Pilot Trial of an Ecological Momentary Intervention for Social Anxiety

Abstract
This paper describes the results of a pilot Randomized Controlled Trial (RCT) on the effects of a mobile prototype delivering an Ecological Momentary Intervention (EMI) for social anxiety disorder (SAnD). 55 participants were randomized into two groups 1) a standalone EMI based on exposure therapy or 2) a waitlist control group. After excluding people who formally withdrew, 49 participants were analyzed. SAnD symptoms and other related outcomes, including download and EMI usage were collected at baseline and post-test. Four participants from the EMI group (15%) and 10 participants from the control group (38%) completed the post-test assessments. Of the four EMI completers, only two downloaded the mobile app. Results showed no significant improvements in SAnD symptoms or other related mental health outcomes relative to the control group (ESs range). There were no significant differences in help-seeking behaviors between groups at post-test. The results suggest increased human-support, or interactive features may be needed to improve engagement and adherence to EMI, and a subsequent study with a larger sample size may be needed to demonstrate differential effects.

Author Keywords
Mental Health; Social Anxiety; Ecological Momentary Interventions; mHealth.
Background

Social anxiety disorder (SAnD), also known as social phobia, is one of the most commonly diagnosed anxiety disorders [21;31]. SAnD has a 12-month prevalence of 4.7% among Australians aged 16-85 [4], and lifetime prevalence of 2.8 to 13% in the United States and Europe [2;21]. The Diagnostic and Statistical Manual of Mental Disorders, 5th edition, defines SAnD as the “continual persistence of fear or anxiety of one or more social situations in which the individual is exposed to the possible scrutiny of others” [3]. Individuals with SAnD may experience symptoms during social situations or through the anticipation of these situations [14]. Social situations are often feared and avoided due to embarrassment and perceived negative judgments from others in anticipation of and during any social interactions [20].

Currently, one of the most effective treatments for SAnD is Cognitive Behavioral Therapy (CBT) [17;18]. Typically, a trained therapist delivers CBT (consisting of cognitive restructuring, exposure therapy, and homework exercises) face-to-face individually or in a group setting [18]. Therapist-delivered CBT is one of the most well-known psychotherapy interventions for treating SAnD [24]. However, SAnD is also associated with low levels of help-seeking which may hinder many individuals from receiving professional help with a therapist [7;26]. Alternative approaches to delivering CBT or other psychotherapy interventions include self-help or therapist guided electronic interventions (e-interventions) for anxiety disorders delivered via a web application or a mobile device, which may be effective in treating symptoms with minimal therapist support [8;10;32].

EMIs are “momentary health treatments provided via hand-held mobile technologies that deliver e-interventions while people are engaged in their typical routines in their everyday life” [16]. EMIs are also sometimes referred to as “Just-In-Time Health Interventions” [12;29;30], which use methods of dynamic tailoring, and intelligent real-time therapy [25;30]. EMIs can be used as an adjunct to existing psychological therapies delivered by a therapist, or they can be implemented as a stand-alone intervention [12;29]. EMIs may be suitable for treating SAnD symptoms that may return before, during or after receiving an intervention or treatment from a therapist [29]. Furthermore, EMIs may be suitable for treating symptoms of depression, generalized anxiety (GAD), and stress [29].

Related Research

A systematic review of randomized controlled trials (RCT) has found promising results for EMIs aimed at reducing symptoms of anxiety and stress, including SAnD [22]. A more recent RCT that compared CBT and Interpersonal psychotherapy (IPT) via smartphones demonstrated CBT to be superior to IPT in reducing SAnD symptoms [11]. Furthermore, another RCT that compared cognitive bias modification delivered on the smartphone demonstrated the intervention to be superior to a control condition in reducing SAnD symptoms [13]. However, to date, no study has examined the efficacy of an unguided self-help EMI delivering exposure therapy alone for SAnD via smartphones.
Research Rationale
The purpose of this paper is to describe the “early-stage” development and pilot trial of a newly developed EMI prototype, and to present the initial findings of a pilot study that examined the effects of an iOS mobile app on the exposure therapy for bipolar disorder, and problems or depression, no history of schizophrenia and no current treatment for anxiety. Eligible participants were granted access to the mobile app following the date of post-test.

