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Suicide Risk Management Protocol for a Randomized Controlled Trial of Cardiac Patients Reporting Hopelessness

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Abstract

Background: Investigators conducting studies that include potentially suicidal individuals are obligated to develop a suicide risk management (SRM) protocol. There is little available in the literature to guide researchers in SRM protocol development.

Objectives: To describe an SRM protocol developed for a randomized controlled trial (RCT) currently enrolling cardiac patients who report moderate to severe levels of hopelessness.

Methods: The SRM protocol identifies suicidal ideation and measures ideation severity through use of the Columbia–Suicide Severity Rating Scale (C–SSRS) risk factor questions. Based on responses, study participants are deemed safe or at low, moderate, or high risk for suicide. The SRM protocol guides research staff through a plan of action based on risk level. The protocol further guides staff through a plan over the course of this prospective study—from hospital enrollment to home-based visits.

Results: Research staff are well-trained to identify suicidal ideation risk factors, initiate specific questioning about suicidal intent, determine level of risk, identify protective factors and a safe environment, and make referrals if needed. Of the 51 patients hospitalized with cardiac disease who reported moderate to severe hopelessness, 43 scored at a safe suicide risk level and eight scored at low risk. Thirty-five of the 51 patients enrolled in the RCT. Of the 35 participants who received home visits to date, there have been three instances of low and one instance of moderate suicide risk. The SRM protocol has been consistently and accurately used by research personnel in both hospital and home settings. One modification has been made to the protocol since study

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This study was approved by the University of Illinois at Chicago Institutional Review Board and Spectrum Health Institutional Review Board. Written informed consent is obtained from the participants of the study. CONSORT guidelines are followed.

The trial was registered at clinicaltrials.gov (NCT03907891); "Reducing Hopelessness Through Enhanced Physical Activity in Adults With Ischemic Heart Disease"; https://clinicaltrials.gov/ct2/show/NCT03907891; date of registration 04/09/19; date first participant enrolled 08/01/19).

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activation, namely the addition of an assessment of counseling history and encouragement of continued counseling. Booster training sessions of research staff will continue throughout the course of the RCT.

Discussion: Use of the SRM protocol identifies study participants who are safe or at risk for suicide in both hospital and home settings, and research staff can refer participants accordingly.

Conclusion: The SRM protocol developed for this RCT can serve as a model in the development of SRM protocols for future research in acute care, community, or home-based settings.

Keywords

hopelessness; protocol; research; risk management; suicide

Suicide is ranked as the 10th leading cause of death for all ages in the U.S., with age-adjusted suicide increasing an alarming 30% from 2000 to 2016 (Hedegaard et al., 2018). Identification of suicidal ideation can occur or be triggered during clinical research. Expressions of suicidal ideation can be found during administration of a research instrument or when a study participant discloses suicidal thoughts during a study interview, intervention, or unplanned contact. Because the safety of participants is of utmost importance in research, personnel must be prepared to evaluate and act on a participant response indicative of suicidal ideation. Investigators conducting research that includes potential suicidal ideation have an obligation to develop and use a suicidal risk management (SRM) protocol. Institutional review boards (IRB) and funding agencies may require an SRM protocol as part of a data and safety monitoring plan.

Suicide screening tools and guidelines are available for the care of patients in emergency (Miller et al., 2017; Posner et al., 2011), hospital (Substance Abuse and Mental Health Services Administration [SAMSHA], 2009), primary care (Diamond et al., 2017; Suicide Prevention Resource Center, n.d.), and community settings (Posner et al., 2011). The Columbia–Suicide Severity Rating Scale (C–SSRS; Posner et al., 2011) and its affiliated Clinical Triage Guidelines (The Columbia Lighthouse Project [CLP], 2016) have been used with research participants in similar settings (CLP, 2019; Mundt et al., 2013; Pumariega et al., 2020). Yet, a significant gap remains in the availability of published SRM protocols for use in suicidal screening of research participants. Such protocols could serve as a model in the development of SRM protocols for future research with a variety of populations, settings, and study designs. This paper describes an SRM protocol developed for a randomized controlled trial (RCT) enrolling cardiac patients with hopelessness.

