Protocol Paper

Study Protocol and Design for the MARIGOLD Study: A Self-Paced Online Positive Emotion Skills Intervention for People with Elevated Symptoms of Depression

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Abstract

**Background:** Living with elevated symptoms of depression can have debilitating consequences for an individual’s psychosocial and physical functioning, quality of life, and healthcare utilization. A growing body of evidence demonstrates that skills for increasing positive emotion can be helpful to individuals with depression. Although online interventions to reduce negative emotion in individuals with depression are available, these interventions frequently suffer from poor retention and adherence, and do not capitalize on the potential benefits of increasing positive emotion.

**Methods:** This study protocol describes the development and testing for MARIGOLD (Mobile Affect Regulation Intervention with the Goal of Lowering Depression), an online positive emotion skills intervention, adapted for individuals with elevated depressive symptomatology. The intervention development is taking place in three phases. In Phase 1, we are tailoring an existing positive emotion skills intervention for individuals with elevated symptoms of depression, and are pilot testing the tailored version of the intervention in a randomized controlled trial with two control conditions (N = 60). In Phase 2, we are developing and testing three enhancements aimed at boosting retention and adherence to the online intervention (N = 75): facilitator contact (FC), an online discussion board (ODB), and virtual badges (VB). In Phase 3, we are conducting a multi-factorial, nine-arm pilot trial (N = 600) to systematically test these enhancement strategies, individually and in combination. The primary outcomes of interest are adherence and retention. With regards to intervention efficacy, the primary efficacy outcome is depressive symptom severity. Secondary efficacy outcomes include positive and negative emotion, psychological well-being, and coping resources.

**Conclusions:** Findings from the present investigation will enable us to develop an optimal package of intervention content and enhancement strategies for individuals with elevated symptoms of depression. If this intervention proves to be effective, it will provide a cost-effective, anonymous, appealing, and flexible approach for reducing symptoms of depression and improving psychological adjustment through increasing positive emotion. Ultimately, the goal of the present research is to develop and test an online positive emotion skills intervention tailored for individuals living with elevated depressive symptoms.

**Trial registration:** The study was registered with Clinicaltrials.gov: Phase 1 at University of California, San Francisco (# NCT01964820, date of registration: October 10, 2013, [https://clinicaltrials.gov/ct2/show/NCT01964820](https://clinicaltrials.gov/ct2/show/NCT01964820)), and Phases 2 and 3 at Northwestern University (#NCT02861755, date of registration: June 13, 2016, [https://clinicaltrials.gov/ct2/show/NCT02861755](https://clinicaltrials.gov/ct2/show/NCT02861755)).

**Keywords:** online intervention, positive emotion, depression, depressive symptomatology, study protocol
Introduction

According to the Centers for Disease Control and Prevention, 7.6% of Americans reported moderate to severe symptoms of depression in 2009-2012 [1]. Living with elevated symptoms of depression can have debilitating consequences for an individual’s psychosocial and physical functioning, quality of life, and healthcare utilization [2-8]. Moreover, elevated depressive symptomatology is a significant risk factor for developing major depression [9-11], and has been associated with increased cardiovascular morbidity and mortality [12-15], risk of disability [16], and carries an estimated annual economic cost of $210.5 billion [17]. However, the majority of Americans with elevated symptoms of depression go untreated or undertreated [18]; many individuals lack access to treatment or do not utilize available services [19-21]. Researchers have begun advocating for early intervention in the prevention of depression, highlighting the importance of targeting at-risk subgroups [22-24] such as those with elevated symptoms of depression [9-11].

Positive Emotion Skills Interventions for Reducing Symptoms of Depression

Most research has focused on the role of negative emotion in depression, while largely ignoring the role of positive emotion. However, there is considerable evidence suggesting that positive and negative emotion are not simply opposite ends of a single continuum; rather, positive and negative emotion appear to be independent of one another [25, 26], can be experienced concurrently [27-32], and positive emotion appears to play a unique role in influencing physical, psychological, and social functioning, over and above the effects of negative emotion [33-37]. In fact, emerging evidence suggests that low positive emotion in particular plays a uniquely important role in predicting depressive symptomatology, independent of negative emotion [38-41]. For instance, low positive emotion has been found to prospectively predict the initial onset of a depressive episode [42], and the dampening of positive emotion has
been linked with increased symptoms of depression [43-46]. These findings, together with a growing body of evidence highlighting the unique benefits of positive emotion for coping with negative life events more generally [47-49], suggest that increasing positive emotion is a promising pathway to target for reducing symptoms of depression.

Indeed, interventions that target increasing the frequency of positive emotion experienced in daily life appear to be helpful for reducing symptoms of depression: A meta-analysis of 25 single and multicomponent interventions focusing on increasing positive emotional states such as gratitude, happiness, and optimism found that positive emotion skills interventions showed a medium effect size for relief of depressive symptoms (median $r = .26$), with stronger effects for currently-depressed participants (median $r = .31$) relative to non-depressed participants (median $r = .13$) [50]. These interventions show comparable efficacy and long-lasting effects as that of psychotherapy or pharmacotherapy treatments [50, 51]. Furthermore, positive emotion skills interventions may help counteract the depression-related motivational deficits that can lead to poor adherence and retention in traditional psychological interventions [50, 52].

**Online Psychological Interventions for Depression**

The internet offers a method for delivering psychological interventions that is time- and resource-efficient, and has the benefit of providing treatment to those who may otherwise lack access to available services [53, 54]. Moreover, online interventions have the potential to overcome many of the barriers to help-seeking that depressed individuals have reported in the past, including: cost, a shortage of trained professionals, concerns about anonymity, convenience, perceived stigma, and ease of accessibility [19-21, 55-57]. For the past two decades, a large number of internet-based interventions for depression have been developed and tested [58-61], and meta-analyses have indicated that such online interventions can be effective at reducing depressive symptomatology [58, 62-65]. However, many online interventions tend to suffer from poorer adherence and retention [51, 66, 67], and these issues can be exacerbated in depressed
samples, potentially due to the specific psychological features of depression, including pessimism, low motivation, loss of energy, and impaired concentration [65, 68-75].