Eligible participants completed a 15-minute online survey at baseline and post-test comprising the following outcome scales: SAnD (Social Phobia Screener (SOPHS) [5] and Mini-Social Phobia Inventory (Mini-SPIN) [9]), anxiety sensitivity (Anxiety Sensitivity Index (ASI) [27]), GAD and depression (Patient Health Questionnaire-4 (PHQ4) [23]), psychological distress (Distress Questionnaire-5 (DQ5) [6]), and help-seeking behaviors (Actual Help-Seeking Questionnaire (AHSQ) [28]). In addition, demographic data were collected at baseline prior to randomization and assignment, and intervention measurements (user satisfaction and acceptability, and mobile app download and usage) were collected in group 1 at post-test.

Data analysis was carried out using SPSS v23.0 [19]. Outcomes were compared between groups using a mixed-models repeated measures approach, which is an intention-to-treat analysis that uses all available data under the missing-at-random assumption. Hedges’ g was used to calculate the between-group effect sizes by subtracting baseline between-group Hedges’ g from the between-group post-test Hedges’ g. Between-group comparison of demographics, outcomes, and post-test attrition was undertaken using an independent samples t-test for continuous data, or chi-square tests for categorical data. Descriptive statistics were used to compare demographic, user satisfaction, and mobile app download and usage measurements.

Method
Participants were recruited from the general community via Facebook, screened, randomized and assigned to one of two study groups; 1) access to download a mobile app with EMI content for 4 weeks for iPhone, iPad, or iPod touch (via TestFlight), or, 2) a waitlist control group. Participants aged 18 and over, with a valid email, a working mobile device with internet access, currently not receiving treatment for anxiety problems or depression, no history of schizophrenia and bipolar disorder, and presence of subclinical SAnD symptoms were eligible to participate. Eligible participants were randomly allocated via computer script to each study arm, stratified by age, gender, and level of SAnD symptoms. The waitlist control group were granted access to the mobile app following the date of post-test.

Figure 1: iOS mobile app screen of the EMI (exposure therapy modules).
Results
A total of 180 people consented to participate in the study, of whom 160 participants were assessed for eligibility (20 were lost to screening for eligibility). Of the latter, 88 participants did not satisfy the inclusion criteria. Thus, a total of 72 participants commenced the baseline survey but of these 17 failed to finish the questionnaire. 55 participants were randomized and allocated to a study arm, although six people (10%) formally withdrew from the study during the 4 weeks study period and were not included in the analyses. The ethics protocol required data to be deleted for participants who formally withdrew from the study however the data from all other participants were included in the outcome analyses. A total of 49 participants (23 intervention and 26 waitlist control) who completed the baseline survey and did not actively withdraw during the study were retained for the present analyses.

Baseline Characteristics
The majority of participants were female 40 (81%). The most common education level was year 12 or equivalent (34.7%), followed by bachelor’s degree (24.5%). Most participants were employed either part-time (38.8%) or full-time (26.5%), with the remainder either students (28.6%) or unemployed (6.1%). Participants mostly lived in major capital cities (46.9%) and major urban metro cities (30.6%), although one-fifth lived in rural or regional areas (22.4%). Most participants used their mobile phones frequently, with one-half reporting use 20 or more times per day (46.9%), and the remainder reporting using their phone 10 to 20 times per day (28.6%), or 5 to 10 times per day (24.5%). The age of participants ranged from 18 to 60 years old (mean = 28.7, standard deviation (SD) = 12.4 years). The average severity of SAnD at baseline fell in the moderate range, based on SOPHS (mean score = 8.98, SD = 3.24) and Mini-SPIN measures (mean score = 6.47, SD = 2.11). At baseline, there were no significant differences between study groups in education, employment, living region, average use of participant mobile phone per day, SAnD, anxiety sensitivity, GAD and depression, or psychological distress.

