RESEARCHER INFORMATION

Principal Investigator Name	Peter Franz
Affiliation (check all that apply)	☐Faculty ☒Graduate Student ☐Post-Doc ☐Undergraduate ☐Extension School Student ☐Staff ☐Visiting Scholar ☐Other (specify):
Faculty Sponsor (if PI is not PI Eligible)	Matt Nock, PhD
Other Advisor Name (if applicable)	

STUDY INFORMATION

Study Title	Testing whether selected blog posts can improve well-being
ESTR Number	IRB19-0843
Version Number	1
Is this a re-submission of a previous Harvard IRB-approved study that has been closed?	☐Yes - Include previous IRB submission # here: ☒No

1. FUNDING INFORMATION

1.1 Is your study funded (either directly or through a sub-award) by a Federal Agency (i.e., HHS, NIH, NSF, DOD, DOE, DOJ, or EPA, etc.)?

☐Yes
☒No

1.2 Is your study funded (or will it be) by the National Institutes of Health (NIH)?

☐Yes
☒No ***(please go to next section)***

1.3 Does your study meet the definition of a "**Clinical Trial**"?

☒Yes
☐No

HHS and NIH define a **clinical trial** as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes."

If your study meets the definition of a **clinical trial**, there are additional requirements that you must follow. Ask your assigned IRB Reviewer or see the HUA IRB website for more information.

2. RESEARCH COLLABORATIONS AND LOCATIONS

LOCATIONS

Locations refer to the geographic location where the research will take place, not to the people or institutions that you may be collaborating with. Knowing the location helps the IRB determine the local context of the research as well as if there are additional laws, regulations, and policies researchers need to adhere to. If conducting online studies, please indicate the location of the researcher who is hosting.

2.1 Where will this study take place?

☒Harvard University
☐At another location in Massachusetts
☐In another US state ***(see below)***
☒Internationally ***(see below)***

If you chose "in another US state" or "Internationally" describe the laws that will need to be considered:

The proposed study will be conducted online. As such, persons from internet access can participate in the study.

Please ensure that what you have marked above matches what has been indicated in the ESTR SmartForm, section "Research Locations."

2.2 Do you plan to obtain data from individuals located in the European Economic Area (EEA)*?

☐Yes – *Please go to next question*
☒No – *Skip to #2.4*

If "YES" the data you obtain may be subject to the E.U. General Data Protection Regulation (GDPR). Click here for more information.

**** The EEA includes the 28 states of the European Union and four additional countries: Iceland, Liechtenstein, Norway, and Switzerland. Note that this regulation may also apply to data obtained over the internet.***

2.3 Will data collected from individuals located in the EEA include any of the following? (mark all that apply)

☐Racial or Ethnic Origin
☐Political Opinions
☐Religious or Philosophical Beliefs
☐Trade Union Membership
☐Sexual Orientation
☐Data concerning a person's sex life
☐Biometric Data
☐Genetic Data

2.4 Are there any U.S. state laws, international laws, or other laws that the IRB will need to consider when reviewing this study?

☐Yes ***(see below)***
☒No

If "Yes" describe the laws that will need to be considered:

2.5 Thinking about the locations where this study will take place, are there any permissions that must be obtained from cooperating institutions, community leaders, government officials? *This may include a review by a local ethics board, school district, Ministry of Health, or other institutional approval process, whether domestic or international. A statement that formal review is not required along with your source of information that the proposed research is in accordance with local laws, regulations, and customs is also acceptable.*

☐Yes ***(see below)***
☒No

If "Yes" describe and if available, upload any permission documents to the ESTR SmartForm section "Local Site Documents."

2.6 Are there any community or cultural differences for the local population of participants that require consideration? *For example, cultural or gender dynamics or social structure considerations.*

☐Yes ***(see below)***
☒No

If "Yes" describe:

COLLABORATIONS/SITES

Collaborations, known as "sites" in ESTR, refer to people or institutions that are also taking part in the research study. An important part of knowing about these collaborations is knowing what each person/institution is doing in the research in order to determine the scope of IRB review.

2.7 Will you be collaborating with any researchers not affiliated with Harvard University Area to carry out this study? *HMS, HSPH, and HSDM are not part of Harvard University Area.*

☒Yes
☐No ***(skip to next section)***

2.8 Will the actions of these collaborators include any of the following: Have contact with human subjects; Have access to data that is identifiable; OR Are responsible for the design, conduct, or reporting of the research?

☒Yes
☐No ***(skip to next section)***

2.9 Will these collaborators receive their own IRB review?

☐Yes, all will receive their own IRB review (skip to next section)
☒No, none will receive their own IRB review
☐Some will receive their own IRB review and some will not

2.10 Is another institution and/or researcher requesting that the Harvard University Area IRB act as the IRB of record ("Reviewing IRB") for that institution's or that researcher's activities on the study?

☐Yes

☒No ***(see below)***

If you chose "No" describe the compliance/ethical oversight that this researcher will have in place:

We are working with engineers and content managers at a social media company called TheMighty. They have agreed to share all raw data with us, as well cede control over what to publish to our lab. Dr. Matthew Nock will oversee compliance with our ethical standards.

2.11 If the Harvard University Area IRB will be providing review for the non-Harvard affiliated collaborating researchers, indicate which institutions they are affiliated with and their role and activities on this study (are they involved in recruitment, data collection, analyzing data, etc.) Add additional lines as necessary.

All three individuals listed below will be working on this project in their capacity as employees of TheMighty, and will not be hired for the purposes of this research. Some or all of these individuals may be listed as co-authors depending on their level of involvement.

Name	Institution	Role on Study	Description of Activities that They will be Conducting
Sara Ray	TheMighty.com	Coder	Coding interventions, managing databases, designing algorithms to maximize engagement and optimize user experience
Daniel Graupensberger	TheMighty.com	Coder	Coding interventions, managing databases, designing algorithms to maximize engagement and optimize user experience
Sarah Schuster	TheMighty.com	User Experience Design	Helping with designing user experience (wording, timing of interventions, etc.)

3. STUDY TEAM QUALIFICATIONS AND TRAINING

3.1 Describe the Principal Investigator's experience with the proposed research procedures, population, and local context.

