The Development and Evaluation of an Ecological Momentary Intervention for Social Anxiety

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Contribution & Declaration

This work has not been previously submitted for a degree or diploma to any higher education institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made.

The meta-review in Chapter 2 and the systematic review in Chapter 3 was conducted in assistance from Emeritus Prof. Kathleen M. Griffiths and Dr. Amelia Gulliver. Emeritus Prof. Kathleen M. Griffiths undertook the quantitative meta-analysis in Chapter 3 and assisted in drafting the meta-analysis section of the systematic review. Rebecca Randall and Kathina Ali assisted in rating all studies in the systematic review.

Emeritus Prof. Kathleen M. Griffiths, A/Prof. Philip J. Batterham, Dr. Amelia Gulliver, and Les Posen provided formal assistance and advice into the development of the mobile app content and structure (described in Chapter 4). Furthermore, Dr. Lou Farrer, Dr. Andrew White, Julia Reynolds and Dominque Kazan provided informal assistance and advice in the development of the mobile app content. Lastly, Arjun Rajshekhar assisted in the development of the mobile app internet-backend to monitor usage and the integrated study management system (with some assistance from Adjunct Prof. David Hawking).

Emeritus Prof. Kathleen M. Griffiths, A/Prof. Philip J. Batterham and Dr. Amelia Gulliver assisted in the design of the Randomised Controlled Trial (RCT) protocol, and assisted in analysing data for the RCT study. A/Prof. Philip J. Batterham, and Dr. Amelia Gulliver assisted in drafting the RCT protocol and outcome chapters. Clinical support was provided by Dominque Kazan to RCT participants.

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Signature:

Date:

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Abstract

Social anxiety is a common mental health problem. Many people do not seek help due to barriers to accessing services. Novel methods have been explored that enhance existing assessments and treatments to be more accessible to people outside a clinic. Ecological Momentary Assessments (EMA) are real-time approaches that allow a person to self-assess their anxiety while they engage in daily activities. Ecological Momentary Interventions (EMI) are approaches that extend EMA to deliver psychological treatment to people in their natural environment. EMIs can be used as an adjunct to existing therapies, or as a standalone intervention.

The current thesis examines the development and evaluation of EMIs for social anxiety through four related studies. The first study is a meta-review of observational and evaluation studies using EMA to assess or target various mental disorders. The study found 14 reviews that examined general psychopathology, mood disorders, borderline personality disorder, smoking addiction, and psychosis. The study concluded that there is a need for higher quality reviews on anxiety and stress and more reviews of studies that evaluate EMI effects. The second study is a systematic review of EMIs for stress and anxiety, which includes a meta-analysis on the EMI effects on generalised anxiety. This study suggests that EMIs may be effective but indicates a research gap in EMIs for social anxiety.

The third study is a case study on the design and development of an EMI for social anxiety. This study demonstrated the use of three software development approaches and discussed the implications of those approaches on the iterative design process, the development of software components, and the challenges of engagement and communication with stakeholders, documentation and time management. The fourth study presents the protocol for a Randomised Controlled Trial (RCT) for the evaluation of an EMI for social anxiety. The RCT protocol was a two-arm study design that examined the EMI effects against a waitlist control group. The final study presents the RCT outcomes in an adult sample (n = 55) testing the effectiveness of the EMI for reducing social anxiety symptoms. This study found the EMI was not associated with significant improvements in social anxiety relative to the control. Nor the EMI was associated with a significant improvement in anxiety sensitivity, psychological distress, generalised anxiety and

depression, or help-seeking. While the participants who used the mobile app reported being satisfied, the study suffered from significant drop out with 83% of the participants not completing the study.

Overall, the current thesis found that EMIs are promising, but more research is needed to address the challenges in developing an EMI for social anxiety that incorporates an iterative and reflexive development process. Furthermore, the RCT on the resulting EMI faced challenges with recruitment and retention, suggesting that alternative methods may be required for increasing the engagement of individuals in self-guided EMIs. Nevertheless, with further technological and methodological developments, EMIs may offer an opportunity to deliver personalised therapy for people experiencing anxiety.

Publication and Conference Presentations arising from this thesis

List of peer-reviewed publications

Loo Gee, B, Griffiths, KM, Gulliver, A. (2014) Effectiveness of mobile technologies delivering Ecological Momentary Interventions for stress and anxiety: a systematic review. *Journal of the American Medical Informatics Association*, 23, 221-229. doi:10.1093/jamia/ocv043.

List of submitted computer science conference papers

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List of conference presentations

Loo Gee, B, Griffiths, KM, Reynolds, J, White, A. (2016) Oral Presentation "Unravelling the design and development of a mobile health intervention for social anxiety: a software development perspective" at the International Society for Research on Internet Interventions (ISRII) 8th Scientific Meeting, Seattle, United States.

Loo Gee, B, Griffiths, KM, Gulliver, A. (2015) Oral Presentation "Effectiveness of mobile technologies delivering Ecological Momentary Interventions for stress and anxiety: a systematic review" at the Society of Ambulatory Assessment 4th Biennial Conference, State College, United States.

Loo Gee, B, Griffiths, KM, Gulliver, A. (2014) Poster "Mobile technologies delivering Ecological Momentary Interventions for stress and anxiety: a systematic review and meta-analysis" at the Society for Mental Health Research Conference, Adelaide, Australia.

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1. CHAPTER 1
Real-Time Assessments and Interventions for Mental Illness and Social Anxiety: An Introduction

1.1. Chapter Overview

Chapter 1 provides an introduction to the thesis on the development and evaluation of Ecological Momentary Interventions (EMI) for social anxiety. Section 1.2 provides an introduction to the global impacts of mental illnesses and social anxiety and the problems of help-seeking for social anxiety. Section 1.3 provides an introduction to the mechanisms of exposure therapy for social anxiety, and the key components that could be used to deliver therapy in real-time in reducing barriers of help seeking for people with social anxiety. Section 1.4 provides an introduction to the barriers to seeking help for people with social anxiety, including the use of internet and mobile-based interventions as an alternative approach to improve help-seeking behaviours. Section 1.5 introduces real-time approaches, such as Ecological Momentary Assessments (EMA) and Ecological Momentary Interventions (EMI), to increase help-seeking for social anxiety and to optimize the delivery of exposure. Finally, section 1.6 provides an introduction to research on the development and evaluation of EMIs for social anxiety and section 1.7 provides the aims of the thesis including a brief summary of the chapters (section 1.7.1 to 1.7.6).

1.2. Impacts of Mental Illnesses and Social Anxiety

Mental illnesses are one of the five major non-communicable diseases with a substantial burden on the global economy (Bloom et al., 2001). Mental illnesses have a lifetime prevalence of 45% and a 12-month prevalence of 20% among Australians aged 16-85 (Australian Bureau of Statistics, 2008); an estimated lifetime prevalence of 25% and a 12-month prevalence of 9.6% in Europe (Alonso et al., 2004); and a lifetime prevalence of 46% and a 12-month prevalence of 26% in the United States (Kessler et al., 2005a, Kessler et al., 2005b). One of the most commonly diagnosed mental disorders is social anxiety disorder also known as social phobia (Kessler et al., 2005a, Stein and Stein, 2008). Social anxiety has a 12-month prevalence of 4.7% among Australians aged 16-85 (Australian Bureau of Statistics, 2008), and lifetime prevalence of 2.8 to 13.0% in the United States and

Europe (Alonso and Lepine, 2007, Kessler et al., 2005a). Social anxiety disorder is defined 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" (American Psychiatric Association, 2013). People with social anxiety may experience palpitations, dizziness, tingling sensation, abdominal distress, dry mouth, sweating, and blushing during social situations or through the anticipation of situations; however for the anxiety to become a disorder, the symptoms must be present over an extended period and must cause disruption to daily functioning (Heimberg et al., 2010, Jakatdar and Heimberg, 2010). Social anxiety may cause people to avoid social situations because of embarrassment and perceived negative judgement from others (Kashdan et al., 2014). Social anxiety has high comorbidity with major depressive disorder, generalised anxiety disorder, and post-traumatic stress disorder, and alcohol abuse (Erica et al., 2014). However, effective treatments for social anxiety exist, primarily Cognitive Behavioural Therapy (CBT) involving cognitive restructuring and exposure therapy (Hofmann et al., 2013, Huppert et al., 2003, Ponniah and Hollon, 2008). This thesis will focus on the delivery of exposure therapy for social anxiety using real-time approaches to optimize the delivery of therapeutic components and mechanisms, which may increase the accessibility of therapeutic content to people who faces barriers in seeking professional help.

