Preliminary Findings from Jaspr Health Clinical Trial

Submitted to NIMH in Response to NOT-MH-20-025 Supplement[1]

Overview: Data from preliminary data from our randomized controlled trial produced a number of very positive findings favoring Jaspr Health. In comparison to the care-as-usual control condition, Japsr Health produced the following outcomes:

- Significant *increase* in the **delivery** of four suicide prevention best practices for suicidal ED patients and the **thoroughness** of their delivery;
- Significant *decrease* in **distress** and **agitation;**
- Significant *increase* in learning to **cope more effectively with** current and future **suicidal thoughts;**
- Significantly **high ratings of overall satisfaction of ED experience**;
- **100% recommended** Jaspr Health for other suicidal ED patients.

Randomized Controlled Trial (RCT). We are currently conducting an efficacy-effectiveness RCT (N=90) comparing Jaspr Health to care-as-usual (CAU) in suicidal ED patients. We applied the same eligibility criteria and recruitment procedures used in the formative evaluation. After baseline, participants are randomized either to Jaspr Health or CAU. A minimization random assignment procedure is used to match participants across conditions on suicide severity and prior history of ED visits for suicidal behaviors. Participants complete a baseline and post-test while in the ED. CAU participants complete the post-test two hours after baseline; Jaspr participants complete the post-test after finishing their use of Jaspr Health (up to two hours of actual use). Tracking of Jaspr Health use and time is paused when participants meet with a member of their care team, then is resumed afterwards. All participants are again assessed at 7-, 30- and 90-days. Proximal primary ED outcome variables include: delivery of recommended best-practice interventions for EDs (presence/absence; thoroughness), distress and agitation while in ED, readiness for discharge, and helpfulness/satisfaction with the ED encounter. Post-ED distal primary outcomes also include: suicidality (death by suicide, suicide attempts, suicidal ideation), ED/hospital readmissions. Jaspr Health-specific outcomes include app satisfaction and *Jaspr-at-Home* use after leaving the hospital.

ED-Based Assessment Instruments and Method. Measures were developed in collaboration with The Emergency Department Safety Assessment and Follow-up Evaluation (ED-SAFE) PI and Jaspr Health consultant, Dr. Bourdeaux and selected for their brevity and simplicity for use with suicidal individuals seeking psychiatric crisis services in an ED. The **Safety and Imminent Distress Questionnaire** (SIDQ) is a four-item self-report survey based on Dr. Boudreaux's Keeping Myself Safe Subject Usability Survey.[68] Participants are asked to rate their feelings in the present moment using a 10-point scale. Items include: intensity of emotional distress (1=no distress; 10=highest distress ever felt); their feeling (1=very calm; 10=very frustrated/agitated); their ability to cope with thoughts of killing themselves (1=no ability to cope; 10=strong ability to cope); ability to go home safely (1=not able; 10=very able). The **Harvard Intensity Ratings Scale** (HIRS)[67] is a six-item face-valid self-report suicidal behaviors measure where respondents rate the intensity of how they feel using a 10-point Likert scale (1=not at all; 10=very strong). Items include: *How intense is your desire to kill yourself right now? How intense is your intention to kill yourself right now*? *How able are you to resist the urge to kill yourself right now? How much hope for the future do you have right now?* The **Optimism and Hope Scale** (OHS)[69; 70; 71] is a 14-item psychometrically sound self-report measure that assesses optimism and pessimism for the future and uses a 4-point Likert Scale (1=definitely true to 4=definitely false). The **Suicide-Related Coping Scale** (SRCS)[72] is a 17-item psychometrically-sound self-report measure of coping with suicidal thoughts, urges, and crises. The SRCS uses a five-point Likert scale (0=strongly disagree to 4=strongly agree). The **Emergency Room Patient Satisfaction Survey** (ER-PSS) is a seven-item measure used to assess patient experience in the ED. The measure was developed in consultation with Mayo Clinic's Patient Experience Office. The first six items use a five-point Likert scale (1=poor to 5=excellent). Items include: helpfulness of ED visit, degree to which patient felt listened to and cared about by their care team, likelihood that they would recommend the ED to others in their situation, and their overall rating of care they received. A final item involves rating their overall ED experience from 1 (the worse) to 100 (the best). The **Jaspr Health Patient Satisfaction Questionnaire** is an eight-item survey that adapts the ER-PSS for Jaspr Health. Using the same five-point Likert scale, users rate its ease of use, helpfulness, degree to which they felt cared about by their virtual guide, etc. Like the ER-PSS, users also rate Jaspr Health on a 100-point scale, and indicate whether they would recommend Jaspr

[1] Content presented here, including tables, have been fully extracted from the supplement submitted to NIMH on April 5, 2020. The data analytic strategy, data analyses, and interpretations of findings have been fully directed and reviewed by Blair Beadnell, PhD, Statistical Consultant, to mitigate against conflict of interest.

