Pilot Trial of an Ecological Momentary Intervention for Social Anxiety

Brendan Loo Gee
Centre for Mental Health Research
Research School of Pop. Health
Australian National University
brendan.loogee@anu.edu.au

Amelia Gulliver
Centre for Mental Health Research
Research School of Pop. Health
Australian National University
amelia.gulliver@anu.edu.au

Philip J. Batterham
Centre for Mental Health Research
Research School of Pop. Health
Australian National University
philip.batterham@anu.edu.au

Kathleen M. Griffiths
Research School of Psychology
Australian National University
kathy.griffiths@anu.edu.au

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.

ACM Classification Keywords
H.5.m. Information interfaces and presentation (e.g., HCI): Miscellaneous;

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.

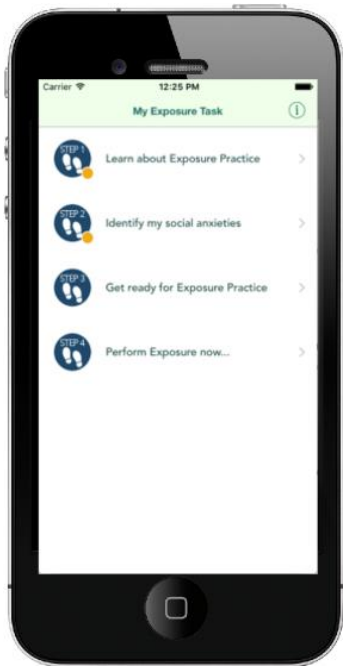

Figure 1: iOS mobile app screen of the EMI (exposure therapy modules).

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 prototype delivering a standalone EMI for SAnD [15]. The iOS mobile app consisted of four brief modules that encapsulate steps for learning and conducting exposure therapy at moments when a person experiences symptoms in real-time (see Fig. 1). The *software architecture* of the iOS mobile app involved a modular structure that was designed to deliver the multiple components of exposure therapy content. Multiple software design approaches (agile modeling, model-driven development, and bottom-up development) were used to develop the app in a collaboration between software developers, trained clinical psychologists, and mental health researchers. We hypothesized that the new EMI prototype would be significantly more effective in reducing symptoms of SAnD, GAD and depression, and stress than a waitlist control group. Further, it was hypothesized that the EMI would increase help-seeking behaviors.

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.

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 variables. Descriptive statistics were used to compare demographic, user satisfaction, and mobile app download and usage measurements.

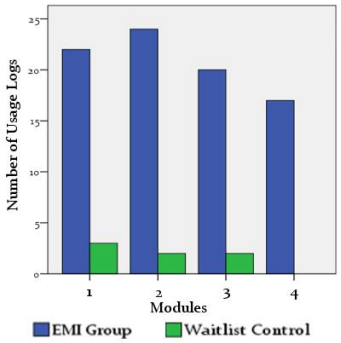

Figure 2: The number of usage logs of each module that were accessed by participants relative to each study group (Of note, the usage logs in the waitlist control were logged after the trial period).

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 analyzes. 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 analyzes. 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 analyzes.

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).

	Pre-test (*n*=23)	Post-test (*n*=4)
SOPHS	9.6 (3.6)	8.7 (1.4)
Mini-SPIN	6.8 (2.3)	6.3 (0.8)
ASI	24.6 (11.8)	28.0 (1.5)
PHQ-4	5.4 (2.7)	7.7 (1.1)
DQ5	12.0 (3.7)	13.3 (0.9)

Table 1: Mean (SD) scores of outcomes for EMI group

	Pre-test (*n*=26)	Post-test (*n*=10)
SOPHS	8.4 (2.7)	7.3 (1.9)
Mini-SPIN	6.2 (1.8)	4.8 (1.1)
ASI	21.6 (9.5)	18.5 (7.1)
PHQ-4	4.3 (1.5)	3.6 (1.0)
DQ5	12.0 (3.2)	12.1 (2.2)

Table 2: Mean (SD) scores of outcomes for waitlist control group

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.

Acknowledgements

The authors will like to acknowledge Julia Reynolds, Les Posen, Dominque Kazan, Lou Farrer, and Andrew White for their advice and input in the development of the content of the mobile app. Further, Arjun Rajshekhar for his work in the mobile app back-end and integrated study management system. Phil J. Batterham is supported by NHMRC fellowship 1083311.

