Testing a Digital Intervention for Adolescents

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Testing a Digital Intervention for Adolescents

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I. RATIONALE AND PURPOSE OF STUDY

a. Background:

Mental disorders among children and adolescents have been on the rise, and have reached a prevalence rate of 16.5% in the U.S. (Twenge, Cooper, Joiner, Duffy, & Binau, 2019; Whitney & Peterson, 2019). Preventative approaches are effective in reducing the adolescent mental health burden, particularly when they target specific risk and protective factors for mental health (Kieling et al., 2011). One specific risk factor for future mental health problems in adolescence is elevated, chronic stress (Anderson et al., 2014), which has rarely been evaluated as an outcome variable in interventions (Feiss et al., 2019) with the exception of school-based stress management interventions. Stress is a growing concern for teens in the U.S., as adolescents have reported higher levels of stress than they perceive to be healthy, levels that are often higher than those reported by adults, and many reported increasing levels of stress (Anderson et al., 2014). What stress-focused interventions exist tend to rely on simple stress reduction techniques (Carter & Garber, 2011; Dozois, Seeds, & Collins, 2009) and these have had limited efficacy. However, adolescent stress may stem from negative cognitions, thus general mental health interventions that incorporate therapeutic approaches to improving negative cognitions may more effectively reduce adolescents' perceived stress levels. Rumination is a transdiagnostic, cognitive process strongly associated with stress, which also exacerbates the negative effects of stress among adolescents (Topper, Emmelkamp, Watkins, Ehring, 2017). There is evidence that both rumination and perceived stress can be reduced with interventions based on Cognitive-Behavioral Therapy (CBT) and mindfulness, suggesting an approach drawing on several therapeutic traditions that target specific positive and negative factors may be the most beneficial (Mazzer & Linton, 2019; Bessette et al., 2020). Unfortunately, little research on adolescent interventions assesses both stress and rumination; therefore, testing an intervention aiming to reduce stress and rumination is warranted.

b. Rationale: Because of the dearth of interventions aiming to reduce stress and rumination in adolescence, particularly ones that are scalable and low-cost, further exploration and dissemination of mental health interventions is warranted. Happify for Teens, a digital product that aims to improve well-being, may be particularly useful for adolescents in reducing perceived stress and rumination due to its holistic approach. Although previous studies have shown that Happify can improve resilience, subjective well-being, anxiety, and depression in adults (Parks et al., 2018; Parks et al., 2020), it has never been tested in a younger age group (ages 13-17). The proposed study will build on previous research by examining

the efficacy of Happify in a new population, and will potentially offer a valuable and accessible mental health resource to teens.

c. Purpose: The purpose of this study is to examine whether a digital product, called "Happify for Teens", can successfully reduce perceived stress and rumination, and improve other outcomes including: sleep disturbance, loneliness, and optimism, for teenagers ages 13-17, when compared to a waitlist control condition. Happify is delivered online and rooted in various therapeutic traditions, including CBT, positive psychology, and mindfulness-based stress reduction. It provides users with tracks and activities that teach skills involving savoring (e.g., mindfulness-based activities), thanking (e.g., gratitude-based activities), aspiring (e.g., optimism and goal-setting activities), giving (e.g., kindness and forgiveness activities), empathizing (e.g., self-compassion and perspective-taking activities), and reviving (e.g., physical activities), which aim to improve mental health. If found to be effective, Happify for Teens will be an accessible and cost-effective resource for teen stress reduction and general mental health.

d. Nature of Study: The nature of this study is confirmatory and exploratory. We will be testing the hypothesis that using the Happify platform will result in greater decreases in perceived stress and rumination over an 8-week period compared to a waitlist control, with users who complete more activities experiencing more improvement. We also aim to explore the effects of Happify on several factors, including: sleep disturbance, loneliness, and optimism. To do this, we will employ a longitudinal randomized design. Participants will be randomly assigned to either the Happify experimental condition or the waitlist control condition after meeting inclusion criteria and taking a baseline assessment. Those in both conditions will be asked to complete assessments at 4 weeks (mid-point), after the 8-week intervention period (immediate post-test), and 1-month post intervention. Participants will be adolescents aged 13-17 with elevated levels of rumination and stress who are recruited online.

