case manager, the presence of:
1. Inability to provide informed consent
2. Unstable medical conditions that would interfere with participation
3. Cognitive impairment that would interfere with participation in the study
4. History of severe aggression or violent behavior posing a risk to study staff or other participants
5. Active suicidal ideation or a history of suicide attempts within the past 12 months

D. Research Design and Methods

Description of Study Intervention:
Subjects will be selected by Tulsa Day Center (TDC) staff based on inclusion criteria. Participants will meet weekly for 30 minutes with their case manager to discuss progress on life goals and determine of the bonus payment has been earned. The participant will receive $10 for their time spent with the case manager each week. The goal is for the participant to maintain seven

days with no disruptive behaviors (or "trouble-free days"*) per week at each visit. This goal will be verified by the case manager and lead study manager prior to the participant's visit each week using the sources of data information described below. When the goal is achieved for a certain week, the participant will receive payment. The payment starts at $20 and each week the amount paid per goal/week will increase by $1. Any week with disruptive behaviors will result in returning to the $20 baseline amount.

*"Trouble free days" definition: Trouble-free days are days during which an individual with a severe mental disorder demonstrates no occurrence of problematic behaviors and maintains a stable mental state without causing harm or disruption to themselves or others.

Table 1: Possible Sources of Data for Baseline and Ongoing Trouble-Free Day Information:

- **Homeless Management Information System:** Shows current case manager, overnight shelter stays (recorded daily), VI SPIDAT scores.
- **Vulnerability Index Service Prioritization Decision Assistance Tool (VI SPIDAT):** records self-reported periods of homelessness, evictions, emergency room visits (physical reasons), hospitalizations (physical reasons), incarcerations, crisis care admissions, hospitalizations (mental health reasons), and substance use.
- **Oklahoma State Courts Network (OSCN):** Shows legal records including evictions, arrests, charges and disposition of cases.
- **City of Tulsa Jail Hub:** Shows City of Tulsa Municipal Court charges (trespassing, erecting an abode unlawfully, etc.)
- **Tulsa Police Department:** Source for arrest records
- **Tulsa Fire Department CARES program:** Tracks number of calls to 911
- **Tulsa City and County court records:** Data base for civil commitment municipal
- **Tulsa Center for Behavioral Health:** Inpatient stays
- **Grand Addiction Recovery Center and Grand Mental Health:** Participation in recovery programs
- **Landlords:** Mental Health Association Oklahoma, Hudson Villas, Tulsa Housing Authority
- **David L Moss Inmate Search:** Arrests and charges
- **MyHealth Access Network:** Emergency room visits, hospital visits, diagnoses, medical care, prescribed medications, etc.
- **Julotta System:** will house information on hospital admissions, arrests, case management notes, medical history, list of medications prescribed, diagnosis, insurance info, ER visits in past 12 months, 911 calls in past 12 months, push notifications, referrals to other programs, program enrollments, past employment, strengths and abilities, financial assessment, past substance abuse. Julotta access will be dependent on implementation in the local community.
- **Other community-**based services as needed (e.g. Salvation Army, social security office, etc.)

Study Duration:
The involvement of each participant in this study will last 18 months. The study will last approximately 2 years.

Outcome:
Participants will decrease the frequency of disruptive behaviors, as defined above, in comparison with the 6-month period immediately prior to recruitment.

Sample Size:
This study exploring feasibility of the CM approach to resolve social dysfunctional behaviors will include up to 15 participants with the goal to obtain 10 completers.

Description of Sites/Facilities Enrolling Participants:
Tulsa Day Center in Tulsa, Oklahoma provides of full range of services and tools to assist clients in overcoming anticipated, situational and chronic homelessness. Their priority is to address client's basic needs: shelter, food, clothing and bathing. They offer rapid rehousing services, emergency shelter, medical assistance, and legal aid to help ensure all of those needs can be met. https://tulsadaycenter.org/

The Blue Team initiative at Tulsa Day Center was launched in September 2022, with the primary focus of working with a subset of the homeless population in Tulsa who have difficulty obtaining and maintaining safe housing due to anosognosia.

Baseline Assessment: The initial status of participants' target disruptive behaviors will be obtained from the 6 months prior to recruitment. This information will be used as a historical, preliminary comparator to the 6 months of CM intervention.

