STUDY PROTOCOL

IRB-approved Study Protocol (including statistical analysis plan)
WCG IRB Tracking #: 20244449
Columbia IRB #: AAAV1378

Title: Zero Suicide Implementation and Evaluation in Outpatient Mental Health (R56)

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Scientific Abstract:

The aim of this study is to develop a manualized suicide prevention intervention to improve the retention and engagement of suicidal clients. (For the purposes of this proposal, engagement is defined as return to treatment after the initial session and retention as treatment attendance in an ongoing manner.) In the prior grant received by the investigators (#R01 MH112139) a large-scale project implementing evidence-based suicide prevention practices in 165 outpatient behavioral health clinics in New York State, it was determinedthat several aspects of the Zero Suicide model were successfully implemented but that treatment engagement and retention of acutely suicidal clients was far from optimal. In this study, investigators will conduct qualitative interviews with clients engaged in outpatient behavioral health for suicide-related reasons, as well as outpatient behavioral health staff (peer specialists and clinicians) with experience working with suicidal clients, to determine to determine client, clinician and situational facilitators and barriers of suicidal clients' engagement in ongoing care. Specifically, interviews will assess if the proposed interventions of shared decision-making (SDM), structured phone outreach (SPO) and peer support are acceptable and feasible from both a client and staff perspective and perceived to be effective in enhancing treatment engagement and retention and decreasing suicidal ideation and behavior. The investigators will also conduct secondary quantitative data analyses with administrative data obtained during the previously-funded project to examine characteristics of those who did not engage or remain in treatment and/or had self-harm behavior during the implementation period, to identify clients who may benefit from additional support or assistance at the outset of treatment and during ongoing care. The investigators will use these findings to develop a manualized treatment engagement and retention protocol.

Lay Abstract:

The proposed research project is designed to guide our next stage of research and to refine our understanding of findings from our previously-funded grant, #R01 MH112139 *"Zero Suicide Implementation and Evaluation in Outpatient Mental Health Clinics."* Our prior research successfully implemented Zero Suicide clinical procedures in outpatient behavior health but demonstrated poor client retention. In this project, we hope to improve client engagement and retention. We will conduct qualitative interviews with clients who enrolled in outpatient behavioral health treatment for suicide-related reasons (either currently or previously enrolled), as well as clinicians and peer specialists with experience working with clients enrolled for suicide-related reasons. Qualitative interviews will explore their experiences with outpatient treatment for clients enrolled for suicide-related reasons, and feedback on approaches to enhance client engagement and retention.

Organizational structure of the multicenter project. This project uses the Multiple Principal Investigator mechanism with two Principal Investigators (PIs). Originally, the two PIs were Drs. Barbara Stanley and Christa D. Labouliere. When Dr. Stanley passed away in late January 2023, Dr. Lisa Dixon became a new MPI alongside Dr. Labouliere (effective March 2023); prior to this time, Dr. Dixon was already an active co-investigator on the grant. *Columbia University is the Lead Institution for this grant*, where Dr. Dixon is CU faculty. As MPI and contact PI, Dr. Dixon will serve as MPI and contact PI for the grant, and will be responsible for oversight and coordination of all team members across institutions. *There are two additional sites participating in the project: the Research Foundation for Mental Hygiene, Inc. – New York State Psychiatric Institute (RFMH-NYSPI) and Research Foundation for Mental Hygiene, Inc. – Central Office (RFMH-CO) Office of Population Health and Evaluation.* Dr. Dixon will oversee all aspects of the project, including the research activities taking place at other sites.

MPI Plan. Drs. Dixon and Labouliere have collaborated extensively over the past 6 years on the Zero Suicide R01 grant project upon which this R56 is based (R01 MH112139; *"Zero Suicide Implementation and Evaluation in Outpatient Mental Health Clinics"*; PI: B. Stanley). Since 2015, they have worked together closely on the development and dissemination of evidence-based clinical training and implementation assistance at the Center for Practice Innovations. As MPIs on this project, Drs. Dixon and Labouliere will be responsible for direct oversight/coordination of all team members; supervision of research design, conduct, and analysis; and preparation of the treatment manual. Dr. Dixon will be specifically responsible for supervision of Columbia staff, interpretation of study data, and expertise in implementation protocols, whereas Dr. Labouliere will be responsible for implementation of the pilot study, oversight of RFMH personnel, data management, expertise in suicide prevention best practices, and liaising with RFMH-CO to obtain data from administrative databases. The MPIs will be jointly responsible for: data interpretation; manuscript and report preparation; monitoring overall project progress; making major decisions affecting project design and implementation; ensuring adherence to human subjects protection standards and regulations; and maintaining data quality, protection, and compliance with all applicable standards of good research practice. The PIs will meet at least weekly, and decision-making will be by consensus. All PIs will have full access to any data generated by the project. A publication policy will be established to recognize the relative scientific contributions of the PIs and key personnel, and order of authorship will be determined by mutual agreement of the PIs. The PIs will follow the intellectual property policies and practices of their institution, with support and assistance from the applicable technology transfer office.