II. PROCEDURES INVOLVED

a. Study Design:

i. This study will build on Happify's existing recruitment strategies and will advertise to parents on social media and existing Happify users who indicate they have adolescents. Parents who take interest in having their child(ren) participate in this study will be directed to an online prescreen questionnaire via Qualtrics that will assess their child(ren)'s eligibility for the study by asking how many kids they have aged 13-17, their child(ren)'s age(s), country of residence, and previous Happify use. They will also be provided with a description of the study and what their child(ren) will be expected to do. If they are still interested and their

child(ren) meets these preliminary inclusion criteria, they will be asked to read and sign the consent form and check a box for each child that they want to participate. They will type their name and email, and child(ren)'s name and email so the child can complete their initial prescreener (in the event that a child does not have their own personal email address, parents will be instructed that they can provide a parent's email address and share the email with their child). After the prescreen, parents will be sent a Thank You email with a link to share the study with other parents who may be interested.

ii. The Qualtrics prescreener link will then be sent to the child. It includes verifying their country of residence, age, and previous Happify use. They will also complete the Perceived Stress Scale (PSS) and Ruminative Responses Scale (RRS) to ensure their scores are above thresholds (PSS ≥ 10; RRS ≥ 14). Finally, the participant must agree to study duties, including: completing the baseline assessment, completing activities via Happify through a computer or smartphone, and being contacted throughout the 12 week period by Happify research staff. Participants are told that they may be assigned to a waitlist control and will not have access to the Happify platform until the end of the study but will still have to complete assessments. They are asked to check a box if they would be willing to continue with the study and not download Happify if assigned to the waitlist. We will ask participants to agree to not discuss the study with friends or family also participating in the study. If the child meets the inclusion criteria, they will be instructed that they'll receive an email inviting them to complete the first assessment (baseline assessment) on the following Monday or Thursday (whichever comes first). They must complete this assessment in order to qualify for the study, and must continue to meet thresholds for perceived stress and rumination, and pass at least one of 7 attention checks during the baseline assessment. This email will have instructions to set up a unique study ID that will be used throughout the study to link participant data across assessments and other data collections.

iii. In this email, participants will be provided an assent form (through Qualtrics) which is shown at the beginning of the baseline assessment. If participants choose to, they will read and agree to a statement that they will provide honest and thoughtful responses throughout the study, and a separate statement agreeing not to discuss the study with any family or friends who may also be participating in the study. Participants must complete the baseline to be randomized to condition. Participants are

required to pass at least one of the attention checks in the baseline assessment. These attention checks require people to select a specific response option (e.g., for the PSS, an attention check item could instruct the participant to select "Never", and this would vary across all assessments). Participants who complete and pass the baseline assessment on Qualtrics will be randomly assigned, via a Qualtrics randomization tool, to either the experimental or waitlist control group, and will receive an email or text (through Simple Text) with information detailing their condition on their corresponding start date. If they are in the experimental condition, they will also receive a link to download Happify. Both groups will complete assessments at 4 (mid-point), 8 (immediate post-intervention), and 12 weeks (one month post-intervention) via their preferred method of contact which was obtained in the baseline (e.g. email or text). All participants will be prompted to provide their user ID and complete the PSS, RRS - Brooding Subscale, LOT-R, PROMIS Pediatric Sleep Disturbance scale, and the RULS-8 via Qualtrics at each assessment point. Participants will also be asked at each assessment point if they have sought out help from other online platforms and what their current schooling situation is (fully remote, hybrid model, fully in person, home-schooled, or not in school). All of the assessments will have one attention check per questionnaire, which will instruct participants to select a specific response option to ensure they are reading questionnaire items and instructions carefully. The SLSS and PANAS-C-S will be administered only during baseline for scale validation purposes, and the experimental group will receive the Happify scale as part of the app experience every 2 weeks. In both cases, participants who do not qualify for the study will be thanked and alerted through Qualtrics that they do not qualify, and all their survey information will be deleted to protect their confidentiality. Participants who do not complete the baseline assessment will not go onto the study and will also have all of their information deleted.

b. Study Measures:

i. Usage statistics such as number of activities completed and number of active days will be collected.

ii. Major assessments will consist of several validated and published scales that assess aspects of participants' mental health, and information about the participant. All scales also have been used in previous peer-reviewed research with adolescents. Scales are listed below, and the full text of all scale items can be found at the end of this document.