To evaluate the inclusion and exclusion criteria, the following procedures will be implemented:

- Diagnoses will be obtained from clinical records obtained by Tulsa Day Center.
- Anosognosia Assessment: Utilize standardized instruments such as the Scale to Assess Unawareness of Mental Disorder (SUMD) to evaluate the presence of anosognosia in potential participants.
- Legal Involvement and Impulsive Behaviors: Review participants' legal records and self-reported incidents within the past six months to assess their history of legal involvement or impulsive behaviors.
- Housing Status Assessment: Obtain information on participants' housing history through self-report or case management records to determine the stability of their housing situation over the past six months.
- Informed Consent: Ensure participants can provide informed consent by assessing their understanding of the study's purpose, procedures, risks, and benefits through a written or verbal quiz.
- Study Procedures Compliance: Assess participants' willingness and ability to comply with study procedures during the screening and informed consent process.

- Participation in Other Interventions: Inquire about potential participants' involvement in any other intervention studies targeting the same population or addressing similar issues.

Clinical and Demographic Information

- Age
- Race/ethnicity
- Gender
- Psychiatric diagnosis
- Legal history
- Housing status
- Medical, mental health and substance use treatment history
- Housing/shelter
- Legal involvement
- Participation in programming
- Emergency Medical Services Authority (EMSA) visits
- Community Outreach Psychiatric Emergency Services (COPES)

Interview and Self-Report Questionnaires

The Scale to Assess Unawareness of Mental Disorder (SUMD): The SUMD has been validated in schizophrenia and schizoaffective disorder and uses a structured interview administered by trained raters. The SUMD derives from Amador's complex model of (Dumas et al. 2013) and includes a symptom checklist in addition to general items related to awareness of illness, attribution of symptoms to a mental disorder, awareness of effects of medication, and awareness of social consequences of illness. Furthermore, SUMD scoring includes subscales that relate the general items to specific symptom constellations.

Vulnerability Index- Service Prioritization Decision Assistance Tool (VI-SPIDAT): The VI-SPDAT examines factors of current vulnerability and future housing stability. It was developed as a pre-screening tool for communities that are very busy and do not have the resources to conduct a full SPDAT assessment for every client. The tool was made in collaboration with Community Solutions, creators of the Vulnerability Index, as a brief survey that can be conducted to quickly determine whether a client has high, moderate, or low acuity. Communities need practical, evidence-informed tools that enhance their ability to satisfy federal regulations and quickly implement an effective approach to access and assessment. The VI-SPDAT is a first-of-its-kind tool designed to fill this need, helping communities end homelessness in a quick, strategic fashion. (Community Solutions: http://www.orgcode.com/product-category/training/spdat/)

E. Gender and Racial/Ethnic Origin of Participants

Demographics for the population in Tulsa, Oklahoma from which participants will be selected from this study are approximately 9% Hispanic/Latino ethnicity. Gender will be approximately 40% female/55% male/5% unreported. Racial composition will be approximately 52% White, 14% Native American, 24% African American, 6% unknown, 1% Asian and 3% Pacific Islander.

F. Participant Risks and Plans to Minimize Risks

Potential Benefits: Potential benefits for study participation include 1) financial compensation for the participants, 2) decreased interaction with the legal system, and 3) increased engagement with the health care system.

Potential Risks: This CM program has no known health risks. Time spent each week with the staff administering CM rewards can be a nuisance to certain participants.

Protection Against Risks: The following risk mitigation strategies will be used during this study:

1. Comprehensive training for staff: We will ensure that all staff involved in the study are thoroughly trained in recognizing signs of distress or potential harm to participants, as well as in managing crisis situations and de-escalating conflicts.
2. Regular mental health assessments: The participating staff will conduct regular mental health assessments of participants to monitor their wellbeing and detect any potential risks or concerns early on.
3. Clear communication of expectations and boundaries: The staff will clearly communicate the rules, expectations, and boundaries of the program to participants, ensuring they understand the goals and requirements of the study.
4. Close collaboration with local support services: LIBR has established strong partnerships with local mental health, medical, and social services to ensure participants have access to appropriate resources and support when needed.
5. Establish a safety protocol: The staff will follow a standard safety protocol in case of emergencies or incidents involving participants, including procedures for contacting appropriate authorities and support services.
6. Confidentiality and data privacy: LIBR will ensure the privacy and confidentiality of participants' personal information and data collected during the study by implementing strict data handling and storage procedures.
7. Continuous monitoring and evaluation: We will regularly monitor and evaluate the program's implementation and effectiveness in promoting safety and reducing disruptive behaviors, making adjustments as needed to enhance participant wellbeing and study outcomes.

Ethical Considerations:
All participants will provide written informed consent prior to enrollment in the study. Participants will complete a short quiz at the end of the consent process to demonstrate they understand the fundamental aspects of the study. Confidentiality of participant data will be

maintained throughout the study. Additionally, an independent medical monitor who is Board Certified in Psychiatry will review study progress.