Peter Franz, M.A. is a graduate student in the Psychology Department under the mentorship of Dr. Matthew Nock, Ph.D. As a graduate student, Peter has conducted and published research about suicide and related mental health concerns with a broad range of populations and in numerous contexts, including hospital inpatient units and using online social networks. Peter has also been clinically trained

to manage risk and help those experiencing suicidal and self-injurious thoughts/behaviors. Dr. Matthew Nock is a Professor and Chair of the Department of Psychology at Harvard. Dr. Nock has extensive experience in clinical research and has conducted and supervised numerous research projects with undergraduate and graduate students. Professor Nock received his Ph.D. in psychology from Yale University (2003) and completed his clinical internship at Bellevue Hospital and the New York University Child Study Center (2003). Professor Nock's research is aimed at advancing the understanding why people behave in ways that are harmful to them, with an emphasis on suicide and other forms of self-harm. His research is multi-disciplinary in nature and uses a range of methodological approaches (e.g., epidemiologic surveys, laboratory-based experiments, and clinic-based studies) to better understand how these behaviors develop, how to predict them, and how to prevent their occurrence. His work was funded by grants from the National Institutes of Health and several private foundations and been published in over 100 scientific papers and book chapters. Professor Nock's work was recognized through the receipt of four early career awards from the American Psychological Association, the Association for Behavioral and Cognitive Therapies, the American Association of Suicidology, and in 2011 he was named a MacArthur Fellow. In addition to conducting research, Professor Nock was a consultant/scientific advisor to the National Institutes of Health, the World Health Organization's World Mental Health Survey Initiative, the American Psychological Association, and the American Psychiatric Association DSM-5 Childhood and Adolescent Disorder Work Group. At Harvard, Professor Nock teaches courses on statistics, research methods, self-destructive behaviors, developmental psychopathology, and cultural diversity—for which he has received several teaching awards including the Roslyn Abramson Teaching Award and the Petra Shattuck Prize.

3.2 Describe how the study staff are trained to ensure that they are adequately informed about this study and study-related duties.

All researchers will receive detailed instruction on how to collect, manage, and analyze patient data in a manner that prioritizes data security. All researchers will undergo CITI training.

We are working with staff members at The Mighty who have agreed to implement the study. At no point will they send us data that may compromise the identity of the research participants. The technology team at TheMighty will manage the platform, administer the surveys, and store the data. They have had extensive experience in surveying their users prior to this research project.

3.3 Are there any other additional study staff whose role in this study requires special qualifications in addition to ethics training (e.g., licensed clinical psychologist, phlebotomist, etc.)?

☐Yes ***(see below)***
☒No

If "Yes" describe:

4. RESEARCH PURPOSE

4.1 Provide a brief, non-technical description of the purpose of the research, including the research questions that you hope to answer.

Suicide is a leading cause of death in the US, and rates have been increasing in recent years. Despite a preponderance of research, few effective interventions exist to curb suicidal thoughts and behaviors (STBs). These interventions tend to be expensive, suffer from low engagement, or pose difficulties to

scale on a population level. Could a highly engaging modality such as social media be designed to decrease STBs?

Social media platforms produce highly engaging materials that can be disseminated quickly and freely to millions. Furthermore, the materials on these websites are produced by patients themselves, which may serve to increase acceptability among those at high risk for STBs. Lastly, these platforms are capable of monitoring data about its users as well as surveying users about their past or current STBs, thereby allowing for rigorous analysis of these thoughts and behaviors. We propose to curate a curriculum consisting of articles which have individually been shown to decrease suicidal ideation (SI) on a social media platform, and to test whether administering this reading curriculum can decrease STBs.

4.2 Describe the scientific background, rationale for the study, and importance of this research in adding to existing knowledge.

Suicide rates have increased in nearly every state over the past decades (CDC, 2018). Currently, there is no effective, widely-used, and economically viable solution to decrease STBs. Some promising work suggests that brief interventions such as sending care letters or text messages to recently discharged inpatients may decrease STBs (Motto et al., 2001, Comtois et al., 2019). Clinical treatment consisting of assigning readings—so-called bibliotherapy— have been demonstrated to decrease depressive symptoms, although not suicidality (Gualano et al., 2017). Other researchers have designed a smartphone-based video game that can reduce STBs in the short term (Franklin et al., 2016). However, the overall effect sizes of these interventions are generally small, the level of patient engagement tends to be low, and these proposed solutions are difficult to implement at scale. Social media platforms have been able to create high engagement by aggregating user-generated materials. Can such a platform be helpful in improving mood and reducing STBs?

TheMighty.com is an online social network that was designed to create online communities for patients who are dealing with healthcare challenges. Many of the user-generated articles on suicide have been viewed hundreds of thousands of times by others. Through surveys and usage patterns, The Mighty has a detailed understanding on how these materials are affecting their users. By reviewing preliminary internal survey data, we plan to help The Mighty curate a list of articles which are correlated with decreased suicidality after users read them. After identifying a set of articles associated with decreased STBs in the short-term, we hypothesize that providing users with a daily curriculum of these helpful articles over the course two weeks may be beneficial to them. We plan to work together with team members at The Mighty to investigate whether administering such a curriculum can decrease STBs, and if so, how long these effect would last. In order to investigate this question, we propose to conduct a randomized controlled trial in which new online users are either randomized to the suicide prevention curriculum with daily surveys, or to a control condition in which users will receive only the same surveys with no suicide prevention curriculum.

If we are successful, we will have designed the first social media-generated intervention that decreases suicidal thoughts and behaviors. The success of this study will have significant clinical implications: clinicians can easily refer patients to subscribe to accessible, effective, and free interventions online.

References:

Comtois, Katherine Anne, Amanda H. Kerbrat, Christopher R. DeCou, David C. Atkins, Justine J. Majeres, Justin C. Baker, and Richard K. Ries. “Effect of Augmenting Standard Care for Military Personnel With Brief Caring Text Messages for Suicide Prevention: A Randomized Clinical Trial.” *JAMA Psychiatry*, February 13, 2019. https://doi.org/10.1001/jamapsychiatry.2018.4530.

