Study Protocol and Statistical Analysis Plan

Engaging Suicidal Patients in Mental Health Treatment

NCT05021224

May 2, 2025

The full study protocol for this trial is published here:

Khazanov GK, Jager-Hyman S, Harrison J, Candon M, Buttenheim A, Pieri MF, Oslin DW, Wolk CB. Leveraging behavioral economics and implementation science to engage patients at risk for suicide in mental health treatment: a pilot study protocol. Pilot Feasibility Stud. 2022 Aug 13;8(1):181. doi: 10.1186/s40814-022-01131-y. PMID: 35964151; PMCID: PMC9375238.

We report Aim 3 results in clinicaltrials.gov. Thus, the information that follows pertains specifically to study Aim 3 and is reproduced from Khazanov et al. (2022).

Protocol for Aim 3 for the Engaging Suicidal Patients in Mental Health Treatment Study

Aim 3 of the *Engaging Suicidal Patients in Mental Health Treatment* study is a multi-aim, non-randomized feasibility trial in which we rapidly prototyped and tested strategies to optimize engagement by using a series of rigorous, iterative tests.

We will develop preliminary strategies to support attendance at initial mental health visits and iteratively test and refine these strategies through rapid prototyping. Secondarily, we will explore the role of two potential mechanisms, self-regulation and social support, in the use of engagement strategies and attendance at initial mental health visits.

Sample

Each strategy will be tested with approximately 5 patients. All patients must be (1) 18 years and older and able to communicate in English and (2) present with elevated suicidal ideation on item 9 of the PHQ-9 (item score ≥1) completed during a primary care visit. In addition, patients must not (1) currently be experiencing a psychotic episode requiring emergency services and/or precluding their ability to provide informed consent, (2) have a documented diagnosis of dementia in the past 2 years, (3) have primary care provider notes demonstrating that participation is not indicated, and (4) have already received a study engagement strategy following a different primary care visit. We will leverage the infrastructure of the Resource Center to recruit from the pool of patients who were referred for a mental health intake following a positive screen for depression or suicide risk in primary care based on the EHR. This provides a mechanism for recruiting patients while also ensuring that there is appropriate clinical screening and expertise to triage individuals in need of acute services. We anticipate that 25 patients will complete the temporal discounting and social support behavioral task and self-report measures, though additional patients may receive the strategies. Attendance data will be available from any individual who receives a strategy as part of routine care quality assurance.

Procedure

A team of experts in implementation science (*n* = 2), behavioral economics (*n* = 2), suicide (*n*= 2), and primary care and behavioral health (*n* = 4, total *N* = 10) will convene a half-day retreat to guide Aim 3 activities and develop strategies for rapid prototyping. This team will review key barriers and facilitators to attendance at initial mental health visits identified in Aims 1 and 2 and then generate strategies for facilitating treatment initiation that address barriers and leverage facilitators. The EAST framework will guide the selection of strategies (Service et al., 2014). We will also favor simple, established strategies (Mehta, 2018) with freely available resources (e.g., Caring Contacts templates from Now Matters Now) to promote scalability (Center for Health Care Innovation, 2019), but will also consider other potential implementation strategies as indicated (Dopp et al., 2019). We will explore both low- and high-tech (e.g., EHR integration) strategies to maximize relevance across contexts. Based on the literature, previous work, and our conceptual model, we hypothesize that strategies that counteract delayed discounting tendencies (e.g., incentives) and foster emotional social support (e.g., Caring Contacts) will be needed (Comtois et al., 2018).

We will then use rapid prototyping to test and refine the strategies identified by the team of experts (Dopp et al., 2019), a process that has been applied successfully at Penn over the past 6 years (Asch et al., 2014; Asch & Rosin, 2015; Thaler & Sustein, 2009; Whiteside et al., 2014). The goal of rapid prototyping is to determine the best strategies for broader implementation in a subsequent trial. Prototype strategy designs will be validated through rapid-cycle tests in this real-world context and in a manner that is quick and inexpensive. This will allow us to fail fast and learn quickly. As we deploy strategies and learn from our experiences, we will adapt and iterate to refine promising strategies.

Strategies will be rolled out in the PIC Resource Center over 6 months. During this period, strategies will be implemented by an embedded mental health intake coordinator as part of routine care. Consent to receive strategies is, therefore, not required. However, because participants will complete measures assessing acceptability and feasibility of these strategies, as well as temporal discounting and social support, we will employ an IRB-approved modified consent procedure prior to implementing strategies that includes a waiver of *written* consent. The modified consent procedure will consist of (1) a brief description of the study purpose, procedures, and potential risks; (2) notification that the strategy is part of a research project for which participation is voluntary; and (3) instructions on declining further participation. This modified approach will allow us to circumvent potential confounds associated with limiting a trial examining engagement to those who provide active, written informed consent to receive engagement strategies. By waiving the requirement of traditional, written informed consent, we will minimize the likelihood of a biased sample and maximize the validity and generalizability of our results

(Simon et al., 2016; Zelen, 1990). We anticipate that each strategy will be tested with ≥5 patients, but this is flexible; additional tests will be implemented as needed.