Attrition and adherence
Of the 55 participants who were randomized (which includes the six who formally withdrew from the study), 41 participants (83%) did not complete the primary outcomes, secondary outcomes or user satisfaction assessments at post-test. This included 24/28 participants in EMI group (85% of EMI group), and 17/27 participants in the control group (62% of control group).

Of the 49 participants who were analyzed, 13 participants in the EMI group downloaded and installed the mobile app (10 did not download and install the app on their device). Only two of the participants in the EMI group who installed the mobile app also completed the post-test assessments. In addition, the two participants in the EMI group who downloaded and installed the app self-reported a mean of three occasions that they accessed the app (median = 3.0, SD = 1.4). A total of 14 participants in the EMI group passively logged at least one or more times while using the mobile app during the study (see Fig. 2). Specifically, the mean number of usage logs that were passively recorded by the mobile app that was used by the participants in the EMI group was 5.93, (median = 5.50, SD = 3.18).
Three participants in the control group downloaded and installed the mobile app on their device, and therefore downloaded the mobile app after the waiting period.

**Outcome Measurements**

The study showed the EMI group had no statistically significant reduction of SAnD symptoms compared to the waitlist control group, based on SOPHS scores ($F(1, 11.6) = 0.280, p = 0.606$, hedges’ $g = 0.38$) and Mini-SPIN scores ($F(1, 11.6) = 1.447, p = 0.250$, hedges’ $g = 1.19$). The EMI group did not show a statistically significant reduction on ASI scores ($F(1, 11.2) = 4.646, p = 0.054$, hedges’ $g = 1.28$), DQ5 distress scores ($F(1, 11.5) = 0.812, p = 0.386$, hedges’ $g = 0.35$), or PHQ-4 scores ($F(1, 14.2) = 3.510, p = 0.082$, hedges’ $g = 3.12$). Tables 1 and 2 display the raw means and standard deviations (SD) of above outcomes for EMI and control groups.

For the AHSQ, a chi-square test did not show a statistically significant difference in help-seeking between the EMI and the control group ($\chi^2(1, n = 13) = 2.359, p = 0.125$). Hence, participants in the EMI group were not significantly more likely to seek help for their anxiety problems in the past 4 weeks (66.7%) than those in the control group (20.0%).

The mean user satisfaction rating out of 10 for enjoyment in using the mobile app, and that the mobile app "taught participants skills in helping them in everyday life", was 6.0, (SD = 0.7). Similarly, the mean ratings for finding the mobile app to be "interesting", and to be "useful in the future", were 6.0, (SD = 1.4). The mean rating (out of 10) for finding the mobile app to be "helpful", was 5.0, (SD = 0.7).

Furthermore, the mean ratings to "recommend the mobile app to other people who might benefit from it", was 7.0, (SD = 1.4). Finally, participants agreed on average that the mobile app was easy to understand (mean score = 8.0, SD = 0).

**Discussion**

The pilot study showed the EMI had no statistically significant benefit in reducing SAnD symptoms compared to the control. Similarly, no significant benefit was found for anxiety sensitivity and psychological distress. These results are largely consistent with previous studies that examined an EMI with therapist support targeting SAnD symptoms [22], but divergent from studies targeting GAD, stress, and depression [22;29;30]. There were also no differences in help-seeking behaviors between the EMI and control. These results may reflect the high rates of attrition (along with poor adherence) and the underpowered sample to detect differential effects of the EMI relative to the control. Moreover, participants may have found it difficult to engage with the EMI’s content and exercises, without human support. The results suggest that participants who engaged with the app were somewhat satisfied with the mobile app which indicate further room for improvements; however, this study did not focus on usability outcomes, which may have produced more favorable results [1]. A redesign of the mobile app may improve the EMI. Additional face-to-face support or real-time online support by a therapist may be needed to show effects of the EMI within the population. For example, an integrated online portal for the therapist with features to adjust the EMI based on the treatment response of the individual may lead to greater engagement.
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References


