STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

IRB Protocol Title: Study of a Brief Intervention for Hospitalized Veterans

Grant Title: Motivational Interviewing to Prevent Suicide in High Risk Veterans

ClinicalTrials.gov Identifier: NCT01544127

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Specific Aims

Psychiatrically hospitalized Veterans are estimated to be at 40-50 times the risk for suicide than the general population in the year following discharge. [1, 2] Despite their elevated risk, there are no clinical studies testing suicide interventions that are tailored to the population. To initiate a program of research that will address this need, we will conduct a randomized controlled trial (RCT) to examine the efficacy of Motivational Interviewing to Address Suicidal Ideation (MI-SI) plus TAU on suicidal ideation (SI) when compared to TAU alone. The study will include 140 high-risk Veterans who are hospitalized on a VA psychiatric inpatient unit. "High-risk" will be defined as scores over 2 on the Beck Scale for Suicidal Ideation (SSI), which prospectively predicts suicide. [3]

All participants will receive a baseline assessment of SI, suicidal behavior, and risk factors for suicide. Half will be randomized to MI-SI plus TAU and half to TAU alone. Participants in the MI-SI group will receive two sessions of MI-SI during their hospitalization plus one MI-SI telephone booster session in the month following discharge, in addition to TAU. All participants will be asked to complete telephone follow-up assessments at 1, 3 and 6 months after discharge. The primary outcome is change in the severity of SI. In exploratory analyses we will also examine the impact of MI-SI on treatment engagement, and treatment engagement as a mediator of the impact of MI-SI on change in the severity of SI.

The impact of the intervention on suicide risk during hospitalization is also of critical importance. In exploratory analyses, we will examine the effect of MI-SI on the severity of SI during the inpatient stay. Additionally, MI has been found to impact clients' in-session talk about making changes, which is associated with treatment outcome. In participants who receive MI-SI, we will examine the impact of in-session living talk (or talk associated with interest in living) and suicide talk (or talk associated with interest in suicide) on the severity of SI during hospitalization.

Aim 1: To conduct a randomized controlled trial (RCT) of 140 participants who are at high-risk for suicide. Participants will be randomized to receive MI-SI plus TAU, or TAU alone.

Aim 2: To evaluate whether MI-SI plus TAU results in significant reductions in suicidal ideation (SI) and increases in treatment engagement when compared to TAU alone.

Primary Hypothesis: Participants who receive MI-SI plus TAU will report greater reductions in SI over follow-up, than participants who receive TAU alone.

Exploratory Hypothesis 1: Participants who receive MI-SI plus TAU will engage in more treatment over follow-up than participants who receive TAU alone.

Exploratory Hypothesis 2: Treatment engagement over follow-up will partially mediate the impact of MI-SI on SI.

Aim 3: To evaluate improvements during hospitalization.

Exploratory Hypothesis 3: Participants who receive MI-SI plus TAU will report greater reductions in SI during hospitalization, than participants who receive TAU alone.

Exploratory Hypothesis 4: In participants who receive MI-SI plus TAU, in-session living talk will be positively associated with reductions in SI during hospitalization.

Exploratory Hypothesis 5: In participants who receive MI-SI plus TAU, in-session suicide talk will be negatively associated with reductions in SI during hospitalization.

Findings from this RCT will set the stage for an RCT to test the efficacy of MI-SI on risk for suicidal behavior in high-risk Veterans, and future studies exploring the mechanisms by which MI-SI may work. Findings will also contribute to the development and implementation of other suicide interventions that target the needs of high-risk Veterans and the implementation of efficacious suicide interventions across VA.

Background and Significance

Psychiatrically Hospitalized Veterans are at High-risk for Suicide. Psychiatric disorders are known to increase risk for suicide in the general population, [4-7] as well as in Veterans. In a study integrating VA medical records with National Death Index (NDI) data, depression, substance use disorders, post-traumatic stress disorder, other anxiety disorders, bi-polar disorder and schizophrenia were shown to increase risk for suicide in Veterans. [8] General population studies indicate that the months following discharge from psychiatric hospitalization are particularly high-risk periods for individuals with psychiatric disorders, [9-12] and these findings have been replicated with Veterans. In a prospective study of psychiatric inpatients from 128 VAMCs, the suicide rate in the year following discharge was 445/100,000, [1] over 40 times the rate in the general population (11/100,000). [13] Nearly half (46%) died within 3 months of discharge underscoring that the initial months are a period of great risk for Veterans. Factors associated with suicide included major depression, substance abuse, and post-discharge treatment engagement. [1] In a study of depressed Veterans who received treatment from VA, [2] the suicide rate in the 12 weeks following hospitalization was 568/100,000, almost five times the rate of Veterans who received outpatient treatment for depression (114/100,000), [2] and 50 times the rate in the general population (11/100,000), confirming the need for preventive interventions for this population.

Existing Interventions Are Inadequate for this Purpose. Existing interventions may not meet the immediate needs of psychiatrically hospitalized Veterans. Most Cognitive Behavioral Therapy (CBT) interventions that have been tested fall into the categories of Cognitive Therapy (CT), Dialectical Behavioral Therapy (DBT), and Problem-Solving Therapy (PST). [14] In general, suicidal behavior is conceptualized as a maladaptive coping strategy and patients are taught problem-solving and coping skills. CT for suicide prevention plus intensive case management plus treatment as usual (TAU) has been shown to reduce suicide attempts when compared to intensive case management plus TAU. [15] DBT has also been found to reduce suicide attempts in comparison to TAU and therapy by experts. [16-18] Although PST has been shown to reduce depressive symptoms, [19] it was not found to reduce suicidal behavior in a meta-analysis. [20] In their current form, CT for suicide prevention and DBT are too intensive to deliver during acute inpatient hospitalization. The average stay on the acute inpatient unit at the Syracuse VAMC is approximately 9 days; CT for suicide prevention lasts ten sessions, and DBT consists of two sessions a week for a year. Thus, research examining the efficacy and effectiveness of brief interventions for psychiatrically hospitalized Veterans at high-risk for suicide is needed.

Motivational Interviewing to Address Suicidal Ideation (MI-SI) is Promising. Motivational Interviewing (MI) is a clinical approach that was originally developed to help motivate patients to change hazardous drinking behavior. It is defined as a "a client-centered, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence," [21] Hypothesized to work through interpersonal and behavioral pathways, [22] MI provides patients with an empathic relationship that helps them feel understood and supported. However, it is also directive in that clinicians actively elicit and reinforce change talk, or talk indicating that the patient is thinking about making changes, and commitment talk, or talk indicating that the patient is committed to making changes, which are predictive of reduced post-treatment substance use. [23, 24] MI can also be used to target ambivalence about living and dying that is often observed in individuals who are thinking about suicide [25]. It provides an empathic relationship that increases patients' willingness to openly discuss their thoughts about living and dying, and also provides techniques that can be used to elicit and reinforce living talk (talk indicating that the client is thinking about living), and commitment talk (talk indicating that the client is committed to living or

trying to make life worth living), thereby reinforcing patients' wish to live and engage in life sustaining and enhancing behavior.

Resolving ambivalence about living and dying may be critical to reducing risk for suicidal behavior. In their conceptualization of SI, Kovacs and Beck wrote that the "overt suicidal act is viewed as the outcome of the internal subjective struggle between the wish to live and the wish to die, rather than the consequence of a single unidirectional motivation. [26] Research testing this hypothesis has used an index of the ratio of the wish to die to the wish to live that was created with items from Beck's Scale for Suicidal Ideation (SSI). [27] Outpatients whose wish to die outweighed their wish to live made more severe attempts [26] and were more likely to die by suicide. [28] Conversely, individuals whose wish to live outweighs their wish to die may be less likely to think about suicide, and subsequently engage in suicidal behavior. [25] They may also be more likely to engage in life sustaining and enhancing behavior such as mental health and substance abuse treatment. [29]

MI-SI's focus on resolving current SI makes it a promising addition to the VA suicide prevention strategy. In general, the VA strategy is based on using a suicide risk assessment to identify high-risk Veterans, mandating the use of a Safety Plan to identify warning signs and coping skills that can be used to reduce risk, and using Suicide Prevention Coordinators to oversee the care of high-risk Veterans. However, the VA does not have a treatment component that directly targets the resolution of current SI, which may impact the effectiveness of the services being offered. Veterans whose wish to die is stronger than their wish to live may not be willing to engage in treatments or services that can reduce their risk for suicidal behavior. For example, the Safety Plan is used to help individuals identify warning signs that indicate increased risk (e.g. physical pain or loneliness) and coping skills (e.g., taking a walk or calling someone) that can be used to reduce their risk. Veterans who want to die more than they want to live may not be willing to develop a Safety Plan or use it to address their warning signs. However, Veterans who want to live more than they want to die may be willing to engage in such activities. MI-SI can be used to explore Veterans' ambivalence about living and dying, and enhance their wish to live and engage in life sustaining and enhancing behavior. Theoretically, MI-SI should therefore complement the Safety Plan and the other components of the VA suicide prevention strategy.

Over 200 RCTs have been conducted using MI, [22] and findings from these studies support its potential as a brief intervention for Veterans at high-risk for suicide. In the most recent comprehensive meta-analysis, an average of two MI sessions was found to have a medium-to-large effect size in the first 3 months after treatment (Cohen's d = 0.77), [30] a period of great risk in psychiatrically hospitalized Veterans. A brief course of MI can be as efficacious as more intensive treatments. In Project MATCH, four sessions of MI yielded outcomes that did not differ from those following twelve sessions of CBT and Twelve Step Facilitation (TSF). [31, 32] MI has been shown to reduce self-injury. In individuals hospitalized for alcohol-related injuries, one session of MI reduced alcohol-related re-injury by almost 50% over 3 years. [33] When added to another treatment, MI has been shown to promote treatment engagement and improve treatment outcome. [30, 34] MI may also be uniquely suited for use with Veterans as it has been found to reduce hazardous drinking in Veterans. [35] It has also been shown to be more efficacious with angry patients than alternative treatments, [31, 32] and anger may interfere with the efficacy of clinical interventions with Veterans. [36] MI-based interventions may also translate to practice within VA as non-research clinicians can be trained to use it effectively. [34]

Study of Speech

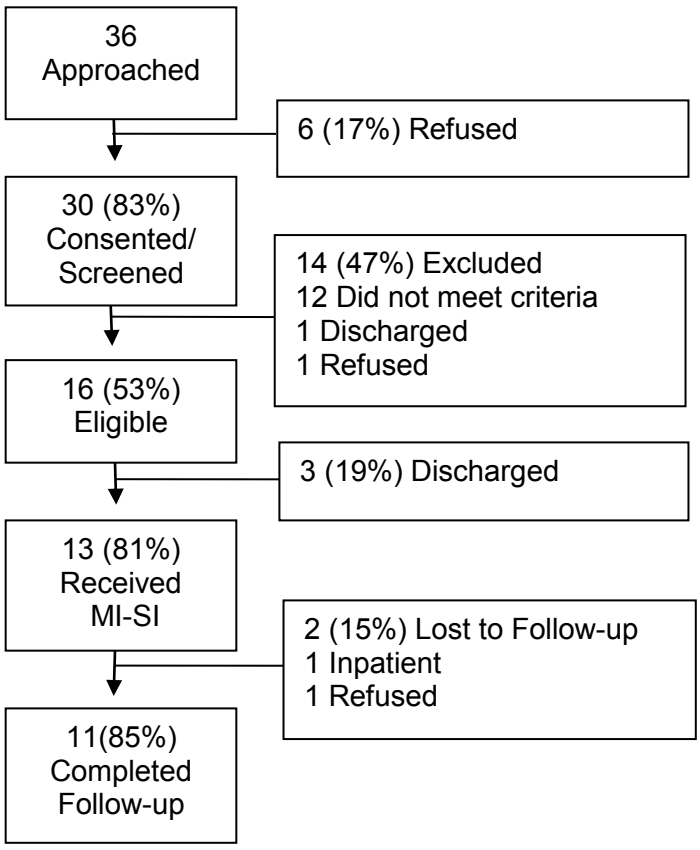
MI theory posits that speech is one pathway through which MI increases clients' motivation to change hazardous behavior. [22] Accordingly, much MI process outcome research examines the impact of clinician and client verbalizations on the outcome of treatment. In studies across problems (e.g., alcohol use, gambling), populations (e.g., adolescents, adults), and treatments (e.g., MI, CBT) change talk (that concerns changing) predicted commitment strength [37] and positive treatment outcomes, [23, 38], commitment strength also predicted treatment outcome. [37, 39, 40] However, counter-change talk (that concerns not changing) predicted negative treatment outcome. [38] Client speech during MI-SI sessions may therefore represent a wealth of information regarding patient risk and degree of improvement. Living talk (that concerns living) and suicide talk (that concerns suicide) that occurs during MI-SI sessions, for example, may be important predictors of treatment outcome. Additionally, the researchers at the CoE are keenly interested in conducting future methodological research on speech and suicide risk and may ultimately examine other aspects of speech (i.e., acoustical).