1.3. Mechanisms of Exposure Therapy for Social Anxiety

Craske (2015) and Craske et al. (2014) suggest that the *inhibitory learning model* is the central mechanism of exposure therapy for fear and anxiety. The inhibitory learning model is central to *fear extinction* learning while additional mechanisms, such as *habituation*, may be involved. *Habituation* is referred to the reduction of the physical responses (i.e., elevated heart rate) associated with the repeated exposure of a fear provoking stimuli, such as a challenging social situation. Physiological arousal and sensations will often decline during exposure therapy, which causes inhibition and extinction of previous learned associated between a fearful social situation and the aversive experiences of the fearful social situation (Anderson and Hope, 2009, Wolpe, 1969). This model of fear conditioning via extinction is considered to be a plausible model for the etiology of panic disorders, and social anxiety (Craske et al., 2014).

Parts of the fear may be left intact as a new or secondary association, during fear conditioning. Hence, an individual's fear of a social situation may return if repeated exposure to the social situation is not continued after completing exposure therapy (e.g., being able to publicly speak at one social event but not being able to publicly speak at another event). Furthermore, fear extinction appears to be specific to the *context*, such that the fear may return when a stimuli (e.g., a public audience) is experienced in a different context (e.g., a public audience at a school event verses a public audience at a friend's party). Fear may also be reinstated in an anxiety-induced context (e.g., being socially rejected from a friend's party).

Craske et al. (2014) outlines eight therapeutic strategies for enhancing inhibitory learning and retrieval of this learning between therapy sessions, or after completing exposure therapy. These strategies include; 1) expectancy violation, 2) deepened extinction, 3) reinforced extinction, 4) removal of safety signals/behaviours, 5) stimulus variability, 6) retrieval cues, 7) multiple context, and 8) reconsolidation. Individual strategies are explained in the context of an intervention in Section 1.5. Linguistic processing involving *affective labelling* can be used to enhance the inhibitory regulation process during fear extinction of social situations. For example, individuals with social anxiety can label the negative valence of public speaking (e.g., sweating, shaking or discomfort) before giving a talk to school friends. In the context of the present research, therapeutic strategies that enhance the inhibitory learning mechanisms of exposure therapy may be most effective if they are encapsulated into intervention components that can be directly delivered to individuals with social anxiety at the right time and place. Section 1.5 explains how these strategies can be delivered in real-time.

1.4. Barriers to Seeking Help for Individuals with Social Anxiety

Individuals with social anxiety may be confronted with several barriers to seeking professional help. Griffiths (2013) summarised the self-reported barriers to seeking help for individuals with social anxiety, which include; a lack of knowledge about to where to seek help, a belief that they did not have an anxiety disorder or could deal with the problem on their own, fear of taking medication, stigma, financial barriers, long waiting times or travel times to see a health provider, personal commitments preventing a person accessing help, avoidance behaviours due to the anxiety disorder itself, and poor detection

of social anxiety by general practitioners. Griffiths (2013) presented a framework, consistent with Ajzen's (1991) "Theory of Planned Behaviour", which comprised factors that can be applied to increase help-seeking among people with social anxiety disorders. This seven-factor framework posits that help-seeking may be increased by improving an individual's a) knowledge, b) beliefs and c) attitudes about social anxiety disorder, as well as improving d) the accessibility of help. Interventions can also target e) the illness factors that prevent face-to-face help-seeking and f) intentions to seeking help, which effectively can result in help-seeking behaviours. It is noted that this framework can be used specifically to inform the content of an intervention for increasing help-seeking for social anxiety. Internet- and mobile-based technologies (also known as e-interventions) can be employed to deliver psychological content to primarily increase the accessibility (factor d) of evidence-based treatments, and reduce symptoms of social anxiety (Christensen et al., 2014, Cuijpers and Schuurmans, 2007). E-interventions are low-cost treatments that can potentially deliver evidence-based health interventions at the right time and place convenient to individuals with social anxiety (Griffiths, 2013). Furthermore, some e-interventions have the capacity to deliver self-help psychological content in real-time within a person's natural environment.

1.5. Real-time Approaches to Increase Help-Seeking and Optimise Exposure Therapy

Real-time approaches consist of two approaches to improve the ecological validity of assessment and interventions for social anxiety. These approaches are Ecological Momentary Assessments (EMA) and Ecological Momentary Interventions (EMI). Ecological validity refers to contextual factors that may be conditional on specific emotions, symptoms, or behaviours under investigation or treatment (Hektner et al., 2007, Hormuth, 1992). EMA is an approach that improves the ecological validity of assessments of social anxiety by frequently monitoring an individual's psychological and behavioural symptoms in their natural environment through the use of repeated assessments (Shiffman et al., 2008). EMI are approaches that extend EMA in which people receive momentary health assessments and interventions while people are engaged in their typical routines in their everyday life (Bell et al., 2017, Heron and Smyth, 2010, Shiffman et al., 2008). EMIs are also sometimes referred to as "Just-In-Time Health Interventions", which may employ dynamic tailoring, or intelligent real-time therapy (Danaher et al., 2015,

Nahum-Shani et al., 2016, Schueller et al., 2017). 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 (Heron and Smyth, 2010, Shiffman et al., 2008). EMIs are designed to be more *ecologically* valid because the treatment is directly available for people anywhere or anytime (that is, during the course of their everyday lives rather than in a consulting room) (Heron and Smyth, 2010). Therefore, EMI provides real-time support to people when they really need it. Mobile technologies such as smartphones and wearables are appropriate tools to deliver EMIs because they are ubiquitous, and they are personal devices that people usually carry around with them every day (Schueller et al., 2017).

Inhibitory learning strategies outlined by Craske (2015) and Craske et al. (2014), can be incorporated in the exposure therapy treatment for social anxiety. For instance, the multiple contexts strategy suggests exposure to a social situation in multiple different context, or different times of a day or varying days of the week. Furthermore, the reconsolidation strategy also suggests increasing periods of times between exposures to multiple social situations. A smartphone app can facilitate these types of strategies also, encouraging individuals to identify a range of feared social contexts and prompting them to complete each exposure in a range of contexts (e.g., public speaking in front of friends, in front of strangers, or in front of the mirror) and scheduled at various times of the day or week with variable spacing of exposure activities. EMIs can allow variations in frequency and time of exposure to be delivered automatically.

Another important aspect of optimising exposure therapy is increasing the self-awareness of a person's reaction to their feared social situations. Reactions include physiological responses, such as increase heart rate or trembling, and enactments of safety behaviours (Anderson and Hope, 2009). Antony and Swinson (2008) suggest 'safety signals' or 'safety behaviours' should be prevented or removed while engaging in a social situation. Safety behaviours for social anxiety, such as following a script during public speaking, are often used to alleviate distress for people with social anxiety in the short term, however when behaviours are not present, the fear returns (Craske et al., 2014). Delivering real-time prompts by smartphone to increase awareness of safety signals, and raised levels of physiological bodily sensations, may facilitate better outcomes of exposure in naturalistic settings. Additional monitoring of heart rate before a feared social situation

using a portable heart rate monitor may also be used to increase awareness of these reactions.

Affective labelling exercises (as outlined in Section 1.3) and positive valence training strategies as proposed by Craske (2015), or positive reappraisal coping exercises as those proposed by Garland et al. (2009) are recommended over other cognitive strategies, such as cognitive restructuring, when conducting exposure in a person's naturalised setting (Craske, 2015). Individuals can be offered affective labelling exercises via a smartphone app which may encourage them to engage in exposure therapy to seek help or approach challenging social situations. Lastly, fear hierarchy is a central part of exposure therapy. This involves individuals developing an ordered list of feared social situations ranked from their least feared situations to their most feared situations (Antony and Swinson, 2008, Bourne, 2005). In contrast to traditional exposure therapy, fear hierarchy in an inhibitory learning model focuses on a stimulus variability strategy, achieved by having items in a fear hierarchy completed in random order without regard to fear levels for each hierarchy item (Craske, 2015, Craske et al., 2014). Similar to a 'to do' list, individuals using a smartphone app can be notified to complete exposure therapy in random social situations stored in a fear hierarchy.

1.6. Research on the Development and Evaluations of Ecological Momentary Interventions (EMIs) for Social Anxiety

Although there has been an increase in research on the development and evaluation of EMIs for social anxiety, there remains limited evidence for their efficacy. Including the present research, three Randomised Controlled Trial (RCT) have examined the efficacy of EMIs in reducing social anxiety symptoms (Dagöö et al., 2014, Enock et al., 2014b, Loo Gee et al., 2016). Moreover, little is known about how to design and develop EMIs for anxiety disorders such as social anxiety (Schueller et al., 2017). Design research into EMIs and other similar e-interventions can be used to understand the development process of EMIs (Zimmerman et al., 2010), especially in the *early stage work* of an EMI before an RCT is deployed to evaluate the efficacy of an EMI on targeted symptoms (Hekler et al., 2016). This thesis presents current research on EMA and EMI studies, research on the design of EMIs, and evaluations of EMIs for social anxiety, culminating in the development and RCT evaluation of a new EMI for social anxiety.