Franklin, Joseph C., Kathryn R. Fox, Christopher R. Franklin, Evan M. Kleiman, Jessica D. Ribeiro, Adam C. Jaroszewski, Jill M. Hooley, and Matthew K. Nock. "A Brief Mobile App Reduces Nonsuicidal and Suicidal Self-Injury: Evidence from Three Randomized Controlled Trials." *Journal of Consulting and Clinical Psychology* 84, no. 6 (June 2016): 544–57. https://doi.org/10.1037/ccp0000093.

Gualano, M. R., F. Bert, M. Martorana, G. Voglino, V. Andriolo, R. Thomas, C. Gramaglia, P. Zeppegno, and R. Siliquini. "The Long-Term Effects of Bibliotherapy in Depression Treatment: Systematic Review of Randomized Clinical Trials." *Clinical Psychology Review* 58 (December 1, 2017): 49–58. https://doi.org/10.1016/j.cpr.2017.09.006.

Motto, J. A., and A. G. Bostrom. "A Randomized Controlled Trial of Postcrisis Suicide Prevention." *Psychiatric Services (Washington, D.C.)* 52, no. 6 (June 2001): 828–33. https://doi.org/10.1176/appi.ps.52.6.828.

"Suicide Rates Rising across the U.S. | CDC Online Newsroom | CDC," September 24, 2018. https://www.cdc.gov/media/releases/2018/p0607-suicide-prevention.html.

5. STUDY PROCEDURES

5.1 Provide a complete overview of the study:

- Describe the procedures participants will be asked to complete or undergo.
- Explain step by step what participants will be asked to do
- Include how long the procedures will take.

If your study includes multiple variations of the procedures, please make clear which procedures are included in the variations.

This study is a randomized controlled trial (RCT) design, in which consenting participants who are 18 or older will be randomized to two conditions: Active Treatment (AT) and Control.

Study Overview: Participants in the AT condition will be assigned to read one story from the mighty per day and to complete a brief online survey. Participants in the Control condition will first be assigned to complete surveys only, but then will receive the same one-story-per-day intervention as the AT condition.

Story selection procedure: We will identify a set of 40-50 already-published stories on TheMighty that are most likely to help individuals thinking about suicide to feel (A) more optimistic about the future and (B) more connected to other people. In order to identify these articles, will use insights from the team at TheMighy as well as qualitative analysis of the content of published stories.

Part 1: Feasibility Trial

In order to ascertain the most appropriate parameters for the clinical trial, a feasibility trial will be run initially with 50 participants. Each of these first 50 participants will be entered into the raffle, regardless of whether they completed 75% of daily surveys.

When potential subjects click on articles relating to suicide, a pop-up asks patients whether they would like to participate in a study. If the user answers in the affirmative, a short questionnaire will screen in the appropriate subjects.

AT Condition: Participants in the AT condition will be provided at least 1 article per day during the 5-to-14-day initial study period by The Mighty platform management team. The articles provided in the AT

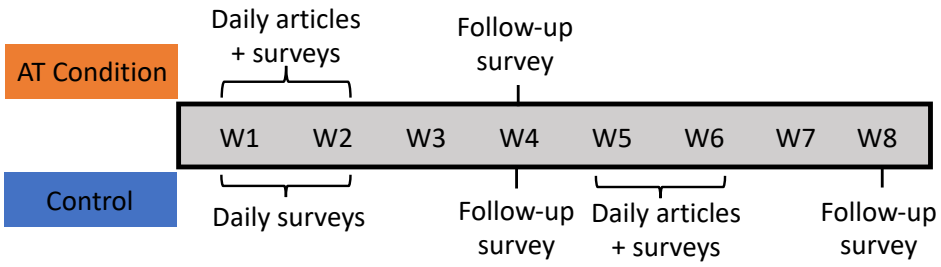
Condition will come from a predefined set of articles. This set of articles was chosen based on preliminary research by The Mighty platform management team suggesting that reading these articles was associated with a reduction in negative mood and/or self-injurious thoughts. The specific AT Condition articles will be provided before participants are recruited. Note: The articles in this condition are publicly posted articles/blog posts written by visitors to TheMighty.com. For a sample of articles see here: https://themighty.com/topic/suicide/. Participants in the AT condition will also receive a survey before and after each article. This survey will contain items assessing the following constructs: optimism, social connectedness, identification with the story's author, and suicidal ideation.

Control Condition: Participants in the Control condition will be sent emails with the same survey as those in the AT condition, but they will not receive articles.

After the feasibility trial is conducted, we will adjust the parameters of the research protocol such as length, timing for sending email, number of articles sent, etc. For example, it is plausible that most participants stop engaging after 5 days. If this is the case, the length of the study may be decreased from 14 days to as few as 5 days.

Part 2: Research Trial (See diagram below for timeline)

The protocol for the actual research trial is nearly identical to the feasibility trial described above. We will recruit 500 patients total during the research trial. Patients will be randomized to either the AT or Control condition, with approximately 50% of the sample in each condition. Based on the results of the feasibility trial, we may adjust parameters in order to maximize meaningful engagement. Such parameters may include the number of articles sent, frequency of sending articles, timing of when articles are sent, etc. Additionally, all patients will receive a follow-up survey at 2 weeks after the 5-14 day intervention period in order to assess whether the effect of reading articles is sustained. These follow-up surveys will assess similar constructs to those assessed at baseline and during the intervention period. One week following administration of the follow-up surveys, participants in the Control condition will receive the same intervention (1 article assigned per day with pre- and post-article surveys) as those in the AT condition, as well as a final follow-up surveys 2 weeks after the intervention. The intent of this design is allow those in the Control condition to also receive any benefits of the intervention.



The below sections contain additional questions depending on the type of research that you are conducting and is meant to supplement the study overview. Please complete each section, as applicable.

SURVEYS/ QUESTIONNAIRES/PSYCHOMETRIC TESTING

Skip this section if not applicable.

5.2 List the names of all surveys/questionnaires/psychometric tests to be used in this study and a description of any that are not standard/formally named (such as study-specific questionnaires).