Summary. Veterans who are hospitalized on Acute Psychiatric Inpatient units are at high-risk for suicide, particularly in the months following hospitalization. MI-SI is a promising intervention to accomplish this because it can be used to resolve ambivalence about living and dying by reinforcing the wish to live, thereby reducing SI and increasing treatment engagement. Moreover, the existing VA suicide prevention strategy does not directly target the resolution of current SI. The proposed study will examine the efficacy of MI-SI on change in SI. It will also explore the impact of MI-SI on treatment engagement and the impact of treatment engagement on change in SI. The study will also provide data for future studies to explore the mediating effects of in-session suicide and living talk, the mechanisms by which MI-SI is hypothesized to work.

Work Accomplished

Pilot Study #1 (MIRB# 00475). We conducted a pilot study to: 1) establish the feasibility of conducting a RCT on the 16-bed acute inpatient unit at the Syracuse VAMC; 2) test the acceptability of MI-SI; and 3) explore the impact of MI-SI on SI and treatment engagement. The study utilized a pre-post design and was approved by the Syracuse VA IRB. Researchers recruited two days a week. Patients who met eligibility criteria (e.g., were permitted to participate by clinicians, from the catchment area, and not psychotic, manic, or demented) were approached. Those who consented completed a screening assessment (e.g., psychosis and mania modules of the Mini International Neuropsychiatric Interview [MINI], [41] Mini Mental Status Exam [MMSE], [42, 43] SSI) [44] to ensure that they were at high-risk for suicide and could engage with therapists in

Figure 2: Study Flow Diagram



MI-SI. High-risk was defined as scores over 2 on the Beck Scale for Suicidal Ideation (SSI), which prospectively predicts suicide. [3] Eligible participants received a baseline assessment, were schedule to complete two MI-SI sessions over three days, a post-treatment assessment, and a 60-day follow-up assessment.

Findings indicated that an RCT is feasible. Recruitment spanned 24 weeks (2/16/2010 to 8/11/2010 with 2 weeks of no-recruiting). Two hundred and eighteen patients were admitted to the unit, 130 (60%) did not meet eligibility criteria, and 52 (24%) were unavailable to researchers as they were scheduled for discharge within 48 hours of identification by study staff. Of the 36 who were approached, 30 (83%) consented, 16 of 30 (36%) had SSI scores over 2, and 3 of 16 (19%) were discharged before receiving the first MI-SI session. Thirteen received MI-SI, for a recruitment mean of 0.54 participants per week. Nine of 13 (70%) completed two MI-SI sessions. Follow-up data was collected for 11 of 13 (85%). One was admitted to an inpatient PTSD unit and was unable to return to Syracuse to complete follow-up. The second withdrew from participating.

All 13 participants were male, average age was 46.77 (10.49), 9 (69.2%) were non-Hispanic white, 7 (53.8%) had seen combat, 8 (61.5%) had a previous suicide attempt, and 5 (38.5%) had more than one. Chart reviews indicated that 11 of 13 (85%) had mood disorders, 10 (77%) anxiety disorders, 7 (54%) substance use disorders, and 2 (15%) attention deficit disorders. All 13 had been engaged in mental health or substance use treatment in the year prior to admission. Findings showed that MI-SI was acceptable to participants. The mean (SD) CSQ-8 score was 3.58 (.40), indicating that they were “3 = mostly” to “4 = very satisfied”.

Findings suggested that MI-SI has promise and is worthy of continued study. Pre-post effect sizes were computed using the formula: $ES = (M_{pre} – M_{post})/SD_{pre}$ (Tables 1 and 2). [45] A standard version (last week) of the SSI was used at baseline and follow-up, and a modified version (past 48 hours) was used at post-treatment. Participants who received MI-SI experienced reductions in the severity of SI, with an effect size of 3.39 from baseline to post-treatment indicating an immediate reduction in SI. The effect size from baseline to follow-up was 1.95, indicating continued reduction. These effect sizes are recognized as clinically significant, [46] and compare favorably to TAU data collected by consultant Dr. Comtois. In a study of 15 participants recruited primarily from inpatient units, with additional patients from the Emergency Department, Consult-Liaison, and Crisis Intervention services from an urban medical center, SSI scores fell 9 points from baseline to 60-day assessment. The reduction was almost half the 17.9-point reduction observed in this study. The percentage of participants whose SSI scores fell below the high risk threshold (< 3) was used to confirm clinical significance. Thirty-three percent of scores from baseline to post-treatment fell below the threshold (< 3), as did 64% of scores from baseline to follow-up. All participants attended one mental health or substance abuse treatment session after discharge. Of the 11 participants with follow-up data, 7 (64%) completed 4 or more sessions, which compares favorably to previously reported rates. [1]

Table 1. Post-treatment Outcomes for MI-SI Pilot Study (N = 9)

Measure	Baseline Mean (SD)	Post-Treatment Mean (SD)	Effect Size	% Below Cutoff
SSI	27.56 (4.88)	11 (10.44)	3.39	33.33 < 3

Table 2. Follow-up Outcomes for MI-SI Pilot Study (N = 11)

Measure	Baseline Mean (SD)	Follow-up Mean (SD)	Effect Size	% Below Cutoff
SSI	23.45 (9.19)	5.55 (9.32)	1.95	63.64 < 3

Pilot Study #2 (MIRB# 00512). Experience conducting the pilot study led to protocol changes that were piloted in a second study. The design of study #2 was identical to study #1 with the following exceptions: the unit was staffed five days a week to reduce the number of patients who were unavailable or scheduled for discharge within 48 hours of identification by study staff, the two MI-SI sessions were completed over two rather than three days to increase the percentage of participants that completed both sessions, and 60-day follow-up assessments were not conducted. Participants were recruited for four weeks from 1/3/2011 to 1/28/2011. Thirty-six patients were admitted to the unit, 22 (61%) were ineligible, and 6 (17%) were unavailable or discharged within 48 hours of identification. These six patients were discharged because they requested release, were transferred for detoxification, or were released because they disrupted the milieu. Of the patients who were admitted to the unit, 8 (22%) were approached and consented, and 2 (6%) met eligibility criteria and completed both MI-SI sessions. Recruiting 5 days a week reduced the number of patients who were unavailable or discharged within 48 hours of identification, and conducted MI-SI sessions on consecutive days increased the percentage of participants who completed both sessions.

Restatement of Aims

Aim 1: To conduct a randomized controlled trial (RCT) of 140 participants who are at high-risk for suicide. Participants will be randomized to receive MI-SI plus TAU, or TAU alone.

Aim 2: To evaluate whether MI-SI plus TAU results in significant reductions in suicidal ideation (SI) and increases in treatment engagement when compared to TAU alone.

Primary Hypothesis: Participants who receive MI-SI plus TAU will report greater reductions in SI over follow-up, than participants who receive TAU alone.

Exploratory Hypothesis 1: Participants who receive MI-SI plus TAU will engage in more treatment over follow-up than participants who receive TAU alone.

Exploratory Hypothesis 2: Treatment engagement over follow-up will partially mediate the impact of MI-SI on SI.

Aim 3: To evaluate improvements during hospitalization.

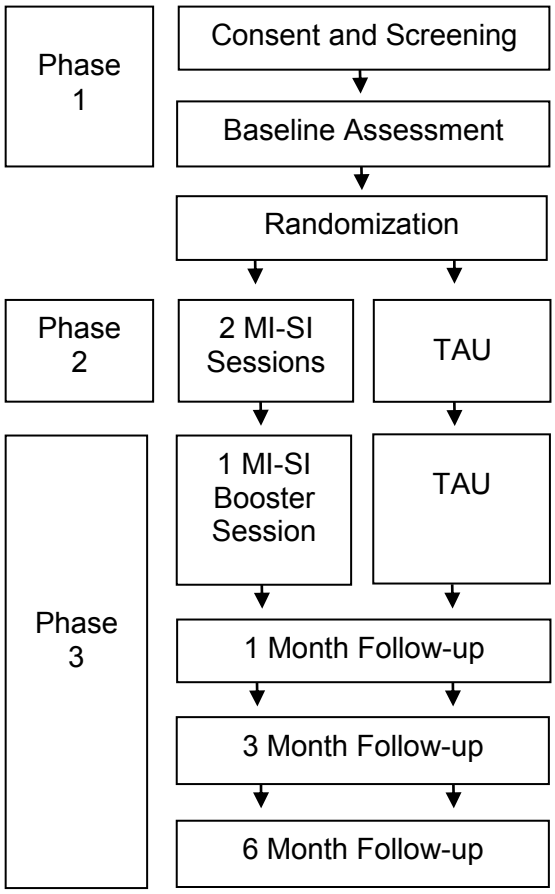
Exploratory Hypothesis 3: Participants who receive MI-SI plus TAU will report greater reductions in SI during hospitalization, than participants who receive TAU alone.

Exploratory Hypothesis 4: In participants who receive MI-SI plus TAU, in-session living talk will be positively associated with reductions in SI during hospitalization.

Exploratory Hypothesis 5: In participants who receive MI-SI plus TAU, in-session suicide talk will be negatively associated with reductions in SI during hospitalization.

Methods

Figure 3: Study Design



Treatment Setting

The study will take place on the 18-bed Acute Psychiatric Inpatient unit at the Syracuse VAMC. In 2009, the previous 16-bed unit treated 498 Veterans, approximately 41 a month, and the average length of stay was 9 days.

Participants

Participants will include 140 Veterans recruited from the Acute Psychiatric Inpatient Unit. Pilot data suggests that we will screen 320 patients to identify 140 participants. A sample size of 140 would provide up to 28 participants for training and piloting, and 112 participants for the RCT. The sample will be predominantly male and white non-Hispanic, though females and minorities will be eligible. [47]

Inclusion criteria. 1) Veteran status, 2) admitted to the unit, 3) age 18 and over, 4) English speaking, 5) able to understand the study and provide informed consent, 6) clinically cleared to participate (e.g., not violent), 7) receiving (or will receive) health care from a VA facility in upstate NY and 8) at increased risk for suicide (SSI > 2)

Exclusion criteria. 1) current psychosis, 2) current mania, 3) dementia, 4) prisoner status, and 5) being inaccessible and discharged from the unit less than 48 hours after being identified by study staff.

Estimated Flow. Pilot data suggests that we can recruit approximately 0.54 participants per week. At this rate, we will recruit an estimated 112 participants in 4 years (208 weeks). Retention at 2 months using face-to-face assessments was 85%. The face-to-face assessment was changed to a telephone assessment to expand the catchment area to improve recruitment and increase retention. Assuming 80% retention at 6-month follow-up, we will have data from 90 Veterans.

General Procedures

Recruitment. Potentially eligible patients will be identified during daily staff meetings. Clinic staff will determine if patients are stable enough to participate and will ask if they are interested in learning about the study. Staff will introduce interested patients to a trained researcher (bachelor's, master's, or doctorate level) who will review the consent form, describe the study in detail, and answer any questions the patient may have in a private setting.