1.7. Outline of this Research Thesis

The current thesis consists of several studies that contribute to our knowledge of the systematic development and evaluation of EMIs for social anxiety. This body of work provides insight into the development process and the efficacy of EMIs for mental health researchers and practitioners who wish to address symptoms of social anxiety in people's everyday lives. This thesis presents the latest research on EMA and EMI, provides a framework for the development of EMA and EMI for social anxiety or similar mental health problems, and reports on the development and RCT of new EMI within the context of this development framework. The subsequent chapters of this thesis contain separate studies, which are arranged in chronological order from the earliest study conducted in March 2013 (Chapter 2) and the latest study finishing in July 2017 (Chapter 6). Readers may expect that some of the content, such as the definition of EMI, will be repeated throughout the chapters of this thesis in order to make each chapter consistent, relevant, and internally coherent. Repeated content will be marked by a footnote to indicate its intent. The following sections will provide a brief summary of the chapters of this thesis. Section 1.7.1 provide a brief summary of Chapter 2. Section 1.7.2 provide a brief summary of Chapter 3. Section 1.7.3 provide a brief summary of Chapter 4. Section 1.7.4 provide a brief summary of Chapter 5. Section 1.7.5 provide a brief summary of Chapter 6. Section 1.7.6 provide a brief summary of Chapter 7.

1.7.1. Chapter 2

Ecological Momentary Assessments for mental disorders: A meta-review

Chapter 2 will present findings of a meta-review study, detailing systematic reviews of EMA studies for mental disorders, conducted in March 2013. The meta-review aims are threefold; 1) to identify systematic reviews of studies using EMA for multiple mental disorders; 2) to provide an overview of the systematic reviews' findings regarding studies using EMA for mental disorders, and 3) to provide an overview of the characteristics of studies using EMA for different mental disorders. The study will report on different technologies for data collection and present review findings from observational studies using EMA and interventions using EMA . The meta-review study conclusions included the need for higher quality systematic reviews of the effects of interventions using EMA for stress and anxiety.

1.7.2. Chapter 3

Effectiveness of mobile technologies delivering Ecological Momentary Interventions for stress and anxiety: A systematic review

A systematic review and meta-analysis of the effects of EMI on anxiety and stress outcomes will be presented in Chapter 3. The study in Chapter 3 has been published in the Journal of American Medical Informatics Association (JAMIA) (Loo Gee et al., 2016). This review examines RCTs on the effects of EMIs on anxiety and stress outcomes. The systematic review presented details evaluation studies that have deployed different EMI types and mobile technologies, including embedded smartphone sensors and text messaging. Furthermore, the review and meta-analysis report on the effectiveness of EMI in reducing generalised anxiety, stress, panic disorders, and social anxiety. The review draws conclusions on the limitation of existing research and ways to optimise the delivery of smartphone app platforms for particular components of the EMI.

1.7.3. Chapter 4

Conceptual design and development process of Ecological Momentary Interventions for mental and behavioural health: A software development perspective

Chapter 4 will present a case study on the design and development of an EMI for social anxiety delivered on a smartphone app. A conference presentation on the case study was delivered by the author at the 2016 International Society of Research on Internet Interventions (ISRII) 8th Scientific Meeting in Seattle, USA. This chapter will provide an introduction to software development approaches used to develop an EMI for social anxiety and include the rationale of using these software design approaches to deliver evidence-based content (exposure therapy) of the EMI on a smartphone app. Key learnings will be discussed in relation to the design and development process, which includes the limitation of the proposed design process. The EMI developed via this case study was evaluated using an RCT to examine the effectiveness of the EMI in reducing social anxiety symptoms with the results presented in Chapter 5 and 6.

1.7.4. Chapter 5

A standalone self-help Ecological Momentary Intervention delivering exposure therapy for social anxiety disorders: Study protocol for a randomised controlled trial

A study protocol of an RCT evaluating the effects of EMI delivering exposure therapy to reduce social anxiety symptoms will be presented in Chapter 5. The study protocol describes a two-arm study design that measures the effects of an EMI against a waitlist control group. Pre- and post-tests evaluation will examine the reduction of social anxiety and other related outcomes. Mobile app downloads and mobile app use are also examined. An intention-to-treat analysis of changes in outcome measure will examine results. Furthermore, descriptive summaries of user satisfaction, mobile app downloads and usage will be provided.

1.7.5. Chapter 6

Ecological Momentary Intervention for social anxiety: Study outcomes from a pilot randomised controlled trial

Chapter 6 will present the results of the RCT study on the effects of an EMI delivering exposure therapy to reduce social anxiety symptoms. The results of the RCT will report on the between-group interaction effects of the EMI on social anxiety, anxiety sensitivity, generalised anxiety and depression, psychological distress, and help-seeking behaviours. Furthermore, the results will provide descriptive statistics of user satisfaction and usage of the EMI after 4 weeks.

1.7.6. Chapter 7

Concluding remarks

Chapter 7 will summarise the key research findings of the thesis on the development and evaluation of an EMI for social anxiety. Specifically, Chapter 7 will provide a discussion of findings, contextualise the thesis findings within previous research, propose theoretical implications of the findings, describe the limitation of the research, and suggest directions for future EMI research, including practical implications for software design and clinical practice. The final chapter will conclude by describing how the current research advances the design and evaluation of EMIs for social anxiety.

2. CHAPTER 2
Ecological Momentary Assessments for Mental Disorders: A Meta-Review

2.1. Introduction and Background

This chapter introduces Ecological Momentary Assessment (EMA) studies in mental health research. The findings of this meta-review are intended for researchers to explore the possible research questions using EMA to investigate multiple mental disorders. Section 2.1.1 provides background on mental disorders and the issues of retrospective recall biases in assessing mental disorders. Sections 2.1.2 to 2.1.4 provide a background on the EMA approach, including a description of EMA protocols and study designs. Section 2.1.5 provides a summary of previous research on the EMA approach, including a brief introduction to meta-review methodology. Section 2.1.6 provides the aims of the meta-review.

2.1.1. Assessing mental disorders: Retrospective recall biases

Historically, self-reporting of emotions, symptoms or behaviours of various mental disorders have relied on techniques or instruments that require a high level of memory recall. Memory or retrospective recall may increase the risk of potential biases and cognitive errors in the self-reporting of mental disorders (Gorin and Stone, 2001). In addition, retrospective recall of emotions, symptoms or behaviours in certain environments such as the clinic and laboratory may be difficult (De Vries, 1992, Stone et al., 2007). Ecological validity refers to contextual factors that may be conditional on the specific emotions, symptoms, or behaviours under investigation (Hektner et al., 2007, Hormuth, 1992). By widening ecological validity, a research approach can be employed that regularly prompts individuals to momentarily self-report moods, behaviours, and context through a rigorous sampling regime (Stone et al., 2007).

2.1.2. Ecological Momentary Assessment (EMA) approach

Ecological Momentary Assessment (EMA) aims to reduce the need for retrospective recall by frequently monitoring an individual's psychological and behavioural symptoms

in their natural environment through the use of repeated assessments (Shiffman et al., 2008). Repeated assessments of the daily experience of an individual is an important part of the EMA approach because it provides data to assist researchers in understanding the daily psychopathological manifestations of mental disorders, especially in relation to the changes over time and place (Shiffman, 2007, Shiffman et al., 2008). In summary, the EMA approach is an important methodology for examining within-person experiences of individuals with mental disorders, with application to mental health assessment and treatment.

2.1.3. Study designs using the EMA approach

EMA has been used in observational studies of mental disorders, and evaluation studies of interventions for various mental disorders. Section 2.1.3.1 to 2.1.3.2 provides a description of potential study designs using the EMA approach.

