Cognitive Reappraisal Intervention for Suicide Prevention (CRISP): An Intervention for Middle-Aged and Older Adults Hospitalized for Suicidal Ideation or Suicide Attempt

Weill Cornell Medicine; NCT 03026127

Operations Manual
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BACKGROUND

Suicide rates in middle-aged and older adults are alarmingly high, and suicide risk increases for those who have been hospitalized for suicidal ideation or suicide attempt. Reducing suicide rates in at-risk populations is a major NIMH priority. To address this need, we developed Cognitive Reappraisal Intervention for Suicide Prevention (CRISP) to help middle-aged and older adults (50 years old and older) reduce their suicide risk after a suicide- related hospitalization.

CRISP draws on recent advances in affective neuroscience and aims to improve cognitive reappraisal ability (i.e. the ability to modify the appraisal of a situation to alter its emotional significance) and reduce suicide risk. Our conceptual framework is based on the premises that: a) suicidal ideation and behavior are associated with unsuccessful attempts to regulate intense negative emotions, including depression, anxiety, hopelessness, irritability, anger, and guilt; b) cognitive reappraisal is an effective emotion regulation strategy with identified and investigated neurobiological correlates; c) decreased cognitive reappraisal is associated with increased suicide risk; and d) cognitive reappraisal strategies can be effectively used to reduce suicide risk in our population. We place emphasis on suicidal ideation, in addition to suicidal behavior, because suicidal ideation after a suicide-related hospitalization is a known significant risk factor for suicide. CRISP also employs environmental adaptations/aids to assist patients in utilizing CRISP techniques between sessions (WellPATH personalized tablet app, written step-by-step plan, phone calls). We focus on the first 3 months post-discharge from a suicide-related hospitalization, a period of high suicide risk.

Behavioral interventions for middle-aged and older adults with depression and suicidal ideation are scarce. This project aims to meet the needs of middle-aged and older adults who have been discharged after a hospitalization for suicidal ideation or suicide attempt with any depression or anxiety disorder. We exclude bipolar patients in mixed, hypomanic, or manic state, and patients with psychosis or dementia. Regulation of emotions associated with mixed, hypomanic and manic state may need different techniques than those covered in CRISP.

Consistent with the NIMH *Strategy 3.1*, CRISP is a novel intervention on a mechanism of action, cognitive reappraisal, to reduce suicide risk. In response to NIMH *Strategy 4.3,* The WellPATH app is an innovative tablet application with personalized cognitive reappraisal techniques to improve cognitive reappraisal and potentially reduce suicide risk. Finally, CRISP's use of cognitive reappraisal, application to cross-diagnostic categories and use of two different levels of analysis are consistent with NIMH's RDOC initiative.

Middle-aged and older adults, who have been hospitalized for suicidal ideation or suicide attempt, are an at-risk and understudied population. If effective, CRISP may

decrease suicide risk, reduce depression, and improve quality of life for this vulnerable group.

STUDY AIMS

The goals of the study are:
MONTHS 1-3:

1. Finalize the CRISP Manual and establish feasibility of therapist training. We will train 4 LMSW/LCSWs: 2 will be trained in the CRISP therapy, 2 will be trained in Supportive Psychotherapy. We will determine the success rate of training and number of hours needed to achieve CRISP certification.

MONTHS 4-24:

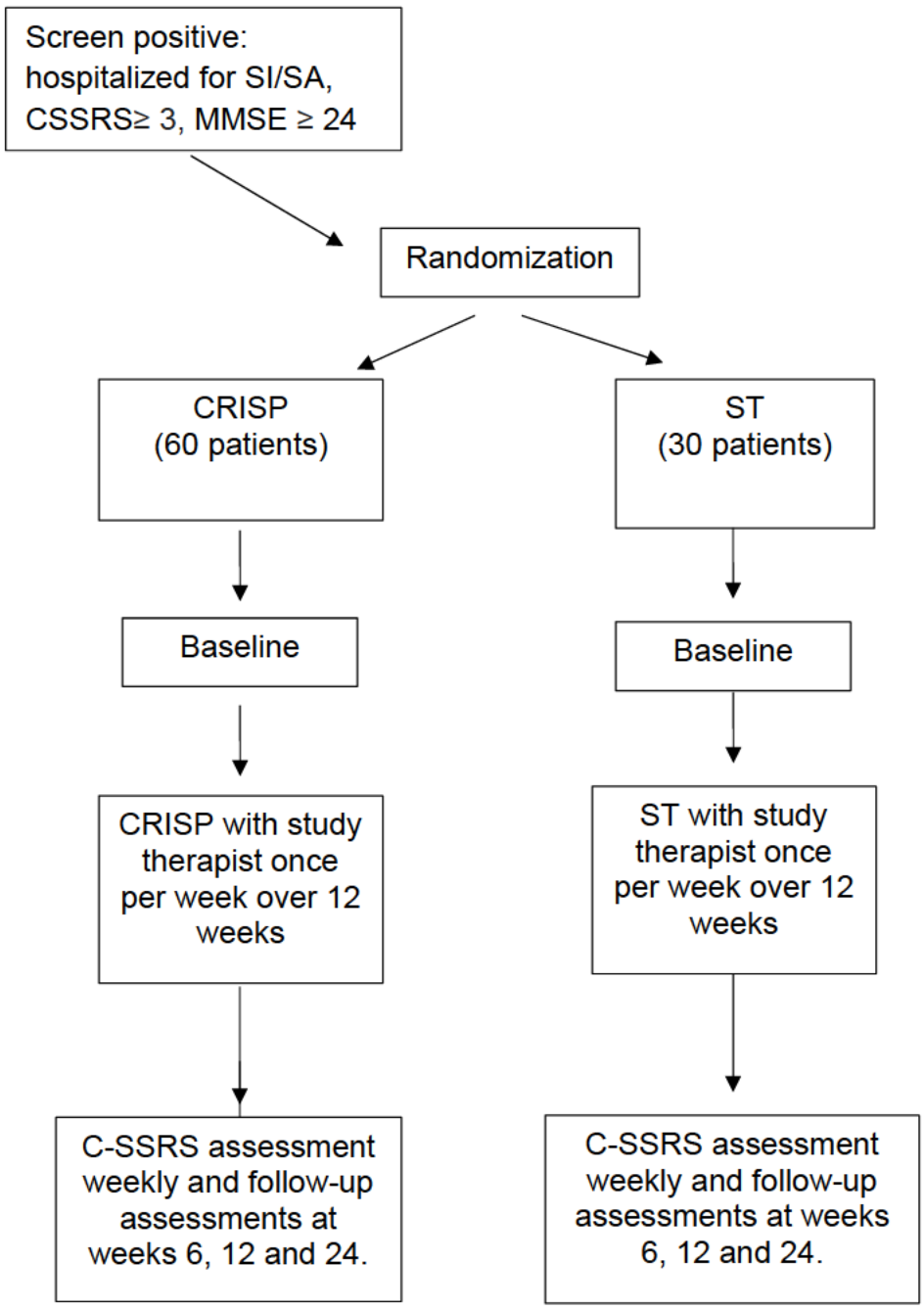
2. Assess CRISP's reach, feasibility and acceptability: We will assess across conditions:
    a. Reach: Number of patients screened, and those who meet inclusion criteria;
    b. Feasibility: Number of patients who receive CRISP or ST for mental health care and research procedures (timely referrals, assessments);
    c. Acceptability: Patient's treatment satisfaction at 6, 12, and 24 weeks.

    Benchmarks of the study progress: Feasibility: At least 75% of CRISP participants will complete CRISP. Acceptability: We will obtain treatment satisfaction scores at the end of CRISP treatment.

3. Preliminary Effectiveness: Over the course of 12 weeks, CRISP participants, compared to participants receiving Supportive Psychotherapy will show an improvement in cognitive reappraisal and have greater (effect size) and clinically significant reductions in suicidal risk.

OVERVIEW OF DESIGN

Figure 1.