Online interventions that are supported by a trained professional (e.g., having a trained professional associated with the study guide the participant through the intervention content via email or telephone) have been found in meta-analyses to produce larger effect sizes and better adherence relative to online interventions that are self-guided [58, 76]. For instance, one meta-analysis found that the average percentage of fully-adherent participants (participants who completed all sessions in the intervention) was 26% for self-guided online interventions versus 72% for supported interventions [76]. However, a disadvantage of supported interventions is that they tend to be more time-intensive, costly, and difficult to disseminate relative to self-guided interventions. The current research aims to develop and test low-cost, resource-efficient, and scalable strategies for promoting adherence and retention in online interventions.

**An Online Positive Emotions Skills Intervention for Reducing Symptoms of Depression**

Our team has previously developed a multicomponent positive emotion skills intervention for individuals coping with the stress of chronic illness (e.g., metastatic breast cancer, HIV, type 2 diabetes) [77-80]. In our studies, this intervention was found to have reduced depressive symptom severity when administered either in person or online, had high retention even among individuals with high levels of depressive symptoms [77-79], and was associated with increased positive emotion in the midst of stressful life events [78-80]. In the present investigation, we are adapting and tailoring the intervention in order to maximize acceptability and relevance for individuals experiencing elevated levels of depression. In addition, the current research aims to address the issues of poor adherence and retention that have plagued previous online interventions. In the current study, we define adherence to the intervention in two ways: a) the number of lesson modules accessed by the participant, and b) the proportion of the intervention content that participants complete (i.e., the number of pages that participants view in
We define retention as the number of assessment questionnaires that participants complete. In order to address issues of adherence and retention in the current study, we are developing and testing three enhancements for boosting adherence and retention to the intervention: a) brief weekly facilitator contact (~5 min per week), b) a moderated online discussion board, and c) virtual badges for completing various goals and challenges. We describe each enhancement strategy below.

**Brief weekly facilitator contact.** Even when interventions are entirely computerized, contact with a person associated with the intervention has been found to increase adherence to the study [58, 61, 72, 81-83]. In the current research, we examine whether receiving brief telephone calls from a trained facilitator (~5 min per week) may help to increase participants’ adherence and retention to the intervention.

**A moderated online discussion board.** Prior research has found that receiving peer support from other users via an online discussion forum can increase rates of adherence to online interventions [84-88]. In the current research, we test whether participation in an online discussion board may help to increase participants’ adherence and retention to the intervention.

**Virtual badges.** Research shows that learning tasks can be made more engaging and memorable when participants are given proximal goals and benchmarks to strive for and when their accomplishments are reinforced with rewards [89, 90]. In the current research, we assess whether receiving rewards (i.e., virtual badges) for accomplishing various goals and challenges within the online intervention may help to increase participants’ adherence and retention to the intervention.

**Overview of the Present Research**

In the present protocol paper, we describe the development and pilot testing for MARIGOLD (Mobile Affect Regulation Intervention with the Goal of Lowering Depression), an online positive emotion skills intervention for individuals with elevated depressive
symptomatology. We are adapting an existing multicomponent positive emotion skills intervention [77-80], and tailoring it for individuals experiencing elevated levels of depressive symptoms. In addition, we are developing and testing three enhancements aimed to boost retention and adherence to the internet-based intervention. MARIGOLD is a five-session intervention designed to teach participants eight skills for increasing positive emotion in their daily lives. The intervention development is taking place in three phases (See Figure 1).

In Phase 1, we are adapting the online positive emotion skills intervention to maximize the acceptability and relevance of the intervention content for people with elevated symptoms of depression, and are pilot testing the tailored version of the intervention. In Phase 2, we are pilot testing three enhancements aimed at boosting retention and adherence: a) facilitator contact (FC), b) an online discussion board (ODB), and c) virtual badges (VB). In Phase 3, we are conducting a multi-factorial, nine-arm pilot trial with 600 participants to systematically test each enhancement strategy, alone and in combination, for retention and adherence. Ultimately, the current research seeks to develop an optimized online positive emotion skills intervention, adapted for people experiencing elevated depressive symptoms.

Methods

Overview of Study Design

In each of the three phases of the MARIGOLD study, individuals with elevated symptoms of depression participate in the same flow of events (See Figure 1). The three study phases differ primarily in terms of the randomization groups and intervention portions of the study sequence (See Figure 1). Each component of the study design is described in further detail below.

Participants
Eligibility. To be eligible for participation in any of the three pilot trials (Phases 1 to 3), participants must: a) be age 18 or older; b) have daily access to Internet, c) own a smartphone; d) live in the United States; e) be fluent in the English language (reading and writing); and f) have elevated depressive symptoms (PHQ-8 depression score ≥ 5) [91]. Respondents are ineligible if they have already participated in a prior phase of the study. All procedures are approved by the Institutional Review Boards at participating institutions (University of California, San Francisco and Northwestern University), and all participants are providing informed consent. The study was registered with Clinicaltrials.gov, Phase 1 at UCSF (#NCT01964820) and Phase 2 at Northwestern University (#NCT02861755).