2.1.3.1. *Observational studies using EMA*

EMA in field research investigates and assesses specific symptoms, behaviours, and environments associated with various health conditions, including mental disorders. EMA can be used to identify the association of various factors with a range of mental disorders, such as the relationships between daily symptoms and behaviours for a specific mental disorder such as depression (Stone et al., 2007). EMA can be used to examine the *intensity and variability* of daily symptoms and behaviours, such as the daily frequency and changes in symptoms in a given period of the day, week, or month (Moskowitz et al., 2009). Importantly, the EMA approach is comprised of the Experience Sampling Method (ESM) which primarily examines the frequency, intensity, and daily patterns of psychological state and thoughts of individuals through *self-reported data* collected at regular intervals (Csikszentmihalyi and Larson, 1992, Hektner et al., 2007). Similar to daily diaries used in therapy, EMA also includes *assessments* for self-monitoring used to record daily states and thoughts during the day. In research on psychopharmacotherapy and psychotherapy treatments, EMA can be used to examine the daily effects of treatment for many mental disorders (Moskowitz and Young, 2006).

2.1.3.2. *Evaluation studies of interventions using EMA*

There has been an increased interest in the research of EMA as part of interventions for different mental health problems, also known as Ecological Momentary Interventions (EMI)[1] (Bell et al., 2017, Smyth and Heron, 2016, Myin-Germeys et al., 2016, Schueller et al., 2017). Moreover, EMIs uses similar data capture techniques, and mobile technologies of the EMA approach (or self-monitoring component) which is employed in observational studies using EMA that examines the day-to-day psychological, behavioural, physiological and contextual variables of people with mental disorders (Bell et al., 2017, Myin-Germeys et al., 2016, Smyth and Heron, 2016). Thus, this makes the research of EMIs distinctly different from observational research studies using EMA. This chapter examines both types of research. It is likely the appeal of EMA in interventions is related to the exponential increase in the use of mobile technologies, such as mobile phones and wearable devices. Shiffman et al. (2008) describe the potential use of EMA as a self-monitoring tool to collect data from individuals involved in interventions. Further, the extension of EMA can provide capabilities for tailoring interventions delivered by a therapist through the precise diagnosis of mental disorders in a person using ongoing EMA monitoring of symptoms (van Os et al., 2013). Additionally, there is the potential of using EMA to monitor and deliver health interventions or treatments instantaneously and within a person's usual surroundings. Health interventions or treatment can be delivered by a human or digital system (such as web application, or mobile device). Smyth and Heron (2016) demonstrated the separate components of an EMI for stress management. The intervention consisted of palmtop computers delivering EMA to self-monitor daily stress, and mobile device prompts of *random* or *tailored* stress management reminders. This recent proof-of-concept study by Smyth and Heron (2016) is an example of the use of the EMA approach in the context of interventions for mental health problems.

2.1.4. Ecological Momentary Assessment protocol

Researchers and practitioners require careful preparation of an EMA protocol when devising a research study using EMA. Development of an appropriate EMA protocol can increase adherence rates and concurrent validity with retrospective clinical assessments,

[1] "Ecological Momentary Interventions (EMI)" is defined in other chapters of this thesis (Chapter 3, Chapter 4, Chapter 5, and Chapter 6).

which can be critical for observational and evaluation studies using the EMA approach (Kimhy et al., 2012). Table 1 provides a definition of the different components of the EMA protocol. Sections 0 to 2.1.4.5 provide a description of the different considerations involved with an EMA protocol, including some of the challenges of the EMA approach.

Table 1. Definition of the different components of the EMA protocol.

Components of EMA Protocol	*Description of Components*
Sampling contingency	Frequency of self-reported assessments that participants complete in a given time period.
Fixed-based interval contingency	A fixed number of self-reported assessments that participants complete at fixed times of the day.
Random-based interval contingency	A random number of self-reported assessments that participants complete at random times of the day.
Event-based interval contingency	Participants complete self-reported assessments based on an actual event or trigger which may occur during the day.
Self-assessment interval	The minimal and maximum number of self-reported assessments that participants are given during a time period. Event-based interval contingency are depended on the event's occurrence during the data collection period.
Delivery method	The method of delivering self-reported assessments to participants.
Active momentary assessments	A delivery method that requires participants to actively engage to manually complete self-reported assessments. Manual data collection methods include pen and paper, or electronic survey delivered on a hand-held device.
Passive momentary assessments	A delivery method that requires participants to passively engage to automatically complete self-reported assessments. Automatic data collection methods include wearables, or biosensors.
Ambulatory devices	A type of data collection device that can track biological, physiological, and contextual factors of participants.

EMA measurements	An outcome measurement of the participant used to measure daily mood, behaviours, context, or other factor relating to observed mental disorders. An example of EMA measurement includes daily positive and negative affect, quality of life indicators, or other psychological traits.
EMA compliance	The participants rate of adherence to completing the required number of self-reported assessments during the data collection period. EMA compliance is often measure by the percentage of completed assessments for a given time period.

2.1.4.1. *Sampling contingency strategy*

The sample contingency strategy (or schedule protocol) is part of the EMA protocol. The *sampling contingency* is the frequency or distribution of self-reported assessments that an individual will receive in order to complete during a given period (Shiffman, 2007). Moreover, the sampling contingency of the EMA protocol can be traced from the ESM approach that was developed and commonly used to self-report daily emotions and thoughts of people as early as the beginning of the 1990's (Csikszentmihalyi and Larson, 1992). Hektner et al. (2007), Shiffman (2007), and Stone et al. (2007) describe the three different protocol schema types: *fixed*, *random*, or *event*. *Fixed-based interval contingency* is a strategy that sends a permanent number of self-report assessments at fixed time periods throughout the day. *Random-based interval contingency* is a sampling strategy that sends self-report assessments at random time periods of the day. *Event-based contingency* is a sampling strategy that gives individuals self-report assessments based on an actual event or trigger which may occur during a day. All three sampling contingency strategies are dependent on the number of days and number of assessments appropriate for the research questions under investigation which may impact on missing data collected during the study (Robinson, 1992, Shiffman, 2007).

2.1.4.2. *Self-assessment intervals for data collection*

Fixed or random-based contingency sampling strategies vary broadly. For example, they can range from sampling once a day, to several times a day, to every 30 to 60 minutes and are time-based (Shiffman, 2007). However, event-based contingency sampling strategies are dependent on the event's occurrence during the data collection period (Shiffman, 2007). Depending on the research question and target population, assessments are variable; they may be spaced across days, weeks, or months, or possibly more frequent in certain periods of days, weeks, or months (Hektner et al., 2007, Shiffman, 2007).

2.1.4.3. *Delivery of EMA assessments*

The delivery method of momentary assessments is another important part of the EMA protocol. *Active* or *passive* momentary assessments can be used to self-report or self-monitor a person's emotions, symptoms, and behaviours over time (Hsieh et al., 2013). Active assessment includes the *Pen and Paper* (P&P) method. P&P requires individuals to use paper and pen to record daily symptoms, behaviours, or events (Hektner et al., 2007). Furthermore, P&P can be used with an *electronic signal device*, such as a beeper, pager, or wristwatch alarm that prompts individuals to complete assessments (Csikszentmihalyi

and Larson, 1992). Passive momentary assessments include wearable real-time *ambulatory devices* (Stone et al., 2007). Ambulatory devices are particular mobile technologies for tracking biological, physiological and sometimes neurological changes in individuals (Stone et al., 2007). Contemporary active and passive approaches for data recording includes the use of *handheld electronic programmable devices*, such as mobile phones, and Personal Digital Assistants (PDA) (Dale and Hagen, 2007), and more recently smartphones (Kimhy et al., 2012).

2.1.4.4. *Measurement outcomes used in EMA research*

The EMA protocol for a mental health intervention will include outcome measurements of mood and behaviours of one or more mental disorders. Smyth and Stone (2003) describe some of the outcome measures for EMA research. Outcome measurements include levels of Positive Affect (PA) or Negative Affect (NA), or specific symptoms of a mental disorder. EMA can be used to measure the mechanisms of current or ongoing stress. Furthermore, EMA can also be used to investigate Momentary Quality of Life (mQoL) indicators, such as social interactions, food and drink consumption, physical activity and sleep activity. There also appears to be some utility of EMA to self-monitor daily effects of treatment for various mental disorders. Data reported in self-report assessments can be binary (yes/no) items, Likert scales, sliding scales or visual analogue scales.

2.1.4.5. *Methodological issues of the EMA approach*

A number of issues are related to the EMA approach. These issues include adherence to completing assessments according to the prescribed sample contingency schedule (Hektner et al., 2007). Poor compliance or adherence may be due to the burden placed on individuals in completing a continuous stream of self-report assessments for a given period (Hufford, 2007). Research indicates that more frequent assessments during a given period can capture a more comprehensive picture of the phenomena; however, this must be balanced as the rate of incomplete assessments is known to increase alongside more frequent assessments (Hufford, 2007).