Maintaining Recruitment Log. Researchers will attend morning staff meetings and maintain a log of all participants who are admitted to the unit during recruitment for three reasons: a) to identify potential participants, b) to keep track of who is potentially eligible and has been approached so as not to approach someone who has already refused, and c) to describe participants who are potentially eligible but were discharged before researchers could approach them for consent. The log will be completed during staffing each morning and stored on the unit. A digital log will also be maintained on the T-drive to describe potentially eligible participants who were discharged before they could be approached. The trial will span over 4 years, a paper log will be overly bulky and a digital log will enable us to search for duplicates. The log will be completed during staffing each morning and researchers will not access medical records until informed consent is provided. Only data that is absolutely necessary will be collected in the log, which will never leave the unit. Categories were taken from the 2010 CONSORT Statement [48], and Explanation and Elaboration [49]. The log will include last name and first initial (to ensure that patients are not approached more than once), date of admission, voluntary status, reported SI, whether the individual was approached, why patients were ineligible (e.g., psychotic, manic, cognitive deficits, active duty, outside catchment area, discharged within 48 hours, other), other reasons they were excluded, and whether they were enrolled.

CPRS Notes. After the informed consent process is completed, researchers will enter a Study Initiation Note into the participants' digital medical record. To ensure that mental health staff is aware of patients' participation, the attending psychiatrist and nurse manager of the unit will be added as a signees. They will also be added to MI-SI session noted which will document whether the individual exhibited suicidal ideation, plan, or intent during the session.

Participant Procedures. The study will consist of three phases. Phase 1, the assessment phase (15 min.), will be conducted on day 2 or 3 of hospitalization to confirm eligibility. Eligible participants will immediately complete the baseline assessment of risk factors and outcome variables (50 min.). Phase 2, the treatment phase, will occur between day 2 or 3 and discharge. Participants will be randomized to MI-SI plus TAU or to TAU alone. The MI-SI plus TAU condition will include one or two sessions of MI-SI (50 mins. each) in addition to TAU. Sessions will be held on consecutive days and recorded using a digital audio recorder, which will be coded for clinician fidelity. Phase 3, the follow-up phase, will take place after discharge. Participants in the MI-SI plus TAU condition will complete 1 booster MI-SI telephone session within 1 month of discharge (30-50 min.). All participants will be contacted by telephone to complete follow-up assessments (50 min.) at 1, 3, and 6 months to measure outcome variables and risk factors. Research assistants who are blind to condition will complete follow-up assessments.

Table 3: Complete List of Measures

Domain	Measure	Purpose	Time of Assessment			
			Screen	Baseline	*Follow-ups in hospital	**Follow-ups after discharge
Demographics	UAB	Screen	√			
Veteran Status	UAB	Screen	√			
Psychotic Disorders	MINI	Screen	√			
Manic Episode	MINI	Screen	√			
Cognitive Deficits	MMSE	Screen	√			
TBI	TBI-ID	Screen	√			
Suicidal Ideation (SI)	SSI	Outcome	√		√	√
Depression	PHQ-9	Risk Factor		√		√
PTSD	PCL-C	Risk Factor		√		√
Anxiety	BAI	Risk Factor		√		√
Alcohol Use	AUDIT	Risk Factor		√		√
Drug Use	DAST-10	Risk Factor		√		√
Substance Use Frequency	SUF	Risk Factor		√		√
Substance Problems	InDUC	Risk Factor		√		√
Insomnia	ISI	Risk Factor		√		√
Anger	LHA	Risk Factor		√		
Suicidal Behavior	C-CSSRS	Risk Factor		√		√
Contemplation Ladders	CL	Risk Factor		√	√	√
Treatment Engagement	TSR	Outcome		√		√
Health Care Climate	HCCQ	Outcome		√	√	
Self-Regulation	SRQ	Outcome		√	√	
Competence	PCQ	Outcome		√	√	
Participatory Decision Making	PDM	Outcome		√	√	√

***In hospital follow-ups occur 2-3 days and 3-5 days after baseline assessment**.
****Post-discharge, follow-ups occur at approximately 1, 3, and 6 months.**

Screening Assessment. The screening assessment will be used to confirm eligibility. Current psychosis and mania were identified as exclusionary criteria because they may interfere with the ability of patients to engage in MI-SI. Dementia and TBI-related dementia were included because they also may interfere with the ability to engage in MI-SI. Measures are highly structured and can be administered by a trained research assistant. A study therapist will review all screening assessments and follow up with individuals who do not have a clear presentation to ensure that they are eligible. Measures will include (Table 3):

1. Standard Demographics (9 items): A standard socio-demographic form will be used.

2. Veterans Status (8 items): Items that are used by Center for Integrated Healthcare at the Syracuse VAMC will be used to assess Veteran experiences.

3. Current Psychosis (14 items): Patients identified as currently having psychotic experiences by clinical staff will be excluded from participating. Patients who consent will be

screened for current psychosis using a two-step process. At step 1, the psychotic disorders section of the Mini International Neuropsychiatric Interview (MINI) [41] will be used to assess for current psychosis. At step 2, research assistants will consult with clinical staff to confirm current psychosis, because the MINI current psychosis scale has been shown to be overly sensitive.

4. Current Mania (7 items): Patients identified as currently manic by clinical staff will also be excluded from participating. The manic episode section of the MINI will be used to assess for current mania. The current mania scale has also been found to be overly sensitive, so the same two-step process proposed used to confirm current psychosis will be used to confirm current mania.

5. Dementia (22 items): The Mini Mental Status Examination (MMSE) [42, 43] is a reliable, valid, and widely used screen for dementia. Dementia will be identified by a score of 23 or lower.

6. TBI (7 items): The Ohio State TBI-ID short form is a valid and reliable screen for TBI. [50] TBI-related dementia will be identified by positive screen for moderate to severe TBI and a score of 26 or lower on the MMSE, the conservative cutoff point for the MMSE. [51]

7. Suicidal Ideation (SI): SI will be measured with the Scale for Suicidal Ideation (SSI) [27]. The SSI is an interview that measures the "intensity of the patient's specific attitudes, behaviors, and plans to commit suicide" (p. 4). [44] Participants will be asked about "current" suicidal ideation defined as occurring during the past week (SSI-C),suicidal ideation at its "worst point" in the patient's life (SSI-W) at baseline, and "acute" suicidal ideation in the last 48 hours. The SSI is considered the gold standard measure for SI, has been found to have good internal consistency ($\alpha = 0.84$), construct validity, [52] and predictive validity as scores over 2 are predictive of suicide, [3] and has been used with Veterans. [53] The SSI-C will be used to measure SI the week prior to admission to obtain an accurate measure of SI during the period of acute risk that preceded hospitalization, and to avoid underestimating the severity of SI due to the benefits of hospitalization. The SSI-C is sensitive to change over time in adult clinical samples and will also be used to assess the severity of SI at follow-up assessments. [3]

Baseline Assessment. To describe the sample, all participants will complete the baseline assessment that will include measures of depression, substance use disorders, PTSD, and trait anxiety as they have been found to increase risk for suicide in Veterans, [8] treatment engagement which is associated with suicide after discharge from psychiatric hospitalization, [1] insomnia which may be associated with suicide risk in Veterans, [54] anger is associated with increased suicide risk and may impact the effectiveness of MI based interventions for Veterans, [31, 32, 36, 55] and previous suicidal behavior which is a robust predictor of suicide. [5] Although there are no measures of motivation to live, we are also interested in piloting a motivation to live measure as a potential risk factor. We are also adding three measures that assess mechanisms through which MI-SI may work and therefore serve as short-term outcomes. They will be used to describe the sample and may be controlled for in the analyses if there are differences between conditions.

1. Depression (9 items): The Physicians Health Questionnaire (PHQ-9) [56] is a reliable and valid self-report assessment of depressive symptoms that is used by VA. [57]

2. PTSD (17 items): The PTSD Checklist Civilian Version (PCL-C) [58] is a reliable and valid self-report assessment of PTSD symptoms [59] that is used with Veterans. [60]

3. Anxiety (21 items): The Beck Anxiety Inventory (BAI) [61] is a reliable and valid self-report measure of anxiety.

4. Alcohol Use Disorders (10 items): Alcohol Use Disorders Identification Test (AUDIT) [62] is a self-report measure designed to assess hazardous alcohol use that is reliable and valid in Veterans. [63]

5. Drug Abuse (10 items): A reliable and valid 10-item short-form of the Drug Abuse Screening Test (DAST) [64] will be used to assess non-prescription drug abuse, not including alcohol abuse. The DAST has been used with Veterans. [65]

6. Substance Use Frequency past 90 days / Drug of Choice (12 items): The Substance Use Frequency Form (SUFF) is a measure that was developed by Dr. Conner to assess substance use frequency and drug of choice. It is based on questions commonly used in the substance abuse literature. [66]

7. Drug Use Consequences (15 items): The Inventory of Drug Use Consequences (INDUC) [67] is the gold-standard self-report assessment of substance-related consequences in the past 90 days. It has been used with Veterans. [68]

8. Insomnia (7 items): The Insomnia Severity Index (ISI) is a widely used, reliable and valid self-report instrument of sleep difficulty. [69]

9. Anger (5 items): The Lifetime History of Aggression Questionnaire (LHAQ) is a brief, valid, and reliable measure of aggression [70].

10. Treatment Engagement (26 items): Treatment engagement will be measured using the Alcohol and Drug Services, Medication, Medical Services, and Psychological Services sections of the Treatment Services Review (TSR-6) which have been shown to be both reliable and valid. [71] The TSR-6 will be used at baseline and the 1, 3 and 6 month follow-ups to inquire about use of these services. The baseline assessment will be used to compare engagement in psychological and alcohol and drug service use between groups to assess whether it needs to be accounted for in the analyses. Engagement in psychological and alcohol and drug services will also be assessed at each follow-up assessment and used as an exploratory outcome. Treatment engagement will be treated as a dichotomous outcome, and will be defined according to the Substance Abuse and Mental Health Services Administration (SAHMSA) Washington's Circle standards, [72] which have been adopted by VA. [73] For residential patients and inpatients, treatment engagement is defined as attending two outpatient visits in the 30-days after discharge. In Veterans with substance use disorders, this measure of treatment engagement has been found to be associated with treatment outcome [74] and hospitalization in those with a suicide attempt history. [75] In Veterans discharged from psychiatric hospitalization, completing two outpatient sessions in at least two of the six months after discharge has also been found to be associated with suicide. [1]

11. Suicidal Behavior (18 items): The Colombia Suicide Severity Rating Scale (C-SSRS) [76] will be used to assess history of suicidal behavior at baseline and at follow-up assessment. It has been mandated for use in medication trials by the FDA. [77]

12. Contemplation Ladders (2 items): There are no motivation to live measures in the suicide literature. However, the substance abuse literature has found that contemplation ladders provide valid and reliable measure of motivation to change substance use behaviors [78, 79] We

have created a contemplation ladder that measures the transition from thinking about suicide to thinking about living, and a second that measures the transition from thinking about suicide to engaging in behavior that makes life worth living.

13. Health Care Climate (6 items): The Health Care Climate Questionnaire (HCCQ) is the short form of a measure that assesses patients' perceptions of their healthcare providers, which is based on a longer measure that has been validated in healthcare environments. [105]

14. Treatment Self-Regulation (17 items): The Treatment Self-Regulation Questionnaire (TSRQ) is a measure that assesses patients' sense of autonomy or self-regulation in deciding if they want to live. It is based on a measure that is validated for other weight loss. [105]

15. Perceived Competence (4 items): The Perceived Competence Questionnaire (PCQ) assesses patients' confidence that they can make healthy changes. It is based on a measure that has been used with a number of populations including diabetics. [106]

16. Participatory Decision Making (PDM) (3 items): The Participatory Decision Making (PDM) is a measure of participant decision making. [107-117]

Maintaining Blind Outcome Assessments. In-hospital and post-discharge follow-up assessments will be conducted by research assistants who are blind to condition. The blind will be maintained by having research assistants who are not involved in the baseline and treatment phases of the study conduct the assessment by telephone from the CoE. After each outcome assessment, research assistants will be asked if they thought the participant was assigned to the experimental condition (MI-SI plus TAU), control condition (TAU alone), or don't know which condition the participant was assigned to. They will also be asked how they decided the condition to ensure that the blind was indeed broken and the determination was not due to extraneous information such as positive outcome, which would presumably lead a research assistant to guess the MI-SI plus TAU over TAU alone. If blinding was successful, research assistants will not be able to determine assignment at a better than chance rate. [80]

Randomization. Prior to randomization, participants will be stratified by SSI scores to increase the probability of balanced assignment, which may decrease the probability of a Type 1 error and increase power. [81] Stratification will be based on a median split using data from pilot study #1. Participants who score below 24 will be in the lower SSI group, and those who score 24 and above will be in the higher SSI group. A blocked randomization procedure using block sizes of 4 and 6 participants will also be used to assure no significant imbalance between the numbers of participants in each condition at any time, and to protect against guessing condition assignment. [82] Randomization will occur prior to the start of the trial and the results will be recorded in sealed envelopes. After the baseline assessment, the researcher will choose the next envelope (within the strata and block) to determine the participant's assignment. The researcher will then inform the study therapist that a participant has been randomized to receive MI-SI.