Procedures

Recruitment and enrollment. Participants for all three pilot trials (Phases 1 to 3) are recruited online and online consent is obtained from each participant. We use online advertisements on platforms like Reddit, posting within discussion threads for depression, stress, coping, and psychology. Recruitment links are also posted on Craigslist, Backpage, clinicaltrials.gov, and emailed to potential participants via ResearchMatch. Ads contain a link to an online eligibility screener (see inclusion/exclusion criteria above). In Phases 1 and 2, eligible individuals are contacted by our research staff via telephone, and the research staff describes the study, and answers any questions that participants may have. Following the telephone call, the research staff sends an email to potential participants that includes a link to the online consent form. In Phase 3, our team eliminated the telephone call and replaced it with an online instructional video. Potential participants in Phase 3 take the online screener, and eligible individuals are automatically directed to a webpage with the instructional video and the online consent form. Phase 3 individuals who are not eligible are automatically notified of their ineligibility, instructed to exit the questionnaire, and are thanked for their time.
Run-in period. Upon consenting to participate in the study, all participants begin the seven-day run-in period to screen participants for compliance. This run-in period must be completed to qualify for randomization. Each day during the seven-day run-in period, participants receive an email with a link to a brief online survey, where they complete a daily emotion report, using the revised Differential Emotions Scale (see Table 1) [49]. Participants who complete at least four emotion reports within the first seven days are randomized to the study. Participants who do not complete at least four emotion reports within the first week are given a second opportunity to do so. If they do not complete at least four emotion reports within the second, seven-day run-in period, they are not randomized in the study. We have used this run-in period in our prior research to screen out noncompliant participants [79].

In addition to the daily emotion reports, participants also complete ecological momentary assessments (EMA) of their positive and negative emotion [92] during the run-in period. Specifically, participants receive text messages on their mobile devices 3 times/day for 3 days over the course of the week, prompting them to answer questions regarding their current emotional experience. In Phases 2 and 3, participants are also completing measures of their daily negative stressors (assessed using the Daily Inventory of Stressful Events (DISE)) [93, 94] during the run-in period. The DISE is included in the brief online survey sent to participants. See Table 1. Although we are collecting EMA and DISE during the run-in period, we are not using this data to inform whether participants are randomized to the study.

Randomization. In Phase 1, participants are randomly assigned to one of the three groups using simple randomization. In Phases 2 and 3, we are stratifying randomization based on gender and level of depressive symptom severity to ensure sufficient numbers of each group within each condition. We are using the PHQ-8 [91] as our measure of depressive symptom severity. In Phase 2, we are stratifying based on three levels of depressive symptom severity (PHQ-8 score: 5-9, mild; 10-14, moderate; ≥15, severe) [91] and by gender. However, to be more
consistent with recommended interpretations of PHQ scores [95], in Phase 3 we are stratifying based on four levels of depressive symptom severity (PHQ-8 score: 5-9, mild; 10-14, moderate; 15-19, moderately severe; ≥20, severe) and by gender.

**Assessments and incentives.** For all three pilot trials (Phases 1-3), we are administering assessments at the following four time-points (See Figure 1): Baseline (BL), Post-intervention (POST; 7 weeks post-baseline), Follow-up 1 (FU1; 1 month post-intervention), and Follow-up 2 (FU2; 3 months post-intervention). The EMA text distribution and data collection are administered using PingQuest [96], a platform for the delivery and management of ecological momentary assessment data, developed by one of the authors (MC). All other assessments are administered online. In Phase 1, we are using Qualtrics survey software [97] for online data collection and management. In Phases 2 and 3, we are using REDCap (Research Electronic Data Capture) [98] for online data collection and management, hosted at Northwestern University. Both Qualtrics and REDCap are secure, HIPAA compliant web-based applications designed to support data collection and management for research studies. Participants for all three pilot trials are compensated up to $60 total: $45 for completion of all assessments ($5 for baseline, $20 for post-intervention, and $10 for each follow-up), and up to $15 for completing the first three weeks of daily website visits and/or completing the intervention.

**Measures.** Assessments include self-report measures of demographic and clinical characteristics, depression, positive and negative emotion, psychological well-being, coping resources, potential moderators, and satisfaction with the intervention. See Table 1 for the full list of measures. The follow-up interviews in Phase 1 and 2 are conducted over the telephone by research staff; if the participant is in the facilitator contact arm (Phase 2 only), we ensure that the research staff conducting the follow-up interview is not the same person who was assigned as the participant’s facilitator. In Phase 3, the follow-up interviews are delivered as an online survey.
The primary efficacy outcome in the proposed research is depressive symptom severity, which we are measuring using the PHQ-8 [91]. We will also assess the CES-D [99] as an additional measure of depressive symptomatology. Emotion is also a central construct in the proposed research. As such, we are measuring it multiple ways: a) daily emotion reports [49], completed daily during the run-in period (which serves as the baseline measure) and during the 5-7 week intervention period, and also daily, in 1-week bursts at each of the 3 post-intervention assessment periods (POST, FU1, and FU2), b) past-week emotion reports [49] at each of the 4 assessment periods (BL, POST, FU1, and FU2), and c) ecological momentary assessment (EMA) [92] completed 3 times per day for 3 days per week during the run-in period (which serves as the baseline measure) and for 1-week bursts at each subsequent assessment (POST, FU1, FU2).

**Positive Emotion Skills Intervention**

*Adapting and refining intervention materials.* We have developed a five-session, multicomponent positive emotion skills intervention that can be administered either in person or online. In prior studies, this intervention has shown promise for reducing depressive symptoms and improving psychological adjustment in people coping with the stress of a chronic illness, including women with metastatic breast cancer [77], people newly diagnosed with HIV [80], and people with type 2 diabetes [79]. The intervention involves teaching participants eight empirically-based skills to increase the frequency of positive emotion experienced in their daily lives: a) noticing positive events [100, 101], b) capitalizing on or savoring positive events [102, 103], c) gratitude [104, 105], d) setting and working toward attainable goals [106, 107], e) mindfulness [108, 109], f) positive reappraisal [30, 110], g) focusing on personal strengths [111, 112], and h) small acts of kindness [113, 114]. At each session, participants are taught up to three of the skills and are asked to practice each skill as “home practice” every day until the next weekly session.
In Phase 1, we adapted the existing online intervention content to address the specific needs and perspectives of people with depression. First, we modified the intervention content to substitute one of the existing skills in the positive emotion skills intervention, skill # 4: setting and working toward attainable goals, with the skill of behavioral activation. Behavioral activation involves teaching participants techniques to monitor their mood and daily activities and to develop plans to increase the number of activities they engage in through activity scheduling. Behavioral activation shares similar principles as the skill of setting and working toward attainable goals; however, behavioral activation has been studied extensively in the context of depression and there is a strong evidence base supporting the effectiveness of behavioral activation for reducing symptoms of depression [115-118]. As such, we incorporated techniques and concepts from behavioral activation into the positive emotion skills intervention.