Role of RFMH-NYSPI. Dr. Christa Labouliere, MPI, will be PI of the subcontract to RFMH-NYSPI and is the Interim Co-Director of the Suicide Prevention –Training, Implementation, & Evaluation (SP-TIE) Program at RFMH-NYSPI, where she is responsible for the design, implementation, and evaluation of statewide suicide prevention efforts with a focus on developing, implementing, and fostering sustainability of evidence-based practices for suicide care. She is also an Assistant Professor of Clinical Psychology (in Psychiatry) at Columbia University. Her experience as project director and co-investigator on the prior grant project upon which this R56 is based makes her well-suited to work with implementation staff at RFMH, NYS Office of Mental Health, Columbia, and all clinical partners. Dr. Labouliere will be responsible for: oversight of all RFMH staff, including supervising qualitative interviews, treatment development, and implementation of the client engagement and retention interventions during the pilot study; site recruitment, including liaising with clinic administrators; coordination of all implementation procedures; and, along with Dr. Dixon, ensuring proper data collection, management, analysis, and interpretation and preparation of manuscripts, reports and presentations at national and international conferences. Dr. Labouliere will oversee: all RFMH personnel; data management, analysis, and interpretation; liaising with RFMH-CO to obtain data from administrative databases; and preparing intervention manuals, progress reports, presentations, and manuscripts for publication.

Role of RFMH-CO. Dr. Emily Leckman-Westin, PI of the subcontract to RFMH-CO, is the director of the New York State Office of Population Health and Evaluation, a co-investigator on this grant, and was an active investigator on the prior grant project upon which this R56 is based. Dr. Leckman-Westin assists with the maintenance of the PSYCKES platform, a Health Insurance Portability and Accountability Act (HIPAA)-compliant, web-based portfolio of tools designed to support quality improvement and clinical decision-making in the New York State Medicaid population. She will assist with recruitment of sites, ensure coordination and alignment between the PSYCKES applications used for acquisition of administrative data, and supervise the development and preparation of the NYS datasets. Data analyst will assist the research team by creating and maintaining databases; assist with data analysis as it pertains to NYS administrative databases; conduct ongoing data quality monitoring and management to ensure project data completeness and timeliness; and ready project data to merge with NYS Medicaid and other state administrative databases in preparation for planned analyses. All RFMH-CO personnel will participate in monthly project meetings, led by Dr. Labouliere.

Study Purpose and Rationale:

Suicide is the 10th leading cause of death in the US, killing more than 48,000 Americans each year (1). US suicide deaths have increased dramatically, a staggering 62% increase over the past two decades (1). While suicide research has made great strides in the development of "best practices" for screening (2), risk assessment (3-4), suicide-specific clinical interventions (5, 6-9), and follow-up protocols (5,10-11), there is a striking gap between assessment and intervention development and the implementation of these practices in typical clinical settings (11,12). Furthermore, very little research has explored if the "best practices" recommended by clinical experts and researchers are deemed feasible, acceptable, or even desirable by clients experiencing suicidal thoughts and behavior.

