PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	A study protocol for a non-randomized comparison trial evaluating the feasibility and effectiveness of a mobile cognitive behavioral program with integrated coaching for anxious adults in primary care.
AUTHORS	Szigethy, Eva; Solano, Francis; Wallace, Meredith; Perry, Dina; Morrell, Lauren; Scott, Kathryn; Jones Bell, Megan; Oser, Megan

VERSION 1 – REVIEW

REVIEWER	Eric Kuhn, PhD National Center for PTSD, VA Palo Alto Health Care System, USA Stanford University School of Medicine
REVIEW RETURNED	19-Sep-2017

GENERAL COMMENTS	This manuscript describes the protocol for a quasi-experimental pragmatic trial of a mobile app with text-based coaching compared to enhanced treatment as usual among primary care patients with mild or worse anxiety symptoms. The protocol is described very thoroughly and the manuscript itself is well-written and relatively free of editing error. Given the need for more of these effectiveness trials with scalable technology interventions, I believe that the manuscript would make a substantive contribution to the literature. However, there are several minor concerns that need to be addressed. Abstract Line 14: “Patients meeting a threshold level” is not clear in this context (seems like those who screen positive for usual care purposes who have clinically significant levels of anxiety). Instead, “a threshold level” refers to the study threshold level, which is mild (i.e., equal to or greater than 5 on the GAD7). This should be stated. Introduction Line 34: The statistic provided for the lifetime prevalence for behavioral health conditions (i.e., 5.8%) seems low. Objective Line 27: No clear criteria are provided to assess if implementing Lantern is feasible (not even in the Data Analysis section). There is an expectation of 50% attrition. It’s not clear if there is more than that if the program would not be deemed feasible. If there is a certain level of use that would be expected to be of clinical (or system) benefit or would outweigh costs (whatever they may be), it would be good to make those explicit. My concern is that any level of use could be used to demonstrate Lantern’s feasibility without an a priori target set.

	Methods Participants It is not clear if only Active Site patients will be invited to participate in the study. Later it is stated that Control site patients will not be providing informed consent. This is a more general problem with the manuscript where certain information only pertains to the Active Site participants but it is not made explicit (e.g., Eligibility Criteria states that patients are eligible if they have access to a smartphone or tablet yet in Figure 1 it appears that this is only true for Active Site patients. Also, it is not clear if patients with current suicidal ideation, current psychosis, etc. will be eligible at Control Sites.) Clinical Selection and Patient Recruitment It is mentioned that at the Control Sites the mean number of visits is 2.2 per year and it appears that that would be when subsequent assessments would take place opportunistically (if so, modal number of visits might be more informative). But later in the Data Collection/Measures it is stated that participants will be asked to complete measures electronically through secure email, which seems to include those in the control condition. It is not clear if the control participants will even know that they are serving in a study and are being asked to complete additional measures (as no informed consent is being obtained). Please clarify. Intervention Line 48: "will learn to avoid things that contribute to and/or maintain anxiety" is confusing as exposure-based interventions typically do not encourage avoidance as a strategy to reduce anxiety. Please clarify. Coaching Model Line 10: The educational requirements (e.g., BA, MA, PhD) and area of study (e.g., social sciences, psychology, social work) of the coaches would be good to include. Table 1 Line 15: 2-month check mark should include an asterisk with a note below the table as this assessment is only for those at Active Sites (or denoting it in some other fashion). Measures Page 9, Lines 50-52: Citations for the common categories and assertion that the GAD 7 is the most widely used measure are needed. Page 10, lines 20 and 26: No psychometric evidence is provided for these measures. Statistical Methods Line 51: Delete the first "moderate." Data Analysis There is no mention of how feasibility will be evaluated. Page 11, lines 26-30: The description of the qualitative analyses does not include mention of the qualitative theory or approach that will guide these analyses.

REVIEWER	Sherry Benton University of Florida Gainesville, FL USA
REVIEW RETURNED	17-Oct-2017

GENERAL COMMENTS	This would be most useful if publication was delayed until results are available. However, the study and design are fine.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Eric Kuhn, PhD
Institution and Country: National Center for PTSD, VA Palo Alto Health Care System, USA, Stanford University School of Medicine
Please state any competing interests: None declared

This manuscript describes the protocol for a quasi-experimental pragmatic trial of a mobile app with text-based coaching compared to enhanced treatment as usual among primary care patients with mild or worse anxiety symptoms. The protocol is described very thoroughly and the manuscript itself is well-written and relatively free of editing error. Given the need for more of these effectiveness trials with scalable technology interventions, I believe that the manuscript would make a substantive contribution to the literature. However, there are several minor concerns that need to be addressed.

