

**Evaluating a Single-session Intervention for Loneliness**

**Study Protocol (includes analysis plan and information sheet)**

**December 7, 2022**

**Procedure:**

*Sample recruitment:* We will use social media and possibly the subject recruitment platform “Prolific” to recruit participants. To advertise the study on social media, we will use both paid and unpaid posts on several social media platforms, potentially including Instagram, Reddit, Tumblr, Twitter, Facebook, LinkedIn, and 4chan. Social media has been used in research studies to recruit thousands of participants in the past (Sanchez et al., 2020; Shroff et al., 2021). We will aim to recruit a sample from diverse populations and online communities.

Our recruitment materials will explain that participants must be at least 16 years old, speak english, and have access to internet and a computer, smartphone, or tablet to be allowed to participate in the study. Next, we will ask participants to complete the ULS-3 loneliness measure. To ensure that we have a sufficient number of participants struggling with loneliness for analysis, if one’s score on the measure meets our criterion for “struggling with loneliness”, we will invite them to participate in the study and offer a reimbursement of a \$10 Amazon gift card that we will email them once they complete the final follow-up 8 weeks later. We will only allow participants to complete the study once. If one’s score on the loneliness measure does not meet our criterion, we will still give them the opportunity to complete the study without compensation. We will also offer them access to the loneliness programs if they prefer to not participate in the study.

*Study process:* After participants read the study information and agree to participate, they will complete baseline self-report measures of mental health outcomes and demographics. Next, they will complete the intervention (see materials for intervention information).

After they complete the intervention, participants will complete a few brief measures of hope and agency as well as engagement with the intervention platform. 4 and 8 weeks later, they will receive links via email to complete follow-up measures of mental health outcomes and engagement. After the 8-week follow-up, participants will be offered access to all three conditions and referred to other online resources for people struggling with loneliness or mental health. The entire study will be conducted using the secure online survey and "experience management" platform Qualtrics. We will include anti-fraud / anti-bot measures in the survey.

### **Materials:**

We created our 25-minute loneliness SSI and the 3-week loneliness intervention by adapting Käll et al.'s 9-week therapist-supported iCBT for loneliness (Käll, Shafran, et al., 2020). Käll et al.'s iCBT focuses on person-level psychological factors contributing to the maintenance of loneliness; it aims help challenge maladaptive thoughts and encourage social behaviors (more information on Käll et al.'s iCBT available at <https://www.iterapi.se/sites/solus/>) (Käll, Shafran, et al., 2020). Following Käll et al.'s iCBT, our loneliness interventions will include the following topics: Understanding Loneliness, Goals and Values, Testing Thoughts and behaviors, Making a plan, Gaining social confidence, and Overcoming barriers. Strategies include behavioral activation, cognitive restructuring, and behavioral experiments.

Our loneliness interventions also pull from Jessica Schleider et al.'s single-session mental health interventions (<http://www.schleiderlab.org>) in terms of aesthetics, some of their content, and using Qualtrics to develop and provide the intervention.

Both the 30-minute SSI and 3-week intervention are text-based and self-guided. The 3-week intervention includes three 10-20-minute self-guided sessions (participants complete the first

session when they start the study, the next session a week later after they receive an email with it, and the final portion the next week when they receive another email reminder).

In the control condition, participants will complete a supportive therapy SSI, called “The Sharing Feelings Project”, of roughly equivalent length and style to the loneliness SSI (J. L. Schleider & Weisz, 2019). Previous work showed this control to be slightly less efficacious in improving mental health outcomes in adolescents than a growth mindset SSI and a behavioral activation SSI (J. L. Schleider et al., 2022; J. Schleider & Weisz, 2018). The supportive therapy SSI “encourages participants to express emotions to close others”, but “does not teach specific skills”. (J. L. Schleider et al., 2022; J. Schleider & Weisz, 2018). We borrowed the supportive therapy SSI from the Lab from Scalable Mental health and slightly modified it to make it more applicable to both teens and adults, as it was originally designed for teens only (link to SSI: <https://osf.tvio/u4axs/>, license: <http://creativecommons.org/licenses/by-nc-sa/4.0/>) (J. L. Schleider & Weisz, 2019).

At the end of each intervention, participants will receive a PDF version and browser version of the intervention to keep and/or share with others.