Methods

Protocol Design

This SRM protocol was developed for an ongoing RCT testing the effectiveness of a motivational intervention for adults with ischemic heart disease who report a moderate to severe level of hopelessness. The protocol was created for use by research staff to assess and safely triage study participants, all of whom are at risk for suicide because of their hopelessness levels. Suicidal ideation is assessed in participants both during their

hospitalization (study enrollment) and at home visits for data collection and the motivational interviewing component of the study intervention. The protocol guides staff through a plan of action based on participant setting.

The SRM protocol incorporates the six screener questions of the C–SSRS (Posner et al., 2011) and its affiliated Clinical Triage Guidelines (CLP, 2016). The C–SSRS, developed by Columbia University, the University of Pennsylvania, the University of Pittsburgh, and in collaboration with the National Institute of Mental Health, is endorsed by the Center for Disease Control and Prevention, the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the World Health Organization (CLP, 2016; Posner et al., 2011;). Based on branching logic, participants respond to two to six C-SSRS questions with "yes" or "no" answers. Hospitalized participants respond to a timeframe of "within the past month." Participants in the home setting respond to "since our last contact with you." Reliability of the C–SSRS has been confirmed in clinical and community settings. The C–SSRS has demonstrated predictive, divergent, and convergent validity and sensitivity to change (Posner et al., 2011).

The RCT and SRM protocols were approved by the sponsoring university and hospital IRBs. Written informed consent is obtained from all study participants.

Procedure

The SRM protocol guides research staff through a plan of action based on the study participant's level of risk (high, moderate, or low) and setting (hospital or home). The SRM protocol is also used if a participant expresses suicidal ideation during unscheduled contact (i.e., during a phone call with study staff). To effectively implement the SRM protocol, research staff are trained to identify suicidal ideation risk factors, initiate specific questioning about suicidal intent, determine level of risk, identify protective factors and a safe environment, and make referrals if appropriate. Documentation of suicidal ideation assessment and any action taken is recorded in the university's secure Research Electronic Data Capture (REDCap) system.

Hospital Setting

Patients who meet the moderate to severe state hopelessness criteria of the RCT (i.e., 1.8 score or higher on the State-Trait Hopelessness Scale [STHS]; Dunn et al., 2014, 2019) are eligible to enroll in the study. Concurrent and predictive validity and reliability of the STHS state ($a > 0.88$) and trait (0.91) subscales were previously established (Dunn et al., 2014). Eligible patients are asked to complete suicidal ideation screening using the C–SSRS, which is administered via interview by a research recruiter and entered into the REDCap system. The recruiter has immediate access to the patient's C–SSRS score, which REDCap calculates in real-time. If a hospitalized patient's response to the C–SSRS results in a high, moderate, or low risk score for suicide, the recruiter notifies the patient's attending nurse. The study's project director and principal investigator (PI) are also notified through an automated, real-time email sent by the REDCap system. In keeping with C–SSRS Clinical Triage Guidelines (CLP, 2016), if a patient scores at high suicide risk, safety precautions are needed and so the research interview is stopped, the patient is excluded from the study so

that attention can be focused on their mental health, and a list of local mental health resources with suicide hotline numbers is provided. If a patient scores at moderate risk, C–SSRS guidelines advise that safety precautions be considered. Moderate-risk patients are provided the resource list and given the option to stop the interview and be excluded from the study. According to C–SSRS guidelines, a patient at low risk should be provided with a behavioral health referral, but safety precautions are not indicated. Low-risk patients are provided the resource list and the study enrollment process continues (Figure 1).