Abstract
Line 14: “Patients meeting a threshold level” is not clear in this context (seems like those who screen positive for usual care purposes who have clinically significant levels of anxiety). Instead, “a threshold level” refers to the study threshold level, which is mild (i.e., equal to or greater than 5 on the GAD7). This should be stated.

Response: This sentence has been modified to read: "All clinics provide electronic screening for anxiety and, within clinics assigned to provide Lantern, patients meeting a threshold level of mild anxiety (i.e., > 5 on GAD7) are recommended Lantern by their physician."

Introduction
Line 34: The statistic provided for the lifetime prevalence for behavioral health conditions (i.e., 5.8%) seems low.

Response: This was a typo. The citation for this claim states lifetime prevalence of 46.4%. This has been changed.

Objective
Line 27: No clear criteria are provided to assess if implementing Lantern is feasible (not even in the Data Analysis section). There is an expectation of 50% attrition. It’s not clear if there is more than that if the program would not be deemed feasible. If there is a certain level of use that would be expected to be of clinical (or system) benefit or would outweigh costs (whatever they may be), it would be good to make those explicit. My concern is that any level of use could be used to demonstrate Lantern’s feasibility without an a priori target set.

Response: This is an excellent point. We have provided further details about how feasibility and acceptability will be assessed in the data analytic section. Feasibility and acceptability will be assessed using two criteria based on similar published studies and eCONSORT guidelines:
1) Among the first 50 patients, at least 50% of eligible participants meeting inclusion criteria should accept participation in the study.
2) At least 50% of participants that initiate Lantern will complete at least 3 techniques

Methods

Participants

It is not clear if only Active Site patients will be invited to participate in the study. Later it is stated that Control site patients will not be providing informed consent. This is a more general problem with the manuscript where certain information only pertains to the Active Site participants but it is not made explicit (e.g., Eligibility Criteria states that patients are eligible if they have access to a smartphone or tablet yet in Figure 1 it appears that this is only true for Active Site patients. Also, it is not clear if patients with current suicidal ideation, current psychosis, etc. will be eligible at Control Sites.)

Response: We agree with the reviewer's suggestions and have clarified participant eligibility and selection/recruitment process across active and control sites accordingly. Screening for anxiety with GAD7 and administration of SF12 occurred as “routine care” at both active and control sites and was offered to all patients who were ages 20-65 by the front desk staff giving patients tablet in waiting room. At both sites, anxiety screens were automatically scored with EHR and for scores >= 5, a best practice alert was sent to the PCPs. At the control sites, the alert informed the doctor of a score consistent with at least mild anxiety while at the Lantern sites, the alert suggested they consider prescribing Lantern.

At active sites, patients with a smart-phone or tablet were invited to sign informed consent to participate in the Lantern program and to have assessments completed at 2, 6 and 12 months. PCPs at Lantern sites were educated about instances where a digital CBT approach may not be appropriate or sufficient such as patients with current SI or psychosis but ultimately each individual PCP decided which patients they deemed appropriate to refer to Lantern.

At the control sites, patients were not consented but instead were provided whatever the individual PCPs deemed routine care. GAD7 and SF12 questionnaires were provided to patients as part of routine care at subsequent visits, if they occurred three months or more from the previous visit. To standardize the approach across different control site PCPs, each was encouraged to give the patients who scored >/=5 on the GAD7 an information sheet about Generalized Anxiety Disorder and its Treatment published by NIMH and also these practices were provided with the names of 3 community mental health centers in the area with intake availability within 3 months.

Clinical Selection and Patient Recruitment

It is mentioned that at the Control Sites the mean number of visits is 2.2 per year and it appears that that would be when subsequent assessments would take place opportunistically (if so, modal number of visits might be more informative). But later in the Data Collection/Measures it is stated that participants will be asked to complete measures electronically through secure email, which seems to include those in the control condition. It is not clear if the control participants will even know that they are serving in a study and are being asked to complete additional measures (as no informed consent is being obtained). Please clarify.