References

1. Aino Ahtinen, Elina Mattila, Pasi Välkkynen, Kirsikka Kaipainen, Toni Vanhala, Miikka Ermes, Essi Sairanen, Tero Myllymäki, Raimo Lappalainen. 2013. Mobile Mental Wellness Training for Stress Management: Feasibility and Design Implications Based on a One-Month Field Study. *JMIR Mhealth Uhealth*, 1, 2: e11.
2. Jordi Alonso and Jean-Pierre Lepine. 2007. Overview of key data from the European Study of the Epidemiology of Mental Disorders (ESEMeD). *Journal of Clinical Pyschiatry* 68, 2: 3-9.
3. American Psychiatric Association (APA). 2013. *Diagnostic and statistical manual of mental disorders: DSM-5*. American Psychiatric Association, Arlington, Va.
4. Australian Bureau of Statistics (ABS). 2008. *National Survey of Mental Health and Wellbeing: Summary of Results*. Australian Bureau of Statistics, Canberra, ACT.
5. Philip J. Batterham, Andrew J. Mackinnon and Helen Christensen. 2016. Community-Based Validation of the Social Phobia Screener (SOPHS). *Assessment*, 24, 7: 958-969.
6. Philip J. Batterham, Matthew Sunderland, Natacha Carragher, Alison L. Calear, Andrew J. Mackinnon and Tim Slade. 2016. The Distress Questionnaire-5: Population screener for psychological distress was more accurate than the K6/K10. *Journal of Clinical Epidemiology*, 71: 35-42.
7. Mariko Chartier-Otis, Michel Perreault and Claude Bélanger. 2010. Determinants of Barriers to Treatment for Anxiety Disorders. *Psychiatric Quarterly*, 81, 2: 127-138.
8. Helen Christensen, Philip Batterham and Alison Calear. 2014. Online interventions for anxiety disorders. *Current opinion in psychiatry*, 27, 1: 7-13.
9. Kathryn M. Connor, Kenneth A. Kobak, Erik L. Churchill, David Katzelnick and Jonathan R. T. Davidson. 2001. Mini-SPIN: A brief screening assessment for generalized social anxiety disorder. *Depression and Anxiety*, 14, 2: 137-140.
10. Pim Cuijpers and Josien Schuurmans. 2007. Self-help interventions for anxiety disorders: An overview. *Current Psychiatry Reports*, 9, 4: 284–290.
11. Jesper Dagöö, Robert P. Asplund, Helene A. Bsenko, Sofia Hjerling, Anna Holmberg, Susanne Westh, Louise Öberg, Brjánn Ljótsson, Per Carlbring, Tomas Furmark and Gerhard Andersson. 2014. Cognitive behavior therapy versus interpersonal psychotherapy for social anxiety disorder delivered via smartphone and computer: A randomized controlled trial. *Journal of Anxiety Disorders*, 28, 4: 410-417.
12. Brian G. Danaher, Håvar Brendryen, John R. Seeley, Milagra S. Tyler, Tim Woolley. 2015. From black box to toolbox: Outlining device functionality, engagement activities, and the pervasive information architecture of mHealth interventions. *Internet Interventions*, 2, 1: 91-101.
13. Philip M. Enock, Stefan G. Hofmann and Richard J. McNally. 2014. Attention Bias Modification Training Via Smartphone to Reduce Social Anxiety: A Randomized, Controlled Multi-Session Experiment. *Cognitive Therapy and Research*, 38, 2: 200-216.

14. Richard G. Heimberg, Faith A. Brozovich and Ronald M. Rapee. 2010. Chapter 15 - A Cognitive Behavioral Model of Social Anxiety Disorder: Update and Extension In *Social Anxiety (2nd. Ed.)*, Stefan G. Hofmann and Patricia M. DiBartolo (Eds.). Academic Press, San Diego, CA, 395-422.

15. Eric B. Hekler, Predrag Klasnja, William T. Riley, Matthew P. Buman, Jennifer Huberty, Daniel E. Rivera and Cesar A. Martin. 2016. Agile science: creating useful products for behavior change in the real world. *Translational Behavioral Medicine*, 6, 2: 317-328.

16. Kristin E. Heron and Joshua M. Smyth. 2010. Ecological momentary interventions: Incorporating mobile technology into psychosocial and health behaviour treatments. *British Journal of Health Psychology*, 15, 1: 1-39.