In addition, we adapted the existing online intervention content (e.g., text, exercises, images) to address the specific needs and perspectives of people with depression. Table 2 shows the original intervention content and the new material we added to ensure that our intervention is applicable and useful to individuals experiencing symptoms of depression. The new material is intended to address biases, motivational deficits, or resource limitations (e.g., lack of social support) that might make it difficult for participants with elevated depressive symptoms to understand the skills or engage with the exercises.

Table 2. MARIGOLD Intervention Content Adapted for Depression

<table>
<thead>
<tr>
<th>Session</th>
<th>MARIGOLD Intervention Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Skills 1 and 2: Noticing and Amplifying Positive Events; Skill 3: Gratitude</td>
</tr>
<tr>
<td></td>
<td>Learning to notice small positive moments in life and savoring or amplifying the positive emotional experience. Noticing positive events can help to reduce stress, even in the face of significant life stress. Cultivating gratitude as another way to savor positive moments. The potential for gratitude to strengthen our connections with others.</td>
</tr>
<tr>
<td></td>
<td>Depression material</td>
</tr>
<tr>
<td></td>
<td>Recognizing cognitive biases that can lead to discounting or failing to notice or remember positive events.</td>
</tr>
<tr>
<td></td>
<td>Exercises</td>
</tr>
<tr>
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<tr>
<td>2</td>
<td><strong>Skill 4: Activation</strong></td>
</tr>
<tr>
<td></td>
<td>Depression material</td>
</tr>
<tr>
<td></td>
<td>Exercises</td>
</tr>
<tr>
<td>3</td>
<td><strong>Skill 5: Mindfulness</strong></td>
</tr>
<tr>
<td></td>
<td>Depression material</td>
</tr>
<tr>
<td></td>
<td>Exercises</td>
</tr>
<tr>
<td>4</td>
<td><strong>Skill 6: Positive Reappraisal; Skill 7: Strengths</strong></td>
</tr>
<tr>
<td></td>
<td>Depression material</td>
</tr>
<tr>
<td></td>
<td>Exercises</td>
</tr>
<tr>
<td>5</td>
<td><strong>Skill 8: Acts of Kindness</strong></td>
</tr>
<tr>
<td></td>
<td>Depression material</td>
</tr>
<tr>
<td></td>
<td>Exercises</td>
</tr>
</tbody>
</table>
**User testing.** Materials were modified and revised in multiple cycles based on feedback from online participants. Specifically, in a prior unpublished study, we collected iterative feedback from 250 online participants with elevated symptoms of depression (PHQ-8 score ≥ 5) recruited from Amazon’s Mechanical Turk [91]. Consistent with standards of user testing to achieve 95% power to detect text that is offensive, unclear, or otherwise problematic [119], each adapted lesson was shown to at least 20 individuals. Participants read sections of text from the adapted intervention and then completed multiple-choice quizzes to assess whether they understood the core idea being presented. Testers also answered Likert-scale questions about whether they found the material enjoyable, understandable, and useful, along with open-ended questions about any material they found offensive or inapplicable. A piece of text was considered acceptable if it met three criteria: a) at least 80% of testers passed the comprehension quiz; b) the average rating for enjoyment and usefulness was above the neutral point on the scale; and c) no testers found the material seriously offensive or inappropriate. Material that failed these criteria was further revised according to testers’ suggestions for improvement and then resubmitted for testing by at least 10 new participants. For example, early testers viewed several lessons as overly optimistic or difficult; after rewriting these lessons, feedback in subsequent rounds of testing was substantially more positive and met criteria for acceptability.

**MARIGOLD intervention content.** The resulting MARIGOLD intervention teaches eight positive emotion skills, using lessons and homework that have been tailored to people with elevated symptoms of depression (see Table 2). The skills are (in the order that they are presented): a) noticing positive events, b) amplifying positive events, c) gratitude, d) behavioral activation, e) mindfulness, f) positive reappraisal, g) personal strengths, and h) acts of kindness. MARIGOLD is delivered as a self-paced, online intervention arranged into five modules containing 1-3 skills each. Each module is designed to be completed within one week, however, to allow for variations in individual schedules and self-pacing, participants are given a total of
seven weeks to complete the MARIGOLD course. Participants must finish the current week’s skills before the next ones become available, so the skills are taught in succession. Each skill is associated with a home practice exercise in a journal format, and participants are encouraged to spend approximately 10 minutes each day reviewing the skill and completing home practice. Participants may also revisit previous weeks’ skills and home practice exercises. After completion of the course, participants maintain access to the course website indefinitely, allowing them to review the skills or continue with their home practice.

In addition, booster sessions that contain brief summaries of the positive emotion skills, along with encouragement and goal setting for continued practice, become available immediately after course completion. For example, if participants are going through a booster session for skill # 8: acts of kindness, they will review a brief summary the skill, as well as a few examples of random acts of kindness. They will also have the chance to review their previous journal entries for the skill, and/or print out a bonus handout on the skill. Finally, in the booster sessions, participants have the opportunity to set a goal to enact the skill. Specifically, participants will be asked to complete the following steps: a) set a goal for enacting the skill (i.e. “I will commit to doing something nice for a friend, loved one, or stranger every day.”), b) a time frame of the commitment (“one week” “two weeks” “one month” or “two months”), c) the frequency of the commitment (“more than once a day” “once a day” “every other day” etc.), d) how they plan to keep track of their commitment (“write about it on the MARIGOLD website” or “talk to a friend or activity partner”), e) write down an encouraging note to themselves for when it gets difficult to enact the skill, and f) digitally sign their name to a summarized page with their commitment. Following these six steps, participants will be emailed a copy of their responses as a reminder.

