NORTHWESTERN-SOLUNA RESEARCH PARTNERSHIP:

IMPLEMENTATION OF SOLUNA SINGLE-SESSION COMPONENTS IN CALIFORNIA

Northwestern



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LAB FOR SCALABLE MENTAL HEALTH

Our Mission:

Design, test, & disseminate brief, barrier-free interventions to reduce mental health problems at scale

What are single-session interventions (SSIs)?

"specific, structured programs that **intentionally** involve just **one visit or encounter** with a clinic, provider, or program"

SSIs may be accessed on one or many occasions ("one at a time"—not "one and done"); they may be self-guided or human-facilitated; and they may be accessed within or outside of formal healthcare settings

In all cases, SSIs drop the (often false) assumption that clients will return and instill the belief that meaningful change is possible at any moment, however brief.

Source: Schleider et al., 2020, Journal of Clinical Child and Adolescent Psychology

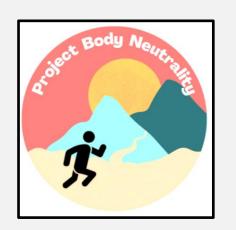
Our lab's evidence-based single-session interventions have served >70,000 youth, young adults, & parents

Via grant-funded randomized-control trials, nonprofit and community partnerships, in 8 languages 40%+ of youth accessing SSIs are racial/ethnic minorities; 75%+ are LGBTQ

All SSIs are accessible as needed, with or without parent involvement











Soluna is **unique** in its integration of SSI into digital mental health **Our scientific goal is to quantify Soluna's impact** on youth mental health, including single-session elements, self-guided supports, and their combination

WE WILL EVALUATE THE ACCESSIBILITY, IMPACTS, AND ADDED VALUE OF SOLUNA'S SINGLE-SESSION COACHING, IN COMBINATION WITH THE PLATFORM'S OTHER SUPPORTS

We will be measure:

- **Use** of the Soluna app
- Emotions, thoughts, & well-being
 - Demographics

(e.g., age, grade level)

These outcomes are all important to students, parents, teachers, and policymakers

Students (250-500) will be compensated up to \$30 for their effort on surveys (baseline, I month, 3 month)

STUDY INCLUSION CRITERIA: USING SOLUNA IN CALIFORNIA, AGES 14-17

- Ages 14 17
- English Proficiency
- Have access to the Internet through the computer, phone, smartphone, etc.
- In California, where Soluna is available for youth
- Passes 'capacity to consent' assessment (Multiple choice)
 - What will you be asked to do in this study?
 - What is a potential risk of participating in this study?
 - What happens if I no longer want to participate in this study?

QUALTRICS DATA

Source	Data Description
Qualtrics Survey	User Outcomes Adverse Childhood Events (ACEs) YP-CORE (Distress) PHQ-8 (Depression) GAD-7 (Anxiety) BHS-4 (Hopelessness) ULS-3 (Loneliness) PROMIS 10 (Global Health) Strengths & Difficulties Questionnaire (SDQ) with Impact Subscale Suicidal Ideation Attributes Scale (SIDAS) Self-Harm Question Multidimensional Scale of Perceived Social Support (MSPSS) Attitudes about Mental Health and Its Treatment Scale (AMIS) Expectancies Bullying Multisession Services
Qualtrics Survey	User feedback • Soluna feedback
Qualtrics Survey	 Demographics Email address (for compensation + risk response), phone number (for risk response), parent/guardian phone # (for risk response), sex assigned at birth, gender identity, sexual orientation, race/ethnicity, primary language, zip code, grade

STUDY QUESTIONS & HYPOTHESES

Hypothesis Ia: Students with access to Soluna will show **reductions** in overall distress

Hypothesis 1b: Students with access to Soluna will show **reductions** in depression, anxiety, hopelessness, mental illness stigma, and loneliness; and **increases** in perceived social support and quality of life

Hypothesis 2: Students will show similar benefits to Soluna, regardless of demographic factors or treatment history

Hypothesis 3: Greater engagement with Soluna will predict larger improvements in wellbeing and mental health-related outcomes among students who use Soluna at least once

Hypothesis 4: Students will find both the **individual single-sessions** and **Soluna's platform overall** to be acceptable and helpful to their wellbeing and mental health

SECONDARY USAGE DATA ANALYSIS

- We anticipate this data will come from 3500-4500 newly registered users of Soluna during the project period, who provided consent to their data being used for research purposes.
- We will obtain their anonymous usage data for 8 weeks thru a one-time data pull. Kooth houses and manages the data they would be providing to us. We will be studying uptake, engagement, and acceptability.
- These are not Medi-Cal data from DHCS. However, the data for Soluna users is specified to be owned in contract by DHCS, and thus, we will also be applying to DRC for secure data usage.