### ***Analysis plan: Evaluating a Single-session Intervention for Loneliness***

#### **Main analysis**

In our main analysis, we will test between-group differences across experimental conditions in change in loneliness (ULS-20) from baseline to 4-week and 8-week follow-up. We will use a mixed-effects model predicting loneliness with condition, time, and the 2-way interaction between condition and measurement time point as predictors and a participant identifier as a random intercept. Using the “lme4” package in R, these analyses will take the following form:

```
lmer(loneliness ~ time*condition + (1|study_id))
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### **Secondary analysis**

We will re-run the same analysis separately for each secondary outcome collected, although the timepoints measured by the “time” variable will differ across outcomes (see table 1).

### **Inclusion criteria**

We will limit our main analyses to only those participants who 1) meet our criteria for struggling with loneliness, 2) are randomized to a condition in analyses (ie, those who consented

to participate and completed the baseline measures), 3) did not indicate that they did not participate seriously at the end of the study, 4) completed the study only once, and 5) spent at least 3 minutes completing the study introduction and baseline measures (ie, were not clearly bots or speeding past most of the content).

### **Missing data handling**

Although we take efforts to avoid missing data (e.g., a financial incentive for completing the study and reminder emails), it is not necessary to impute missing data before performing a longitudinal mixed-model analysis (Twisk et al., 2013). Participants with missing data at some assessments will be included in the analysis and results will be modeled on the basis of the available data. For all analyses, we will use the standard  $p < 0.05$  criterion for determining statistical significance.

To test for faulty randomization, we will use chi-squared tests with Yates's continuity correction and t-tests with Welch's approximation of degrees of freedom and assuming unequal variance. If any effects are found, we will adjust for them using the confounding variable as a

covariate in model testing and will note them in our interpretation of results. We will also use these tests to check for differential dropout.

### **Additional analyses**

1. We will duplicate the main analysis with the subset of participants who did not meet our criteria for struggling with loneliness and thereby participated in the study without being compensated.

2. We will duplicate the main analysis with the subset of participants who completed the week 8 follow-up.

3. We will duplicate the main analysis but will include the following covariates in the mixed-effects model: gender (multiple choice), age (continuous), ethnicity (categorical), sexual orientation (categorical), education level (categorical), socioeconomic status (continuous), whether participants completed the program on a computer or smartphone, and whether participants answered at least one written response question.

4. We will use a one-way ANOVA to test between-group differences in loneliness at 8-week follow-up. If the omnibus ANOVA produces a significant F-score, we will conduct two planned contrasts to compare the experimental condition to each control condition, and will compute Cohen's ds of these comparisons. We will run the same ANOVA on the 4-week follow-up data. We will also conduct these ANOVAs on secondary outcomes and at post-intervention for outcomes collected then.
5. We will calculate Cohen's d effect sizes reflecting within-group intervention effects on the primary DV for each SSI condition from baseline to 4-week and 8-week follow-ups.
6. We will run four logistic regression models with all baseline measures to determine if they predict which participants drop out either before completing the intervention, before the post-intervention questions, or before the 4- and 8-week follow-ups.

#### Tables describing measures

**Table 1.** Full list of primary, secondary, and screening variables collected during the study, including when during the trial they were assessed.

<b>Measure (Primary, Secondary, Other)</b>	<b>Baseline</b>	<b>Post-Intervention</b>	<b>4-week follow-up</b>	<b>8-week follow-up</b>
UCLA Loneliness Scale (primary)	X		X	X
Depression Anxiety and Stress Scale – Short Form (secondary)	X		X	X
3-item Mini Social Phobia Inventory (secondary)	X		X	X



Short form of the General Self-Efficacy Scale (secondary)	X	X	X	X
Beck Hopelessness Scale – 4-item (secondary)	X	X	X	X
Frequency of actions and thoughts scale (secondary)	X		X	X
Program Feedback Scale (secondary)		X		
Credibility and Expectancy Questionnaire (secondary)		X		
Insight experience (secondary)		X		
Star rating (secondary)		X		
MacArthur Scale of Subjective Social Status – Youth Version (secondary)	X			
UCLA loneliness scale – 3 item (screening)	X			
Patient Health Questionnaire – 4-item (screening)	X			

**Table 2.** Measures organized by dimension

Dimension	Application to project	Study Measurement(s)
Effectiveness	Improvements in symptoms and functioning	<b>Primary:</b> ULS-20 (loneliness) <b>Secondary:</b> DASS-9 (depression, anxiety, and stress), Mini-SPIN (social anxiety), GSE-6 (general self-efficacy), Beck Hopelessness Scale, FATS (frequency of adaptive behaviors and thoughts related to therapeutic change),
Engagement	Satisfaction with intervention and aspects of experience	<b>Intervention appeal:</b> PFS (satisfaction with SSI), CEQ (intervention credibility and expectations of impact), experience of an insight moment, frequency of using one’s list of popular online content links, insight experience, star rating (program quality)