2.1.5. Existing research in the EMA approach

Previous literature reviews of EMA research, and EMI research, have investigated various mental disorders, such as panic disorders and phobias, anxiety and depression, stress and psychosis, and addiction (Alpers, 2009, Schueller et al., 2017, Lukasiewicz et al., 2007, Myin-Germeys and van Os, 2007). These literature reviews provided examples of EMA for specific mental disorders; however, no previous reviews have used a collective approach by combining findings from systematic reviews of multiple mental disorders to provide the broad overview of the literature required to understand the overall use of EMA in the field.

2.1.5.1. *Meta-review rationale*

"Meta-reviews", or "Review of Reviews", are designed to extract information from multiple systematic reviews in order to provide a synthesis of the evidence on different treatment or assessments on a single medical condition, on the same treatment or assessment for different outcomes and medical conditions, or different outcomes of the same treatment or assessment (i.e., EMA) for a single medical condition (i.e., mental disorders) (Hartling et al., 2014, Thomson et al., 2010). In contrast to systematic reviews that focus on a direct *pairwise comparison* of a single method or intervention, meta-reviews can indirectly compare similar methods or interventions for different medical conditions or populations across multiple systematic reviews (Hartling et al., 2014). In this meta-review, it aims to synthesise the findings of included systematic reviews of primary studies using EMA (observation and evaluation studies) to investigate multiple mental disorders (see Figure 1).

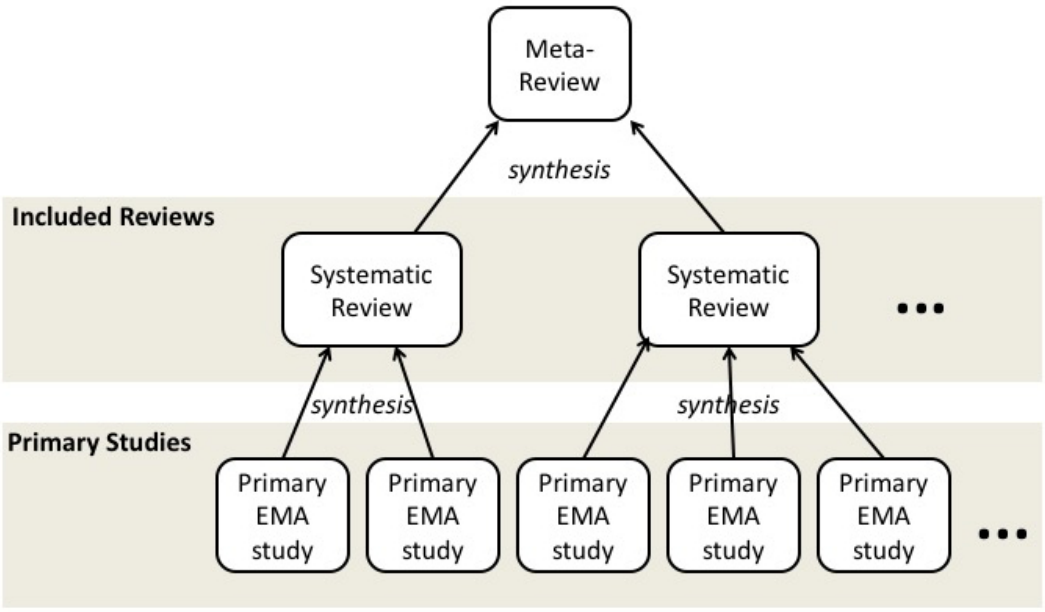

Figure 1. Diagram demonstrating meta-review synthesis of include reviews and primary studies using EMA

2.1.6. Objectives

This current study aims to provide a meta-review of primary EMA studies for various mental disorders. The purpose was to broadly understand the EMA approach in the research of mental disorders and to use the findings of the meta-review to inform the areas of EMA research that requires more investigation. The meta-review address three research questions:

- *What are the gaps in current systematic reviews of EMA research?*
- *What are the systematic reviews that has been conducted for different mental health problems and mental disorders?*
- *What are the areas in the current research that needs more attention?*

2.2. Method

This study adhered to the meta-review guidelines outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Becker and Oxman, 2011).

2.2.1. Search method for identification of reviews

A search for systematic reviews of primary EMA studies on a range of mental disorders was conducted. The Cochrane Library, Centre for Reviews and Dissemination, Health

Services/Technology Assessment Text, Health Technology Assessment Programme, PubMed, Medline (via the Ovid database), PsycInfo (via Ovid), and ScienceDirect databases were searched in March 2013. Main search concepts included a combination of *"ecological momentary"*, *"mental health"*, *"mobile"*, *"meta-analysis"* and *"systematic review"*. MeSH (Medical Sub-Heading) and Subject Heading keywords from relevant databases were included. A restriction was applied to the databases to limit the searches to 'review' papers. No restriction was applied to publication date.

2.2.2. Inclusion criteria

Reviews were included if they; 1) were published in English; 2) were published in a peer-reviewed journal (prior to the date of the search, March 2013); and 3) included search methodology details (the review must have included the minimal details of a) search terms, b) inclusion criteria, and c) literature databases searched); 4) focused on mental disorders or mental health problems (classified under ICD-10 codes for mental and behavioural disorders); 5) examined EMA studies that assessed participants in their natural environment as part of the study protocols; and finally 6) examined EMA studies that implemented a form of repeated self-report assessments or real-time assessment of emotions or behaviours for a specific period as part of the study protocol. Self-report assessments included traditional and electronic diaries, mobile or PDA applications, or pen and paper diaries.

2.2.3. Exclusion criteria

Systematic reviews were excluded if they; 1) were not published in English; 2) were not published in a peer-reviewed journal; 3) *did not* document appropriate details of literature search methodology (such as search terms, inclusion criteria, and literature databases); 4) focused on the general population; 5) *did not* examine EMA studies that assessed participants in their natural environment; 6) *did not* examine EMA studies that deployed repeated self-report assessment or real-time assessment of emotions or behaviours for a specific period as part of the study protocol. Review studies that examined diary approaches that *did not* study one of the possible protocols (fixed-, random-, and event-based schedules) for repeated assessments were excluded. The author believed that a traditional diary method (e.g., behavioural activation and sleep diaries) was able to satisfy at least one of the relevant sample contingency strategies, but not satisfy all of the possible

sample contingency strategies for EMA. An example of such study is a review of a single diary method with only a fixed interval schedule. Therefore, any review study that examined this type of EMA design was excluded from this meta-review.

2.2.4. Selection of included reviews

Figure 2 (below) displays the PRISMA flowchart for this meta-review (Moher et al., 2009). A total of 2351 records were identified by the literature search strategy conducted in the relevant databases. The author (BLG) screened all titles and abstracts of all database records to identify eligible articles that met the selection criteria. Of the database records that were screened, 2209 records were excluded using the inclusion and exclusion criteria listed above. From these, the full text of 142 articles was screened, and 128 additional articles were excluded based on the section criteria. A total of 14 relevant review papers were included for data extraction and qualitative data synthesis.

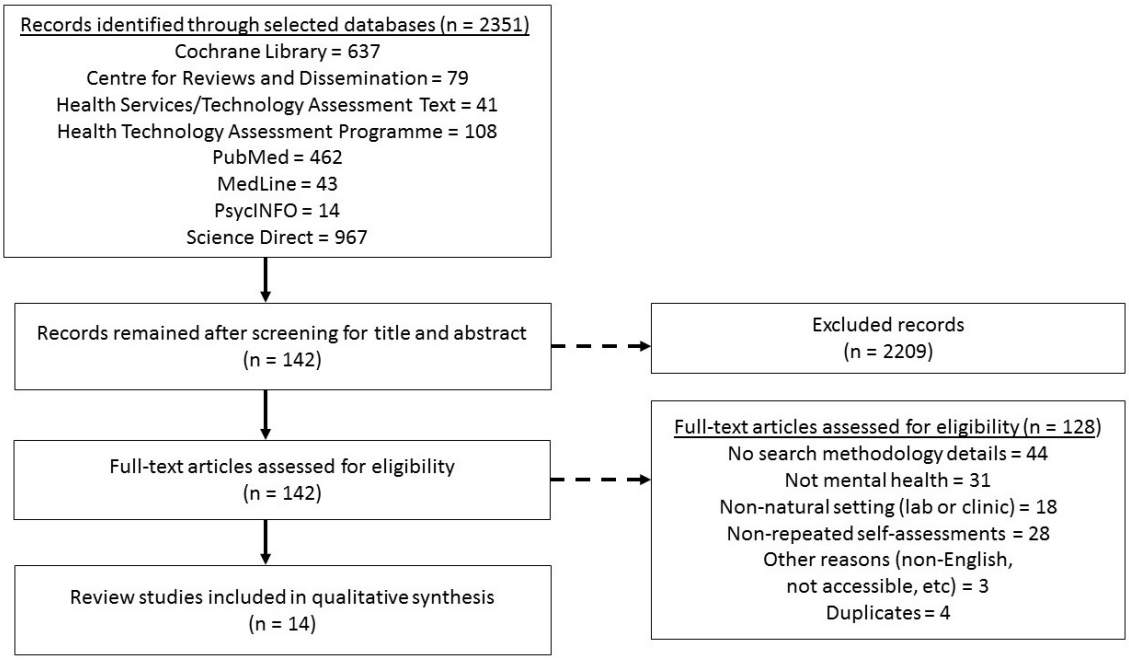

Figure 2. PRISMA flowchart of this meta-review

2.2.5. Data extraction

Data extraction was independently conducted by BLG. Tables were formulated and used to extract information on the EMA protocol details and the findings of the included primary EMA studies that were reported in all of the included reviews. Details of the

systematic review's methodology and evidence were critically evaluated using a checklist by EPOC (Cochrane Effective Practice and Organisation of Care Group) (Moher et al., 2009). The criteria according to the checklist were used to identify, include and critically appraise evidence presented in each of the included reviews.