DATA REQUESTING FROM KOOTH

Source	Data Description
Soluna platform	User registration, feature utilization (tools, peer community, coaching, resources), content utilization
Soluna platform	Coaching frequency, time, care navigation usage
Soluna platform	Measures - PHQ4, SWAN-OM, SWEMWBS, end of session survey, in app feedback

RECRUITMENT

- All recruitment will happen through Soluna's digital platform.
 Within the Soluna platform, students will receive a message informing them of the opportunity to participate in a research study.
- Individuals who click on the link in the message will be taken to a web page on Qualtrics that will contain information about the study and a link to the baseline survey.
- The survey will ask participants to answer questions that will determine their eligibility for the study.

SURVEYS AND COMPENSATION

- During this study, participants who choose to be in the study through the Soluna app will be eligible to receive a \$10 gift card after completion of each of the three surveys (i.e., up to \$30, across baseline, 1 month, & 3 month surveys).
- All gift cards will be sent to the email address provided.
 Participants do not incur costs for participating in the study.
- This study will not involve more than minimal risk to participants; thus, additional compensations for research related injury does not apply to this project. Participants will be provided their gift cards within 10 business days of completing the survey.

RISK

- This study will involve no more than minimal risk. Participants may feel potential discomfort due to the length and content of the survey questionnaires. Participants may feel uncomfortable or sad when answering questions about their history of suicide or self-harming behaviors.
- Participants are told in the consent form and reminded throughout the online survey that they can skip any questions they prefer not to answer as well as stop participating at any time.

RISK RESPONSE

- We are asking questions about suicidal ideation over the past month, in the form of the SIDAS scale, as well as a question around self harm thoughts or behaviors in the last month (Self-Harm Question), and a question about self harm thoughts in the last week (YP-CORE).
- In the event a participant endorses a non-zero response to any item on the SIDAS scale, OR a "yes" answer to the self harm question, OR a non-zero answer to item 7 of the YP-CORE they will:
 - Immediately be presented with the mental health resources again supplemental materials). They will have already provided both their phone number, and their parent or guardian's phone, alongside their email address (at each survey timepoint, all of which are required fields).
 - They will receive a message explaining they will be contacted by a trained team member within 24 hours, who will conduct a
 risk assessment over the phone per the attached flowchart. There will be an automated message sent to those research
 team members alerting them of this need.
- The trained team members (Schleider & Cohen) have experience conducting risk assessments as part of research studies.
- If imminent risk is determined based on the assessment phone call, the youth's parent or guardian will be called, and 911 will be called. In situations per the attached flowchart where a Safety Plan is to be completed, "My Coping Plan" is a document previously used by the NU study team for risk response. It will here be used by the NU study team if risk arises; our team members will complete the document collaboratively with the participant.

SUMMARY OF RISKS & BENEFITS

Safe for Soluna Users

Questionnaires are all validated and safe

They will help us understand how Soluna is working & improve outcomes for future students

No Changes to Soluna Availability

Users will still have access to Soluna as-usual—they'll also be invited to be part of our study

Information Kept Private

Information confidential unless we learn about risk to users (suicide or self-harm risk) thoughts, or self-harm thoughts or behaviors, are reported

Users at-risk will be contacted within 24 hours by our team

Benefits for Soluna Users

Soluna users receive up to \$30:3 surveys over 3 months, for \$10 each

DATA PROTECTIONS

- Data is de-identified and no identifying information will be published.
- Files stored on the server containing identifiable data are additionally protected via confidential passwords only known to research personnel and will be stored on a secure network at FSM Res Files. The identifying email addresses will only be stored with the data until data collection is complete and participants are compensated. Once compensation has been completed, all data will be deidentified. Participants' numeric codes linked to subject names are contained in a separate file with a separate access code.
- The original identifiable data will remain on Qualtrics, through the NU Qualtrics license, for the next six years. It allows for data to be collected and for analysis to be conducted.
- Data provided directly from the Soluna app will be kept on the secure Northwestern University internal ResFiles for 6 years, which is the standard timeframe for NUIT.



Thank you! Questions for us?

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