Health to others in their situation. A **brief semi-structured interview** conducted at the end of the post-test session seeks to identify what, if any, suicide prevention best practices the participant received while in the ED. When positively affirmed, patients are asked to rate the thoroughness with which they received the best practice using a five-point Likert scale (1=not very thorough; 5=very thorough). They were also asked who delivered the best practice (a member of their care team, Jaspr Health, or both). Participants who affirmed learning behavioral skills or engaging with PLEs were also asked to report the number of skills learned and PLEs met.

To date, 31 participants were recruited and randomized to condition (Jaspr Health=14; CAU=17) from two large healthcare organizations between January 24, 2020 and February 26, 2020. The rapid spread of COVID-19 required that recruitment efforts be temporarily suspended at all healthcare organizations. As of this writing, follow up data are still being collected with these individuals. While the study is ongoing, preliminary analyses were conducted in collaboration with statistical consultant Blair Beadnell, PhD and with DSMB approval for this HEAL supplement proposal. The sample to date was 64.5% female and 85% Caucasian. Participants ranged in age from 18 to 68 and averaged 34.4 years old (SD=15.17). 32% of the sample reported graduation from high school as their highest educational attainment, 13% completed a two-year college degree, 13% completed a four-year undergraduate degree, and 6% had earned a graduate degree; 36% had attended some college but had not earned a degree. 74% of the sample had made a suicide attempt in their lifetime (M=3.4; SD=6.4); 61% engaged in non-suicidal self-injurious behaviors over their lifetime at an average rate of 8.8 times in the past 3 months. No differences were detected between conditions at baseline on demographics and outcome variables. Collectively, participants averaged a length of stay of 17 hours prior to the start of the baseline assessment.

	% saying 'yes'		Difference (%)	p value
	Jaspr (N=14)	CAU (N=17)		
Crisis Plan	100%	12%	88%	P<.000
Lethal Means	85%	6%	79%	p<.000
Skills	93%	12%	81%	p<.000
PLE	93%	6%	87%	p<.000

Table 3: Received Best Practice Interventions

	#	Thorough
	M (SD)	M (SD)
Crisis Plan		3.4 (1.1)
Lethal Means		3.5 (1.3)
Skills	2.7 (1.3)	3.7 (1.4)
PLE	3.7 (2.6)	4.1 (.86)

Table 4: Degree Exposure

Preliminary Findings. Analyses focused exclusively on the pre/post data gathered in the ED. Several key findings emerge. **First**, in comparison to CAU, Jaspr Health participants reported receiving significantly more of the best practice brief interventions recommended for suicidal individuals while in the ED. These outcomes are summarized in Table 3. Specifically, 100% of Jaspr Health participants completed a crisis safety plan compared to 12% in CAU; 85% of Jaspr Health participants completed lethal means counseling compared to 6% in CAU; 93% of Jaspr Health participants received messages of hope and wisdom from videos of PLEs compared to 6% in CAU. Finally, 100% of Jaspr Health participants received a standardized, comprehensive evidence-based suicide risk assessment (CAMS); none did in CAU. Table 4 shows that Jaspr participants reported extensive exposure to these brief interventions. Jaspr Health participants indicated that they learned 2.7 new skills (SD=1.3) and "met" with 3.7 (SD=2.63) PLEs. Degree of thoroughness with which they received best practices ranged from an average of 3.4 (SD=1.1; crisis plan) to 4.1 (SD=.86; PLE) on the 5-point scale. **Second** (see Table 5), compared to CAU, Jaspr Health patients reported statistically significant *decreases* in intensity of agitation and distress, and significant *increases* in their ability to cope with thoughts of killing oneself during the two-hour experimental procedure (eta-squared ranged from .15 to .17, large-sized Time X Condition