Study Design (Figure 1)
Phase 1: Pilot test of the online positive emotion skills intervention tailored for participants with elevated symptoms of depression. Participants \( (N = 60) \) are randomized into one of three arms: a) MARIGOLD intervention \( (N = 30) \), b) active control (daily emotion reporting during the 5-week intervention period; \( N = 15 \)), or c) waitlist control \( (N = 15) \).

Participants in the intervention arm receive a five-session positive emotion skills intervention tailored for participants with elevated symptoms of depression (described above). Participants in the daily emotion reporting arm complete the Differential Emotions Scale [49] daily for the 7-week duration of the intervention period. In past research, we have established that emotion reporting is acceptable as a control condition (retention rates of approximately 80%, similar to the intervention), and that participants perceive it as being beneficial, providing some of the features of a placebo control [79]. Participants in the waitlist control group only complete the assessment questionnaires. Upon completion of the FU1 assessment, participants in both the emotion-reporting and waitlist control arms receive access to the MARIGOLD intervention.

Following Phase 1, we review the study feedback from telephone interview transcripts, and modify and refine the study design, staff training, and intervention content accordingly.

Phase 2: Pilot test of three enhancements to increase retention and adherence. In Phase 2, we are pilot testing three enhancements that can be added to the online intervention for the purpose of boosting retention and adherence among people with elevated depressive symptoms. Participants \( (N = 75) \) are randomized into one of three arms, the intervention plus one enhancement: a) intervention + facilitator contact (FC) \( (N = 25) \), b) intervention + online discussion board (ODB) \( (N = 25) \), and c) intervention + virtual badges (VB) \( (N = 25) \). Each enhancement is designed to improve retention and adherence to the intervention by removing practical and motivational barriers to continued engagement. The enhancements are:
1. **Facilitator contact (FC).** Participants assigned to this enhancement arm are contacted once per week by a facilitator, who encourages them to continue with the program and answers any questions they have about the study. Contact is limited to no more than 5 minutes per week. The facilitator schedules a time each week to call the participant by telephone. If they cannot agree on a time or the participant cannot be reached that week, the facilitator contacts the participant by email. The content of the facilitator script is similar for both telephone and email communication. Prior to contacting the participant (either via telephone or email), the facilitator checks in on the participant’s progress in the course (e.g., the skills accessed that week, home practice completion, daily emotion survey completion). The facilitator begins the facilitator contact (both telephone and email) by briefly summarizing to the participant their progress in the course that week. Next, facilitators check in with the participant about: a) the skill(s) covered that week, b) the home practice that week, c) the daily emotion surveys, and d) any issues with the technology. Specifically, the facilitator asks participants how each component (e.g., skills covered, home practice) went that week, whether the participant experienced any challenges, difficulties, or barriers with each component that week, and whether they had any comments or questions. The facilitator contact ends with the facilitator confirming the time for next week’s FC call, unless it’s the final week (week 7). When facilitators email participants, facilitators encourage participants to reply with questions, comments, technology issues. The facilitator does not offer counseling to the participant during the facilitator contact. If the participant begins to request counseling, the facilitator reminds the participant that the facilitator is not in the position to provide advice or therapy to the participant, and reinforces that their role is to answer questions, help the participant progress through the course, and discuss challenges, goals, or technology issues. The facilitator encourages the participant to identify opportunities to apply the MARIGOLD
skills in their daily life, using language from the course content. In cases where the participant is actively seeking counseling, the facilitator recommends that the participant speak with their medical provider, and if they don’t have a medical provider, the facilitator offers resources for the participant to find medical coverage (see training section below).

2. **Online discussion board (ODB).** Participants assigned to this enhancement arm are able to share questions, experiences, and encouragement with other participants in a pseudonymous online environment (i.e., each participant has a consistent username but it contains no information about their identity). Research assistants serve as moderators, checking the discussion board one or more times weekly to remove posts that are inappropriate (e.g., profanity, advertisements, bullying), to identify any concerns about participant safety and/or suicidality, to post prompts or suggestions to start discussions, to provide encouragement, and to answer broad questions about the study. Moderators remind users regularly and as needed about guidelines for the discussion board (e.g., its supportive purpose, the importance of protecting privacy). They do not provide detailed answers to questions about the intervention or discuss individual exercise responses.

3. **Virtual badges (VB).** Participants assigned to this enhancement arm receive virtual flower badges for accomplishing tasks and meeting milestones. These colorful badges are collected on participants’ personal green “garden plot” and individuals are encouraged to “grow their garden” (see Figure 2). Flowers are awarded for different behaviors that can occur once or be repeatable. For example, participants can earn a blue sunflower each time they read a skill (repeatable) and one purple sunflower after they read all the skills (single occurrence). Completing home practice and logging into the website are also incentivized, with badges awarded for completing at least one home practice exercise for 4 consecutive days (repeatable), and logging into the website for 7 consecutive days (repeatable).
Following Phase 2, we review the study feedback from participants and modify and refine the study design, staff training, enhancements, and intervention content accordingly.

**Phase 3. A multi-factorial randomized controlled pilot trial to test each intervention enhancement for retention and adherence.** Participants ($N = 600$) are randomized to receive the basic intervention, the intervention plus one or more of the three enhancements, or an emotion-reporting only control condition. Specifically, the study is a multi-factorial design in which participants are randomized into one of the following nine arms (approximately 67 per arm): a) intervention only, b) intervention + facilitator contact (FC), c) intervention + online discussion board (ODB), d) intervention + virtual badges (VB), e) intervention + FC + ODB, f) intervention + FC + VB, g) intervention + ODB + VB, h) intervention + FC + ODB + VB, and i) emotion reporting only control.