Home Setting

Interviewers collecting data in participant homes are blinded to participants' C–SSRS scores from their hospitalization. Participants are asked to complete the STHS as part of their home visits at 2, 9, and 25 weeks posthospital discharge. Suicidal ideation screening is initiated using the C–SSRS for participants scoring at 1.8 or higher on the STHS. If a participant scores at high risk, the data collector stops the interview, directly addresses the risk with the participant, and informs them that it is best if they withdraw from the study so they can focus on their mental health. The data collector provides the participant with a list of local mental health resources with suicide hotline numbers and assists them in initiating a call to one of the resources. The data collector contacts the participant's designated family member or friend to stay with the participant and then stays with the high-risk participant until they are supervised. If a participant scores at moderate risk, the data collector follows the same processes as described for high risk with the exception that the participant is given the option of remaining in the study. For a participant at low risk, the data collector provides the list of resources and continues with the data collection visit. For participants at any risk level, the project director and PI are notified by a REDCap email. The project director contacts the participant's primary care provider to report a participant scoring at moderate or high risk and the triage steps that were taken (Figure 2).

Nurses delivering the study intervention are blinded to study participants' prior C–SSRS scores. The nurses do not collect data but are trained to assess for signs or symptoms of suicidal ideation in participants. If a participant expresses suicidal ideation, the nurse initiates the suicidal ideation screening using the C–SSRS in REDCap. If a participant scores as high, moderate, or low risk for suicide, the nurse follows the same protocol used by data collectors (Figure 2).

Unscheduled Contact

Unscheduled contact can occur when research personnel call a participant to schedule or confirm a home visit or when a participant calls staff for any reason. If a participant expresses suicidal ideation during unscheduled contact, the staff member will contact the study's project director. The project director will talk with the participant by phone and ask them to complete the C–SSRS. If a participant scores at high, moderate, or low risk, the project director will follow the same protocol used by data collectors and nurses. The study director will read the resource list to the participant and stay on the phone with the participant until they are supervised by a significant other. The resource list is sent by email or postal mail to the participant (Figure 2).

SRM Training

SRM training includes the online video training, self-assessment, and certificate of completion provided by the CLP website (CLP, 2019), in-person training with the project director that includes simulated patient situations, and REDCap system training. Retraining is completed with in-person booster training sessions as needed but occurs a minimum of annually. Study protocol manuals contain detailed SRM training materials, including use of the C–SSRS in REDCap and the document listing mental health resources with suicide hotline numbers.

Confidentiality

For research that includes suicide risk screening, study participants must be informed in the consent document of the screening and the action that will be taken if they are deemed to be at risk for suicide. The limits of confidentiality must be addressed in the participant consent form. Examples of potential wording for a consent form are included in Table 1.

Safety Monitoring of Suicidal Ideation as an Adverse Event

The RCT described here is monitored by a safety monitoring committee (SMC) consisting of members who are independent of the study protocol and represent the interest of study participants. The SMC meets biannually but is convened for any serious adverse event or as needed. For this study, suicide risk at any level (high, moderate, or low) is considered an adverse event, reported to the project director and PI within 24 hours, and shared at biannual SMC meetings. High or moderate suicide risk levels are considered serious adverse events and the SMC is convened within 48 hours. Upon completion of the SMC review of a serious adverse event, the event and any SMC recommendations are reported to the IRBs. Serious adverse events and any IRB-approved revisions to study protocol are reported to the NIH program officer.

Results

Research Staff Training

All research staff have been trained to use the SRM protocol to identify suicidal ideation risk factors, initiate questions about suicidal intent, determine level of risk, identify protective factors and a safe environment, and make referrals. Staff completed the CLP online training and received the certificate of completion, in-person training with simulated patient situations, and training on the use of the C–SSRS using REDCap. Staff were provided copies of the SRM protocol and SRM training materials. Accurate use of the protocol was confirmed through evaluation of in-person, simulated patient situations and review of practice charting in REDCap.