- Hopelessness (Beck Depression Inventory; Beck, A. T., Weissman, A., Lester, D., & Trexler, L. (1974). The measurement of pessimism: the hopelessness scale. *Journal of consulting and clinical psychology*, *42*(6), 861.)
- Perceived burdensomeness (Interpersonal Needs Questionnaire; Van Orden, Kimberly A., et al. "Thwarted belongingness and perceived burdensomeness: Construct validity and psychometric properties of the Interpersonal Needs Questionnaire." *Psychological assessment* 24.1 (2012): 197.
- Depressive symptoms (Patient Health Questionnaire; Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9: validity of a brief depression severity measure. *Journal of general internal medicine*, *16*(9), 606-613.)
- Self-injurious thoughts and behaviors (shortened version of the SITBI-SR; Nock, M. K., Holmberg, E. B., Photos, V. I., & Michel, B. D. (2007). Self-Injurious Thoughts and Behaviors Interview: Development, reliability, and validity in an adolescent sample.)

5.3 How often will participants be asked to complete the surveys/questionnaires/psychometric tests and how long will it take to complete?

All participants who qualify for the study (inclusion/exclusion criteria are described in Section 7.2 below) and provide written informed consent will complete a battery of questionnaires described in Section 5.2 at three time points: at the beginning of the 14-day study period (T0), at the conclusion of the 14-day study period (T1), and four weeks after the end of the study period (Follow-up; T2).

5.4 Will you be using any survey software (such as Qualtrics)?

☒Yes (see question below)

☐No

If "Yes" which survey software will you be using? :

We will use a survey tool built internally by TheMighty. This company has previously had extensive experience surveying their users about their experience on the website.

INTERVIEWS/ORAL HISTORY/FOCUS GROUPS

Skip this section if not applicable.

5.5 Explain where interviews/focus groups will take place (including possible online venues such as Skype, online chat rooms, etc.)

5.6 Describe any steps you will take to protect the participant's privacy during the interview/focus group.

5.7 Describe the number of interviews/focus group sessions you anticipate for each participant and approximately how long you expect each interview/focus group to last.

OBSERVATIONAL/ETHNOGRAPHIC RESEARCH

Skip this section if not applicable.

5.8 If you will be actively participating in the field (as in participant-observation), describe what this will entail.

5.9 Describe what and who will be observed and in what settings (such as public events, religious ceremonies, household activities, work meetings, internet chat-rooms and social media sites, etc.)

5.10 Will any observational data be considered private, according to the standards of that community?

☐Yes ***(see below)***
☐No

If "Yes" describe the information that would be private.

5.11 Will the data you collect contain any information that identifies specific individuals?

☐Yes
☐No

5.12 Do you plan to quote the remarks of participants in your study?

☐Yes
☐No

5.13 Will you notify participants that they are being observed?

☐Yes
☐No ***(see below)***

If "No" explain the circumstances why you would not be able to let participants know they are being observed.

5.14 If permission to observe participants is obtained, how will you ascertain whether there are individuals who do not want to participate, and how you will manage such a situation?

AUDIO-RECORDING/VIDEO-RECORDING/PHOTOGRAPHS

Skip this section if not applicable.

5.15 What type of recording will take place? (check all that apply)

- ☐Audio-Recording
- ☐Video-Recording
- ☐Photography
- ☐Other ***(see below)***

If "Other" describe:

5.16 Explain what types of data will be recorded or photographed.

5.17 If you will be collecting sensitive data, will you use any procedures to de-identify or anonymize the recordings or photographs?

5.18 Explain what will happen to the recordings/photographs at the end of the study.

DECEPTION AND INCOMPLETE DISCLOSURE

Skip this section if not applicable.

Deception is the intentional misleading of a subject about the nature of the study. While withholding of full information is known as incomplete disclosure.

5.19 Describe what information will be withheld from participants or what misinformation will be provided to participants.

5.20 Explain why this research involves no more than minimal risk to participants and why it would be impracticable to carry out the research without the use of deception or incomplete disclosure.

5.21 Describe the plans for debriefing participants after their participation. If you do not plan to debrief participants, explain why.

Please be sure to attach a copy of the debriefing script (if applicable) to the "Local Sites Documents" section in the ESTR SmartForm.

USING PREVIOUSLY COLLECTED DATA

Please complete this section if you are receiving data that has already been collected. This section does not pertain to data that is being collected through interaction or intervention as part of this study. Skip this section if not applicable.

5.22 Indicate the identifiability of the data:

- ☐Will not contain any direct or indirect identifiers; will be anonymous.
- ☐Will not be directly identifiable, but there will be a code held by the data source that links to the identities; will be coded.
- ☒Will contain direct or indirect identifiers, but this research team will remove them upon receipt; will be de-identified data.
- ☐Will contain direct identifiers; will be identifiable.

5.23 Describe which data sets you plan to analyze, who is providing the data to you, and whether the data are public use data sets, restricted access datasets, or another type of dataset.

The data set from The Mighty will include characteristics of users including IP address, time spent on the page, articles viewed, and location (city, state, and country). If the user is a registered on The Mighty platform, we can gather additional information available through The Mighty, such as their self-stated interests and history of viewed articles.

5.24 Provide an overview of the types of variables that are contained in the dataset (for example, identifiable data such as names, dates of birth, addresses, or any data that are considered sensitive).
Secondary data will be used. Variables include information that users have filled out in their TheMighty account, which includes age, gender, geographical location, and prior activity on TheMighty website. The users' names will be deleted from the research analyses in order to protect privacy.

5.25 Was the data you plan to analyze collected in a previous research study?

☐Yes ***(see below)***
☒No

If "Yes" provide the title/name of the previous research study and which institution and researcher collected the data for the previous study. If the data were collected in a previous Harvard University research study, provide the ESTR number assigned to that study.

5.26 Will any of your data be obtained from internet sites (including data mining and data scraping activities)?

☒Yes ***(see question below)***
☐No

If "Yes" what websites will you access to obtain the data?

Please know that it is your responsibility to check the terms of service of any websites from which you plan to collect data to determine whether your planned data collection is compatible with the terms of service.

Similar to other online social networks, TheMighty owns the user data and is therefore permitted to conduct research on the data. We will only conduct research using secondary data of individuals who have consented to being part of the study. The relevant language from the terms of service is copied below:

"USE OF CONTENT SUBMITTED BY YOU

BY UPLOADING, POSTING, SENDING OR SUBMITTING PHOTOGRAPHS, PICTURES, IMAGES OR ANY OTHER CONTENT INCLUDING, WITHOUT LIMITATION, GRAPHICS, VIDEO, DATA, TEXT, FILES, LINKS, SOFTWARE, MUSIC, SOUND ("CONTENT"), YOU ARE CONSENTING TO BE BOUND BY THESE TERMS OF USE. IF YOU DO NOT AGREE, DO NOT UPLOAD, POST, SEND OR SUBMIT ANY CONTENT TO THIS SITE.