Response: At control sites, questionnaires were completed opportunistically – banking on the known annual mean frequency of visits at these sites being 2.2 per year. Control subjects only complete assessments at primary care visits.
At the active sites, participants completed measures electronically through secure email and those who did not respond were contacted by clinical staff to complete the questionnaires by phone.

We have clarified this within the Data Collection/Measures section.

Intervention
Line 48: “will learn to avoid things that contribute to and/or maintain anxiety” is confusing as exposure-based interventions typically do not encourage avoidance as a strategy to reduce anxiety. Please clarify.

Response: This has been corrected and clarified. It was a typo and should have stated: “will learn how avoiding things contributes to and/or maintains anxiety”. It has been further modified to read: “Participants will learn the behavioral cycle of avoidance and how this maintains anxiety.”

Coaching Model
Line 10: The educational requirements (e.g., BA, MA, PhD) and area of study (e.g., social sciences, psychology, social work) of the coaches would be good to include.

Response: We have added this information: Lantern primarily employs Master’s-level coaches with backgrounds in health and wellness coaching or mental health treatment. And we noted that all coaches are supervised by licensed clinical psychologists.

Table 1
Line 15: 2-month check mark should include an asterisk with a note below the table as this assessment is only for those at Active Sites (or denoting it in some other fashion).

Response: This has been added as recommended.

Measures
Page 9, Lines 50-52: Citations for the common categories and assertion that the GAD 7 is the most widely used measure are needed.

Response: Citation added.

Page 10, lines 20 and 26: No psychometric evidence is provided for these measures.

Response: The Lantern Helpfulness and Satisfaction scale is intended to be descriptive and adapted from the Client Satisfaction Questionnaire.
This citation has been added: Larsen, D.L., Attkisson, C.C., Hargreaves, W.A., and Nguyen, T.D. (1979). Assessment of client/patient satisfaction: Development of a general scale, Evaluation and Program Planning, 2, 197-207.

The Behavioral Health Utilization measures was modified from Cornell Services Index. The Cornell Services Index has good psychometric properties. We will provide internal consistency psychometrics from our sample in the primary outcomes paper.
This citation has been added: Sirey, J. A., Meyers, B. S., Teresi, J. A., Bruce, M. L., Ramirez, M., Raue, P. J., ... & Holmes, D. (2005). The Cornell Service Index as a measure of health service use. Psychiatric Services, 56(12), 1564-1569.

Statistical Methods
Line 51: Delete the first “moderate.”

Response: This word was redundant and is now deleted.

Data Analysis
There is no mention of how feasibility will be evaluated.

Response: We provided further details about how feasibility and acceptability will be assessed. Feasibility and acceptability will be assessed using two criteria based on similar published studies and informed by the eCONSORT guidelines:
1) Among the first 50 patients, at least 50% of eligible participants meeting inclusion criteria should accept participation in the study.
2) At least 50% of participants that initiate Lantern will complete at least 3 techniques

Norlund, Fredrika, et al. "Treatment of depression and anxiety with internet-based cognitive behavior therapy in patients with a recent myocardial infarction (U-CARE Heart): study protocol for a randomized controlled trial." Trials 16.1 (2015): 154.

Eysenbach, G., & Consort-EHEALTH Group. (2011). CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. Journal of medical Internet research, 13(4).

Page 11, lines 26-30: The description of the qualitative analyses does not include mention of the qualitative theory or approach that will guide these analyses.

Response: A thematic analytic approach will be used. In-depth qualitative telephone interviews will be conducted to explore patient experiences with Lantern Interviews will be conducted at 6 months to understand patient experiences with and expectations of the Lantern program, including their experience with coaching.

Additional changes:
We revised Figure 1 Active sites for consistency in clarifying study exclusion criteria.

VERSION 2 – REVIEW

REVIEWER	Eric Kuhn, Ph.D. National Center for PTSD, VA Palo Alto Health Care System, USA Stanford University School of Medicine
REVIEW RETURNED	28-Nov-2017

GENERAL COMMENTS	I appreciate that the authors were highly responsive to this reviewer's comments. All issues raised in the initial review have been adequately addressed.