Hospital recruiters have reported a high level of comfort in screening patients for suicide risk due in part to an established suicide protocol already in existence within the hospital. The recruiters described the SRM protocol as comprehensive. They identified the branching logic of the suicide risk questions within REDCap as particularly helpful in directing them to a correct course of action. The recruiters have reported no need for additional training.

Data collectors reported an adequate comfort level in using the SRM protocol after initial training, acknowledging that their comfort level improves with experience. They identified the in-person training with simulated patient situations as the most helpful training component. They suggested additional booster training sessions focus on patients with high and moderate suicide risk, making a practice call to a suicide hotline number, and practicing documentation of the suicide screening and action taken. To address their concerns, one-on-one booster training— provided by one of the study's research specialists (a nurse overseeing data collection)—was held with each data collector and included review of the SRM protocol and role-play scenarios at each suicide risk level. An additional one-on-one session was provided by the research specialist with a focus on patients who screen at moderate and high suicide risk, practice making a call to a hotline number, and charting results and action taken. Since completion of the booster sessions, data collectors report increased comfort in following the protocol for patients at all risk levels.

The nurses completing the intervention and attention control activities for the RCT have reported a high level of comfort with the SRM protocol, attributing this to prior clinical experience using suicide protocols and the training they received for the current study. One nurse—who identified a suicidal ideation statement made by a study participant—followed the SRM protocol accurately in screening for suicide and providing resources when the participant screened at low risk. A group booster session was provided for the nurses by a research specialist (a nurse overseeing the study interventions) with a focus on participants who screen at moderate and high risk and documentation of the screening results and action taken in REDCap. The nurses found the booster training helpful and continue to report a high level of comfort.

Patients Screened for Hopelessness and Suicide Risk Levels

Participant recruitment began in August 2019. Use of the SRM protocol for the RCT has been effective in identifying participants (adults with ischemic heart disease who report hopelessness) as safe or at risk for suicide in both hospital and home settings. As seen in Table 2, of the 98 hospitalized patients who screened for hopelessness to date, 51 reported moderate to severe state hopelessness. Of the 51 hopeless patients, 43 scored at a safe level and eight scored at low suicide risk level. Of the 51 hopeless patients, 35 enrolled in the RCT. Of the 35 participants who have had data collection home visits, there have been three instances of low level and one instance of moderate level suicide risk (one low risk at 2 weeks, two low risk at 9 weeks, and one moderate risk at 9 weeks). Consistent and accurate use of the SRM protocol has been confirmed through monitoring of REDCap data at all time points, random in-person observations of recruiters, and random review of home visit audiotapes (with participant consent).

A Case Leading to SRM Protocol Revision

One modification has been made to the SRM protocol since study activation, based on use of the protocol with the one participant who scored at moderate suicide risk. This participant was a female with a myocardial infarction who screened as hopeless and scored at low suicide risk during her hospitalization. At the time of the low suicide risk score, the attending nurse was notified, and the study recruiter provided the participant with a list of

local mental health resources with suicide hotline numbers. At the 9-week data collection home visit, the participant scored at moderate suicide risk. Following the SRM protocol, the data collector stopped the data collection interview to address the risk with the participant and provided and reviewed the list of mental health resources. However, the participant declined calling a hotline number, stating that she meets with a counselor weekly and had a counseling visit scheduled the following day. The participant was provided the option of leaving the study, but she chose to continue. The SRM protocol was followed throughout the visit. The SMC met within 24 hours and determined the moderate suicide risk—a serious adverse event—was not study related. This case provided a real test of the SRM protocol and after a comprehensive review of the case, the protocol was revised to include the assessment of counseling history. The protocol now reads that for participants scoring at a moderate or high suicide risk during a home visit or unscheduled contact, study staff will assess a participant's counseling history. If there is a history of counseling, the participant will be encouraged to contact the counselor to discuss their suicidal ideation (Figure 2).