17. Stefan, G. Hofmann, Jaqueline Bullis and Cassidy Gutner. 2013. Social Anxiety Disorder: Treatment Tragets and Strategies In *CBT For Anxiety Disorders : A Practitioner Book*, Gregoris Simos and Stefan G. Hofmann (Eds.). John Wiley & Sons, Somerset, NJ, 87-105.

18. Jonathan D. Huppert, Deborah A. Roth and Edna B. Foa. 2003. Cognitive-behavioral treatment of social phobia: new advances. *Current Psychiatry Reports* 5, 4: 289-296.

19. IBM, 2013. IBM SPSS Statistics for Windows, Version 22.0, Armonk, NY: IBM Corp.

20. Todd B. Kashdan, Fallon R. Goodman, Kyla A. Machell, Evan M. Kleiman, Samuel S. Monfort, Joseph Ciarrochi and John B. Nezlek. 2014. A Contextual Approach to Experiential Avoidance and Social Anxiety: Evidence From an Experimental Interaction and Daily Interactions of People With Social Anxiety Disorder. *Emotion*, 14, 6: 769-781.

21. Ronald C. Kessler, Patricia Berglund, Olga Demler, Robert Jin, Kathleen R. Merikangas and Ellen E. Walters. 2005. Lifetime Prevalence and Age-of-Onset Distributions of DSM-IV Disorders in the National Comorbidity Survey Replication. *Archives of General Psychiatry* 62, 6: 593-602.

22. Brendan Loo Gee, Kathleen M. Griffiths and Amelia Gulliver. 2016. Effectiveness of mobile technologies delivering Ecological Momentary Interventions for stress and anxiety: a systematic review. *Journal of the American Medical Informatics Association*, 23, 1: 221-229.

23. Bernd Löwe, Inka Wahl, Matthias Rose, Carsten Spitzer, Heide Glaesmer, Katja Wingenfeld, Antonius Schneider and Elmar Brähler. 2010. A 4-item measure of depression and anxiety: Validation and standardization of the Patient Health Questionnaire-4 (PHQ-4) in the general population. *Journal of Affective Disorders*, 122, 1: 86-95.

24. Evan Mayo-Wilson, Sofia Dias, Ifigeneia Mavranezouli, Kayleigh Kew, David M. Clark, A E Ades and Stephen Pilling. 2014. Psychological and pharmacological interventions for social anxiety disorder in adults: a systematic review and network meta-analysis. *The Lancet Psychiatry*, 1, 5: 368-376.

25. Inbal Nahum-Shani, Shawna N. Smith, Bonnie J. Spring, Linda M. Collins, Katie Witkiewitz, Ambuj Tewari and Susan A. Murphy. 2016. Just-in-Time Adaptive Interventions (JITAIs) in Mobile Health: Key Components and Design Principles for Ongoing Health Behavior Support. *Annals of Behavioral Medicine*, 1-17.

26. Mark Olfson, Mary Guardino, Elmer Struening, Franklin R. Schneier, Fred Hellman and Donald F. Klein. 2000. Barriers to the Treatment of Social Anxiety. *American Journal of Psychiatry*, 157, 4: 521-527.

27. Steven Reiss, Rolf A. Peterson, David M. Gursky, Richard J. McNally. 1986. Anxiety sensitivity, anxiety frequency and the prediction of fearfulness. *Behaviour Research and Therapy*, 24, 1: 1-8.

28. Debra Rickwood and Valerie Braithwaite. 1994. Social-Psychological Factors Affecting Help-seeking for Emotional Problems. *Social Science & Medicine*, 39, 4: 563-572.

29. Stephen M. Schueller, Adrian Aguilera and David C. Mohr. 2017. Ecological momentary interventions for depression and anxiety. *Depression and Anxiety*, 34, 6: 540-545.

30. Joshua M. Smyth and Kristin E. Heron. 2016. Is providing mobile interventions "just-in-time" helpful? An experimental proof of concept study of just-in-time intervention for stress management. In *Proceedings of the IEEE Wireless Health Conference*, 1-7. https://doi.org/10.1109/WH.2016.7764561.

31. Murray B. Stein and Dan J. Stein. 2008. Social anxiety disorder. *The Lancet* 371, 9618: 1115-1125.

32. Andrew J. White, Tillmann Neben, Aliona von der Trenck, Armin Heinzl and Georg W. Alpers. 2013. Personalized Tracking of Goals and Gains after Psychotherapy Using Behavioral Data. In *Computer Human Interaction (CHI) 2013*, 1-4. http://www.personalinformatics.org/docs/chi2013/white.pdf.