The following information was extracted from all included review papers: author's name and year of publication, target population of the systematic reviews, subgroups types of the systematic reviews (i.e., community population, or age group), the systematic review outcomes (i.e., summary of findings of primary studies and/or meta-analysis), the EMA protocol details reported in the systematic reviews (such as sampling contingency strategies, delivery mode of EMA assessments, data collection periods, and feasibility issues, including protocol adherence), rationale of EMA studies (i.e., primary observation studies using EMA or primary evaluation studies of interventions using EMA), and the findings of primary EMA studies reported in the systematic reviews.

2.2.6. Quality of included reviews

The reviewer (BLG) assessed the methodological quality of the included reviews, using the 'Assessment of Multiple Systematic Reviews' (AMSTAR) measurement tool (Shea et al., 2007). The AMSTAR items assessed the design of the included reviews, information on literature search strategy, characteristics of the studies of the included reviews, and information on the method to assess the quality of the primary EMA studies of the included reviews.

2.2.7. Data synthesis

Descriptive statistics were used to provide a quantitative summary of the included systematic reviews in the meta-review. A qualitative summary of the EMA protocol details reported in the included reviews was provided. Furthermore, a qualitative summary of the included reviews findings of primary studies using EMA was synthesised into relevant themes, or by the relevant mental disorder classifications. The summary of the included review findings of EMA protocol details and primary studies using EMA were presented in tables shown in the appendices of the thesis (see Appendices A to C).

2.3. Results

Sections 2.3.1 to 2.3.3 present the results of the meta-review of primary EMA studies on multiple mental disorders. Section 2.3.1 shows a quantitative synthesis or summary of included reviews. Section 2.3.2 presents a qualitative summary of the included review findings of primary observational studies using the EMA approach, including a summary of the EMA protocol details of primary studies reported in the included reviews. Section 2.3.3 provides a qualitative summary of the included review findings of primary evaluation studies of interventions using EMA, including a summary of the evaluation study design of primary studies reported in the included reviews.

2.3.1. Summary of included reviews

Of the 14 included systematic reviews, 11 reviews reported details of the EMA protocol (aan het Rot et al., 2012, Burton et al., 2013, Cain et al., 2009, Ebner-Priemer and Trull, 2009, Haedt-Matt and Keel, 2011a, Haedt-Matt and Keel, 2011b, Myin-Germeys et al., 2009, Nica and Links, 2009, Oorschot et al., 2009, Telford et al., 2012, Wenze and Miller, 2010). Ten of the 14 review studies reported on observational studies using EMA (aan het Rot et al., 2012, Burton et al., 2013, Cain et al., 2009, Ebner-Priemer and Trull, 2009, Haedt-Matt and Keel, 2011a, Haedt-Matt and Keel, 2011b, Myin-Germeys et al., 2009, Nica and Links, 2009, Oorschot et al., 2009, Telford et al., 2012). Six of the 14 review studies reported on findings from evaluation studies of interventions that used the EMA approach (aan het Rot et al., 2012, Ebner-Priemer and Trull, 2009, Heron and Smyth, 2010, Telford et al., 2012, Wenze and Miller, 2010, Whittaker et al., 2012a).

The 14 included reviews examined General Psychopathology (including addiction) (n = 4) (Cain et al., 2009, Ehrenreich et al., 2011, Myin-Germeys et al., 2009, Oorschot et al., 2009), Mood Disorders (n = 4) (aan het Rot et al., 2012, Burton et al., 2013, Telford et al., 2012, Wenze and Miller, 2010), Eating Disorder (n = 2) (Haedt-Matt and Keel, 2011a, Haedt-Matt and Keel, 2011b), Mood Disorders and Borderline Personality Disorder (n = 1) (Ebner-Priemer and Trull, 2009), Borderline Personality Disorder (BPD) (n = 1) (Nica and Links, 2009), Smoking Addiction (n = 1) (Whittaker et al., 2012a), and Psychosis (n = 1) (Oorschot et al., 2009). One of the two included reviews on eating disorders was a revised study although it included new findings therefore both were included (Haedt-Matt and Keel, 2011a, Haedt-Matt and Keel, 2011b). One included review examined adults (aged 18 and 85)

(Burton et al., 2013), and one included review focused on older adults (aged 50 years and over) (Cain et al., 2009). The remaining twelve included reviews did not specify an age group target (aan het Rot et al., 2012, Ebner-Priemer and Trull, 2009, Ehrenreich et al., 2011, Haedt-Matt and Keel, 2011a, Haedt-Matt and Keel, 2011b, Heron and Smyth, 2010, Myin-Germeys et al., 2009, Nica and Links, 2009, Oorschot et al., 2009, Telford et al., 2012, Wenze and Miller, 2010, Whittaker et al., 2012a). No included reviews targeted a specific gender.

2.3.1.1. *The quality of included reviews*

Ten of the 14 included reviews qualitatively reported on findings of primary observational studies of mental disorders using EMA and primary evaluation studies of interventions using EMA, of which the majority of primary studies were controlled or uncontrolled observational primary studies (n = 161), and a minority of the primary evaluation studies reported in the included reviews reported on Randomised Controlled Trials (RCT) (n = 35) (aan het Rot et al., 2012, Cain et al., 2009, Ebner-Priemer and Trull, 2009, Ehrenreich et al., 2011, Heron and Smyth, 2010, Myin-Germeys et al., 2009, Nica and Links, 2009, Oorschot et al., 2009, Telford et al., 2012, Wenze and Miller, 2010). The remaining four included reviews conducted a meta-analysis of quantitative findings of primary observational studies (Haedt-Matt and Keel, 2011a, Haedt-Matt and Keel, 2011b, Burton et al., 2013), and primary evaluation studies on interventions (Whittaker et al., 2012a).

Table 2 presents the methodological quality for each of the included systematic reviews using the AMSTAR checklist. Most of the included reviews were low quality or unclear in managing duplicate study selection and data extraction, stating the status of the publication (i.e., grey literature) as part of the inclusion criteria, providing appropriate lists of the included and excluded primary studies, providing the characteristics of included primary studies, formulating the conclusion recommendations of the systematic review through methodological and scientific rigour, presenting graphical aids and statistical tests for publication biases, and reporting on the potential of conflict of interest.

Table 2. Methodological quality of included systematic reviews assessed by AMSTAR checklist.