1. Perceived Stress Scale (PSS; Cohen, Kamarck & Mermelstein, 1983): 10-item measure of perceived stress

2. Ruminative Responses Scale (RRS) - Short Form - Brooding Subscale (Treynor, Gonzalez, & Nolen-Hoeksema, 2003): 5 items which measure moody pondering over 7 days
3. Life Orientation Test-Revised (LOT-R; Scheier & Carver, 1985), 10-item measure on optimism
4. Roberts UCLA Loneliness Scale (Roberts, Lewinsohn, & Seeley, 1993): 8-item measure of subjective feelings of loneliness and social isolation
5. PROMIS Pediatric Sleep Disturbance Scale - Short Form 4a (Yu et al., 2012): 4-item scale measuring the frequency of sleep disturbances over 7 days

iii. Other Outcomes

1. Happify Scale (proprietary scale, developed by A.C. Parks): 9-item measure of cognitive and emotional well-being. This scale is given every 2 weeks, as part of the Happify platform experience.
2. Student Life Satisfaction Scale (SLSS; Huebner, 1991): measures life satisfaction in school-aged children and adolescents; is only given during the baseline assessment in order to validate the Happify Scale with adolescents.
3. Shortened Positive and Negative Affect Schedule for Children (PANAS-C-S; Ebesutani et al., 2012), which measures positive and negative emotions in youth; is only given during the baseline assessment for validation purposes.
4. Demographic Questions (baseline assessment only):
    a. Race and Ethnicity Question: “What is your race or origin?” (check all that apply). Participants will select from, “American Indian or Alaska Native”, “Asian”, “Black or African American”, “Hispanic or Latinx”, “Native Hawaiian or Other Pacific Islander”, “White”, or “Some other race or origin”. Then participants will be asked if they identify with a race or origin that was not on the list, and if they select “yes”, participants will be asked to “Please specify”, and they will be given a text box to type in.
    b. Gender Question (optional): Participants will be asked “What is your gender?” and they will be provided with a text box to type in their response.
    c. Age: “What year were you born?” (text box to respond)
    d. Parental Happify Usage: “To your knowledge, have either of your parents used Happify before?”; participants will

respond with “Not that I know of”, “Yes, one of my parents” or “Yes, both of my parents”

5. Schooling Question (at each assessment point): 1 item asking “What is your schooling situation right now?” Participants will select from “Fully in person”, “Fully online learning”, “Hybrid model”, “Homeschool”, or “Do not attend school.”
6. Self-Care App Use (at each assessment point): 1 item asking participants if they have used any self-care or wellness apps. If they indicate yes, they will be prompted with “Which apps?” in which they will type in their response.

iv. Participants will receive reminders if they have not completed these assessments on time, and if a participant has not completed an assessment within 7 days of its scheduled date, a member of the research team will reach out via text message or email (depending on their preferred mode of contact) to check in. We will remind them that they receive $20 for every major assessment completed (after baseline) and receive a $20 bonus for completing all four assessments.

Optional Qualitative Follow-Up

An optional qualitative follow-up survey will be offered to participants who complete at least 1 activity in the Happify for Teens application, complete the follow-up assessment and at least one of the following: Midpoint or Post Assessment. This survey will include 13 open-ended questions, 2 close-ended questions, and 3 fill in the blank questions. The survey questions will focus on 3 topics: overall perceptions and preferences of Happify, perceived impacts of the app for improving mental health, and overall usability, acceptability and likability of Happify for Teens.
The survey is estimated to take 40 minutes to complete per participant. See Appendix K for details describing this follow-up

c. Study Conditions:

i. Happify: Participants assigned to the experimental condition will be sent a link to download the Happify Teens platform, as well as instructions on how to get started. These participants will have full access to the Happify for Teens platform for the entire 12-week study period. Happify for Teens has multiple tracks that target specific issues (e.g., “The Friendship Project”), which contain activity variants and games based on research in positive psychology, cognitive-behavioral therapy, mindfulness, etc.. Track activities are organized into five categories based on the acronym STAGER: savor (savoring and mindfulness), thank