Screening	Inclusion in main analyses and reimbursement	ULS-3 (loneliness), PHQ-4 (depression/anxiety)

**University of California, Irvine  
Study Information Sheet**

Brief Internet Interventions to Reduce Loneliness

**Lead Researcher  
Benjamin Kaveladze  
Psychological Science  
Phone: (949) 342-6253 Email: bkavelad@uci.edu**

**Faculty Sponsor  
Dr. Stephen Schueller  
Psychological Science  
Phone:(949) 824-3850 Email: s.schueller@uci.edu**

- Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.
- You are being asked to participate in a research study. Participation in this study is voluntary. You may choose to skip a question or a study procedure. You may refuse to participate or discontinue your involvement at any time without penalty or loss of benefits. You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately.**
- You are eligible to participate in this study if you are at least 16 years of age and fluent in English, and if you have access to the internet, a computer or smartphone, and an email address for the next 8 weeks. You may only complete the study once.
- You are being asked to participate in a research study to examine if different self-directed online programs can help people to overcome loneliness. The programs include written information based on evidence from research on well-being, as well as brief exercises. The programs can be completed on a computer, tablet, or smartphone.
- All research data collected will be stored securely and confidentially in the encrypted servers of the cloud-based survey platform Qualtrics. When the data is downloaded for analysis, it will be stored in an encrypted format on a locked computer.
- The research procedures involve answering some anonymous questions about yourself and your feelings, then completing an online program, and then giving your feedback on the program and answering more questions about yourself. 4 weeks and 8 weeks after you complete the initial survey, we will e-mail you with a few more questions to see what impact the program may have had. In total, this should take about 1 hour and 10 minutes broken up into 3 sessions or 2 hours and 10 minutes broken up into 5 sessions, depending on the intervention to which you are randomly assigned. At the end of the study, we will give you access to all the interventions we have available.

- Possible risks/discomforts associated with the study are as follow: feeling distress at some of the questions we ask about your life, finding the content of the program upsetting, and a potential breach of confidentiality if our data are compromised (although we take extensive measures to avoid such a breach).
- There are no direct benefits from participation in the study. However, this study may teach us how to make more helpful online interventions for loneliness and other mental health-related struggles. If a program is found to be useful, we will do our best to make it available to as many people as we can.
- If you do not wish to participate in this study but still want to try the program, please email the research team and we will be happy to send it to you.
- You will receive a \$10 gift card to Amazon.com after you complete the 8-week follow-up study, provided you completed the first two parts of the study and have not completed the study before.
- There is no cost to you for your participation in this study.
- The research team, authorized UCI personnel, and regulatory entities may have access to your study records to protect your safety and welfare. While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.
- We will use the information you provide us to conduct our study. Once the study is done, we plan to share a completely anonymous version of this information publicly online so that other researchers can also use it for their studies. The information we share will be de-identified, meaning it will not contain any private identifiable information that could reveal it came from you. We will not ask you for additional permission to share this de-identified information.
- In accordance with UC Office of the President policy, information will be retained for 10 years after the end of the calendar year in which the research is completed.
- If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.
- If you have any comments, concerns, or questions regarding the conduct of this research please contact the researchers listed at the top of this form.
- It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can call the lead researcher at the number listed at the top of this form.

- Stephen Schueller has financial interests in Headspace, Inc., a company with interests related to this study. Stephen Schueller is a consultant for the company and receives stock options, which is in addition to their salary from the University of California, Irvine. The nature of this financial interest and the design of the study have been reviewed by the UCI Conflict of Interest Oversight Committee (COIOC). The COIOC has determined that the researcher's financial interests are appropriately managed as to avoid compromising the quality or reliability of the study and furthermore, the UCI Institutional Review Board has determined that appropriate safeguards are in place to avoid adversely affecting your safety and welfare.
- Please contact the UCI Institutional Review Board by phone, (949) 824-6662, by e-mail at [IRB@research.uci.edu](mailto:IRB@research.uci.edu) or at 160 Aldrich Hall, Irvine, CA 92697-7600 if you are unable to reach the researchers listed at the top of the form and have general questions; have concerns or complaints about the research; have questions about your rights as a research subject; or have general comments or suggestions.

**What is an IRB?** An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.