Reviews	*An 'a priori' design*	*Study selection and data extraction*	*Literature search strategy*	*Status of publicat-ion used in inclusion*	*List of included and excluded primary studies*	*Charact-eristic of included primary studies*	*Scientific quality of included primary studies*	*Scientific quality of conclusi-on*	*Combini-ng findings*	*Publicat-ion bias*	*Conflict of Interest Stated*
Wenze & Miller (2010)	✓	*?*	✓	X	*?*	X	*?*	✓	*N/A*	X	X
aan het Rot et al. (2012)	✓	*?*	✓	✓	*?*	✓	✓	✓	*N/A*	X	✓
Telford et al. (2012)	✓	*?*	✓	X	*?*	✓	✓	*?*	*N/A*	X	✓
Burton et al. (2013)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ebner-Priemer & Trull (2009)	*?*	*?*	✓	X	X	X	*?*	✓	*N/A*	X	X
Nica & Links (2009)	✓	*?*	✓	*?*	*?*	✓	✓	*?*	*N/A*	X	✓
Oorschot et al. (2009)	*?*	*?*	X	X	X	X	✓	*?*	*N/A*	X	X
Haedt-Matt and	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X

Keel (2011a)											
Haedt-Matt and Keel (2011b)	✓	✓	✓	✓	*?*	✓	✓	✓	✓	✓	X
Myin-Gemeys et al. (2009)	*?*	*?*	X	*?*	X	X	✓	*?*	***N/A***	X	✓
Cain et al. (2009)	✓	✓	✓	*?*	✓	✓	✓	✓	***N/A***	X	✓
Ehrenreich et al. (2011)	✓	✓	✓	✓	✓	✓	✓	✓	***N/A***	X	✓
Whittaker et al. (2009)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Heron & Smyth (2010)	✓	*?*	✓	*?*	*?*	✓	✓	✓	***N/A***	X	X
Did not meet criteria, studies n (%)	**3(21%)**	**8(57%)**	**2(14%)**	**8(57%)**	**9(64%)**	**4(28%)**	**2(14%)**	**4(28%)**	**0(0%)**	**10(71%)**	**6(42%)**

✓= Yes; x = No; *?* = Can't Answer; ***N/A*** = Not Applicable

2.3.2. Included review findings for primary observational studies

Sections 2.3.2.1 to 2.3.2.2 provide a summary of the included systematic review findings of the primary EMA observational studies. Section 2.3.2.1 presents the findings of the *EMA protocol details* reported in the primary EMA studies and subsequently reported in the included reviews, and section 2.3.2.2 presents the findings of the primary observational studies using EMA reported in the included reviews.

2.3.2.1. *EMA protocol details of primary observation studies of included reviews*

Appendix A presents a summary of the EMA protocol details of the primary observational studies using EMA reported in the included reviews. The following sections present a summary of the reported sampling contingency of the primary EMA studies reviewed in the included reviews (section 2.3.2.1.1), the self-assessment intervals for data collection periods (section 2.3.2.1.2), the delivery mode (section 2.3.2.1.3), and any feasibility issues of the EMA protocol of the primary EMA studies reported in the included reviews (section 2.3.2.1.4).

2.3.2.1.1. Sampling contingency strategies

In the included reviews, r*andom-based interval sampling strategies* were reported in three primary EMA studies on mood disorders and three primary borderline personality disorders (aan het Rot et al., 2012, Ebner-Priemer and Trull, 2009, Myin-Germeys et al., 2009, Nica and Links, 2009). *Fixed-based interval sampling strategies* were reported in four primary EMA studies on bipolar disorders and nine primary EMA studies on the general psychopathology of older adults (Ebner-Priemer and Trull, 2009, Cain et al., 2009). *Event-based sampling strategies* were reported in the one primary EMA study on Borderline Personality Disorder (BPD) and three primary EMA studies on the psychological states of older adults (Cain et al., 2009, Nica and Links, 2009). Included reviews on eating disorders found the majority of primary EMA studies targeting eating disorder (78%) used event-based sampling strategies that examined the internal states of individuals before and after a binge or purging episode (Haedt-Matt and Keel, 2011a, Haedt-Matt and Keel, 2011b).

2.3.2.1.2. Self-assessment intervals for data collection

One included review found the average data collection period was 11 days (3-54) with a mean of seven assessments (2-10) per day in primary EMA studies on mood disorders (aan het Rot et al., 2012). One included review on the use of activity monitoring for depression

reported data collection periods ranging from 2-30 days (Burton et al., 2013). The included review of aging adults reported the data collection of primary EMA studies ranged from 1-365 days (Cain et al., 2009). A single included review reported data collection periods ranged from 24 hours to 1 month in primary EMA studies on BPD (Nica and Links, 2009). The included reviews on eating disorders reported the data collection periods of primary EMA studies ranged from 1 eating period to 5 weeks (Haedt-Matt and Keel, 2011a, Haedt-Matt and Keel, 2011b).

2.3.2.1.3. Delivery mode

Included reviews on mood disorders reported the use of Pen and Paper (P&P) and signal device (such as beeper or wristwatch signal) to be the simplest data collection method for primary EMA studies on mood disorders (aan het Rot et al., 2012, Ebner-Priemer and Trull, 2009, Wenze and Miller, 2010). One included review reported the use of P&P visual mood charts to report depressive symptoms (Wenze and Miller, 2010). Included reviews reported P&P to be feasible for primary EMA studies on BPD and the general psychopathology of older adults (Cain et al., 2009, Nica and Links, 2009). Mobile phones and Portable Device Assistants (PDA) were reported in primary EMA studies of included reviews on depression, bipolar and BPD (aan het Rot et al., 2012, Ebner-Priemer and Trull, 2009, Nica and Links, 2009, Wenze and Miller, 2010). Wrist actigraphy, portable saliva testing, blood pressure monitors, skin conductance sensors, and heart rate monitors were reported in the primary EMA studies of included reviews on mood disorders, BPD, psychosis, and mental health of aging adults (aan het Rot et al., 2012, Cain et al., 2009, Myin-Germeys et al., 2009, Oorschot et al., 2009, Telford et al., 2012, Wenze and Miller, 2010). Particular devices that measure psychomotor activity, such as actigraphy devices, were reported in primary EMA studies of included reviews on depression (Ebner-Priemer and Trull, 2009, Burton et al., 2013, Wenze and Miller, 2010). Two included reviews reported on potential validity problems for actigraphy devices when used outside the laboratory for primary EMA studies on mood disorders (Wenze and Miller, 2010, Burton et al., 2013). Other laboratory instruments such as electroencephalography (EEG), pupilometer, and functional magnetic resonance imaging (fMRI) were used to measure brain activity for primary EMA studies reported in included reviews on mood disorders and psychosis (aan het Rot et al., 2012, Oorschot et al., 2009).

2.3.2.1.4. Feasibility and adherence issues

Included reviews showed the EMA approach to be feasible for primary observational studies for mood disorders and bipolar disorders (Telford et al., 2012, Wenze and Miller, 2010). However, one included review reported on a primary EMA study found people with bipolar completed fewer assessments than those without bipolar disorder (Wenze and Miller, 2010). Additionally, the same included review found no clear interaction between the severity of symptoms and adherence to the EMA protocol (Wenze and Miller, 2010). Included reviews showed adherence in individuals with bipolar was superior when clinicians gave feedback to the individual on their low adherence (aan het Rot et al., 2012, Telford et al., 2012). One included review reported older adults to adhere well to the EMA protocol, with 10% of EMA studies reporting compliance rates under 18% (Cain et al., 2009). For included reviews on eating disorders, the compliance rates were 84.1% of random signals for random-based interval sampling employed in primary EMA studies on eating disorders, and 91.5% of interval ratings for fixed-based interval sampling employed primary EMA studies on eating disorders (Haedt-Matt and Keel, 2011a, Haedt-Matt and Keel, 2011b).

2.3.2.2. *Included review findings of primary observational studies*

Appendix B presents a summary of the included review findings of the primary observational studies using EMA. Section 2.3.2.2.1 to 2.3.2.2.5 presents a summary of the included review findings for primary studies on mood disorders, borderline personality disorders, psychosis, panic disorders, eating disorders, and psychological addictions.

2.3.2.2.1. Mood disorders

Several relevant themes were derived from the findings of primary EMA studies on mood disorders reported in the included systematic reviews (aan het Rot et al., 2012, Burton et al., 2013, Cain et al., 2009, Ebner-Priemer and Trull, 2009, Myin-Germeys et al., 2009, Telford et al., 2012). Relevant themes included systematic review findings of primary observational studies using EMA related to affective states of mood disorders, the daily changes of physiological mechanisms and biological processes of mood disorders, included review findings on bipolar, mood disorders in work environment, young and aging people with mood disorders, and included review findings on remitted patients with

mood disorders and treatment progress. These themes are reported below from sections 2.3.2.2.1.1 to 2.3.2.2.1.8.

2.3.2.2.1.1. Affective states of mood disorders

Included reviews reported on primary EMA studies that found day-to-day changes of Positive Affect (PA) and of Negative Affect (NA) may be associated with changes of daily stress and positive and negative event for people with mood disorders, such as Major Depressive Disorder (MDD) or bipolar (aan het Rot et al., 2012, Ebner-Priemer and Trull, 2009, Myin-Germeys et al., 2009, Telford et al., 2012). Three included reviews reported on primary EMA studies that found changes of diurnal rhythm was associated with daily changes to PA and NA among people with MDD (Ebner-Priemer and Trull, 2009, Myin-Germeys et al., 2009, Telford et al., 2012). Furthermore, included reviews reported on primary EMA studies that suggest associations between daily levels of PA and NA and mQoL indicators for people with mood disorders (aan het Rot et al., 2012, Myin-Germeys et al., 2009, Telford et al., 2012). Two included reviews found an association between daily PA and NA levels with sleep quality; however, one included review also added that these findings remain inconclusive in the adult population. The included review by aan het Rot et al. (2012) found no such association, and suggested that the difference between sample characteristics, compliance rates of the EMA protocol, and sleep quality assessments of the studies could have influenced the uncertain results (aan het Rot et al., 2012, Telford et al., 2012). One included review by aan het Rot et al. (2012) reported on a primary EMA study that found physical activity may be influenced by changes in daily PA and NA; however, aan het Rot et al. (2012) reported the primary EMA study employed subjective recordings of physical activity through active assessments, and not objective measurements through passive assessments such as a wrist actigraphs, which may have shown different findings.