	Jaspr (n=14)			CAU (n=17)				
	Pre	Post	Cohens d effect size	Pre	Post	Cohens d effect size	Time X Condition	
	M (SD)	M (SD)		M (SD)	M (SD)		p value	eta-squared
OHS*	2.8(.5)	2.7(.7)	-0.5	2.9(.5)	2.9(.6)	-0.1	.28 F(1,29)	0.04
SRCS	34.8(11)	44.8(11.7)	1.1	37.6(13.3)	39.5(14.2)	0.3	<.01 F(1,29)	0.21
HIRS (1-10)								
Desire to Kill Self	5.1(2.6)	4(2.7)	-0.6	5.4(2.9)	5(2.6)	-0.2	.35 F(1,26)	0.03
Resist the Urge	7.3(2.1)	7.3(3)	0.0	6.2(3)	6.5(2.5)	0.1	.81(1,26)	0
Make Environment Safe	7.8(2.7)	8.6(1.7)	0.4	7.5(3.3)	7.5(2.7)	0.0	.31 F(1,27)	0.04
Cope Effectively	7 (2.4)	8.3(1.4)	0.5	7.1(2.5)	7.3(2.4)	0.1	.28 F(1,26)	0.04
Hope for Future	5(3.2)	6.7(2.8)	0.8	3.9(1.7)	4.9 (2.8)	0.5	.39 F(1,22)	0.03
SIDQ (1-10)								
Distress	6.7 (2.0)	4.4 (2.4)	-1.01	7.3 (2.7)	6.7 (2.5)	-0.33	<.05 F(1,29)	0.15
Agitation	5.9 (2.6)	4.2 (2.2)	-0.61	6.1 (2.8)	6.3 (2.1)	0.11	<.05 F(1,28)	0.16
Coping Ability	4.6 (2.3)	6.6 (2.7)	0.9	4.9 (2.3)	5.3 (2.3)	0.32	<.05 F(1,28)	0.17
Readiness to Go Home Safely	6.8(3.3)	7.9(2.3)	0.28	4.4(3.4)	4.4(3)	0.05	.38 F(1,24)	0.03

Note: interpretation of Cohen's d is .20 small, .50 medium, and .80 large; of eta squared .01 small, .06 medium, .14 large. *Lower the score=greater hope/optimism

Table 5 ED Outcomes

ED Patient Satisfaction (1-5)	Jaspr (n=14)	CAU (n=17)	Between-condition	
	M (SD)	M (SD)	p value F(2,29)	Cohen's d
Helpfulness of ER Visit	3.8(1)	3.2(1.2)	0.13 F(2,29)	0.5
Felt Listened to	4.2(1)	3.5(1.2)	0.13 F(2,29)	0.6
Felt Cared About	4.1(1.2)	3.7(1.1)	0.25 F(2,29)	0.4
Ready to Return Home	3.4(1.5)	2.8(1.4)	0.27 F(2,29)	0.4
Recommend ER	4.3(1.2)	3.5(1.2)	0.1 F(2,29)	0.7
Overall Rating of Care	4.2(1)	3.4(1.2)	<.05 F(2, 29)	0.8

Note: interpretation of Cohen's d is .20 small, .50 medium, and .80

effects). Within-condition effect sizes were large for Jaspr Health participants' decreases in agitation and distress (Cohen's d = -.61 and -1.01, respectively) and increases in coping ability (d = .90). In contrast, effects sizes for CAU participants were small. Specifically, a small *increase* in agitation (d = .11), decrease in distress (d = -.33), and increase in coping ability (d = .32) were observed in CAU. While not statistically significant, eta-squared for readiness to go home safely was small to medium. **Third**, in comparison to CAU, Jaspr Health participants reported a significant increase in their SRCS-measured suicide-related coping capability, with a large Time X Condition effect. **Fourth,** most HIRS ratings, though not significant in this relatively small sample, favored Jaspr Health. **Fifth,** while not generally statistically significant, effect sizes for ED patient experience also favored Jaspr Health and were medium to large in magnitude (See Table 6). For example, *felt cared about* (d = .42), and *felt listened to* (d = .60), *readiness for discharge* (d = .41). A statistically significant difference was observed however on arguably the most important ED Patient Satisfaction item *Overall Rating of Care*, again favoring Jaspr Health. **Finally**, Jaspr Health users rated the app with high marks. Specifically, 100% recommended **Jaspr Health** to others in their situation. Additionally, average satisfaction rating for Jaspr Health was 4.4 (SD=.63) using a five-point Likert Scale where 1=poor and 5=excellent.

COMMENT: Data from both preliminary studies produced very positive findings favoring Jaspr Health. Even with a relatively small sample size, a number of important and statistically significant differences favored Jaspr Health over CAU. Perhaps most importantly, in comparison to those receiving CAU and *after an average wait time of 17 hours*, Japsr Health ensured both the **delivery** of four suicide prevention best practices for suicidal ED patients and the **thoroughness** of their delivery. Consistent with a finding we observed in our initial observational research, Jaspr Health provided an emotion regulation function, where levels of distress and agitation significantly decreased over the course of its use, whereas agitation ratings *increased* in CAU. In comparison to CAU, Jaspr Health also helped them learn to cope more effectively with their current suicidal thoughts and future suicide crises. While participants in both conditions felt generally positive about their ED experience, Jaspr Health participants provided a statistically significant higher overall rating of their ED experience. In both studies, 100% of suicidal ED participants recognized Jaspr Health's value and recommended it to others in their shoes; and satisfaction ratings were very strong. These positive outcomes also validate our team's design method and capability, our capacity to conduct complex research with vulnerable suicidal patients, our ability to leverage the expertise of suicide science experts and PLEs, and to engage large healthcare organizations as research partners.