**Training, fidelity, and protection of human subjects**

All staff members receive training on the overall study design and procedures relevant to their staff assignment, including: a) the technology for participant tracking and data collection (e.g., REDCap, Qualtrics, PingQuest); b) procedures for serving as a facilitator in the facilitator contact enhancement (e.g., training on scheduling telephone and email correspondence with participants, conducting the brief facilitator telephone calls using a standardized facilitator script (see above) to ensure consistent delivery of facilitator contact); c) procedures for serving as a moderator of the online discussion board; d) training on the booster sessions; and e) protocol for responding to participant suicidality or distress.

Facilitators are trained on how to handle cases of extreme distress/suicidality expressed over the telephone, via email, or on the online discussion board. In cases of extreme distress/suicidality, the research staff is trained to emphasize to the participant that MARIGOLD is not therapy, and to tell participants to contact 9-1-1 in the case of an emergency. As part of the
distress-suicidality protocol developed by one of the authors (EA), any signs of distress, however small, is reviewed collaboratively by the facilitator, EA, and the study coordinator (ES) to monitor the safety and well-being of participants, and to respond appropriately. Facilitators do not offer medical advice, and instead encourage participants to consult their medical provider, offer resources to find a medical provider if he/she does not have one, and provide relevant resources to participants (e.g., a suicide hotline).

Training sessions are conducted initially during the study start-up and when onboarding new staff members, on an ongoing basis as the study protocol is updated across the three phases, and on an as-needed basis to address individual cases and procedural issues. All staff members maintained updated Human Subjects Research Training either through Collaborative Institutional Training Initiative (CITI) or the National Institutes of Health (NIH) Human Subjects Training Module.

**Planned analyses**

In all 3 phases of the study, we plan to conduct intention-to-treat analyses to examine: a) retention and adherence to the intervention and b) preliminary efficacy of the intervention. In Phase 3, we will have sufficient power to conduct additional analyses examining: c) moderators of retention and adherence within each randomization arm, d) moderators of the primary and secondary efficacy outcomes within each randomization arm, and e) whether intervention effects are mediated by increases in positive emotion.

**Retention and adherence.** Retention will be defined as completing the baseline, post-intervention, and follow-up assessments. We will categorize retention at each assessment as a binary outcome and will test for differences in the proportions of participants who are retained at each assessment using a binary logistic regression model using dummy variables to represent each arm. Adherence will be assessed in intervention participants only and measured in two
ways: a) the number of skills accessed, and b) the proportion of the intervention completed (i.e.,
the number of pages viewed out of the total possible pages across all lesson modules in the
intervention). In the Phase 1 pilot, we will report descriptive statistics of adherence in the
intervention arm, and will explore whether retention differs as a function of arm (intervention vs.
emotion-reporting control vs. waitlist control) using a binary logistic regression, with dummy
variables to represent each arm. In the Phase 2 pilot, we will explore whether retention and
adherence differ as a function of enhancement type, using a binary logistic regression for
retention and linear regressions for adherence, with dummy variables to represent each arm. In
the Phase 3 pilot, we will use additional contrast tests to explore whether retention and
adherence differ as a function of enhancement type received (no enhancement, facilitator contact,
virtual badges, or online discussion board), as well as whether receiving certain combinations of
enhancements offers additional benefits for increasing retention and adherence.

**Preliminary efficacy.** Although the current investigation is mainly focused on optimizing
adherence and retention to the intervention, we will conduct analyses examining the preliminary
efficacy of the intervention. Our primary measures of preliminary efficacy will be depressive
symptom severity, as assessed by the PHQ-8 [91]. We will also assess change in positive and
negative emotion and other indicators of psychological adjustment (e.g., perceived stress,
meaning and purpose) as secondary outcomes.

For each outcome, we will estimate growth curves within a multilevel modeling
framework (MLM) [120] to assess change in each outcome across the four assessment points
(baseline, post-intervention, FU1, and FU2). MLM offers an approach that accommodates
missing data points and non-independence in observations. We plan to model time at Level 1 and
randomization arm at Level 2, using dummy variables to represent each arm. In Phase 1, the
primary parameters of interest will be the differences in the magnitude of change in preliminary
efficacy outcomes between the intervention arm and each of the control arms over time. In Phase
2, the primary parameters of interest will be the magnitude of change in outcomes across all three randomization arms over time. In Phase 2, we will also explore whether the three enhancement arms (facilitator contact, online discussion board, virtual badges) differ in their magnitude of change in preliminary efficacy outcomes over time. In Phase 3, the primary parameter of interest will be the difference in the magnitude of change in preliminary efficacy outcomes over time for the arms that received the intervention relative to the emotion-reporting control. In Phase 3, we will also explore whether there are differences in the magnitude of change in outcomes over time as a function of enhancement type (no enhancement, facilitator contact, online discussion board, or virtual badges), as well as whether receiving certain combinations of enhancements may influence magnitude of change in outcomes over time. We will use significance tests comparing the information criteria of different models to determine which covariates to include in the final model.

**Moderators of retention and adherence.** In Phase 3, we will assess baseline depressive symptom severity, gender, race/ethnicity, and comfort with technology as moderators of retention and adherence. This will allow us to detect whether certain enhancements to the intervention increase adherence or retention for some subpopulations but not others. For each potential moderator, we will re-run the binary logistic regression analyses with a set of interaction variables between the moderator and the dummy condition variables. Due to power limitations, we will not test all four moderators in the same model or explore any interactions among the moderators.

**Mediational analyses.** Finally, in Phase 3, we will test whether positive emotion mediates any effect of the intervention on overall depressive symptoms. For the mediational analyses, we will combine intervention arms to explore the effects of intervention (regardless of enhancement type). We plan to conduct multilevel moderated mediation analyses [121] using a multilevel SEM (MSEM) framework [122]. More specifically, mediation effects will be estimated by
examining the indirect effect of the intervention on change in depressive symptom severity through the effect of change in the positive emotion. We will test the significance of the specific indirect effect in the MSEM model using the Monte Carlo method with 20,000 bootstraps [123, 124]. In addition, we will conduct exploratory multilevel moderated mediational analyses to explore whether improvements in positive emotion mediate the intervention effects on secondary outcomes (e.g., psychological well-being, perceived stress, meaning and purpose).