(gratitude), aspire (goal-setting, reframing/optimism, and meaning), give (prosocial behavior, kindness, and forgiveness), empathize (perspective-taking and self-compassion), and revive (physical health). Although participants have access to all tracks on the Teens platform, four tracks related to stress and rumination will be featured: *Stress Buster 101, Stop the Worry Cycle, Be Kinder to Yourself, and Fight Those Negative Thoughts*. Participants will also have access to instant play activities. An example of an activity on Happify is called "Today's grateful moment", which asks participants to spend a few moments writing about something they are grateful for. They will not be told directly how often to engage with the platform; however, we will encourage them to engage with the platform regularly. Participants also will receive push notifications on their mobile device every other day to remind them to access the platform, and they will receive weekly emails as part of the Happify Health platform to help increase engagement. If a participant has not completed any activities within the platform for 7 days, they will also receive a text message or email (depending on their preferred mode of contact) from a member of the research team to check in. Participants will continue to have access to the Happify for Teens platform for an additional 4 weeks after the intervention period ends (until the 12-week assessment), but will receive no instructions, reminders or push notifications to use the platform during this time.

ii. Waitlist comparison: Participants assigned to this condition will be notified that they have been assigned to the waitlist control condition and will receive access to the Happify for Teens platform after the 12 week study period. They will be asked to refrain from downloading Happify in this time period and that they will still need to complete assessments in 4 weeks, 8 weeks, and 12 weeks time as part of the study.

d. Study Duration: It is expected that this study will take 12 weeks to complete. Users will be asked to complete a baseline questionnaire after assenting to participate in the study, and based on completion, will then be assigned to either the Happify condition or the waitlist control condition. Participants will be asked to complete a mid-point assessment at 4 weeks, a post-test questionnaire at the end of the 8-week intervention period and one month after the post-assessment, users will be asked to complete a follow-up questionnaire. They will receive check-ins via their preferred method of contact every 2 weeks throughout the study that ask if they have any questions and thank them for their participation. Participants and parents of participants will also receive thank you messages at the end of the study.

e. Design and Proposed Statistical Analysis

I. Changes in Stress and Secondary/Exploratory Outcomes: To assess whether changes in participants' perceived stress differed across the two groups, we plan to conduct a 2 (group: intervention vs. control) x 4 (time: baseline, 4 weeks, 8 weeks, 12 weeks) repeated-measures ANOVA on participants' PSS scores, controlling for participant age and gender. Similar analyses will be conducted on secondary and exploratory outcome measures. To determine whether usage predicted changes in these outcomes, we will also conduct regression analyses among participants in the intervention condition regressing their scores on each outcome variable onto the number of activities completed within the Happify for Teens platform, while controlling for corresponding baseline scores on that outcome.

ii. **Rumination as a Potential Mediator**: To test whether any observed changes in perceived stress can be attributed to changes in brooding, we also plan to conduct mediation analyses using Hayes' PROCESS macro for SPSS.

iii. **Data Exclusion**: Because careless responding is problematic with online surveys and may artificially increase relationships between variables, we plan to use to two separate a priori mechanisms for identifying low quality data: (1) failing 3 or more attention checks in an assessment, and (2) completing an assessment at a rate faster than 1 second per item. We will then re-run the analyses described above without these participants to test whether effects differ when removing low quality data.

iiii. **Happify Scale Validation**: To validate the scale for internal purposes, we will conduct confirmatory factor analysis testing the two-factor structure of the scale, and examine convergent validity by computing correlations between the positive emotion subscale and the PANAS-C-S and between the life satisfaction subscale and the SLSS that are collected at baseline.

III. RECRUITMENT

a. Study Population: This study will recruit adolescents aged 13-17 (Target *N*=800) by advertising to parents on social media (e.g. Facebook, online forums, word of mouth etc…) and existing Happify users who have previously indicated they are parents of adolescents as part of the Happify onboarding process. We will also use a snowballing recruitment method, in which parents who complete the prescreener will be encouraged to share the study with others. We will continue recruiting until 800 participants have met inclusion criteria, successfully completed the baseline assessment, and have started the study.