In our previously-funded grant, #R01 MH112139 *"Zero Suicide Implementation and Evaluation in Outpatient Mental Health Clinics,"* we were able to implement the recommended Zero Suicide clinical practices successfully (e.g., screening, risk assessment, safety planning). However, we found that engaging and retaining high-risk suicidal clients placed on the suicide care pathway in outpatient care was the least successful aspect of implementation. After being identified as at-risk and placed on the suicide care pathway during intake, 36% of suicidal clients did not return to the clinic for a second visit; fewer than 30%of clients received >6 sessions during their 12-week period on the suicide care pathway, and only 2%attended 12 weekly sessions as recommended. Thus, attention to implementing effective engagement and retention strategies is crucial to maximizing the effectiveness of evidence-based suicide prevention. Naturally, evidence-based suicide prevention interventions are effective only if suicidal clients receive a sufficient treatment dose. Unfortunately, once identified as at-risk, suicidal individuals are often difficult to engage in treatment (13). Much of our understanding of what enhances treatment engagement focuses on brief interventions to enhance the transition from emergency crisis care to outpatient care (14,15) or examines which characteristics of suicidal clients are related to treatment drop out (16). Much less is known about facilitators and barriers to treatment engagement and retention of suicidal individuals in ongoing outpatient treatment (17), or staff and organizational approaches that facilitate or impede engagement and retention in outpatient care.

A WHO survey across 24 countries found that client attitudinal barriers were often seen as more critical than structural barriers to treatment engagement (18). The survey found that a desire to handle the problem on one's own (63.8%) was a common barrier to treatment, while perceived ineffectiveness of treatment (39.3%) and negative experiences with treatment providers (26.9%) were the most reported reasons for treatment drop-out. Similar results were found in the National Comorbidity Survey-Replication (19), where a desire to handle the problem on one's own was a commonly cited reason for not seeking treatment (72.6%) and dropping out (42.2%). Additionally, similar attitudes of self-reliance and help negation have been frequently documented among suicidal clients (20, 21).

While client barriers may be a deterrent to treatment engagement and retention, how to overcome these barriers in suicidal clients has received little attention. Ultimately, while there are promising approaches (i.e., structured phone outreach, shared decision-making, and peer support) to improve the treatment engagement and retention of suicidal individuals, these approaches were predominantly developed by clinicians with minimal input from clients themselves.

Relatively few studies have directly asked clients about what they want from mental health services and how these needs could be best met. This project can begin to address how clients enrolled in behavioral health care for suicide-related reasons view barriers and facilitators to treatment and what factors they perceive, both within the traditional treatment and other approaches, can prevent suicidal behavior and decrease suicidal thoughts and urges. Specific aims and hypotheses are as follows: **Aim 1: To conduct qualitative interviews with clients enrolled in outpatient behavioral health care for suicide-related reasons to determine:**

1. Factors influencing their decision to drop out or remain in care over the three months following admission, including factors influencing the frequency of outpatient visits;
2. Factors they identify as facilitating outpatient engagement;
3. Barriers to engaging in outpatient care; and
4. Alternatives to outpatient care that they consider might be helpful.

Specifically, interviews will also assess if the proposed interventions of shared decision-making (SDM), structured phone outreach (SPO), and peer support are: acceptable; feasible; and perceived to be effective in: 1. enhancing treatment engagement and retention; and 2. decreasing suicidal ideation and behavior. **Aim 2: To conduct qualitative interviews with peer specialists and clinicians with experience working with clients enrolled in outpatient behavioral health for suicide-related reasons to determine:**

1. Client, clinician and situational facilitators of clients' engagement in ongoing care;
2. Client, clinician and situational barriers to clients' engagement in ongoing care.

Specifically, interviews will also assess if the proposed interventions of shared decision-making (SDM), structured phone outreach (SPO) and peer support are: acceptable from both a client and staff perspective; feasible from both a client and staff perspective; and perceived to be effective in: 1. enhancing treatment engagement and retention; and 2. decreasing suicidal ideation and behavior. **Exploratory Aim 3:** To identify, via an inductive approach, potential mediators of treatment engagement and retention associated with greater acceptability and perceived effectiveness (e.g. Clients: increased autonomy, sense of validation/empathic understanding, and social support; decreased stigma and logistical barriers; Staff: decreased clinician workload burden; increased collaboration/rapport, validation/empathy, knowledge and self efficacy for treating suicidal clients). **Aim 4:** To conduct secondary quantitative data analyses with administrative data obtained during our currently funded project to examine characteristics of those who: a. did not engage in treatment; b. did not remain in treatment (retention); and c. had self-harm/suicidal behavior during the implementation period. These analyses will help to inform strategies to identify clients who may benefit from additional support or assistance at the outset of treatment and during ongoing care. **Aim 5:** To develop a manualized treatment engagement and retention protocol (using data derived from aims 1-4) and conduct a pilot study to assess the protocol's: a. feasibility and acceptability to clients and staff (peer specialists and clinicians), and b. preliminary effectiveness, as indicated by client satisfaction and engagement.