Clinical Monitoring:
Clinical monitoring will be conducted to ensure that the rights and well-being of trial participants are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with International Conference on Harmonisation Good Clinical Practice (ICH GCP), and with applicable regulatory requirement(s).

Overall external monitoring for this study will be performed by Dr. Matthew Meyer. Internally, the study PI or Dr. Salvador Guinjoan, a psychiatrist at LIBR, will engage in regular discussions of the study progress with the clinical monitor, perform random reviews of study endpoint, safety, and other key data to verify completeness of data acquisition.

Reasons for Study Termination:
The study will be terminated for the following reasons: 1) participant misses 3 consecutive case manager visits, 2) at the determination of the participant's case manager when deemed necessary for safety reasons of the participant, staff, and milieu at TDC.

By implementing this detailed CM procedure, the study will be able to assess the feasibility and effectiveness of using positive reinforcement to promote behavior change among homeless individuals with psychotic disorders and anosognosia.

G. Statistical Methods

The statistical analysis for this study will be conducted using appropriate statistical software to ensure the validity and reliability of the results. The primary goal of the analysis is to evaluate the effectiveness of the CM program in preventing disruptive behaviors among homeless individuals with psychotic disorders and anosognosia.

Descriptive statistics will be calculated for all variables, including demographics, clinical characteristics, and outcome measures. These statistics will include measures of central tendency (mean, median) and dispersion (standard deviation, interquartile range) for continuous variables, as well as frequencies and proportions for categorical variables.

To compare the intervention and control historical period, we will employ Chi-square or Fisher's exact tests for the proportion of weeks free of disruptive behaviors.

The primary outcome measure will be the proportion of disruptive behavior-free weeks in the 6 months of the intervention compared with the previous 6 months. We will use linear or logistic regression models to analyze the relationship between these outcomes and the intervention,

adjusting for potential confounding factors such as age, gender, ethnicity, and baseline clinical characteristics, including psychiatric diagnosis.

For all statistical tests, a two-sided p-value of less than 0.05 will be considered statistically significant. To account for multiple comparisons, we will apply appropriate correction methods, such as the Bonferroni or Benjamini-Hochberg procedures.

In addition to the primary analysis, we will conduct exploratory subgroup analyses to assess the intervention's effectiveness among specific subpopulations, such as individuals with different levels of anosognosia severity, specific diagnoses within the Schizophrenia Spectrum or Bipolar and Related Disorders, or varying degrees of substance use.

Finally, we will perform sensitivity analyses to assess the robustness of our findings and to evaluate the impact of missing data or potential biases on the study results. These analyses may involve multiple imputation, propensity score matching, or other relevant techniques.

H. Data Storage and Confidentiality

Data collection is the responsibility of the study staff under the supervision of the PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. Data collected for the study will be stored in REDCap, a 21 CFR Part 11-compliant data capture system provided by LIBR staff. The data system includes password protection.

Data safety and monitoring will be carried out to ensure and maintain the scientific integrity of this project and to protect the safety of participants. Only information that is required to fulfill the objectives of the study will be collected. Records of the subject's participation in this study will be held confidential except as disclosure is required by law or as described in the informed consent document (under "Confidentiality"). The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the Institutional Review Board (IRB), will be able to inspect and copy confidential study-related records that identify the subject by name. Therefore, absolute confidentiality cannot be guaranteed.

Each subject will be given a unique identifier with a code. Information for each participant is entered into the Laureate Institute for Brain Research subject database and they are automatically given a LIBR ID e.g. AA001. The code key that links the unique identifier to the subjects' names is kept in a separate file. Other than the PI, there is no need for personally identifying information to be known to other investigators. If the results of this study are published or presented at meetings, the subjects will not be identified. All data analysis is performed on de-identified data. Subjects will not be identified in any reports or publications.

Any electronic data will have all identifiable information encrypted and be stored in a firewalled and password-protected database on a secure server managed by the Laureate Institute for