Treatment Conditions. Participants will be randomized to MI-SI plus TAU or TAU alone.

MI-SI. Participants who are randomized to the experimental treatment will receive one or two sessions of MI-SI on the unit (see manual in Appendix). The overarching goal of MI-SI is to shift motivation away from suicide and towards living and recovery. MI-SI consists of three phases: 1) exploring the presenting problem, 2) building the motivation to live, and 3) strengthening the commitment to living. In phase 1, clinicians and patients explore patients' presenting problem and their thoughts about suicide, which amplifies their reasons for living. In

phase 2, clinicians help patients explore their reasons for living including a detailed exploration of their beliefs and values to enhance their motivation to live. In phase 3, clinicians instill hope and strengthen patients' confidence that they can establish a life that is worth living by helping them develop a concrete plan. The plan is written out on a worksheet that is provided to the patient at the end of the session. Transitioning between phases is dependent on the willingness of participants to follow the clinicians' direction, as requiring participants to transition through the phases before they are ready to do so may reduce the impact of MI-SI. For example, requiring patients who are not ready to develop concrete plans to do so has been found to undermine their commitment to follow-through with their plans. [22]

In session 1, clinicians will attempt to proceed through all three phases. In session 2, clinicians will summarize session one and use patients' response to the summary to decide which phase to return to. If patients are in phase 3, clinicians' will help them refine and reinforce their plan. If they are undecided about mental health or substance abuse treatment, clinicians will return to phases 1 or 2 and explore reasons against engaging in treatment, build the motivation to engage in it, and strengthen their commitment to do so. Veterans in the MI-SI condition will also complete one telephone booster MI-SI session (30-50 mins.) within one-month (weeks 3-6) after discharge. Telephone contact within one month after discharge is a component of treatments that have been found to reduce risk for suicidal behavior and will be used to increase the dosage of MI-SI. [83, 84] Participants will be provided a handout with the scheduled telephone follow-up and therapist contact information. Telephone sessions will consist of an abbreviated MI-SI interview following the strategy of session 2. For telephone sessions, phase 3 will include a review of their mental health and substance abuse treatment and explore alternative or additional treatments if they are called for. All MI-SI sessions will also be recorded for coding.

TAU. All patients that are admitted to the acute psychiatric unit receive standard inpatient treatment that includes medication management, case management, meals and a bed, and milieu therapy consisting of creative and social activities (e.g., crafts, video games, karaoke). Families of Veterans may also receive education concerning the Veteran's problems to create a supportive home environment. Suicidal patients receive additional services. VA mental health clinicians are required to complete a Safety Plan with all suicidal Veterans, and each VAMC has hired a Suicide Prevention Coordinator (SPC) to oversee the care of high-risk patients. The Syracuse VAMC also hired Case Managers to help meet essential living needs of suicidal Veterans. SPCs and Case Managers work collaboratively to help suicidal patients transition from inpatient to outpatient treatment. Chart reviews will provide a detailed description of the components of TAU that each participant receives so that suicide-specific TAU can be described in detail. Suicide-related TAU will be controlled for in analyses if differences are observed between conditions.

In-Hospital Follow-ups. These assessments will be conducted 2-3 days and 3-5 days after the baseline assessment, during the course of hospitalization. If patients are discharged during this time, only the first follow-up will be obtained. Participants will be asked to complete a "modified" SI that assesses suicidal ideation over the past 48 hours to assess recent change [85, 86], Contemplation Ladders and the PDM. When it is time to conduct the in-hospital follow-up assessment, a researcher on the unit will call a researcher at the CoE who will conduct the assessment by telephone. This will ensure that outcome assessments are conducted by researchers who are blind to condition.

Post-Discharge Follow-ups. Follow-up assessments will be conducted at 1, 3, and 6 months via telephone. A telephone follow-up will enable us to expand the catchment area and assess

participants who are hospitalized or in residential treatment and unable to return to the medical center. Procedures will include mailing participants the assessment measures to ease administration. There is precedence for this strategy, as the telephone administered SSI was the primary outcome for the PROSPECT trial, supporting use of the method. [87, 88] In addition to the SSI, we will also use all risk-factors measures that are used at baseline including the PHQ-9, PCL-C, BAI, AUDIT, DAST-10, SUF, InDUC, ISI, C-SSRS, Contemplation Ladders, HCCQ, TSRQ, PCQ, PDM as well as the exploratory outcome measure the TSR-6 (Table 3). The window for each assessment will open at the midpoint between the previous assessment and the current assessment, and close at the midpoint between the current assessment and the following assessment (e.g., open two weeks before month 1 and close at the end of month 2, the midpoint between 1 and 3 month assessments), and close 3 months after the 6-month follow-up.

Comprehensive tracking procedures will be implemented to follow-up with participants. Because we found no methodological papers on following-up with Veterans our follow-up procedures were informed by the substance abuse research methodology literature as individuals with substance use disorders are notoriously difficult to follow. [89-91] Procedures were revised after the pilot study. Tracking procedures will include: 1) careful hiring, training, and supervision of study personnel; 2) establishing rapport and clarifying procedures with participants; 3) obtaining detailed identifying information and locator data; 4) obtaining contact information for friends and family members who may assist in locating the participant; 5) remunerating participants for their time and effort; 6) making it easy for participants to contact staff personnel and leave messages; 7) providing assistance to participants when they request it; 8) maintaining flexibility and ease in scheduling and keeping appointments; 9) designing a follow-up assessment battery that is not burdensome; 10) providing a handout with scheduled follow-up assessments and researchers contact information; 11) contacting participants in advance of appointments; 12) making repeated and varied contact attempts; 13) updating contact information regularly using contacts and medical records; 14) and asking for consent to contact VA and non-VA treatment facilities that they may receive care from. The follow-up assessment will be used to measure outcomes and risk factors for suicidal behavior.

At each follow-up we will also inquire about use of the Safety Plan that was completed on the inpatient unit. We will ask 1) if participants remembered doing the Safety Plan, 2) where they keep their Safety Plan, 3) if they used it while having suicidal thoughts, and 4) how they used it.

Chart Reviews. Research assistants will review participants' charts at two points during the study. The baseline chart review will take place after the baseline interview. Research assistants will cull treatment data from VA medical records using a protocol that we have used in a previous study. Center staff has received 8 hours of training in the protocol and achieved inter-rater reliability as part of the previous study. The protocol emphasizes suicidality, service engagement in the past year, services received during the visit prior to hospitalization, and risk factors for suicide such as depression and substance use disorders. Follow-up chart reviews will occur in concordance with the 6-month follow-up assessment. The protocol will be an abbreviated version of baseline protocol, with the time period limited to the 6 months following discharge. The chart review will also be used to assess use of VA suicide prevention services including the Safety Plan, SPCs, High-risk List, and case managers so that we can describe TAU components that participants receive. Center research assistants already trained in the chart review protocol that will be used. If additional assistants need training, we will use the existing training protocol, which consists of 8 hours of training in the protocol and reviewing practice charts.

Research Assistant Training and Supervision. Research assistants will conduct all assessments and receive detailed training and supervision to ensure standardization.

Initial Training. The PI will provide initial training in the detailed interview-based measures. In this initial training, all staff will also receive training in the safety procedures (described in the patient safety section). The interviews contain three measures that require extensive training and supervision to achieve consistency of administration and scoring: SSI, TSR, and C-SSRS. Training for these measures will make use of lectures to learn about the measures and role-plays to reach proficiency. The PI will observe research assistants' first two research interviews to ensure that they are using the instruments appropriately and provide corrective feedback. If indicated, interviews will be observed until proficiency is reached. Training and supervision for each measure are included below. All administrations will be recorded and random samples will be independently coded for reliability. Researchers will use digital recorders on the unit, and earbuds that plug into the recorders for telephone assessments.

SSI training: Dr. Conner has received training from the developers of the SSI, used it extensively, and trained the PI in its administration and scoring. The PI will provide two hours of training for the research assistants.

TSR training: The PI has used the TSR in both pilot studies that were conducted with high-risk Veterans. Research assistants will receive two hours of training for the measure.

C-SSRS training: The PI has received training in the administration and scoring of the C-SSRS from Dr. Posner, the developer of the measure. He will provide two hours of training in the C-SSRS for the research assistants.

Weekly Supervision. The PI will provide weekly supervision for the research assistants and lead a monthly half-day meeting in Canandaigua. The agenda will include a review of participant flow including recruitment, scheduling, and retention of subjects; issues pertaining to administration, scoring, entering, and storing interview protocols; subject safety issues; consensus meetings for SSI ratings; consensus meetings for chart reviews; discussion of adverse events; and on a quarterly basis, reviewing the quality of data gathered. Research assistants will also review one another's interview packets for completeness and errors at these meetings.

MI-SI Training and Supervision. MI-SI will be delivered by masters and doctorate-level research clinicians who will have received specialized training and supervision.

MI-SI Training. Training will consist of sixteen hours. It will consist of 8 hours of training in general MI followed by eight hours of MI-SI training. Training modalities include listening to power-point presentations, selected readings from the MI text [21] and the MI-SI manual (included in Appendix), MI exercises, and listening to and discussing recorded examples of MI-SI. The PI will observe the first two interviews to ensure that therapists meet MITI fidelity criteria and provide corrective feedback. Additional training activities will be scheduled as necessary.

MI-SI Supervision. An RCT evaluating methods for training MI clinicians found that ongoing coaching and/or feedback is needed to maintain proficiency in MI. [92] The PI will provide weekly supervision for MI-SI clinicians, focusing on promoting the fidelity of MI-SI by discussing

difficult cases, listening to and discussing recorded MI-SI interviews, and reviewing MI materials and publications.

Interview Coding and Training. MI-SI sessions will be recorded and coded for fidelity using the MITI, [93] which requires specialized training.

MITI Coding and Training. The MITI is a behavioral coding system that is used to code 20-minute samples of tape for adherence to MI principles (e.g. empathy, autonomy support) and use of specific MI techniques (e.g. reflections, open questions). Summary values from coded interviews will be used to assess fidelity, [94] and provide material for supervisory sessions. A random selection of interviews will be double-coded and inter-rater reliability will be computed using inter-class correlation coefficients. [95]

The PI will provide MITI training to the research assistants who are coding the MI-SI therapy sessions. The protocol that will be used is identical the one use by Kurt Derman, Ph.D., an MI Training expert who trained coders for Project MATCH, [31, 32] and trained the PI. Training will consist of eight hours and include reviewing the MITI coding scale, coding MI interviews and comparing the codes to "gold standard" codes available on the MI website, [96] and coding recordings of MI-SI interviews. Coders will be considered reliable when they achieve reliabilities of good or better (ICC > .60) on 80% of MITI codes. [97]

MI-SCOPE Coding and Training. The Sequential Code for Observing Process Exchanges (SCOPE), [98] will be adapted for use with suicidal clients. SCOPE is a coding scheme developed to examine sequential therapeutic interactions between clinicians and clients to study the psychotherapy process and its relation to treatment outcome. [24] It includes the codes used for the MITI, and additional codes for clinicians (e.g., confrontation, emphasize control, feedback), and clients (e.g., follow, ask, commitment). We will adapt the MI-SCOPE by adding codes for living and suicide talk, and other suicide-related statements. Interviews are transcribed, and both transcripts and audio recordings are used for coding. A random selection of interviews will be double-coded and inter-rater reliability will be computed using inter-class correlation coefficients. [95]

The PI will also provide MI-SCOPE training to the research assistants who are coding the therapy sessions. The MI-SCOPE protocol is identical to that used by the developers of MI-SCOPE. [24] Because the MI-SCOPE is more intensive, training will consist of sixteen hours and include reviewing the MI-SCOPE coding scale, coding MI-SI interviews and comparing the codes to "gold standard" codes that the PI derives. Coders will be considered reliable when they achieve reliabilities of good or better (ICC > .60) on 80% of MITI codes. [97]

Analytical Plan

Data Preparation. All data will be screened for missing data, outliers, non-normality, non-linearity, and non-homoscedasticity. A combination of statistics and graphic representations will be used to complete these screens. Specifically, missing values analyses, descriptive analyses, frequencies, scatter plots and histograms will be used. The assumptions underlying the proposed statistical analyses will also be tested, which may lead to data transformations or the use of more appropriate statistics. Additionally, imbalances in important covariates between randomized groups will be tested at baseline, which may lead to the identification of covariates to be included in the analyses. Findings will be used to fine-tune the analytical plan if statistical assumptions are unmet or model fit is poor. All analyses will be based on an intent-to-treat approach, analyzed as randomized, include all available data, use multiple imputation for missing data if appropriate, and use one-tailed tests with $p < .05$ as the cutoff for statistical significance. The study is not powered to test exploratory hypotheses, and we therefore do not

expect to detect significant differences between groups. If the analyses are reported as part of the primary RCT, we will use a p-value of .01 to define statistical significance.

