ASSIST: Advancing Student Suicide Interventions with Scalable Technologies

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Grant Number: P50MH129701 subaward

ClinicalTrials.gov: NCT07211373, Protocol ID: UMassIRB6366

Most recently renewed by UMass IRB #6366, expiration 3/3/2026

Updated 10/9/2025

Study Protocol and Data Analytic Plan

1. Brief Description of Protocol

1.1 Protocol Overview

Suicide is a leading cause of death for college-aged individuals,[1] yet student health centers struggle to keep pace with the rise in behavioral health issues.[2] Mobile-based applications, such as JasprHealth, can deliver evidence-based skills intended to reduce imminent suicide risk (e.g., reducing means access), improve emotional states (e.g., via distraction and coaching to act opposite to emotions), and reduce feelings of social isolation (e.g., via shared stories). Although mobile-device-delivered interventions hold the potential to make interventions widely accessible, user engagement presents a substantial barrier to efficacy.[3,4] The proposed study, ASSIST: Advancing Student Suicide Interventions with Scalable Technologies, aims to improve engagement with mobile-delivered suicide prevention applications, with the ultimate goal of reducing suicidal thoughts and behaviors in college students. Including human elements alongside JasprHealth has the potential to improve the uptake of this evidence-based, accessible mobile-device-delivered intervention.[5,6]

The aim of this study was to examine the effects of the technological application resource Jaspr vs. Jaspr+ human augmentation (e.g., motivationally focused orientation plus prompts) on acceptability, preliminary effectiveness, and engagement among 50 college students who screen positive for suicide risk (n=25 per condition) over the course of 2 months. Candidate mechanisms (e.g., coping skills, self-stigma) will also be assessed. Participants were randomized via the Redcap randomization module[7], stratified by site.

1.2 Methods Summary

Self-report measures will be assessed at baseline, week 4, week 8, along with weekly for some secondary measures.

Table 2. Aim 2 and 3 Jaspr Implementation Outcomes

Construct	Definition	Measure	Time point
Effectiveness	Effectiveness of Jaspr+ vs. Jaspr	1. Suicide Ideation Questionnaire (SIQ[8]) – past month 2. C-SSRS[95,96] self-report screener past month (lifetime at baseline) and past week (weekly for Weeks 0-4)	✓ Baseline ✓ Weekly ✓ 4wk ✓ 8wk
		1. Candidate mechanisms: 17-item suicide-related coping,[9] ways of coping,[10] 16-item personal suicide stigma questionnaire[11] (PSSQ), and self-reported engagement 2. Acceptability of Implementation Measure (AIM)[12] - 4-item measure to determine whether Jaspr is liked, appealing, welcomed and approved (patient [109]) 3. Client Satisfaction Questionnaire – 8 (CSQ8[13–15]) for patients	

2. Data Analytic Plan

2.1 Preliminary Analyses

Preliminary analyses will examine descriptive data to examine distributional properties of each variable. Transformations (e.g., log transformations) will be applied for variables not meeting normality assumptions. Alternative models (e.g., logistic, Poisson, negative binomial) will be used for variables that are not sufficiently normalized by these transformations and for count and dichotomous outcomes, as appropriate. Extreme outliers will be considered and adjusted if necessary.

We will consider data missingness. If the data are in fact missing not completely at random, we may only include the ITT sample that also completed at least one of the timepoints. If data are MAR, we will use Full Information Maximum Likelihood Estimation (FIML),[16]

Covariates will be considered per analysis. We will consider including covariates that show associations with the dependent variables (DVs) in analyses[17] particularly if they differ across conditions, including demographic variables. Given the small sample size, nonsignificant variables in models may be trimmed from final model reporting.

2.2 Primary Analyses

Given that most of these outcomes will be assessed at Weeks 0 (baseline), 4, and 8, along with secondary measures weekly from Weeks 0-4, for most primary analyses we will plan to use mixed effects models. We plan to evaluate whether the data are appropriate for use of multilevel models which account for the interdependence of multiple repeated measures within individuals, using full maximum likelihood estimation. Consistent with recommended practices,[18] we will consider a series of models to test how to consider time, levels, and which (if any) random effects to include. If such models do not accurately capture the data, we may resort to single-level regressions. In addition, it is important to consider variability in the group clusters, which is a key strength of using multilevel model analyses to model complex change over time. Alpha will be set to .05 for primary pre-specified outcomes without error correction given the small sample size.

2.2.1 Primary Outcomes

We will examine the effect of condition (Jaspr vs. Jaspr+) on effectiveness on the SIQ and CSSRS. We will also examine the effect of time overall in either condition on effectiveness outcomes. We may also examine change slopes within each condition and test how these slopes differ.

2.2.2 Secondary Outcomes

We will examine the effect of condition (Jaspr vs. Jaspr+) on effectiveness on coping, suicide-related self-efficacy, and suicide stigma, as well as perceived engagement. We will also examine the effect of time overall in either condition on effectiveness outcomes. We may also examine change slopes within each condition and test how these slopes differ.

As described above, where appropriate we will leverage the repeated measures nature of these data to increase power, but may collapse across levels of data if appropriate to best model variability (e.g., we may create difference scores for startle outcomes across categories; we may aggregate counts of self-injury or attempts post treatment as a single level outcome rather than modeling change via a latent growth curve model if insufficient fluctuation in these outcomes is found). Mixed effects models will test the change across time in self-reported affect, skin conductance, and heart rate variability in the paradigms over treatment, and will compare these time effects across conditions.

2.3 Additional Analyses

Additionally, we will consider sex (if adequately powered), and other demographic characteristics (ethnic, racial, gender, and sexual identities, age) and psychopathology as moderators of treatment response.

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