Discussion

It is important for researchers to have a plan to assist individuals expressing suicidal thoughts. Without a plan, research staff may not know how to respond to study participants, what resources to provide, or who to call, thus increasing anxiety for all involved during a moment of potential crisis. The SRM protocol has been consistently, accurately, and safely used by research staff for this RCT in both hospital and home settings. Previous research describing the use of the C–SSRS emphasizes the need for ongoing evaluation of the C–SSRS and any associated protocol throughout the course of a study (Interian et al., 2018; Pumariega et al., 2020). The protocol for this RCT is regularly assessed and was modified by adding the assessment of counseling history and encouragement of continued counseling as appropriate. The research team will continue to assess all incidents of suicidal ideation to determine if further protocol changes are needed.

The SRM protocol developed and used for this RCT can serve as a model for other studies in adult populations. Modifications of the protocol would be needed for research that is focused on different populations (such as pediatric participants) or with research in other settings (such as palliative care). For example, parents or guardians may need to be notified if children are involved. More training may be needed in potential abuse situations. Indeed, as the risk increases, more training and resources may be needed. In addition, research collecting anonymous data regarding depression, hopelessness, or other mental health variables would need a modified SRM protocol to focus on providing suicidal ideation resources to all participants. In this instance, resource sheets would need to include a statement about using the referral information provided if a participant is having suicidal thoughts. Researchers administering mailed or self-administered questionnaires need to be mindful about questions related to suicide being embedded in the instrument. Questionnaires need to be reviewed in a timely manner so as not to miss an opportunity to assist an individual who reaches out for help using this mechanism.

The CSSR–S, the suicide risk screening measure of the SRM protocol, has been consistently and accurately used by the study's staff to date. This is similar to previous findings with

adults in outpatient and community settings that has shown successful screening for suicidal ideation in individuals in primary care (Kearney et al., 2015), an outpatient psychiatric clinic (Viguera et al., 2015), outpatients with epilepsy (Hesdorffer et al., 2013), neuropathic pain and fibromyalgia (Pereira et al., 2013), and university students (Blasco et al., 2019). The FDA has emphasized the importance of suicidal ideation assessment in clinical drug trials (U.S. Food & Drug Administration, 2012). Although the CSSR–S has been widely used in clinical drug trials since 2012, information regarding SRM protocol development for research is limited.

Conclusion

The SRM protocol developed for this RCT can serve as a model in the development of SRM protocols for future research with a variety of populations, settings, and study designs. With suicide incidence increasing, it is imperative that researchers have a well-founded and adaptable protocol to guide staff in assisting study participants in an effective and timely manner.