Aim 2: To evaluate whether MI-SI plus TAU results in significant reductions in suicidal ideation (SI) and increases in treatment engagement when compared to TAU alone.

Primary Hypothesis: Participants who receive MI-SI plus TAU will report greater reductions in SI over follow-up than participants who receive TAU alone.

Primary Analysis 1: An over-dispersion Poisson generalized linear mixed model (GLMM) with maximum likelihood estimation will be used to examine the effect of MI-SI on the severity of SI at 1, 3, and 6 months follow-up. GLMM was chosen because random effects are added to the model to account for repeated measures within subjects. An over-dispersion Poisson GLMM will be used because the SSI is bounded at zero and had a standard deviation larger than the mean at follow-up in our pilot data, indicating over-dispersion. If data do not meet the assumptions of a Poisson distribution, we will use a negative binomial or zero-inflated negative binomial. The benefit of using maximum likelihood estimation is that it yields unbiased estimates in the presence of missing data, if data are missing at random. Because participants may receive one or two sessions of MI-SI, and the change pattern may not be linear over time, we will test sessions of MI-SI, time of assessment, and their interaction in follow-up analyses. As an added measure of clinical significance, we will report the number of participants in each group who fall below the two-point cut-off.

Because the presence of any suicidal behavior (i.e., attempted suicide, interrupted attempts, preparatory behavior) is an important outcome, we will use a mixed effects general logistic model to examine the effect size of MI-SI on the incidence of suicidal behavior as measured by the C-SSRS over follow-up assessments.

Exploratory Hypothesis 1: Participants who receive MI-SI plus TAU will engage in more treatment over follow-up than participants who receive TAU alone.

Exploratory Analysis 1: Multivariable logistic regression will be used to examine the effect of MI-SI on treatment engagement. The Hosmer-Lemeshow statistic will be used to evaluate model fit, and odds ratios with 95% confidence intervals will be derived using the method of maximum likelihood. [99] Because participants may receive one or two sessions of MI-SI, we will conduct a sensitivity analysis examining the number of MI-SI sessions as a predictor of treatment engagement. Because this is an underpowered exploratory analysis, we will also conduct secondary analyses using other definitions of treatment engagement such as number of sessions attended.

We will also examine the impact of the intervention on use of the Safety Plan coping strategies. To test treatment differences, we will use a multivariable logistic regression.

Exploratory Hypothesis 2: Treatment engagement over follow-up will partially mediate the impact of MI-SI on SI.

Exploratory Analysis 2: Analyses will examine treatment engagement as a mediator of the impact of MI-SI plus TAU on SI. Treatment engagement is expected to partially mediate the relationship between randomization to the MI-SI group and SI over follow-up, such that the relationship is smaller but the effect size is still significant. Structural equation modeling (SEM) will be used to examine this potential mediation relationship. SEM is a method for creating latent

variables and identifying and describing causal relationships between the latent variables. We decided to use SEM because it simultaneously tests independent and conjoint relationships and uses latent variables, which minimizes measurement error. The model will consist of both latent and observed variables. Latent variables will be used for variables such as SI (via the SSI) to fit the data for this population. Observed variables will be used for variables such as randomization to MI-SI and treatment engagement (via the TSR). Because these analyses will be underpowered, this exploration will be based on effect sizes rather than statistical significance. Furthermore, we will also conduct more basic mediation regression models as secondary analyses.

Aim 3: To evaluate improvements during hospitalization.

> Exploratory Hypothesis 3: Participants who receive MI-SI plus TAU will report greater reductions in SI during hospitalization, than participants who receive TAU alone.
>
> Exploratory Hypothesis 4: In participants who receive MI-SI plus TAU, in-session living talk will be positively associated with reductions in SI during hospitalization.
>
> Exploratory Hypothesis 5: In participants who receive MI-SI plus TAU, in-session suicide talk will be negatively associated with reductions in SI during hospitalization.

Exploratory Analyses 3-5: Data will be analyzed using GLMM to account for repeated measures within subjects [100] with a focus on within subject decreases in SI (assessed with SSI scores). A minimum of two GLMMs will be used to examine the effect of MI-SI on the severity of SI at 2-3 and 3-5 days after the baseline assessment, the strength of in-session living and suicide talk and the severity of SI at 2-3 and 3-5 days after the baseline assessment. We will also examine the associations between in-session living and suicide talk on the severity of SI over 1, 3, and 6 months follow-up.

Power Analysis: Recruitment will provide data on 112 participants. Assuming a retention rate of 80%, data on 90 participants will be available at the 6 month follow-up. To estimate the statistical power afforded by 90 participants for the severity of SSI, power analyses were conducted using STATA 11 [101] "sampsi2" package, which uses calculations based on Frison and Pocock model. [102] Specifying method of analysis (change), number of baseline assessments (1), number of post assessments (3), correlation between baseline and follow-up scores (r = .50), correlation between follow-up scores (r = .70), and standard deviation (sd = 8.4) for the outcome variable using Frison and Pocock's recommendations and our pilot data, we would have .94 power to identify a 5-point difference in mean SSI scores between treatment arms, .81 power to identify a 4-point difference, and .60 power to identify a 3-point difference. The study would therefore be adequately powered to find an effect size of .5 for the primary outcome. If there is concern that the experimental intervention caused harm and the trial is not stopped, we will conduct two-sided analyses instead of the one-sided analyses we proposed. Power analyses suggest we will have .88 power to identify a 5-point difference, .71 power for a 4-point difference, and .47 power for a 3-point difference with the proposed 90 participants (45 in each group), indicating that the trial will still be fairly well powered.

Data Management, Entry, and Storage

Overview. All data will be collected during in-person interviews in private offices at the Acute Psychiatric Inpatient Unit at the Syracuse VAMC, by phone in a private office at Canandaigua VAMC, or chart reviews that take place in either the Syracuse or Canandaigua

VAMC. The Research Compliance Officer for Canandaigua VAMC will be called when patients are consented and given participants' last name and last four digits of their social security number. Other copies of the consent will be delivered in person or through secure VA mail to the Syracuse Institutional Review Board and Syracuse VAMC Medical Records. Only research staff associated with the study will handle or have access to any of the research data collected for this study. Individuals with access to the data will be persons listed on the IRB-approved study protocol. Once paper consent, interview forms, and electronic digital recordings (digital recording machine) are completed, they will be stored in locked file cabinets in a study-dedicated office maintained by the Center for Integrated Healthcare (CIH) located in the D-wing of the Syracuse VAMC, or by the CoE located at the Canandaigua VAMC. All consent forms will be signed by the PI, or co-investigators Dr. Conner or Dr. Pigeon.

Data from interviews, audio recordings, and chart reviews will be entered into electronic databases from designated offices located at the CIH at the Syracuse VAMC, and the CoE at the Canandaigua VAMC. The study-related research staff or assistants will enter data into a database located in a secure folder on the VISN 2 remote/disconnected "T" drive maintained by the Canandaigua VAMC for use by CoE staff to store all research data. Access to the folder in which the database is located will be restricted to those individuals listed on the IRB-approved study protocol as being associated with this project. Data will be analyzed on the "T" drive as well as the Veteran's Informatics and Computing Infrastructure (VINCI, see http://www.hsrd.research.va.gov/for_researchers/vinci/), a secure workspace for accessing, storing, and analyzing VA data located on VA secure servers behind VA firewalls will be used to analyze the data. VINCI is funded by HSR&D and is a collaboration between the VA Office of Information Technology (OI&T) and the Veterans Health Administration's Office of Research and Development (VHA ORD). VINCI workspaces are supported by server level redundant backup systems and secured behind extensive VA cyber security systems including VPN secured access, VA authentication systems, encryption and firewall. During the analysis phase data will temporarily be copied to secure storage on the VINCI workspace through a secure file copy. VINCI offers a suite of analytical tools including that will be used to produce the analysis. When the analysis is complete, data stored on the VINCI secure workspace will be returned to the "T" drive. When all data are entered, processed, and analyzed, the paper forms and digital recordings will be maintained and/or destroyed in whatever manner is recommended by the Information Security Officer. De-identified data will be stored indefinitely so it can be used in future publications.

Data Collected During the Screening, Baseline, and Follow-up Assessments. To explain in detail, for each participant, there will be three paper packets, a consent file that contains the patient's name, unique participant ID#, other identifying information, and a copy of the consent form, a data file that contains the measures with the unique participant ID# written at the top of each page but no other identifying information that is stored at the Syracuse VAMC, and a second data file from telephone assessments that is stored at the CoE. In this way, sensitive information from the interviews contained in the measures cannot be linked with identifying information unless one has the consent and a data packet.

Data Collected from Audio Recordings. At the beginning of all audio recordings, the investigator will speak the participant's unique ID#, type of session (e.g., MI-SI session #1, one-month follow-up assessment), and the date of the interview. The recording device will be locked in the file cabinet with the paper packets. The recorded information will be copied to a secure server on a password and firewall protected computer and then the data on the recorder will be erased. The recorded data will remain on the server until it is coded and will be erased

according to VA guidelines. Data from coded MI-SI sessions will also be recorded on paper score sheets that will be stored in the participant's packet with the other measures.

Access to Data. Only the research staff collecting data at Syracuse (not staff or patients at the Syracuse VAMC), research staff responsible for coding, entering and analyzing data, along with Dr. Britton will have access to the keys to the cabinets and the password protected computer where data are stored. We will not transmit or share data outside of the VA.

Data Management. Interviewers will visually review all forms for completeness while the participant is in the interview. He or she will discuss any incomplete sections with the participant and encourage completion of the form. Specific forms corresponding to each of the assessment areas (aggression, etc.) will be developed and each page will contain the participant's unique ID# in case pages become detached. A check sheet detailing what needs to be collected during each interview will be kept to ensure data quality. Also, a master check sheet will be developed with a form for each participant to ensure that all procedural requirements (e.g., Consent signed by PI, IRB and Research Compliance Officer notified of new participant, CPRS note entered) are accomplished for each participant.

Data Entry. Once all forms are complete, the interviewer will have his/her packet edited by another member of the study team, and will then enter the data. The system will have appropriate logical and data entry checks built into it to reduce the most common types of data entry errors. The study database will be held on a password protected hard drive that will be backed up weekly. Dr. Britton will define the requirements of the system and maintain or refine the system as needed. Once all information is entered and verified, then the original paper records will be returned to their locked cabinets. Dr. Britton will review the data each month in order to identify any logical inconsistencies or omissions that may have occurred. Any problems will be brought to the attention of the programmer for remediation. All identifying information will be destroyed in consultation with the Information Security Officer (ISO) in agreement with VA policy.