Measures

After testing each strategy, we will quantitatively assess patients' perceptions of its feasibility, acceptability, and appropriateness using three brief, validated questionnaires: Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM), that were developed to better evaluate and monitor implementation outcomes (Weiner et al., 2017). Each questionnaire consists of four items (total of 12 items) rated on a 1–5 Likert-type scales ranging from "Completely disagree" to "Completely agree." The total score ranges from 4 to 20 for each measure, with higher scores indicating greater acceptability, appropriateness, or feasibility, respectively. Reliability was demonstrated with Cronbach's alphas of .85 for acceptability, .91 for appropriateness, and .89 for feasibility, and test-retest reliability was demonstrated with correlations of .80 for acceptability, .73 for appropriateness, and .88 for feasibility.

Statistical Analysis Plan for Aim 3 of the Engaging Suicidal Patients in Mental Health Treatment Study

Data analysis plan for primary outcomes: Descriptive statistics will be used to describe feasibility, acceptability, and appropriateness of strategies as assessed with the AIM, IAM, and FIM. We will also use logistic regressions to examine the impact of engagement strategies on attendance at initial mental health visits using attendance information derived from the administrative data (did/did not attend). These analyses will provide us with a preliminary estimate of the effectiveness of each engagement strategy. Finally, we will use descriptive analyses to examine attendance at initial mental health visits. These analyses are exploratory to inform mechanisms to investigate in future trials.

Power analyses: Consistent with recommendations for pilot studies (e.g., Leon et al., 2010), we have not conducted power analyses for Aim 3. We instead focus on exploring the data at this stage, as well as examining the feasibility and acceptability of strategies to support attendance at initial mental health visits. Analyses will be oriented towards identifying promising strategies and mechanisms to focus on in subsequent studies.

References Cited

Asch DA, Terwiesch C, Mahoney KB, Rosin R. Insourcing health care innovation. N Engl J Med. 2014;370:1775. doi: 10.1056/NEJMp1401135.

Asch DA, Rosin R. Innovation as discipline, not fad. N Engl J Med. 2015;373(7):592–594. doi: 10.1056/NEJMp1506311.

Center for Health Care Innovation. 2019; https://healthcareinnovation.upenn.edu/. Accessed 28 Jan 2019.

Comtois KA, Kerbrat AH, DeCou CR, Atkins DC, Majeres JJ, Baker JC, et al. Effect of augmenting standard care for military personnel with brief caring text messages for suicide prevention: a randomized clinical trial. JAMA Psychiatry. 2019;76(5):474–483. doi: 10.1001/jamapsychiatry.2018.4530.

Dopp AR, Parisi KE, Munson SA, Lyon AR. Integrating implementation and user-centred design strategies to enhance the impact of health services: protocol from a concept mapping study. Health Res Policy Syst. 2019;17(1):1. doi: 10.1186/s12961-018-0403-0.

Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. J Psychiatr Res. 2011;45:626–629. doi: 10.1016/j.jpsychires.2010.10.008.

Mehta SJ. Scaling and spreading innovation in health care delivery. Jt Comm J Qual Patient Saf. 2018;44(10):564–565. doi: 10.1016/j.jcjq.2018.07.002.

Service O. Hallsworth M, Halpern D, Algate F, Gallagher R, Nguyen S, et al. EAST: four simple ways to apply behavioral insights. 2014.

Simon GE, Beck A, Rossom R, Richards J, Kirlin B, King D, et al. Population-based outreach versus care as usual to prevent suicide attempt: study protocol for a randomized controlled trial. Trials. 2016;17(1):452. doi: 10.1186/s13063-016-1566-z

Thaler RH, Sustein CR. Nudge: improving decisions about health, wealth, and happiness. Revised and expanded edition. New York: Penguin Books; 2009.

Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, et al. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci. 2017;12(1):108. doi: 10.1186/s13012-017-0635-3.

Whiteside U, Lungu A, Richards J, Simon GE, Clingan S, Siler J, et al. Designing messaging to engage patients in an online suicide prevention intervention: survey results from patients with current suicidal ideation. J Med Internet Res. 2014;16(2):e42. doi: 10.2196/jmir.3173.

Zelen M. Randomized consent designs for clinical trials: an update. Stat Med. 1990;9(6):645–656. doi: 10.1002/sim.4780090611. [DOI] [PubMed] [Google Scholar]