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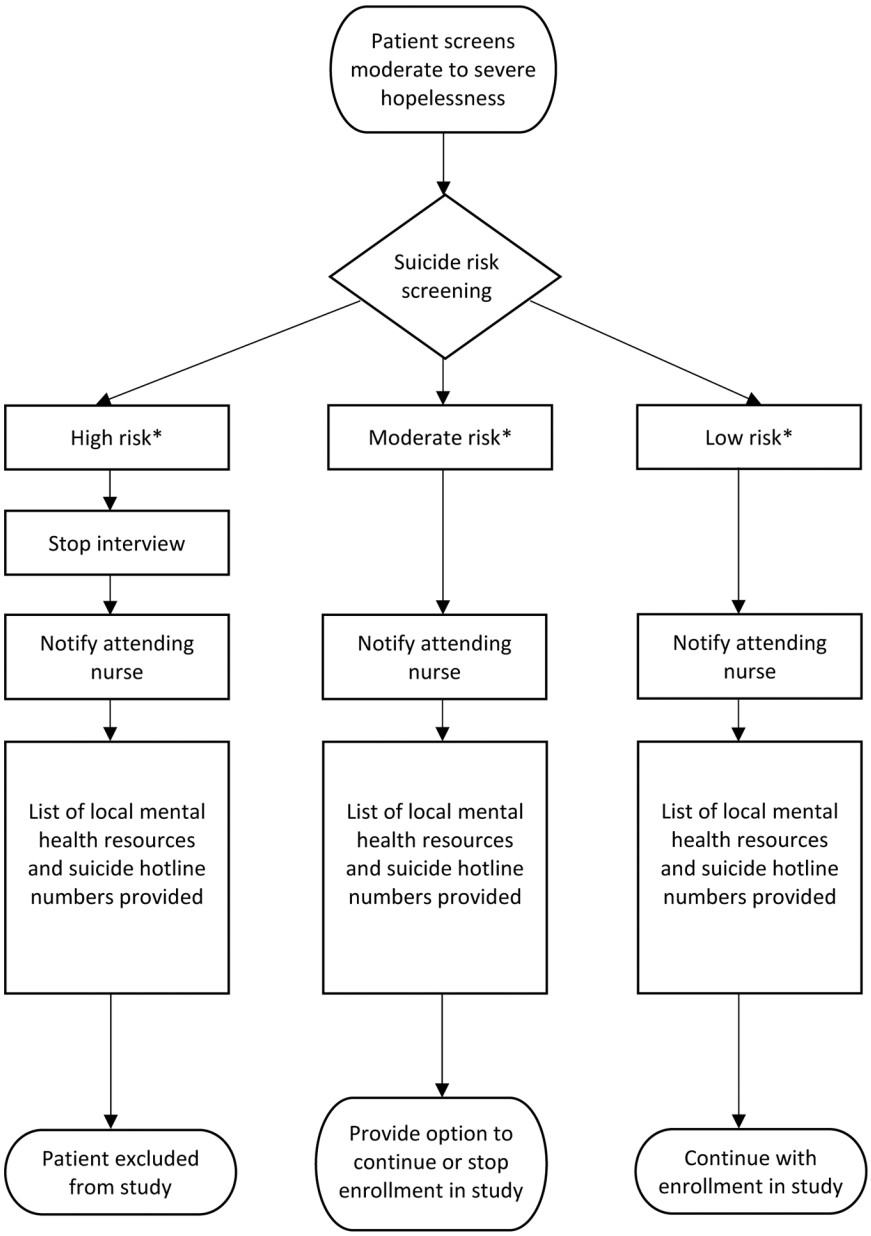