Compensation

Research staff will collect participant's names, social security numbers, and the addresses they wish their reimbursement check be sent to. The information will be shared with CoE support staff, who will instruct accounting to issue a check in the patient's name to be sent to the desired address. Checks will be issued after the patients are discharged from the unit, and after follow-up assessment. Participants who complete the screen will be compensated with a $10 personal check that will be sent to the address of their choice. Patients who meet eligibility criteria and continue through phase 2 and 3 will receive an $80 check for completing each follow-up assessment. Participants who are discharged prior to completing both MI-SI sessions will still be eligible for the follow-up appointment. An $80 remuneration for the follow-up is required to compensate subjects for any expense they have to make the interview, time for the assessment, and as encouragement to maintain contact with the researchers. This level of remuneration is consistent with the minimum recommended amount for retaining subjects in substance abuse treatment research, does not promote substance abuse and is not perceived as coercive by participants [103, 104]. By completing the screen ($10), and the 3 follow-up assessments ($240), participants can earn $250.

Human Subjects

Risk to Subjects

Human Participants Involvement and Characteristics. All participants will be at high risk for emerging suicidality, suicidal behavior, and other negative outcomes. Suicidal behavior is also an outcome and is therefore expected to occur. Safeguards will be built into the study to prevent suicidal behavior before it occurs, and to ensure an appropriate response.

Potential Risks. There are no physical risks in this study. Psychological risks are 1) emerging suicidality, 2) distress caused by the personal nature of the interview, recalling distressing events and life problems, and discussing suicide-related issues, and 3) potential need to break confidentiality in the event of suicide risk or violence risk or child abuse.

Protection from Risk

Suicidality. Participation in the study will provide patients who are at elevated risk for emerging suicidality, suicidal behavior, and other negative outcomes with a formal assessment of suicide risk on the unit and a re-assessment of risk one, three and six months after discharge. Participating in the study will provide more information on patients' suicide risk than would otherwise be available. If the interviewer becomes aware that a participant might be thinking about or planning to make an attempt, the interviewer will ask the following questions: 1) Do you have a desire to kill yourself that you think you might act on? 2) Do you have a plan for killing yourself?, and 3) Do you intend to carry the plan out? After the interviewer has noted any suicide desire, plans, or intent, the interviewer will review available assessment measures that may help evaluate the severity of the participant's risk. If the interviewer determines the participant is at imminent risk, the appropriate safety plan will be initiated.

Inpatient Safety Plan. Baseline and MI-SI interviews will take place while participants are on the unit, ensuring 24-hour availability of hospital staff and emergency services. If patients are determined to be at imminent risk for suicide, the interviewer will inform clinical staff of the participant's risk so that staff can attend to their needs. All participants will be informed that interviewers will need to disclose participants' risk level to clinical staff during the informed consent process. To aid in the protection and treatment of participants, interviewers will always inform participants of their desire to inform clinical staff. If a decision is made to notify staff, the interviewer will speak with a member of the treatment staff responsible for clinical care by phone or in person. The persons to contact will be clarified with program administrators prior to implementing the study, and information that bears directly on risk (e.g., level of depression, suicide plan, access to a weapon, prior attempts, etc.) will be disclosed. If clinical staff desires, interviewers will serve as a resource to treatment staff, providing guidance and consultation in developing a safety plan. All clinical decisions will be made by the Syracuse VA clinical staff, and interviewers will in no way usurp their authority.

To protect participants who are involuntarily hospitalized to ensure that they realize that their participation in the study is voluntary, researchers will have a staff member witness the informed consent process (please note that there is a witness signature line on the consent form).

Telephone Safety Plan. Participants who are randomized to the Motivational Interviewing to Address Suicidal Ideation (MI-SI) condition will receive one telephone MI-SI session after discharge and all follow-up assessments will be conducted by telephone. Emergency procedures will be initiated if patients are determined to be at imminent risk for suicide using the risk assessment described above. Participants determined to be at risk will be asked if they are

willing to be transferred to the Veteran Crisis Line. Veteran Crisis Line responders are well trained in emergency procedures and have working protocols for locating callers and initiating rescues. All telephone sessions will be conducted at the Center of Excellence (CoE) to ensure that the clinicians' telephone is set up for transfers to the Crisis Line. Calls can be transferred with a four step process.

Warm Transfer Process

1. Press the **conference** button.
2. Dial 1-800-273-8255 press option 1 and a Crisis Line responder will answer.
3. Describe the participants risk and provide name and telephone number.
4. Pressing the **conference** button and participants will be linked with Crisis Line counselors.

It is possible that participants may refuse to be transferred to the Crisis Line or hang up. As a result, research clinicians will ask participants to use a landline for MI-SI telephone sessions so that the number can be tracked to an address if emergency services are needed. For participants who only have a cell phone, interviewers will begin each session by asking the participant for the address from which they are calling so that the clinician can send help if it is needed. Because participants may give a false address, clinicians will consult with Crisis Line responders who have a protocol for emergency responses for cell phone callers.

Adverse Events (AE). All suicide attempts and episodes of imminent risk that require intervention will be considered adverse events and will be addressed according to IRB regulations. The determination of an AE will be made by an investigator other than the PI (i.e., Dr. Conner or Dr. Pigeon), to reduce the possibility of bias. Syracuse VA IRB also requires that serious adverse events, any event leading to a deviation from the protocol such as emergency hospitalization (e.g., to address acute suicidality) or death, be reported to the principal investigator within 24 hours, who is required to report them to the IRB within 48 hours. Adverse events that are minor such as temporary distress will be recorded by interviewers and reported to the IRB annually. All adverse events will be reported to the principal investigator within 24 hours to establish the level of significance and determine the appropriate procedure.

Distress. If, during any interview, participants appear to be disturbed by the content of the interview, the interviewer will stop asking questions and provide support, and if distress persists, suspend the interview. If distress is experienced by participants on the unit, interviewers will disclose the participants' distress to treatment providers so that staff may follow up with the participant therapeutically and monitor their condition, with the participants' permission. In the rare event that distress is severe such that there is immediate danger to the participant or to others, staff will be informed immediately. Participants, however, will be informed of the interviewer's decision. Discomfort may also arise later that day. Participants will be informed this may occur and will be encouraged to speak with a staff member, the interviewer, or another investigator involved in the study. If participants become distressed during the follow-up interview, interviewers will discuss scheduling an appointment at a local facility during the follow-up assessment session to increase the chance that the participant will engage in treatment, and provide the phone number of the National Veterans Crisis Line (1-800-273-TALK).

Confidentiality. During the informed consent process, participants will be informed of the limits of confidentiality which include the need to break confidentiality if the participant is determined to be a threat to self or others and if a child is exposed to abuse or neglect. The assessment battery does not contain questions about planned acts of violence or questions about abuse or

neglect of children, other than the suicide risk assessments. If participants spontaneously report plans or intent to carry out an act of violence, or spontaneously disclose child maltreatment, the interviewer will contact the primary investigator to make a plan that may include, depending on the nature of the information, a disclosure to treatment staff and making a child abuse report.

To add a further layer of protection for our participants we will apply for a Certificate of Confidentiality from the National Institute of Mental Health (NIMH). Confidentiality Certificates are issued by the National Institutes of Health (NIH) pursuant to Section 301 (d) of the Public Health Services Act (42 U.S.C. Section 241(d)) to afford special privacy protection to research participants. A Certificate helps the researcher avoid compelled "involuntary disclosure" (e.g. subpoenas) of identifying information about a research participant. It does not prevent voluntary disclosures such as disclosure to protect the subject or others from serious harm, as in cases of child abuse. Also, a researcher may not rely on a Certificate to withhold data if the participant consents to the disclosure. NIMH requires a letter of approval from the IRB prior to awarding a Certificate of Confidentiality to an investigator. Certificates of Confidentiality were successfully obtained for the two pilot studies we conducted on the Acute Inpatient Unit at the Syracuse VAMC.

Data Monitoring Committee

The Centralized CSR&D Data Monitoring Committee (DMC) will be providing additional oversight for the project and function as a Data Safety Monitoring Board (DSMB). The DMC is charged with guiding the safe scientific and ethical conduct of projects. At least once a year, the PI will send information to the DMC on recruitment progress, participant retention, and progress of data management and analyses. Serious adverse events and unanticipated problems are reported to the DMC as they occur. DMC recommendations on study performance, continuation or alteration of a protocol, and participant safety strategies or concerns are formulated after each data reassessment and forwarded to the PI and ACOS/R of each site. The DMC may consider study performance to be sufficiently poor that the project should be placed on probation, and specific conditions associated with continuation. The DMC may recommend study termination in some circumstances. Local institutional rules for conducting research and reporting issues to the facility R&D Committee and/or IRB are not changed by being monitored simultaneously by a centralized DMC. Upon receipt of the report, the PI will be responsible for transmitting a copy of the report to the IRB.

Potential Benefit of the Proposed Research to the Subject and Others

There may or may not be direct benefits to participants. However, participants at elevated risk for suicide will be identified so that the issue can be addressed during treatment and at follow-up. Knowledge resulting from the research may also contribute to the prevention of Veteran suicides.

References

1. Desai RA, Dausey DJ, Rosenheck RA. Mental health service delivery and suicide risk: The role of individual patient and facility factors. *Am J Psychiatry*. 2005;162(2):311-318. Ameran Psyhatr Assn. Available from: Desai, Rani A.: rani.desai@yale.edu.
2. Valenstein M, Kim HM, Ganoczy D, et al. Higher-risk periods for suicide among VA patients receiving depression treatment: Prioritizing suicide prevention efforts. *J Affect Disord*. 2009;112(1-3):50-58.
3. Brown GK, Beck AT, Steer RA, Grisham JR. Risk factors for suicide in psychiatric outpatients: A 20-year prospective study. *J Consult Clin Psychol*. 2000;68(3):371-377. Ameran Psyhooga Assn.
4. Cavanagh JTO, Carson AJ, Sharpe M, Lawrie SM. Psychological autopsy studies of suicide: A systematic review. *Psychol Med*. 2003;33(3):395-405.
5. Harris EC, Barraclough B. Suicide as an outcome for mental disorders: A meta-analysis. *British Journal of Psychiatry*. 1997;170(3):205-228.
6. Nock MK, Borges G, Bromet EJ, Cha CB, Kessler RC, Lee S. Suicide and suicidal behavior. *Epidemiol Rev*. 2008;30:133-154.
7. Yoshimasu K, Kiyohara C, Kazuhisa M. Suicidal risk factors and completed suicide: Meta analyses based on psychological autopsy studies. *Environmental Health and Preventive Medicine*. 2008;13(5):243-256.
8. Ilgen MA, Bohnert AS, Ignacio RV, et al. Psychiatric diagnoses and risk of suicide in veterans. *Arch Gen Psychiatry*. 2010;67(11):1152-1158.
9. Appleby L, Shaw J, Amos T, et al. Suicide within 12 months of contact with mental health services: National clinical survey. *BMJ*. 1999;318(7193):1235-1239.
10. Goldacre M, Seagroatt V, Hawton K. Suicide after discharge from psychiatric inpatient care. *Lancet*. 1993;342(8866):283-286.
11. Meehan J, Kapur N, Hunt IM, et al. Suicide in mental health in-patients and within 3 months of discharge. national clinical survey. *British Journal of Psychiatry*. 2006;188:129-134.
12. Qin P, Nordentoft M. Suicide risk in relation to psychiatric hospitalization: Evidence based on longitudinal registers. *Arch Gen Psychiatry*. 2005;62(4):427-432.
13. Centers for Disease Control and Prevention. Wisqars injury mortality reports 1999-2007. http://www.cdc.gov.ezpminer.urmc.rochester.edu/ncipc/wisqars/. Accessed 5/20, 2011.
14. Tarrier N, Taylor K, Gooding P. Cognitive-behavioral interventions to reduce suicide behavior: A systematic review and meta-analysis. *Behav Modif*. 2008;32(1):77-108. Available from: Tarrier, Nicholas: nicholas.tarrier@manchester.ac.uk.
15. Brown GK, Have TT, Henriques GR, Xie SX, Hollander JE, Beck AT. Cognitive therapy for the prevention of suicide attempts: A randomized controlled trial. *JAMA: Journal of the American Medical Associatio*n. 2005;294(5):563-570. Available from: Brown, Gregory K.: gregbrow@mail.med.upenn.edu.
16. Linehan MM, Comtois KA, Murray AM, et al. Two-year randomized controlled trial and follow-up of dialectical behavior therapy vs therapy by experts for suicidal behaviors and borderline personality disorder. *Arch Gen Psychiatr*y. 2006;63(7):757-766. Available from: Linehan, Marsha M.: linehan@u.washington.edu.
17. van den Bosch LMC, Koeter MWJ, Stijnen T, Verheul R, van den Brink W. Sustained efficacy of dialectical behaviour therapy for borderline personality disorder. *Behav Res The*r. 2005;43(9):1231-1241. Available from: van den Bosch, Louisa M.C.: wiesvdbosch@planet.nl.
18. Verheul R, van den Bosch LMC, Koeter MWJ, de Ridder MAJ, Stijnen T, van den Brink W. Dialectical behaviour therapy for women with borderline personality disorder: 12-month, randomised clinical trial in the netherlands. *British Journal of Psychiatr*y. 2003;182(2):135-140. Available from: Verheul, Roel: roel.verheul@deviersprong.net.