You agree that any Content you upload, post, email, transmit or otherwise make available via the Service is non-confidential and that we shall have a perpetual, worldwide, non-exclusive license to use any such Content in connection with the Service and our business (and any successor), including without limitation for promoting and redistributing part or all of the Service (and derivative works thereof) in any media formats and through any media channels. You also hereby grant each User a non-exclusive license to access your Content through the Site, and to use, reproduce, distribute, prepare derivative works of, display and perform such Content as permitted through the functionality of the Site and under these Terms of Service. The submission of any materials to us irrevocably waives any and all "moral rights" in such materials, including the rights of paternity and integrity."

The full terms of service are here for your reference:
https://intercom.help/themighty/en/articles/1781523-terms-and-conditions

5.27 Is the data publicly available on the internet (i.e., freely available without permission, sign-in, or other restrictions)?

☐Yes
☒No

5.28 Do you plan to access any data that is Protected Health Information (PHI) under the HIPAA law (for example, data held by a hospital or other healthcare provider or insurer)?

☐Yes
☒No ***(skip to question #5.31)***

5.29 Which organization will provide the HIPAA PHI to you?

5.30 How will permission to allow the use/disclosure of individual's protected health information (PHI) be obtained?

HRP-330 WORKSHEET: HIPAA, which may be found in the ESTR library, provides an overview of items pertaining to HIPAA that may be helpful to the study team.

5.31 Do you plan to access any data that is FERPA protected (data that are held as education records by an educational institution)?

☐Yes
☒No

HRP-331 WORKSHEET: FERPA COMPLIANCE which may be found in the ESTR library provides an overview of items pertaining to FERPA that may be helpful to the study team.

5.32 Do you plan to obtain data that has been obtained under "Broad Consent" (as part of the 2018 Requirements)?

☐Yes
☒No
☐ Uncertain

USING PREVIOUSLY COLLECTED BIOLOGICAL MATERIALS

Please complete this section if you are receiving biological material that has already been collected. This section does not pertain to biological material that is being collected through interaction or intervention as part of this study. Skip this section if not applicable.

5.33Indicate the identifiability of the biological materials:

☐Will not contain any direct or indirect identifiers; will be anonymous.
☐Will not be identifiable, but there will be a code held by the data source that links to the identities; will be coded.

☐Will contain direct or indirect identifiers, but this research team will remove them upon receipt; will be de-identified data.

☐Will contain direct identifiers; will be identifiable.

5.34 How will you obtain the material? (check all that apply)

☐Residual clinical material

☐Material obtained from a vendor

☐Material that was collected as part of another research study ***(please see below)***

☐Other – ***(see below)***

If you chose "another research study" provide the title/name of the previous research study and which institution and researcher collected the specimens for the previous study. If the specimens were collected in a previous Harvard University research study, provide the ESTR number assigned to that study.

If "another research study" or "Other" please specify:

5.35 Will the material consist of any of the following? (check all that apply)

☐Embryonic tissue

☐Embryonic stem cells

☐Stem cells

☐Fresh human fetal tissue

☐None of the above

5.36 Provide an overview of the types of variables that will accompany the biological materials (for example, identifiable data such as names, date of birth, addresses, or any data that are considered sensitive).

DEVICES

Skip this section if not applicable.

5.37 List the device(s) that you plan to use in this study (add additional lines as necessary):

Device Brand Name	Generic/Common Name	Manufacturer	Purpose	Function/Operation

5.38 Is the device(s) that you plan to use FDA-approved/cleared?

☐Yes

☐No

5.39 If any of the devices that you plan to use require a certified professional to operate, please explain who is certified to operate this device and whether they are on your study team.

Please complete HRP-307 WORKSHEET: DEVICES which may be found in the ESTR library and attach to the "Local Site Documents" section in the ESTR SmartForm.

DRUGS

Skip this section if not applicable.

5.40 List the drug(s) or biologic(s) that you plan to use in this study (add additional lines as necessary):

Drug/Biologic Brand Name	Generic/Common Name	Manufacturer	Purpose	Function/Operation

5.41 Is the drug(s)/biologic(s) that you plan to use FDA-approved/cleared?

☐Yes

☐No

5.42 Please explain who is qualified to dispense this drug/biologic and whether they are on your study team.

Please complete HRP-306 WORKSHEET: DRUGS which may be found in the ESTR library and attach to the "Local Site Documents" section in the ESTR SmartForm.

6. RISK AND BENEFIT ASSESSMENT

6.1 Describe the foreseeable risks associated with your study. Please include discussion of any physical risks and non-physical risks, such as economic, psychological, social, and legal harms.

1. Asking subjects about suicide may cause distress in some patients.
2. Despite the fact that the articles selected by TheMighty decrease the level of suicidal ideation collectively, there may be certain subjects who experience increased SI after reading the assigned articles.
3. If there is mismanagement of data, user names and/or emails may be associated with their activity in the research database, and may become visible to the researchers

6.2 Describe the steps that you will take to minimize risks to your participants (for example, using pseudonyms or a coding system, etc.)

1. In order to address this concern, we will take several measures. First, during the consenting process, we will include language that warns subjects that some of the survey questions may induce distress. Second, we will make sure that subjects can easily exit the study at any time.

It is important to note that research has demonstrated that asking patients about suicide does not appear to increase the level of suicidality (Dazzi et al, 2014). The research team will meet regularly to review data and any adverse effects. Dr. Matthew Nock, licensed clinical psychologist, will oversee these meetings.

2. At the end of each survey, we will provide users with a pop-up that provides information on how to get in touch with a suicide hotline.
3. We will institute an automatic data cleaning process that ensures that all names and emails will be deleted from the database before any researchers have access.

6.3 Are provisions needed for medical and/or psychological support resources (for example, in the event of research-related distress or incidental findings)?

☒Yes

☐No

6.4 If applicable, what steps will you take if a participant becomes distressed during your study or reports intent to harm themselves or others?