**Discussion**

This paper describes the study protocol for the development and pilot testing for MARIGOLD, an online positive emotion skills intervention adapted for individuals with elevated depressive symptomatology. In the current work, we are tailoring the intervention content to meet the needs and challenges of individuals with elevated symptoms of depression, and are pilot testing the tailored version of the intervention along with three enhancements aimed at boosting retention and adherence to the online intervention content: facilitator contact (FC), an online discussion board (ODB), and virtual badges (VB). Ultimately, the goal of the present research is to develop an optimized package of relevant content and retention and adherence strategies for individuals with elevated depression.

There are a number of strengths to the current work. One strength is its innovative focus on positive emotion. Whereas most psychological interventions for depression tend to target the reduction of negative emotions, the current intervention targets increasing positive emotion, which may be an especially promising pathway for helping individuals with elevated depressive symptoms. Another strength of the current work is its focus on developing tailored intervention content and enhancement strategies that specifically address the depression-related motivational deficits that can lead to poor adherence and retention. A third strength of the current work is systematic development and testing of the intervention over three phases: the development and
pilot testing of the intervention content (Phase 1), the development and pilot testing of the three enhancement strategies (Phase 2), and a multi-factorial randomized controlled trial, systematically testing each enhancement strategy, alone and in combination (Phase 3). A fourth strength of the current work is the online delivery of the intervention. If the intervention is found to be effective, the self-guided, online delivery of the intervention offers the potential for low-cost, widespread dissemination of the intervention over the internet.

Despite these strengths, potential limitations of this study design should be acknowledged. One significant challenge that faces our project is the potential for our enhancement strategies to actually reduce adherence or efficacy for some users. For example, individuals who are less comfortable or experienced with technology may have difficulty accessing and/or utilizing the enhancements (e.g., their virtual garden plot, online discussion board). In addition, another limitation is that our follow-up assessments are conducted relatively close to the intervention, with the final follow-up assessment at 3-months post intervention. Future research should include longer follow-up assessments (e.g., one year pots intervention), so that we may examine whether the effects of the intervention persist over an extended period of time.

Furthermore, individuals who have more severe symptoms of depression may be reluctant to engage in online social interactions. We are collecting extensive quantitative and qualitative feedback regarding the intervention content and enhancement strategies, which will give us the opportunity to address any issues that participants may have regarding the accessibility and user-friendliness of the online platform, and to remedy any off-putting content or features of the intervention. Additionally, detecting potential moderators of the intervention (e.g., comfort with technology, baseline depression severity) will be valuable in itself. Learning more about which intervention features work for which participants will contribute to the development of more sophisticated and targeted interventions in the future.
Finally, research that focuses on the benefits of increasing positive emotion can sometimes be misunderstood as minimizing the significance of depression and its harmful individual and societal consequences. This is not our intent. On the contrary, we understand that depression is real, complex, and painful. We are not encouraging people to simply adopt a “don’t worry-be happy” attitude, nor do we proclaim that increasing positive emotion is a panacea. However, a growing body of evidence demonstrates that increasing positive emotion can promote psychological and physical benefits and catalyze an upward trajectory for people experience depression, or other hardships.

In sum, the goal of the present investigation is to develop and test an online positive emotion skills intervention, tailored for individuals living with elevated depressive symptoms (MARIGOLD). If this intervention proves to be effective, it can provide a cost-effective, anonymous, and flexible approach for reducing depressive symptoms and improving psychological adjustment in individuals living with elevated symptoms of depression.

**Trial status**

Data collection is complete for Phases 1 and 2. Recruitment for Phase 3 began on February 14, 2017. The final participants are expected to complete their final follow-up assessments in May 2018.
List of abbreviations.

MARIGOLD: Mobile Affect Regulation Intervention with the Goal of Lowering Depression

PHQ: Patient Health Questionnaire

CESD: Center for Epidemiologic Studies, Depression Scale

DES: Differential Emotions Scale

DISE: Daily Inventory of Stressful Events

REDCap: Research Electronic Data Capture

FC: Facilitator Contact

ODB: Online Discussion Board

VB: Virtual Badges

RI: Run-in Period

I/C: Intervention (or Control) Period

BL: Baseline Assessment

POST: Post-intervention Assessment (7 weeks post-baseline)

FU1: Follow-up 1 Assessment (1 month post-intervention)

FU2: Follow-up 2 Assessment (3 months post-intervention)

CITI: Collaborative Institutional Training Initiative

NIH: National Institutes of Health
Declarations

Ethics approval and consent to participate

All procedures are approved by the Institutional Review Boards at participating institutions (UCSF and Northwestern University), and all participants are providing informed consent. All staff members maintained updated Human Subjects Research Training either through CITI or the NIH Human Subjects Training Module.

Consent for publication

Not applicable

Availability of data and material

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Author’s contributions

JM, MC, YL, and LS initiated, conceptualized, and designed Phases 1-3 of the study protocol. MC and LS coordinated the study at UCSF. ES coordinated the study at Northwestern. All authors assisted with the development of the study and finalized the study protocol. EC, EA, SB, ES, and SS developed the first draft of the manuscript. All authors read and approved the final manuscript.

Acknowledgments

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References


77. Cheung, E.O., et al., *A randomized pilot trial of a positive affect skill intervention (lessons in linking affect and coping) for women with metastatic breast cancer*. Psycho-Oncology, 2016: p. n/a-n/a.