19. Bell AC, D'Zurilla TJ. Problem-solving therapy for depression: A meta-analysis. *Clin Psychol Re*v. 2009;29(4):348-353.
20. Hawton K, Townsend E, Arensman E, et al. Psychosocial versus pharmacological treatments for deliberate self harm. *Cochrane Database of Systematic Review*s. 2000(2):001764.
21. Miller WR, Rollnick S. *Motivational Interviewing: Preparing People for Change (2nd Ed.).* New York, NY: Guilford Press; 2002.
22. Miller WR, Rose GS. Toward a theory of motivational interviewing. *Am Psycho*l. 2009;64(6):527-537.
23. Moyers TB, Martin T, Christopher PJ, Houck JM, Tonigan JS, Amrhein PC. Client language as a mediator of motivational interviewing efficacy: Where is the evidence? *Alcoholism: Clinical and Experimental Researc*h. 2007;31(Suppl 3):40S-47S.
24. Moyers TB, Martin T, Houck JM, Christopher PJ, Tonigan JS. From in-session behaviors to drinking outcomes: A causal chain for motivational interviewing. *Journal of Consulting & Clinical Psychology*. 2009;77(6):1113-1124.
25. Britton PC, Williams GC, Conner KR. Self-determination theory, motivational interviewing, and the treatment of clients with acute suicidal ideation. *J Clin Psycho*l. 2008;64(1):52-66.
26. Kovacs M, Beck AT. The wish to die and the wish to live in attempted suicides. *J Clin Psycho*l. 1977;33(2):361-365.
27. Beck AT, Kovacs M, Weissman A. Assessment of suicidal intention: The scale for suicide ideation. *J Consult Clin Psycho*l. 1979;47(2):343-352.
28. Brown GK, Steer RA, Henriques GR, Beck AT. The internal struggle between the wish to die and the wish to live: A risk factor for suicide. *Am J Psychiatr*y. 2005;162(10):1977-1979.
29. Britton PC, Patrick H, Williams GC. Motivational interviewing, self-determination theory, and cognitive behavioral therapy to prevent suicidal behavior. *Journal of Cognitive Behavioral Practic*e. 2011;18(1):16-27.
30. Hettema J, Steele J, Miller WR. Motivational interviewing. *Annual Review of Clinical Psychology*. 2005;1(1):91-111. Available from: Hettema, Jennifer: jhettema@unm.edu;Steele, Julie: jmsteele@unm.edu;Miller, William R.: wrmiller@unm.edu.
31. Project MATCH Research Group. Matching alcoholism treatments to client heterogeneity: Project MATCH posttreatment drinking outcomes. *J Stud Alcoho*l. 1997;58(1):7-29.
32. Project MATCH Research Group. Matching alcoholism treatments to client heterogeneity: Project MATCH three-year drinking outcomes. *Alcoholism: Clinical and Experimental Researc*h. 1998;22(6):1300-1311.
33. Gentilello LM, Rivara FP, Donovan DM, et al. Alcohol interventions in a trauma center as a means of reducing the risk of injury recurrence. *Ann Sur*g. 1999;230(4):473-80; discussion 480-3.
34. Carroll KM, Ball SA, Nich C, et al. Motivational interviewing to improve treatment engagement and outcome in individuals seeking treatment for substance abuse: A multisite effectiveness study. *Drug & Alcohol Dependenc*e. 2006;81(3):301-312.
35. Bien TH, Miller WR, Boroughs JM. Motivational interviewing with alcohol outpatients. *Behavioural and Cognitive Psychotherap*y. 1993;21(4):347-356.
36. Forbes D, Creamer M, Hawthorne G, Allen N, McHugh T. Comorbidity as a predictor of symptom change after treatment in combat-related posttraumatic stress disorder. *Journal of Nervous & Mental Disease*. 2003;191(2):93-99.
37. Hodgins DC, Ching LE, McEwen J. Strength of commitment language in motivational interviewing and gambling outcomes. *Psychology of Addictive Behavior*s. 2009;23(1):122-130.
38. Baer JS, Beadnell B, Garrett SB, Hartzler B, Wells EA, Peterson PL. Adolescent change language within a brief motivational intervention and substance use outcomes. *Psychology of Addictive Behavior*s. 2008;22(4):570-575.

39. Amrhein PC, Miller WR, Yahne CE, Palmer M, Fulcher L. Client commitment language during motivational interviewing predicts drug use outcomes. *J Consult Clin Psycho*l. 2003;71(5):862-878. Available from: Amrhein, Paul C.: amrhein@unm.edu.
40. Aharonovich E, Amrhein PC, Bisaga A, Nunes EV, Hasin DS. Cognition, commitment language, and behavioral change among cocaine-dependent patients. *Psychology of Addictive Behavior*s. 2008;22(4):557-562.
41. Sheehan DV, Lecrubier Y, Sheehan KH, et al. The mini-international neuropsychiatric interview (M.I.N.I.): The development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J Clin Psychiatr*y. 1998;59(Suppl 20):22-33;quz.
42. Crum RM, Anthony JC, Bassett SS, Folstein MF. Population-based norms for the mini-mental state examination by age and educational level. *JAM*A. 1993;269(18):2386-2391.
43. Folstein MF, Folstein SE, McHugh PR. Mini-mental state. *Journal of Psychiatric Researc*h. 1975;12:189-198.
44. Beck AT, Brown GK, Steer RA, Dahlsgaard KK, Grisham JR. Suicide ideation at its worst point: A predictor of eventual suicide in psychiatric outpatients. *Suicide and Life-Threatening Behavio*r. 1999;29(1):1-9.
45. Feske U, Chambless DL. Cognitive behavioral versus exposure only treatment for social phobia: A meta-analysis. *Behavior Therap*y. 1995;26(4):695-720.
46. Cohen J. *Statistical Power Analysis for the Behavioral Sciences.* 2nd ed. Hilsdale, NJ: Erlbaum; 1988.
47. Yano EM, Hayes P, Wright S, et al. Integration of women veterans into VA quality improvement research efforts: What researchers need to know. *Journal of General Internal Medicin*e. 2010;25(Suppl 1):56-61.
48. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. *J Cin Ep*i. 2010.
49. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trial. *J Clin Ep*i. 2010.
50. Corrigan JD, Bogner J. Initial validity and reliability of the ohio state university TBI identification method. *Journal of Head Trauma Rehabilitatio*n. 2007;22(6):318-329.
51. O'Bryant SE, Humphreys JD, Smith GE, et al. Detecting dementia with the mini-mental state examination in highly educated individuals. *Arch Neuro*l. 2008;65(7):963-967. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medl&AN=18625866; http://openurl.lib.rochester.edu/find?url_ver=Z39.88-2004&rft_val_fmt=info:ofi/fmt:kev:mtx:journal&rfr_id=info:sid/Ovid:medl&rft.genre=article&rft_id=info:doi/&rft_id=info:pmid/18625866&rft.issn=0003-9942&rft.volume=65&rft.issue=7&rft.spage=963&rft.pages=963-7&rft.date=2008&rft.jtitle=Archives+of+Neurology&rft.atitle=Detecting+dementia+with+the+mini-mental+state+examination+in+highly+educated+individuals.&rft.aulast=O%27Bryant.
52. Beck AT, Brown GK, Steer RA. Psychometric characteristics of the scale for suicide ideation with psychiatric outpatients. *Behav Res The*r. 1997;35(11):1039-1046.
53. Bell JB, Nye EC. Specific symptoms predict suicidal ideation in vietnam combat veterans with chronic post-traumatic stress disorder. *Mil Me*d. 2007;172(11):1144-1147.
54. Pigeon W, Britton PC, Ilgen MA, Conner KR. Sleep disturbance preceding suicide among veterans. *Am J Public Healt*h. in press.
55. Giegling I, Olgiati P, Hartmann AM, et al. Personality and attempted suicide. analysis of anger, aggression and impulsivity. *J Psychiatr Re*s. 2009;43(16):1262-1271.
56. Spitzer RL, Kroenke K, Williams JBW, Patient Health Questionnaire Primary Care Study Group, US. Validation and utility of a self-report version of PRIME-MD: The PHQ primary care study. *JAMA: Journal of the American Medical Associatio*n. 1999;282(18):1737-1744.

57. Corson K, Gerrity MS, Dobscha SK. Screening for depression and suicidality in a VA primary care setting: 2 items are better than 1 item. *Am J Manag Car*e. 2004;10(11 Pt 2):839-845.
58. Weathers FW, Ruscio AM, Keane TM. Psychometric properties of nine scoring rules for the clinician-administered posttraumatic stress disorder scale. *Psychol Asses*s. 1999;11(2):124-133.
59. Keen SM, Kutter CJ, Niles BL, Krinsley KE. Psychometric properties of PTSD checklist in sample of male veterans. *Journal of Rehabilitation Research & Developmen*t. 2008;45(3):465-474.
60. Hankin CS, Spiro A,3rd, Miller DR, Kazis L. Mental disorders and mental health treatment among U.S. department of veterans affairs outpatients: The veterans health study. *Am J Psychiatr*y. 1999;156(12):1924-1930.
61. Beck AT, Epstein N, Brown G, Steer R. An inventory for measuring clinical anxiety: Psychometric properties. *Journal of Consulting & Clinical Psycholog*y. 1988;56(6):893-897.
62. Saunders JB, Aasland OG, Babor TF, de la Fuente JR, Grant M. Development of the alcohol use disorders identification test (AUDIT): WHO collaborative project on early detection of persons with harmful alcohol consumption--II. *Addictio*n. 1993;88(6):791-804.
63. Bradley KA, McDonell MB, Bush K, Kivlahan DR, Diehr P, Fihn SD. The AUDIT alcohol consumption questions: Reliability, validity, and responsiveness to change in older male primary care patients. *Alcoholism: Clinical & Experimental Researc*h. 1998;22(8):1842-1849.
64. Skinner HA. The drug abuse screening test. *Addict Beha*v. 1982;7(4):363-371.
65. Justice AC, McGinnis KA, Atkinson JH, et al. Psychiatric and neurocognitive disorders among HIV-positive and negative veterans in care: Veterans aging cohort five-site study. *AIDS*. 2004;18(Suppl 1):S49-59.
66. Gmel G, Graham K, Kuendig H, Kuntsche S. Measuring alcohol consumption--should the 'graduated frequency' approach become the norm in survey research? *Addictio*n. 2006;101(1):16-30. Available from: Gmel, Gerhard: ggmel@sfa-ispa.ch.
67. Tonigan JS, Miller WR. The inventory of drug use consequences (InDUC): Test-retest stability and sensitivity to detect change. *Psychology of Addictive Behavior*s. 2002;16(2):165-168. Available from: Tonigan, J. Scott: jtonigan@unm.edu.
68. McKay JR, Lynch KG, Shepard DS, Pettinati HM. The effectiveness of telephone-based continuing care for alcohol and cocaine dependence: 24-month outcomes. *Arch Gen Psychiatr*y. 2005;62(2):199-207.
69. Bastien CH, Vallieres A, Morin CM. Validation of the insomnia severity index as an outcome measure for insomnia research. *Sleep Me*d. 2001;2(4):297-307.
70. Coccaro EF, Berman ME, Kavoussi RJ. Assessment of life history of aggression: Development and psychometric characteristics. *Psychiatry Re*s. 1997;73(3):147-157.
71. Cacciola JS, Alterman AI, Lynch KG, Martin JM, Beauchamp ML, McLellan AT. Initial reliability and validity studies of the revised treatment services review (TSR-6). *Drug & Alcohol Dependenc*e. 2008;92(1-3):37-47.
72. Garnick DW, Lee MT, Chalk M, et al. Establishing the feasibility of performance measures for alcohol and other drugs. *Journal of Substance Abuse Treatmen*t. 2002;23(4):375-385.
73. VA Office of Quality and Performance. Continuity of care VHA performance measure. Washington, DC: VA Office of Quality and Performance; 2005.
74. Harris AHS, Humphreys K, Bowe T, Tiet Q, Finney JW. Does meeting the HEDIS substance abuse treatment engagement criterion predict patient outcomes? *The Journal of Behavioral Health Services & Researc*h. 2008;37(1):25-39.
75. Glass JE, Ilgen MA, Winters JJ, Murray RL, Perron BE, Chermack ST. Inpatient hospitalization in addiction treatment for patients with a history of suicidal attempt: A case of support for treatment performance measures. *Journal of Psychoactive Drug*s. 2010;42(3):315-325.