Should a participant report elevated suicidal ideation, a pop-up screen will be triggered and will provide contact information for a suicide hotline

6.5 Describe any potential direct benefits to participants in the study. If there are no individual benefits, indicate as such.

The intent of this study is to evaluate the efficacy of a reading certain articles in reducing STBs. Should it be successful, patients may experience fewer STBs. Participants may benefit from developing insight as to how reading materials affect their thoughts and feelings.

6.6 Describe any potential benefits to society.

If successful, this study will validate the first social media intervention that decreases suicidal thoughts and behaviors. We believe that validating this type of intervention would be particularly impactful given the ease with which clinicians can recommend this free intervention.

7. CHARACTERISTICS OF THE STUDY POPULATION

7.1 Indicate the estimated number of participants, by subgroup if applicable. *If it is not possible to estimate the number of participants (e.g., open online survey), please indicate that it is not possible and provide an explanation of why it is not possible.*

For the initial feasibility trial, we will enroll 50 users in order to test out operations. After process optimization (adjusting timing of sending articles, number of articles sent, etc.), we plan to recruit a

total of 1000 participants for the RCT. Half (500 participants) will be randomized to the AT Condition, and half will be randomized to the Control Condition.

7.2 Describe the criteria for enrollment – Will you be limiting your enrollment to a certain age range, gender, people with certain health conditions, etc.? Please also describe any criteria that will exclude people from enrollment.

Enrollment Criteria: In order to qualify for the study, participants must report:

- having thought about suicide in the past 12 months, and
- that they are at least 18 years old
- English is primary language

Exclusion Criteria: Prospective participants will be excluded from the study if they report:

- a high level of suicide intent (as indicated by a 7 or greater on a 10-point scale of intent to act on suicidal thoughts)

7.3 Are there any potential vulnerable populations or individuals proposed for involvement in the research? (check all that apply)

☐Children
☐Wards of the State
☐Prisoners/Detainees
☐Pregnant Women
☐Adults not Competent to Consent
☐Non-English Speaking
☐Employees of Harvard University (as a focus of the study)
☐Undergraduate Students of Harvard University (as a focus of the study)
☐Staff or students that are part of your lab or for whom you provide oversight
☐ Other – ***(see below):***

If "Other" please specify:

CHILDREN

Skip this section if not applicable.

7.4 What is the age range of children participating in your study?

7.5 Are there any special considerations that need to be taken into account? For example, do the children have a learning disability?

PRISONERS

Skip this section if not applicable.

7.6 Describe any advantages that prisoners may accrue through their participation in the research, especially in comparison to the general living conditions, medical care, quality of food, amenities, and earning opportunities in the prison.

7.7 Explain whether the risks of the research are commensurate with risks that would be accepted by non-prisoner research participants.

EMPLOYEES OR STUDENTS OF HARVARD UNIVERSITY

Skip this section if not applicable.

7.8 Explain how you will minimize the potential for employees and/or students of Harvard University to feel coerced or experience undue influence to participate in the research.

8. RECRUITMENT

8.1 Will potential participants be provided with information about the study?

☒Yes ***(see below)***
☐No ***(skip to next section)***

If "Yes" indicate how, when, where, and by whom participants will be recruited. If you are recruiting from a Harvard University Study Pool, describe how you meet their requirements.

New users who open certain articles will be recruited by a pop up screen. Patients can easily close the screen and ignore the study if they so choose. There will also be an option for users to prevent further pop ups.

8.2 Are there any materials that will be used to recruit participants (e.g., websites, emails, posters, oral scripts)?

☒Yes ***(see below)***
☐No

If yes, list the materials by document name here, and be sure to attach copies to the "Consent and Recruitment Materials" portion of the "Local Site Documents" section in the ESTR SmartForm.

Please refer to the file "Consent Form" and "Recruitment Language and Surveys"

HRP-315 WORKSHEET: ADVERTISEMENTS which may be found in the ESTR library provides an overview of items pertaining to advertisements that may be helpful to the study team.

9. SCREENING

9.1 Will you be screening participants for eligibility? *Note that If you are using inclusion or exclusion criteria, you will be "screening" individuals in order to determine who is eligible.*

☒Yes
☐No ***(skip to next section)***

9.2 Explain what your screening criteria will be and how you will conduct the screening process.

When new users access certain types of articles, a dialog box will appear asking them if they are interested in participating in a study aimed at helping The Mighty understand the impact of the articles posted by other users on its platform and asking if they would like more information. Prospective participants who respond "yes" will be prompted to fill out a brief screening survey to indicate their age and history of suicidal thoughts and behaviors.

9.3 Do you plan to destroy the data from people who participate in the screening process and do not qualify to be in the study as soon as the screening process is over?

☐Yes
☒No ***(see below)***

If "No" explain why you will keep the data collected in the screening process for people who are not eligible to participate in this study.

We plan to destroy data from participants who participate in the screening process and do not qualify for the study after the enrollment has ended. However, we would like to retain screening data from the participants who do not qualify for the study to ensure that they do not attempt to re-enroll and provide false screening information at a later time.

10. INFORMED CONSENT PROCESS

If you plan on having more than one consent process (such as signed, written consent for one population and use of an online "click" consent script for another population), please explain which variations of the study will use which types of consent process with each of these questions.

ADULT PARTICIPANTS

If you will not include adults in your study, please skip this section.

10.1 Will you be obtaining informed consent or an agreement to participate (for Exempt studies) from participants that take part in your study?

☒ Yes, I will be obtaining informed consent or an agreement to participate.

☐ No, I will not be obtaining consent or an agreement to participate **(skip to next section after answering below)**

If you will not be obtaining consent or an agreement to participate, please explain:

- ***why this research involves no more than minimal risk to participants and***
- ***why it would be impracticable to carry out the research with consent or an agreement to participate***

Participants will consent to their data from their user profile in TheMighty to be be linked with their survey responses.

10.2 Will the consenting or an agreement to participate process involve obtaining a signature?

☐ Yes

☒ No ***(see below)***

If a signature is not obtained, explain why:

The proposed study will be conducted online, so a physical signature is not feasible. An electronic consent form will be used instead.