Figure 1.
Flowchart of Suicide Risk Management Protocol in the Hospital Setting

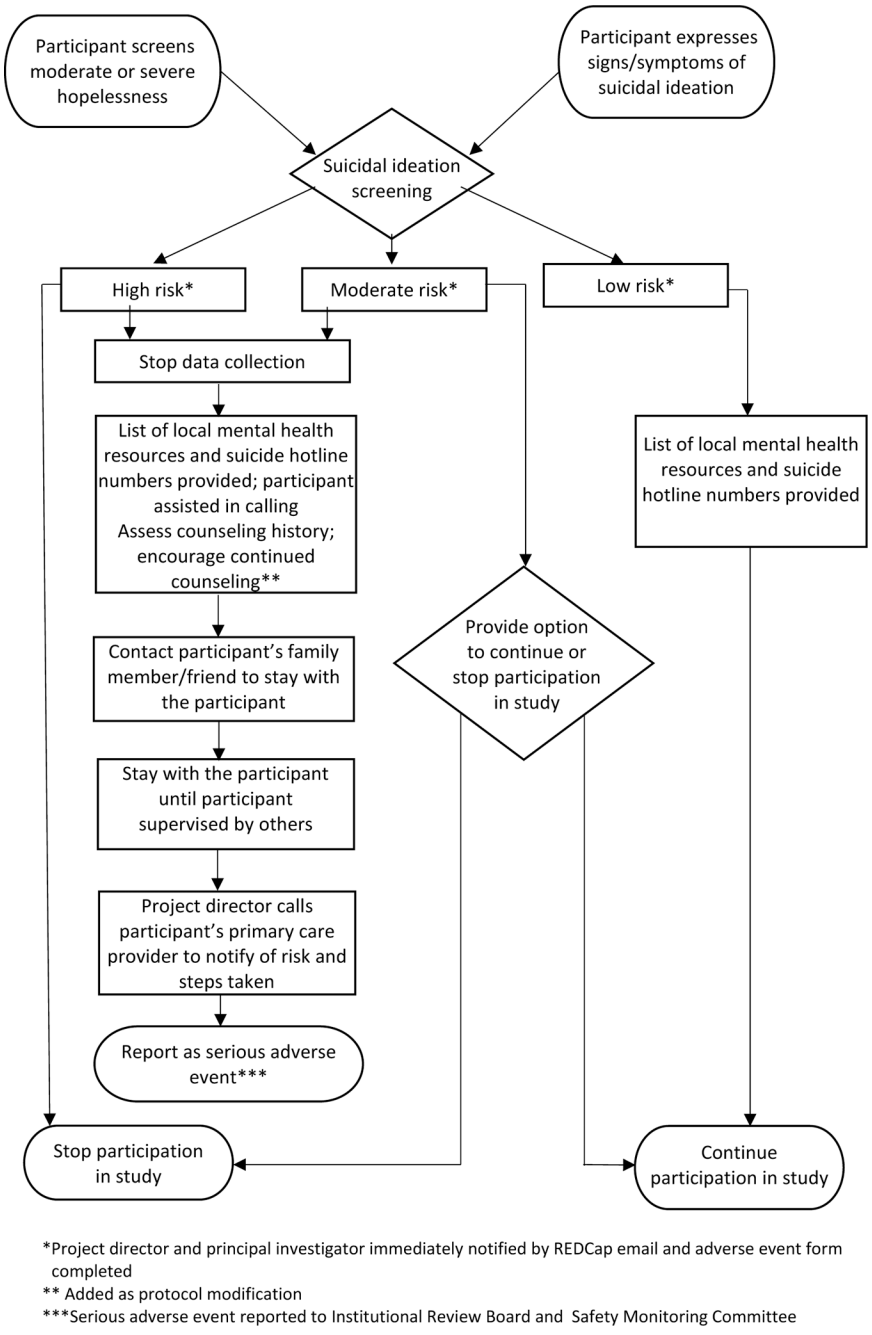

Figure 2.

Flowchart of Suicide Risk Management Protocol in the Home Setting: Scheduled and Unscheduled

Table 1

Sample Wording for Informed Consent Document

Beneficence: • To ensure the safety of yourself and others, state law requires that if you are at immediate risk of harm to yourself, including risk for suicide, we must contact your designated family member/friend, primary care provider, or emergency services staff. • In the event that you answer yes to questions about having thoughts about harming yourself, or you tell the research staff that you have thoughts of harming yourself or suicide, the staff will ask you more questions about these thoughts. Depending on your answers to these questions, the research staff may contact your designated family member/friend, primary care provider, or emergency services staff.
Confidentiality: • The research staff may not be able to keep confidential any disclosure or endorsement of thoughts to harm yourself or suicide.

Table 2

Number of Patients Screened for Hopelessness and Suicide Risk Over Study Time Points

	Screening for Hopelessness		Suicide Risk Status			
Study Time Point* (Location)	**Screened**	**Reported Moderate to Severe State Hopelessness**	**Safe**	**Low**	**Moderate**	**High**
Enrollment (hospital)	98	51**	43	8	0	0
Week 2 (home)	26	18	17	1	0	0
Week 8 (home)	24	17	14	2	1	0
Week 24 (home)	1	1	1	0	0	0

Note.

*No suicidal ideation was identified during unscheduled contact with participants

**35 of 51 hopeless patients enrolled in the study