Brain Research. All research documents, such as paper copies of consents, screening forms, the Research Privacy Form, testing results, and any other forms or papers containing Personally Identifiable Information (PII), as well as collected research data, will be stored electronically on the LIBR Network and/or REDCap (Research Electronic Data Capture), and/or in locked cabinets at the Laureate Institute for Brain Research. Access to the LIBR Network and to REDCap is granted only to authorized personnel; only approved study personnel will have access to any records that have identifying information. The LIBR Network is protected by the Palo Alto PA-5250 Layer 7 firewall with licenses for Wildfire, AV, Threat Prevention, and URL filtering. All LIBR Network data is stored on site. REDCap is a secure web application for building and managing online surveys and databases. The REDCap Consortium, a vast support network of collaborators, is composed of thousands of active institutional partners in over one hundred countries who utilize and support REDCap in various ways. Vanderbilt University, in collaboration with consortium partners, developed REDCap as a toolset and workflow methodology for electronic collection and management of research and clinical trial data. While REDCap can be used to collect virtually any type of data (including 21 CFR Part 11, FISMA, and HIPAA-compliant environments), it is specifically geared to support online or offline data capture for research studies and operations. REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from the information technology staff. The iterative development and testing process results in a well-planned data collection strategy for individual studies. REDCap servers are housed in a local data center at Laureate Institute for Brain Research and all web-based information transmission is encrypted. REDCap was developed specifically around HIPAA-Security guidelines and is recommended to LIBR researchers by both our Privacy Office and the Western Institutional Review Board (WIRB). REDCap has been disseminated for use locally at other institutions and currently supports 240+ academic/non-profit consortium partners on six continents and over 26,000 research end-users (www.project-redcap.org).

To further protect the privacy of the participants, the researchers will obtain a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS). With this Certificate, the researchers cannot be forced (for example, by court order or subpoena) to disclose information that may identify a participant in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify a participant, except to prevent serious harm to the participant or others.

Continuous, close monitoring of participant safety will prompt reporting of safety data (i.e., adverse/serious adverse events) to the local IRB. Serious adverse events will be reported to the IRB within 48 hours of the time project staff become aware of the incident. The PIs will provide a summary of the safety conduct in a written report required by the IRB as part of the annual IRB renewal. Should the protocol or data collection plans be amended as a result of data review, the relevant IRBs will be notified, and the amendment approved prior to study amendment implementation. In addition, the participants will be notified of any significant new findings that develop during the course of research (e.g., other potential risks)

that may affect their wish to continue participation in the study. Study information will be made available to the subjects when there has been sufficient data analysis to make reasonable aggregate conclusions. We can share general study characteristics (how many people were recruited, age, primary disorder etc.) early in the process, but will not share study results with subjects until the quality of the data is close to publication level. If the PI leaves LIBR, an agreement will be made between LIBR and the PI's new institution to transfer the data so that the study can continue.

I. Process and Documentation of Consent

Informed Consent will be obtained by members of the research team that have received training from the PI to obtain consent for this study. All participant interactions including consenting will be conducted in private interview/exam rooms.

Documented Consent: Documented informed consent will be obtained once the consent has been reviewed and the individual agrees to participate using the appropriate approved informed consent document. Participants will be provided with a copy of the consent. All volunteers will be at least 18 years old and will be asked to give fully informed documented consent following approved consent procedures. Care is taken to appropriately describe IRB-approved consent forms as documented by signature of the person giving permission and the person obtaining informed consent.

Measures to decrease coercion of participants: The researcher will remind the subject that participation is strictly voluntary and remind them that they have the right to withdraw at any time without penalty. Family members will be allowed to be present and discuss the consenting process with the participant if requested. When recruited, subjects will be asked to arrive 30 minutes early in order to have sufficient time to consent and answer questions.

• **Subject Capacity:** All subjects enrolled in this study will have the capacity to consent. As noted previously, individuals with moderate to severe neurocognitive disorders will be excluded from the study.

• **Subject/Representative Comprehension:** During the written informed consent process, the subject's understanding of the study protocol will be assessed using a questionnaire with open-ended questions. If they are unable to communicate understanding of the protocol, they will not be enrolled in the study.

• **Costs to the Subject**. The only anticipated expense to participants is the amount of time spent conducting the experiment. The total time involved in this experiment will be approximately 30 minutes per session.

J. Payment for Participation

Participants will be paid $10 each week for their time spent in the 30-minute case manager meeting. In addition, participants will be paid for "trouble free days" as part of the contingency management (CM) component. The payment starts at $20 and will increase by $1 each week

for maintaining trouble-free days. The maximum amount for CM at the end of the 18 months (76 weeks) is $95 during the final week of the study. Over the course of 18 months, the maximum amount a participant may receive is $5390 if they attend every meeting with the case manager ($770) and maintain “trouble-free” days throughout the study ($4620). Any week with disruptive behaviors will result in returning to the $20 baseline amount with $1 increments for future weeks.

If participants do not complete each part of the session, the payment will be prorated according to the payment information above. Participants will be paid with a ClinCard (similar to a check card) after each study visit. The compensation on the ClinCard will be available for use within approximately 24 hours of the study visit.

K. Bibliography

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