10.3 Where will the consent or an agreement to participate process take place?

☐In-person

☒Online

☐Over the telephone

☐Other ***(see below)***

If other, please describe:

10.4 Who will obtain consent or an agreement to participate from participants? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain consent?*

The consent form will be an automatic pop-up on TheMighty's website, which will be managed by team members at TheMighty.

10.5 Describe the process that will be used to obtain consent or an agreement to participate.

Consent will be obtained digitally, by simply having the participant click "agree" before they can continue. There will be an option for users to print or download the consent form for their records.

10.6 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

Research subjects can decline participation. We will include language that explicitly states that participation is entirely voluntary, and that refusal to participate will not limit their access to the resources on the website in any way

CHILDREN PARTICIPANTS

If you will not include children in your study, please skip this section.

If you are including children in your research study, know that consenting or requesting an agreement to participate from a child is comprised of two parts: child assent and parent permission.

10.7 Will you be obtaining assent or an agreement to participate (for Exempt studies) from child participants that take part in your study?

☐ Yes, I will be obtaining assent or an agreement to participate.
☐ No, I will not be obtaining assent or an agreement to participate ***(skip to next section after answering below)***

If you will not be obtaining assent or an agreement to participate, please explain:

- ***Why this research involves no more than minimal risk to participants and***
- ***Why it would be impracticable to carry out the research with assent or an agreement to participate:***

10.8 Will the assenting or an agreement to participate process involve obtaining a signature?

☐ Yes
☐ No ***(see below)***

If a signature is not obtained, explain why:

10.9 Where will the assent or an agreement to participate process take place?

☐In-person
☐Online
☐Over the telephone
☐Other ***(see below)***

If other, please describe:

10.10 Who will obtain assent or an agreement to participate from child participants? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain the assent?*

10.11 Describe the process that will be used to obtain assent or an agreement to participate from children.

10.12 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

PARENT PERMISSION

If you will not be including children in your research, please skip this section.

10.13 Will you be obtaining parent permission or an agreement to participate (for Exempt studies) from parents whose child takes part in your study?

☐ Yes, I will be obtaining parent permission or an agreement to participate.
☐ No, I will not be obtaining parent permission or an agreement to participate ***(skip to next section after answering below)***

If you will not be obtaining parent permission or an agreement to participate, please explain:

- ***Why this research involves no more than minimal risk to participants and***
- ***Why it would be impracticable to carry out the research with parent permission or an agreement to participate:***

10.14 Will the parent permission or an agreement to participate process involve obtaining a signature?

☐ Yes

☐ No (see below)

If a signature is not obtained, explain why:

10.15 Where will the parent permission or an agreement to participate process take place?

☐In-person
☐Online
☐Over the telephone
☐Other ***(see below)***

If other, please describe:

10.16 Who will obtain parent permission or an agreement to participate from the parents? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain the permission?*

10.17 Describe the process that will be used to obtain parent permission or an agreement to participate from parents.

10.18 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

OTHER TYPES OF PARTICIPANTS

If this section is not applicable, skip to next section.

10.19 If you will be including **Wards of the State**, explain how consent of legal guardian(s) of ward(s) will be obtained. How will you ensure that the appropriate person granted permission for each ward to participate?

10.20 If you will be obtaining consent from special populations such as **non-English speaking participants**, **illiterate participants**, or **adults not competent to consent**, please explain how you will obtain consent from those individuals.

10.21 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

Please be sure to attach copies of all informed consent/parent permission/assent materials to the "Local Site Documents" section in the ESTR SmartForm.

11. PARTICIPANT COMPENSATION AND FINANCIAL OBLIGATION

11.1 Will your study offer any compensation/incentive to participants (including cash, gift cards, course credit, etc.)? *Please refer to the Harvard University Financial Policy on Human Subject Payments.*

☐Yes
☐No ***(skip to #11.6)***

11.2 What type of compensation will you provide to participants?

☐Cash
☐Check
☒Gift Card/Gift Certificate
☐Course Credit
☐Lottery/Raffle
☐Other ***(see below)***

If you chose "Other" please specify:

11.3 What amount will the compensation be worth?

Compensation for the study will include entry into a raffle to win one of two $250 checks. One check will be allocated to participants in the AT condition and the other to those in the Control condition.

11.4 Describe which participants will receive compensation and when the compensation will be given.

Participants in each condition (AT and Control) will be assigned one numbered token for each completed survey during the entire study period. Participants will need to complete 75% of the daily surveys in order to qualify for a raffle, in which one token from the each group will be randomly selected at the end of study (week 4 for AT condition; week 8 for the Control condition). The two owners of those tokens will be asked for their physical mailing address so we can send them each a $250 check. If a winning participant is not able to provide a mailing address, they will not be eligible to win the $250 check.

11.5 Will you provide partial compensation for participants who do not complete all the study procedures?

☐Yes **(see below)**

☒No

If "Yes" please explain how partial compensation will be managed:

HRP-316 WORKSHEET: PAYMENT which may be found in the ESTR library provides an overview of items pertaining to payment that may be helpful to the study team.

11.6 Will participants incur any financial costs by taking part in this study?

☐Yes ***(see below)***

☐No

If "Yes" please explain.

12. DATA SECURITY AND MANAGEMENT

12.1 Describe the identifiability of the data when first obtained/collected:

☐Will not contain any direct or indirect identifiers (Anonymous)

☐Will not be directly identifiable but there will be a code held by the data source that links to the identities (Coded) – *i.e., if receiving data from another site*

☒Will contain direct identifiers (Identifiable)

12.2 Describe the identifiability of the data when stored:

☐Will be directly labeled with personal identifying information (identifiable)

☒Will be labeled with a code that the research team can link to personal identifying information (Coded)

☐Will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information (Anonymous or De-identified)

☐Other - explain here:

12.3 Which category of information best describes the data according to the Harvard Research Data Security Policy? ***Please know that it is the researcher's responsibility to ensure compliance with the Harvard University Data Security Policy at all times.***

☐LEVEL 1 - Data that is publicly available or not identifiable. Examples:

- Research data that has been de-identified in accordance with applicable rules;
- Published research data; published information about the University;
- Course catalogs;

- Directory information about students who have not requested a FERPA block;
- Faculty and staff directory information.