b. Inclusion Criteria: Participants are those who are 13-17 years old, are located in the United States, are a new user of Happify, willing and able to complete the study activities, agree to potentially being selected for the waitlist comparison, agree to not discuss the study with friends or family, report elevated levels of perceived stress (PSS score of at least 14) and rumination (RRS-Brooding score of at least 10), and have a

parent who is willing to consent to the study. Participants are required to complete and pass the baseline assessment to be included in this study.

c. Exclusion Criteria: Participants may withdraw from the study or skip assessments at any time; however during the prescreening and/or baseline process, potential participants will be disqualified if they indicate:

i. They are not 13-17 years old.
ii. They reside outside of the United States
iii. They have previously registered for or used Happify
iv. They are not willing and able to complete the study activities
v. They indicate that they are not willing to continue the study or refrain from downloading Happify if selected to be on the waitlist
vi. They are not willing to use a mobile app or internet website
vii. They do not agree to refraining from discussing the study with friends or family
viii. They have a PSS score of below 14
ix. They have an RRS-Brooding score of less than 10
x. They do not agree to be contacted
xi. Their parent does not consent to the study
xii. Participants will also be excluded if they do not complete the baseline assessment, or if they do but fail at least 7/7 attention checks.

2. **Sample Size:** We will recruit 800 participants to be in this study, 400 in each condition.
3. **Withdrawal:** Participants may choose to withdraw from the study at any time. Data that has been collected up until that point will be available to the research team for analysis. Participants can withdraw by contacting the research team, and then they will be promptly removed from the study.

IV. CONSENT PROCESS

a. Consent Process: Parents who are interested in having their adolescent children participate must read about the study procedures and requirements, and actively check a box that indicates they understand the requirements of the study. To consent, they will draw their signature on an online form through Qualtrics. They will draw a signature and check a box for each child. Adolescents who would like to participate read about the procedures and requirements of the study, and actively check a box that indicates that they understand the requirements of the study before they begin the baseline assessment. To assent, they click a box that says, “YES, I would like to participate in this study.” Consent and assent will be obtained for all participants before enrolling them in the study and beginning the baseline assessment.

b. Consent Documentation: Electronic records of participant assent and parental consent will be downloaded through Qualtrics and moved to Happify servers, where they will be maintained.

V. INCOMPLETE DISCLOSURE OR DECEPTION

a. Incomplete Disclosure/Deception: Not applicable; participants will be provided with all necessary information before participating in this study.

VI. RISKS TO PARTICIPANTS

a. Risks: To our knowledge, there are no anticipated risks to participating in this study. The research makes no claim of providing treatment for mental illness (which will be made clear to individuals prior to participating). Rather, the research team is interested in improving the psychological wellbeing of teens with elevated levels of perceived stress and rumination. Both parents and teens will be required to check a box that indicates they understand this study does not provide treatment for any condition and is not a substitute for medication or therapy. Since this study uses the internet, there's a possibility that someone could see the participants computer or phone screen and see the information they are sending us. Each participant may choose to answer the surveys in a private room or behind closed doors, to protect their privacy.

VII. BENEFITS TO PARTICIPANTS

a. By participating in this study, participants will gain access to an online program that may benefit them. We cannot guarantee that participants will benefit directly by participating in this study; however, we are testing this platform because we believe there is a good chance that it will be helpful to participants and other users in the future.

i. There is a dearth of evidence-based digital platforms for teens that aim to decrease stress and rumination, while improving psychological well being. Therefore, if it is shown to be effective, Happify would be an accessible, low cost resource in which teens can attain mental health care early on through the reduction of perceived stress and rumination. This program would benefit teenagers themselves, but also their schools and parents, thus improving society at large.

VIII. FINANCIAL COMPENSATION

a. Financial Compensation:

i. Parents will be entered into a raffle for a $50 Amazon gift card for referring other parents to the prescreener via a link we send them. They

will receive one additional entry for each person they refer to the study and who reports their name and/or email. The raffle will be conducted once a month throughout recruitment, and the parent will be emailed their gift card.

ii. Participants in both conditions will be compensated for completing the major assessments, after baseline. They will receive $20 Tango cards for completing assessments at each point: 4 weeks (mid-point), 8 (end-point), and 12 (follow-up) weeks. If participants complete each of these assessments, they will receive $60 total in Tango gift cards. In addition, those who complete all 3 assessments will receive a $20 bonus, leading to a possible total compensation of $80.

iii. Tango cards will be delivered immediately after assessment completion through Qualtrics to the participant's preferred method of contact (phone or email). Participants receive a reward link and will be directed to the Tango Card site, where they can choose which gift card they want from 80 popular brands.

iv. Participants will not be compensated for use of the intervention, only the completion of assessments.