Figure Titles

Figure 1. Flow chart of study timeline for Phases 1 to 3.
Figure 2. Example garden plot with virtual flower badges and accompanying key in the Virtual Badges enhancement.
Table 1. Study measures and administration frequency

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Description</th>
<th>Phase</th>
<th>Administered</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>2</td>
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<tr>
<td>Demographic and Clinical Characteristics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demographics</td>
<td>Gender, race/ethnicity, age, income</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Clinical History</td>
<td>Self-reported clinical information: prior diagnosis of depression, current or past use of medication for depression or anxiety, current or past use of psychotherapy/ counseling</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Patient Health Questionnaire (PHQ-8) [91]</td>
<td>8 items measuring depressive symptom severity.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Center for Epidemiologic Studies, Depression Scale (CESD) [99]</td>
<td>20 items measuring depressive symptomatology.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Positive and Negative Emotion</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Past Week Emotion: Modified Differential Emotions Scale (DES) [49]</td>
<td>26 items measuring the frequency of positive and negative emotion experienced over the past week.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Daily Emotion Report: Modified Differential Emotions Scale (DES) [49]</td>
<td>26 items measuring the frequency of positive and negative emotion experienced over the past day.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Momentary Emotion: Ecological Momentary Assessment of Emotion [92]</td>
<td>5 items measuring the extent to which participants were currently feeling 3 positive and 2 negative emotions (happy, excited, content, anxious, and sad). EMA prompts were delivered via text message 3 times/day for 3 days/week (days 1, 4, and 7).</td>
<td>x</td>
<td>x</td>
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</tbody>
</table>
Notes. BL = baseline assessment; RI = run-in period; I/C = intervention (or control) period; POST = post-intervention assessment (approximately 7 weeks post baseline); FU1 = follow-up assessment 1 (1 month post-intervention); FU2 = follow-up assessment 2 (3 months post intervention). *Baseline measure administered during the eligibility screening.
Table 1 (cont’d). Study Measures

<table>
<thead>
<tr>
<th>Instrument</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>BL</td>
<td>R</td>
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<tr>
<td>Perceived Stress Scale (PSS) [125]</td>
<td>10 items assessing participants’ stress.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Neuro-QOL Positive Affect and Well-being [126]</td>
<td>9 items assessing positive affect, life satisfaction, and an overall sense of purpose and meaning.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>PROMIS Meaning and Purpose [127]</td>
<td>8 items assessing meaning and purpose.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Daily Inventory of Stressful Events (DISE) [93, 94]</td>
<td>7 items assessing whether the negative daily stressors experienced over the past day.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Psychological Well-being [128]</td>
<td>6 items assessing participants’ satisfaction with their life, job, relationships, their general health, sleep quality, and happiness.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Pain [129]</td>
<td>Single item assessing the pain experienced during the past week.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td><strong>Psychological Well-being</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Coping Resources</strong></td>
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<tr>
<td>Positive Skills Usage [77]</td>
<td>10 items assessing the frequency of using the positive emotion skills (e.g., positive reappraisal, gratitude) over the past week.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Five Facet Mindfulness Questionnaire (FFMQ) [130]</td>
<td>7 items excerpted from FFMQ, assessing elements of mindfulness (i.e., observing, describing, acting with awareness, non-judging, non-reactivity).</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Prioritizing Positivity Scale [131]</td>
<td>6 items measuring the extent to which a person seeks out positive emotional experiences when organizing their day-to-day life.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Brief Resilience Scale (BRS) [132]</td>
<td>6 items measuring self-reported resilience.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Depression Self Stigma Scale (DSSS) [133]</td>
<td>32 items measuring self-stigma related to depression.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Self Stigma Depression Scale (SSDS) [134]</td>
<td>16 items assessing levels of measures shame, self-blame, help-seeking inhibition and social</td>
<td>x</td>
<td>x</td>
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</table>
inadequacy regarding depressive symptoms.

|   |   |   |   |   |   |   |

Notes. BL = baseline assessment; RI = run-in period; I/C = intervention (or control) period; POST = post-intervention assessment (approximately 7 weeks post baseline); FU1 = follow-up assessment 1 (1 month post-intervention); FU2 = follow-up assessment 2 (3 months post intervention).
<table>
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<th>Instrument</th>
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<th>Administered</th>
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<tbody>
<tr>
<td><strong>Coping Resources (cont’d)</strong></td>
<td></td>
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</tr>
<tr>
<td>Self-Compassion Scale, Short Form (SCS-SF) [135]</td>
<td>12 items assessing levels of self-compassion.</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Happiness Inducing Behavior Scale (HIBS) [136]</td>
<td>38 items measuring how often participants have completed happiness-inducing behaviors.</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Stress Management Self Efficacy Scale (SMSE) [137]</td>
<td>4 items measuring the perceived ability to cope with stress.</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Moderators</strong></td>
<td></td>
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</tr>
<tr>
<td>Behavioral Activation for Depression Scale - Short Form [138]</td>
<td>9 items measuring behavioral activation (e.g., accomplishing goals, participating in activities).</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Conscientiousness [139]</td>
<td>2 items assessing participants’ conscientiousness</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Comfort with Technology</td>
<td>6 items assessing a participant’s overall frequency of and confidence with technology use</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Technology Use for the Study</td>
<td>1-item administered assessing the most frequent mode of technology used for the study.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Motivation to Practice Positive Emotion Skills [140]</td>
<td>16 items assessing participants’ motivations (e.g., intrinsic, extrinsic) for using the skills from the MARIGOLD study (intervention only).</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Expectancy Credibility Scale [141]</td>
<td>6 items assessing participants’ expectancy and credibility beliefs regarding the intervention.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>General Behavior Inventory (GBI) - Mania subscale [142]</td>
<td>7 items assessing symptoms of mania.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>Acceptability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feedback Survey</td>
<td>Quantitative and qualitative items assessing participants’ views of the content they received during the intervention (or control) period and the enhancements (e.g., satisfaction or dissatisfaction with</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
the intervention, and intention to continue using the skills.)

Notes. BL = baseline assessment; RI = run-in period; I/C = intervention (or control) period; POST = post-intervention assessment (7 weeks post baseline); FU1 = follow-up assessment 1 (1 month post-intervention); FU2 = follow-up assessment 2 (3 months post intervention).a The waitlist control group in Phase 1 received the feedback survey after the FU2 assessment. The feedback survey was administered at POST for all other groups in Phases 1-3.