☐LEVEL 2 - Information the University has chosen to keep confidential but the disclosure of which would not cause material harm. Examples:

- Research data that is identifiable but is not considered sensitive;
- Patent applications and work papers, drafts of research papers;
- Building plans and information about the University physical plant.

☒LEVEL 3 - Information that could cause risk of material harm to individuals or the University if disclosed. Examples:

- Information protected by the Family Educational Rights and Privacy Act (FERPA) to the extent it is not covered under Level 4 including non-directory student information and directory information about students who have requested a FERPA block;
- HUIDs associated with names or any other information that could identify individuals;
- Harvard personnel records (employees may discuss terms and conditions of employment with each other and third parties);
- Institutional financial records;
- Individual donor information;
- Other personal information protected under state, federal and foreign privacy laws not classified as Level 4 or 5.

☐LEVEL 4 - Information that would likely cause serious harm to individuals or the University if disclosed. Examples:

- High Risk Confidential Information (HRCI) and research information classified as Level 4 by an IRB;
- Personally identifiable financial or medical information;
- Information commonly used to establish identity that is protected by state, federal, or foreign privacy laws and regulations;
- Individually identifiable genetic information that is not Level 5;
- National security information (subject to specific government requirements);
- Passwords and Harvard PINs that can be used to access confidential information.

☐LEVEL 5 - Information that would cause severe harm to individuals or the University if disclosed. Examples:

- Research information classified as Level 5 by an IRB or otherwise required to be stored or processed in a high security environment and on a computer not connected to the Harvard data networks;
- Certain individually identifiable medical records and genetic information, categorized as extremely sensitive.

12.4 In what format will the research data be **collected**?

☐Paper
☒Electronic
☐Other – ***(see below)***

If "Other" please specify:.

12.5 In what format will the research data be **stored**?

☐Paper
☒Electronic
☐Other – ***(see below)***

If "Other" please specify:.

12.6 Explain **where** the research data will be stored while the study is active (e.g., personal laptop, thumb drive, departmental computer server, office file cabinet, etc.).

The data will be initially stored on encrypted servers by TheMighty and will be then transferred to Harvard University computer servers.

12.7 Will the data be managed by Harvard researchers either remotely or housed at Harvard (e.g., physically or Harvard Cloud Storage)?

☒Yes
☐No

12.8 Do you anticipate that the research data will be transferred or transported from your possession to another at any time?

☐Yes
☒No ***(skip to question #12.10)***

12.9 Explain what methods you will use to transfer/transport the data and how you will minimize the risks of a data breach during the transmission process.

12.10 Will data be transferred from the EEA* to Harvard or another non-EEA location?

☐Yes
☒No
**** The EEA includes the 28 states of the European Union and four additional countries: Iceland, Liechtenstein, Norway and Switzerland.***

12.11 Will (or has) a Certificate of Confidentiality (CoC) be (been) obtained for this study? *If your study meets the definition of a clinical trial according to the NIH, a CoC will be automatically issued with your funding.*

☐Yes
☒No

12.12 What will happen to the data at the conclusion of the study? (check all that apply)

☐Direct identifiers* and/or the key to the codes will be destroyed upon completion of the research (all data will be stripped of identifying information and/or the key to codes destroyed, identifiable paper documents shredded, identifiable electronic files purged, Identifiable electronic media securely erased).
☐Retained for study record keeping purposes per institutional policy.
☒Retained by the investigator for future research use.
☐Retained for future research use (create repository/bank).
☐Restricted use data will be destroyed or will be returned to the source.

☐No direct or indirect identifiers* are being collected. This anonymous data will be retained at the discretion of the investigator.

☐This research is a clinical trial conducted under FDA regulations. Direct identifiers* and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations.

☐Other – ***(see below)***

**** Direct identifiers.*** *These are variables that point explicitly to particular individuals or units. Examples include: names, addresses, including ZIP and other postal codes, telephone numbers, including area codes, Social Security numbers, other linkable numbers such as driver's license numbers, certification numbers, etc.*

Indirect identifiers. *These are variables that can be problematic as they may be used together or in conjunction with other information to identify individual respondents. Examples include: detailed geographic information (e.g., state, county, province, or census tract of residence), organizations to which the respondent belongs, educational institutions (from which the respondent graduated and year of graduation), detailed occupational titles, place where respondent grew up, exact dates of events (birth, death, marriage, divorce), detailed income, offices or posts held by respondent.*

If "Other" please specify:.

13. SHARING DATA WITH OTHERS

13.1 Will the data be released to anyone who is not on the Harvard University Area research team?

☒Yes

☐No ***(skip to question #13.4)***

13.2 Other than the Harvard University Area research team, who will have access to the data?

☒Colleagues/Collaborators at other institutions

☐Transcribers/coders hired by the research team

☐Sponsor/Funding Agency

☐Other ***(see below)***

If "Other" please specify:.

13.3 How will the data be shared/disclosed beyond the Harvard University Area research team?

☐Without any identifiers

☒Coded

☐With Identifiers

13.4 Will you be sharing research findings with study participants?

☐Yes ***(see below)***

☒No

If "Yes" please describe which findings will be shared, when they will be shared, and how they will be shared with participants (in-person, over the telephone, etc.):

13.5 Does the study include establishing a repository for sharing data or specimens with other researchers?

☐Yes ***(If so, please know that a separate IRB submission will be needed if a data or specimen repository will be created)***

☒No

GENOMIC DATA SHARING

13.6 Will you be submitting data to a national data repository (dbGaP, GEO, etc.) or other type of repository for broad sharing of data?

☐Yes

☒No ***(skip to next section)***

13.7 Will you require a Genomic Data Sharing (GDS) Institutional Certification per NIH GDS policy?

☐Yes

☐No

13.8 Include a description of all fields to be submitted to the repository:

13.9 Describe the plan for de-identifying data for inclusion in the repository, including how the key linking the identity of participants will be maintained and who will have access:

If data will be prospectively collected, specific elements are required to be included in the informed consent form that you will be using in this study. Please see the NIH guidance document.

If data that will be submitted have already been collected under another IRB or other collection protocol, please be sure to attach a copy of the IRB approval and approved consent form(s) used to collect the underlying data/specimens to the "Local Site Documents" section in the ESTR SmartForm.