IX. PARTICIPANTS' PRIVACY INTERESTS

a. Data Privacy: The privacy of participants in this study will maintain the same privacy of regular users of Happify, which is strictly confidential, and this project's data will only be accessible to Happify researchers. All questionnaire data will be stored securely in the research coordinator's password protected-Qualtrics account, and access will be limited to the research team. Once the study is complete, data will be downloaded to the PI's secure, password-protected computer and saved using secure storage on Happify servers. In addition, when data are exported from that secure server for analysis, they will be exported in a de-identified format (without name, location, or IP address data). Data, therefore, can only be analyzed anonymously by the research team, which will help to safeguard participants' privacy interests. Any data collected about participants in the experimental condition via the Happify for Teens platform also will be stored securely using Happify servers

b. Publication: Data will be analyzed for internal use and publication. We intend to pursue publication of one or more papers in peer-reviewed journals and may be presenting preliminary findings at conferences. All data will be presented in aggregate form, with no identifying information attached that would reveal a participant's identity.

c. The research team leads who will be able to manage, access, and determine access to data are:

i. Eliane Boucher, PhD (PI, Research Scientist at Happify)
ii. Nicole Harake, PhD (Research Associate at Happify)
iii. C.J. Miles (Clinical Research Coordinator at Happify)

X. CONFIDENTIALITY AND DATA MANAGEMENT

a. **Confidentiality:** Research data, including questionnaire data and information about participants' engagement with the Happify platform (e.g., number of activities completed during the study) will be stored securely on Happify servers and will be stored separately from any information that might be used to identify participants. Data will be contained in password-protected digital files and stored on a secure server from Happify. Only the PI and associated research staff will have access to the data files. Computers to be used by the researchers are also password-protected.
    i. Parent email and name and child email and name will be collected in the prescreener for referral and contact purposes. Child phone number will also be collected in the baseline assessment if that is their preferred method of contact for the purposes of contacting participants about the study (participants will consent to this, and contact information will be stored in a separate database).
    ii. Users will be asked to create a user ID which they will use to take the remaining assessments. This will allow us to de-identify the data but also attain participant contact information when needed. We will also obtain emails/phone numbers for contacting people regarding missed assessments and/or lack of usage. Participants who have not completed a major assessment or used Happify for 7 days will be flagged and the research coordinator of the research team will login to a secure portal to receive a report of email addresses that have been flagged. No record matching of the email addresses to contact information will be saved, and only contact information will be used for contacting purposes.
    iii. The prescreener, consenting process, and major assessments will take place outside of Happify's platform and will be administered via Qualtrics. This data will be stored securely within a password protected Qualtrics account and the password will be shared only with the Principal Investigator and other members of the research team. Prescreen data will be downloaded regularly, and this data will be downloaded to a secure, password-protected computer and then shared securely with only members of the research team who will be contacting potential participants.
    iv. Data from participants who are not eligible and do not complete the baseline assessment will be deleted from our records.

v. After the study concludes, data will be retained for our records and stored on a secure, password-protected computer and in a secure, password-protected Dropbox account, separate from research data.

XI. QUALIFICATIONS TO CONDUCT RESEARCH

a. Dr. Eliane Boucher (PI) is a Research Scientist at Happify who specializes in social psychology, interpersonal communication, interpersonal relationships, uncertainty, social anxiety, computer-mediated communication and judgmental accuracy.

XII. REFERENCES

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APPENDIX III.

a. Happify Scale
b. Perceived Stress Scale
c. Student Life Satisfaction Scale
d. Revised Life Orientation Test
e. Ruminative Responses Scale Short Form
f. UCLA Loneliness Scale
g. PROMIS - Pediatric Sleep Disturbance Short form 4a
h. Shortened Positive and Negative Affect Schedule for Children
i. Baseline Assessment for Child (described in section II)
j. Major Assessment(s) for Child (described in section II)
k. Optional Follow-up Survey