Please note that this IRB protocol will only cover Aims 1-3 of the proposed project. Data for aim 4 was previously collected as part of the original project (R01 MH112139, *"Zero Suicide Implementation and Evaluation in Oupatient Mental Health Clinics"*), designated by NIH and the NYSPI IRB (#7356) as not human subjects research pursuant to 45CFR46.102(e). Activities for Aim 5 will be covered as a separate IRB protocol, as data from Aims 1-4 is needed to develop and adequately describe the intervention to be piloted in aim 5.

Study Design:

The investigators will conduct qualitative participatory research that explores preferences for mental health treatment, how treatment engagement and retention can be improved, and perceptions of current suicide prevention efforts. One-time qualitative interviews will be conducted with participants from two stakeholder groups: 1) clients receiving outpatient behavioral healthcare for suicide-related reasons and 2) outpatient behavioral health staff (peer specialists and clinicians) working with suicidal clients. Research will be non-interventional, non-randomized, descriptive qualitative research. The results of these interviews will be used for developing a treatment engagement and retention approach.

Prior to conducting interviews, interview guides will be developed based on topics of interest and will be reviewed and revised by a steering committee formed in the initial stage of the project. The investigators will recruit participants for qualitative interviews from programs that participated in the previously-funded project. Potential client participants will be recruited if they received suicide-related outpatient behavioral health care at a clinic that participated in our original project, while potential behavioral health staff (clinicians and peer specialists) will be recruited if they worked at any clinic that participated in the original project. Potential participants can have been affiliated with clinics either during the duration of the original project (2017-2019) or any time since, as suicide-safer care practices were maintained in clinics after their study participation ended. For potential client participants, a brief phone screen assessing inclusion/exclusion criteria will be administered; to ensure safety, callers' contact information and location will be requested at the beginning of the call and all callers will be briefed as to limits of confidentiality, including noting that interviews will be recorded and the researchers' obligation to ensure safety in the case of imminent risk. All potential participants (clients and staff) will be provided with further information about the purpose/procedures of the study and any questions will be answered. All potential participants will provide verbal consent before any screening questions are asked and documented informed consent will be provided via a HIPAA-compliant telehealth platform prior to the beginning of the qualitative interview. All interviews will be conducted by trained staff experienced with the assessment, treatment, and management of suicidal thoughts and behavior. The investigators will administer semi-structured qualitative interviews about the participants' experiences with treatment and obtain feedback about approaches to enhance engagement and retention. Data collected will include: demographic information; suicidal thoughts and behaviors in the past 90 days, as assessed by the C-SSRS (client participants only); and client, clinician and situational facilitators and barriers of suicidal clients' engagement in ongoing care, including factors they believe influence suicidal clients' decision to drop out, remain in care, or frequency of outpatient visits. Interviews will also assess aspects of care clients find desirable, inappropriate or undesirable, and/or alternatives to outpatient care that clients consider helpful. Specifically, interviews will assess if the proposed interventions of shared decision-making (SDM), structured phone outreach (SPO) and peer support are acceptable and feasible from both a client and staff perspective and perceived to be effective in enhancing treatment engagement and retention and decreasing suicidal ideation and behavior. All interviews will be transcribed, de-identified and coded by two independent coders. To check reliability of codes, inter-rater reliability will be calculated using kappa-coefficients. Coded NVivo data will then be analyzed through descriptive statistics. Data will be used to develop a protocol to improve treatment engagement and retention for suicidal outpatient clients.

STUDY PROCEDURES

Client participants will complete a qualitative interview with a trained (M.A. or higher) interviewer, assessing:

1. demographic information
2. suicidal thoughts and behaviors in the past 90 days
3. factors influencing their decision to initiate treatment, drop out, or remain in care over the 90-days following admission, including factors influencing the frequency of their outpatient visits
4. factors they identify as facilitating outpatient engagement and/or aspects of care they find desirable
5. barriers to engaging in outpatient care and/or aspects of care they find inappropriate or undesirable
6. alternatives to outpatient care that they consider might be helpful.