76. Posner K, Oquendo MA, Gould M, Stanley B, Davies M. Columbia classification algorithm of suicide assessment (C-CASA): Classification of suicidal events in the FDA's pediatric suicidal risk analysis of antidepressants. *Am J Psychiatr*y. 2007;164(7):1035-1043. Available from: Posner, Kelly: posnerk@childpsych.columbia.edu.
77. Meyer RE, Salzman C, Youngstrom EA, et al. Suicidality and risk of suicide- definition, drug safety concerns, and a necessary target for drug development: A consensus statement. *J Clin Psychiatr*y. 2010;71(8):e1-e21.
78. Biener L, Abrams DB. The contemplation ladder: Validation of a measure of readiness to consider smoking cessation. *Health Psychology*. 1991;10(5):360-365. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med3&AN=1935872; http://openurl.lib.rochester.edu/find?url_ver=Z39.88-2004&rft_val_fmt=info:ofi/fmt:kev:mtx:journal&rfr_id=info:sid/Ovid:med3&rft.genre=article&rft_id=info:doi/&rft_id=info:pmid/1935872&rft.issn=0278-6133&rft.volume=10&rft.issue=5&rft.spage=360&rft.pages=360-5&rft.date=1991&rft.jtitle=Health+Psychology&rft.atitle=The+Contemplation+Ladder%3A+validation+of+a+measure+of+readiness+to+consider+smoking+cessation.&rft.aulast=Biener.
79. Hogue A, Dauber S, Morgenstern J. Validation of a contemplation ladder in an adult substance use disorder sample. *Psychology of Addictive Behavior*s. 2010;24(1):137-144. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medl&AN=20307121; http://openurl.lib.rochester.edu/find?url_ver=Z39.88-2004&rft_val_fmt=info:ofi/fmt:kev:mtx:journal&rfr_id=info:sid/Ovid:medl&rft.genre=article&rft_id=info:doi/&rft_id=info:pmid/20307121&rft.issn=0893-164X&rft.volume=24&rft.issue=1&rft.spage=137&rft.pages=137-44&rft.date=2010&rft.jtitle=Psychology+of+Addictive+Behaviors&rft.atitle=Validation+of+a+contemplation+ladder+in+an+adult+substance+use+disorder+sample.&rft.aulast=Hogue.
80. Schulz KF, Grimes DA. Blinding in randomized trials: Hiding who got what. *The Lance*t. 2002;359(9307):696-700.
81. Kernan WN, Viscoli CM, Makuch RW, Brass LM, Horwitz RI. Stratified randomization for clinical trials. *J Clin Epidemio*l. 1999;52(1):19-26. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med4&AN=9973070; http://openurl.lib.rochester.edu/find?url_ver=Z39.88-2004&rft_val_fmt=info:ofi/fmt:kev:mtx:journal&rfr_id=info:sid/Ovid:med4&rft.genre=article&rft_id=info:doi/&rft_id=info:pmid/9973070&rft.issn=0895-4356&rft.volume=52&rft.issue=1&rft.spage=19&rft.pages=19-26&rft.date=1999&rft.jtitle=Journal+of+Clinical+Epidemiology&rft.atitle=Stratified+randomization+for+clinical+trials.&rft.aulast=Kernan.
82. Schulz KF, Grimes DA. Unequal group sizes in randomized trials: Guarding against guessing. *Lance*t. 2002;359(9310):966-970.
83. Fleischmann A, Bertolote JM, Wasserman D, et al. Effectiveness of brief intervention and contact for suicide attempters: A randomized controlled trial in five countries. *Bulletin of the World Health Organizatio*n. 2008;86(9):703-709.
84. Vaiva G, Vaiva G, Ducrocq F, et al. Effect of telephone contact on further suicide attempts in patients discharged from an emergency department: Randomised controlled study. *BMJ*. 2006;332(7552):1241-1245.
85. Miller IW, Norman WH, Bishop SB, Dow MG. The modified scale for suicidal ideation: Reliability and validity. *Journal of Consulting & Clinical Psychology*. 1986;54(5):724-725.
86. Russ MJ, Kashdan T, Pollack S, Bajmakovic-Kacila S. Assessment of suicide risk 24 hours after psychiatric hospital admission. *Psychiatric Service*s. 1999;50(11):1491-1493.

87. Alexopoulos GS, Reynolds CF,3rd, Bruce ML, et al. Reducing suicidal ideation and depression in older primary care patients: 24-month outcomes of the PROSPECT study. *Am J Psychiatr*y. 2009;166(8):882-890.
88. Bruce ML, Ten Have TR, Reynolds CF3, et al. Reducing suicidal ideation and depressive symptoms in depressed older primary care patients: A randomized controlled trial. *JAM*A. 2004;291(1):1081-1091.
89. BootsMiller BJ, Ribisl KM, Mowbray CT, Davidson WS, Walton MA, Herman SE. Methods of ensuring high follow-up rates: Lessons from a longitudinal study of dual diagnosed participants. *Subst Use Misus*e. 1998;33(13):2665-2685.
90. Desmond DP, Maddux JF, Johnson TH, Confer BA. Obtaining follow-up interviews for treatment evaluation. *J Subst Abuse Trea*t. 1995;12(2):95-102.
91. Twitchell GR, Hertzog CA, Klein JL, Schuckit MA. The anatomy of a follow-up. *Br J Addic*t. 1992;87(9):1327-1333.
92. Miller WR, Yahne CE, Moyers TB, Martinez J, Pirritano M. A randomized trial of methods to help clinicians learn motivational interviewing. *J Consult Clin Psycho*l. 2004;72(6):1050-1062. Available from: Miller, William R.: wrmiller@unm.edu.
93. Moyers TB, Martin T, Manuel JK, Hendrickson SML, Miller WR. Assessing competence in the use of motivational interviewing. *J Subst Abuse Trea*t. 2005;28(1):19-26. Available from: Moyers, Theresa B.: tmoyers@unm.edu.
94. Miller WR, Mount KA. A small study of training in motivational interviewing: Does one workshop change clinician and client behavior? *Behavioural and Cognitive Psychotherap*y. 2001;29(4):457-471.
95. Shrout PE, Fleiss JL. Intraclass correlations: Uses in assessing rater reliability. *Psychological Bulleti*n. 1979;2:420-428.
96. Motivational Interviewing Network of Trainers (MINT). Training. http://motivationalinterview.org/training/index.html. Accessed 2/28, 2011.
97. Cicchetti DV. Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instruments in psychology. *Psychol Asses*s. 1994;6(4):284-290.
98. Martin T, Moyers TB, Houck JM, Christopher PJ, Miller WR. Motivational interviewing sequential code for observing process exchanges (MI-SCOPE) coder's manual. http://casaa.unm.edu/download/scope.pdf. Accessed May/20, 2010.
99. Hosmer DW, Lemeshow S. *Applied Logistic Regression.* New York: Wiley; 1989.
100. Dobson AJ, Barnet AG. *Introduction to Generalized Linear Models.* 3rd ed. Boca Raton, FL: Chapman and Hall/CRC; 2008.
101. STATA Corporation. STATA statistical software. College Station, TX:2008;10.
102. Frison L, Pocock SJ. Repeated measures in clinical trials: Analysis using mean summary statistics and its implication for design. *Statistics in Medicin*e. 1992;11(13):1685-1704.
103. Festinger DS, Marlowe DB, Croft JR, et al. Do research payments precipitate drug use or coerce participation?. *Drug & Alcohol Dependenc*e. 2005;78(3):275-281.
104. Festinger DS, Marlowe DB, Dugosh KL, Croft JR, Arabia PL. Higher magnitude cash payments improve research follow-up rates without increasing drug use or perceived coercion. *Drug & Alcohol Dependenc*e. 2008;96(1-2):128-135.
105. Williams GC, Grow VM, Freedman ZR, Ryan RM, Deci EL. Motivational predictors of weight loss and weight-loss maintenance. *J Pers Soc Psychol*. 1996;70(1):115-126.
106. Williams GC, Freedman ZR, Deci EL. Supporting autonomy to motivate patients with diabetes for glucose control. *Diabetes Care*. 1998;21(10):1644-1651.
107. Hong J1, Reed C, Novick D, Haro JM, Aguado J. Clinical and economic consequences of medication non-adherence in the treatment of patients with a manic/mixed episode of bipolar disorder: results from the European Mania in Bipolar Longitudinal Evaluation of Medication (EMBLEM) study. *Psychiatry Res.* 2011 Nov 30;190(1):110-4.

108. Novick D1, Haro JM, Suarez D, Perez V, Dittmann RW, Haddad PM. Predictors and clinical consequences of non-adherence with antipsychotic medication in the outpatient treatment of schizophrenia. *Psychiatry Res.* 2010 Apr 30;176(2-3):109-13.
109. J Scott, M Pope. Self-reported adherence to treatment with mood stabilizers, plasma levels, and psychiatric hospitalization. *Am J Psychiatry*. 2002;159(11): 1927-1929.
110. ML Parchman, JE Zeber, Palmer RF. Participatory decision making, patient activation, medication adherence, and intermediate clinical outcomes in type 2 diabetes: a STARNet study. 2010. *Ann Fam Med*. 2010. 8(5): 410-417.
111. M Heisler, RR Bouknight, RA Hayward, et al. The Relative Importance of Physician Communication, Participatory Decision Making, and Patient Understanding in Diabetes Self-Management. *J General Internal Med*. 2002; 17(4): 243–252.
112. J Schneider, SH Kaplan, S Greenfield, Li W, Wilson IB. Better Physician-Patient Relationships Are Associated with Higher Reported Adherence to Antiretroviral Therapy in Patients with HIV Infection. *J Gen Intern Med*. 2004;19(11): 1096–1103.
113. Haskard Zolnierek KB, DiMatteo RM. Physician Communication and Patient Adherence to Treatment: A Meta-analysis. *Med Care*. 2009 Aug; 47(8): 826–834.
114. Zygmunt A, Olfson M, Boyer CA, et al. Interventions to improve medication adherence in schizophrenia. *Journal of Psychiatry*. 2002;159(10): 1653-1664. *Psychiatry Res*. 2011 Nov 30;190(1):110-4. doi: 10.1016/j.psychres.2011.04.016. Epub 2011 May 14.
115. Kaplan SH, Gandek B, Greenfield S, Rogers WH, Ware JE. Patient and Visit Characteristics Related to Physicians' Participatory Decision-Making Style: Results from the Medical Outcomes Study. *Medical Care*. Vol. 33, No. 12 (Dec., 1995), pp. 1176-1187
116. Kaplan SH, Greenfield S, Gandek B, Rogers WH, Ware JE. Characteristics of Physicians with Participatory Decision-Making Styles. *Ann Intern Med.* 1996;124(5):497-504.
117. J Hamann, R Mendel, R Cohen, S Heres. Psychiatrists' use of shared decision making in the treatment of schizophrenia: patient characteristics and decision topics. *Psychiatric Services*. 2009;60:1107–1112.