RESEARCH ASSESSMENTS

[redacted]

Inclusion Criteria:

1. Age equal to or more than 50 years and up to age 90.
2. Any DSM-5 depression or anxiety diagnosis, including major depressive disorder, bipolar depression, depressive disorder Not Elsewhere Classified, anxiety disorder Not Elsewhere Classified, adjustment disorder with anxiety and depressed mood.
3. Hospitalized for suicidal ideation (either active or passive) or suicide attempt; at hospital admission, Columbia Suicide Severity Rating Scale should greater or equal to 3.
4. Mini Mental State Exam more than or equal to 24.
5. English speaking.
6. Capacity to consent.

Exclusion Criteria:

1. Not having Major Depressive Disorder (by SCID, DSM-IV.)
2. Primary Psychotic Disorder.
3. Currently Hypomanic, Manic or Mixed Episode.
4. Diagnosis of Dementia.
5. Active SI to the point they present as a danger to themselves or others.
    a. *Alert Dr. Kiosses & complete Suicide Risk Assessment.
6. Acute or Severe Medical Illness (i.e., delirium; decompensated cardiac, liver or kidney failure; major surgery; stroke or myocardial infarction during the three months prior to entry).
7. Aphasia, sensory problems and/or inability to speak English.

*Note: Patients on psychotropic medications, opioids or benzodiazepines will be included if they do not meet DSM-5 criteria for opioid, anxiolytics or other substance abuse disorders (Human Subjects).

INTERVENTION

CRISP:
CRISP utilizes a structured, yet personalized, approach. The goals of CRISP are to use cognitive reappraisal techniques to reduce negative emotions associated with self-harm and to increase involvement in meaningful and pleasurable activities. The CRISP therapist uses the following techniques: identification and evaluation of negative emotions and their relationship with patient's difficulties, suicidal ideation and suicidal behavior (e.g. explore utility of negative emotions and change perspective about trigger) and use of a range of emotion regulation techniques (e.g. situation selection, situation modification, attentional deployment, cognitive reappraisal and response modulation). Environmental aids, including a personalized tablet application are used to augment the CRISP intervention. Finally, at the end of treatment CRISP therapists provide to patients a personalized summary of treatment that highlights the problems that were addressed, and the successful techniques that had been used to solve them.

Comparison Condition: **Supportive Therapy:**
ST is a control intervention not aimed to improve emotion regulation, including cognitive reappraisal. The ST therapist strives to create a positive alliance with the patient by emphasizing non-specific therapeutic interactions and techniques that convey to the patient, interest, concern and understanding. For the purposes of this study, an effort will be made to avoid all emotion regulation techniques that relate to Cognitive Reappraisal Intervention for Suicide Prevention (CRISP).

FOLLOW-UP ASSESSMENTS

Follow-up assessments are conducted by the WCM research assistant at 6, 12, and 24 weeks after the baseline and include measures of depression and anxiety symptoms, medical burden, and suicidal ideation. Subjects will receive $50 (cash, check, or gift card) as compensation for completing each assessment. They may also be eligible for up to an additional $10 for one of the EEG computer tasks.

PROCEDURES FOR TREATMENT AFTER STUDY COMPLETION

Participants whose follow-up assessments indicate a need for continued mental health services will be provided with mental health referrals.

DATA MANAGEMENT

Data will be collected by the study RA at baseline and at follow-up assessments. The RA will also be responsible for writing and presenting patient summaries to the PI. The therapist will complete updates on the progress of their therapy sessions. Brian Liles manages the CRISP database and weekly reporting.

Research records will be kept confidential to the extent permitted by law. Subjects will be assigned ID numbers by the CRISP study team, and all identifying information will be removed from records that are submitted to Weill Cornell Medicine for data analysis. Paper research records will be kept in locked file cabinets. When necessary for purposes of auditing, the Cornell IRB, NIMH, and all Federal oversight agencies will be provided access to these files. Computers will be password-protected, and all staff participating in the study will be trained in protecting human subjects in research. Data will be published in aggregate form without unique identifiers. No analyses will be published in which it is possible to identify individuals based on data.