In addition to these general prompts, interviews will also describe some promising approaches to improving treatment engagement (structured phone outreach, shared decision making, and peer support) and specifically assess if they are: a. acceptable; b. feasible; and c. perceived to be effective in: (i) enhancing treatment engagement and retention; and (ii) decreasing suicidal ideation and behavior. If recruited from the prior study, client participants will only complete one interview. For clients who are newly entered treatment, we will conduct a second interview at 90 days to get their treatment perceptions.

Clinician and peer specialist participants will complete a qualitative interview with a trained (M.A. or higher) interviewer, assessing:

1. demographic information
2. factors they believe influence suicidal clients' decision to drop out or remain in care over three months following admission, including factors influencing the frequency of outpatient visits
3. client, clinician and situational facilitators of engaging in outpatient care, and
4. client, clinician and situational barriers to engaging in outpatient care

Please note that ALL study procedures in this protocol are conducted remotely via HIPAA-compliant teleconferencing software or web-based platforms, both for participant convenience and also to reduce participant risk of contracting COVID-19.

Research Question(s)/Hypothesis(es):

Aim 1: To conduct qualitative interviews with clients enrolled in outpatient behavioral health care for suicide-related reasons to determine:

1. Factors influencing their decision to drop out or remain in care over the three months following admission, including factors influencing the frequency of outpatient visits;
2. Factors they identify as facilitating outpatient engagement;
3. Barriers to engaging in outpatient care; and
4. Alternatives to outpatient care that they consider might be helpful.

Specifically, interviews will also assess if the proposed interventions of shared decision-making (SDM), structured phone outreach (SPO), and peer support are: acceptable; feasible; and perceived to be effective in: 1. enhancing treatment engagement and retention; and 2. decreasing suicidal ideation and behavior.

Aim 2: To conduct qualitative interviews with peer specialists and clinicians with experience working with clients enrolled in outpatient behavioral health for suicide-related reasons to determine:

1. Client, clinician and situational facilitators of clients' engagement in ongoing care;
2. Client, clinician and situational barriers to clients' engagement in ongoing care.

Specifically, interviews will also assess if the proposed interventions of shared decision-making (SDM), structured phone outreach (SPO) and peer support are: acceptable from both a client and staff perspective; feasible from both a client and staff perspective; and perceived to be effective in: 1. enhancing treatment engagement and retention; and 2. decreasing suicidal ideation and behavior. **Exploratory Aim 3:** To identify, via an inductive approach, potential mediators of treatment engagement and retention associated with greater acceptability and perceived effectiveness (e.g. Clients: increased autonomy, sense of validation/empathic understanding, and social support; decreased stigma and logistical barriers; Staff: decreased clinician workload burden; increased collaboration/rapport, validation/empathy, knowledge and self efficacy for treating suicidal clients).

Statistical Procedures:

To analyze interviews, themes will be derived from interview data using a combination of narrative and directed content analysis (18-19), guided by the "grounded theory" approach described by Strauss and Corbin (20-21). Interviews will be transcribed and coded using NVivo 12 software, allowing for the emergence of new theoretical constructs. A codebook will be developed to derive codes for qualitative interview data (22) within major categories and sub-categories. Initial codes will be revised and refined in an iterative fashion through re-reading of textual data and discussion by the research team. Data that do not fit the categories will be reviewed systematically over the course of the study for the purpose of adding other codes to the codebook, and the final coding scheme will be achieved through consensus. The research team will explore how constructs are related and differ in frequency or meaning across interviews. The validity of our qualitative material will be derived from analytic induction by searching for deviant cases and using the constant comparative method. All coding will be conducted independently in NVivo by two trained research team members and inter-rater reliability will be calculated using kappa-coefficients. We will use an inductive approach to explore and elaborate on factors that influence treatment engagement and retention, and a deductive approach to identify themes related to the acceptability, feasibility, and perceived effectiveness of our proposed approaches (SPO, SDM and peer support). Themes and key findings from inductive approaches (exploration of factors that influence treatment engagement and retention) will subsequently inform the development and selection of our proposed approaches (SPO, SDM and peer support). Specifically, we will use input on the acceptability and feasibility of these approaches to further refine the approaches and their implementation in real world settings. In this manner, qualitative data from inductive and deductive approaches will iteratively inform development and implementation of a manualized treatment engagement and retention protocol.