2.3.2.2.1.2. Physiological mechanisms

Two included review studies identified primary EMA studies that examined the physiological changes of people with mood disorders using a mixture of active and passive recording devices (Burton et al., 2013, Ebner-Priemer and Trull, 2009). The included review and meta-analysis by Burton et al. (2013) found a significant difference in objective measurements of day-time activity using actigraphy devices for people with depression and people in the control group (standardised mean difference: -0.76, 95% CI, -1.05 to -

0.47). The other included review by Ebner-Priemer and Trull (2009) suggested on primary EMA studies that found changes in motor activity levels were associated with changes in sleep activity of people with MDD, such as day-time and night-time activity. Other included review findings by Ebner-Priemer and Trull (2009) suggest that people with MDD may experience changes in bright light exposure and heart rate during physical activity, especially the differences between day-time and night-time activity. Furthermore, Ebner-Priemer and Trull (2009) reported on a primary EMA study that found physical activity levels fluctuated during inactive periods of people with bipolar disorder.

2.3.2.2.1.3. Biological processes

Included reviews reported on primary EMA studies that found some association with changes of salivary levels of the cortisol and daily changes of psychosocial factors, hassles and negative events, but not daily heart rate variability among people with MDD (aan het Rot et al., 2012, Ebner-Priemer and Trull, 2009, Telford et al., 2012). Two included reviews found associations between daily experiences of rumination and self-esteem and patterns of EEG alpha activity measured in the laboratory among people with mood disorders (aan het Rot et al., 2012, Myin-Germeys et al., 2009). Other included review findings also suggest daily changes of PA and NA among people with mood disorders were associated with changes in pupil dilation measured in the clinic (aan het Rot et al., 2012, Myin-Germeys et al., 2009). One included review study found an association between daily PA and striatal activity measured in the laboratory, but no association of daily NA with striatal activity among people with mood disorders (aan het Rot et al., 2012).

Genetic factors of mood disorders were reported in several included reviews. Telford et al. (2012) reported on a primary EMA study that found daily PA acted as a protective factor for daily NA reactivity. The authors suggested a potential association between the genes of people with depression and the experience of high NA from daily stress. The review studies by Ebner-Priemer and Trull (2009) and Myin-Germeys et al. (2009) reported on a primary EMA study on female twins both with and without MDD. Ebner-Priemer and Trull (2009) and Myin-Germeys et al. (2009) reported the primary EMA study found co-twins with depression showed larger mood responses to stress than co-twins without MDD. This may indicate a potential endophenotype for people with depression.

2.3.2.2.1.4. Bipolar disorder

Three included reviews reported on EMA studies for bipolar disorder. The findings suggested that there were differences in daily levels of PA and NA between people with bipolar and people with other mood disorders; however, these differences may be based on differences in the clinical representation of particular facets of each mental disorder, such as belong alone, self-esteem, and stress (aan het Rot et al., 2012). Other included reviews found daily PA and NA levels and self-esteem may be associated with time spent alone or in passive leisure activities, such as watching television at home (aan het Rot et al., 2012, Myin-Germeys et al., 2009). One included review reported on a primary EMA study that found changes in sleep activity and mood were followed by hypomania or mania the following day (Ebner-Priemer and Trull, 2009).

2.3.2.2.1.5. Mood disorders in the work environment

Several included reviews reported on primary EMA studies on the economic impacts of mood disorders. The included reviews by Ebner-Priemer and Trull (2009), Myin-Germeys et al. (2009), and Telford et al. (2012) found depressive symptoms may be associated with work productivity. The included review findings suggested daily symptoms of depression may influence degrees of absenteeism, work performance, and task focus.

2.3.2.2.1.6. Young people with mood disorders

The included review by aan het Rot et al. (2012) found daily changes of PA may be associated with sleep activity and daily NA may be associated with wakefulness. The review by aan het Rot et al. (2012) suggested that young people with MDD who have poor sleep quality may benefit more from sleep hygiene practices than adults with MDD. Another included review found caffeine use was associated with sleep problems, whereby younger people with MDD were more likely to smoke, have urges to smoke, and consume more alcohol than those without MDD (Myin-Germeys et al., 2009).

2.3.2.2.1.7. Aging people with mood disorders

The included review by Cain et al. (2009) was the only study that reported on primary EMA studies that examined mood disorders in aging adults. The included review found daily activity levels were not associated with the experiences of bereavement among aging adults with MDD. However, Cain et al. (2009) reported on a primary EMA study that showed daily PA and positive events were associated with changes in stress among aging

adults with MDD. Furthermore, Cain et al. (2009) also reported on a primary EMA study on Parkinson's Disease (PD) that examined the daily levels of PA and NA of aging adults. The included review by Cain et al. (2009) found day-to-day PA and NA levels may be influenced by aging adults in long-term care facilities.

2.3.2.2.1.8. Remitted patients with mood disorders and treatment progress

Remitted patients with mood disorders were reported in two included reviews (aan het Rot et al., 2012, Myin-Germeys et al., 2009). An included review reported on a primary EMA study that found high daily levels of NA and stress occurred after receiving inpatient treatment for people with MDD, which may predict relapse of symptoms (aan het Rot et al., 2012). Furthermore, the same included review found no association of physical activity and daily levels of NA, but increases in daily PA for remitted patients with mood disorders (aan het Rot et al., 2012). Another included review reported on a primary EMA study that found daily hassles were associated with stressful events among people with remitted bipolar (Myin-Germeys et al., 2009).

Five of the included reviews reported on primary EMA studies that examined treatment progress (aan het Rot et al., 2012, Burton et al., 2013, Ebner-Priemer and Trull, 2009, Myin-Germeys et al., 2009, Telford et al., 2012). Authors of these reviews reported on primary EMA studies that found mQoL indicators such as enjoyment of activities, physical complaints, and mood were associated with side-effects of psychopharmacology treatment and treatment drop-out for people with mood disorders (aan het Rot et al., 2012, Ebner-Priemer and Trull, 2009, Telford et al., 2012). In particular, one included review reported that medication treatment did not significantly change mQoL but stabilised it (Myin-Germeys et al., 2009). While mQoL may stabilise after treatment, other findings suggest a decrease in daily NA over the course of treatment, and an association of daily levels of PA and NA with pleasurable activities through increases in reward experiences (aan het Rot et al., 2012, Telford et al., 2012, Myin-Germeys et al., 2009). One review reported a primary EMA study that found young people who spent more time with close peers were more likely to recover after receiving treatment than young people who spent more time with general peers (aan het Rot et al., 2012). Furthermore, another included review found physical activity levels were found to increase with daily changes in levels of PA and NA after people received treatment (Myin-Germeys et al., 2009). The included review and meta-analysis conducted by Burton et al. (2013) reported a significant increase

in the objective measure of daytime physical activity, using actigraphs, following treatment (standardised mean difference: 0.53, 95% CI, 0.2 to 0.87). The meta-analysis also found a small reduction in night-time physical activity following treatment (standardised mean difference: -0.36, 95% CI, -0.65 to -0.06), and a small improvement on sleep efficiency (standardized mean difference: 0.19, 95% CI, -0.38 to 0.76). Finally, included reviews by aan het Rot et al. (2012), Ebner-Priemer and Trull (2009), and Telford et al. (2012) found daily stress was associated with early treatment response to psychotherapy for people with mood disorders, which may be a positive predictor for completing treatment such as psychotherapy.

2.3.2.2.2. Borderline Personality Disorder (BPD)

Several themes were identified through the three included reviews of EMA studies on BPD (Ebner-Priemer and Trull, 2009, Myin-Germeys et al., 2009, Nica and Links, 2009). Relevant themes include daily affective instability among people with BPD, stress reactivity, behavioural associations with stress, and physiological and biological associations of changes in affective instability. These themes are reported from sections 2.3.2.2.2.1 to 2.3.2.2.2.5.

2.3.2.2.2.1. Affective instability

Three included reviews reported on primary EMA studies finding rapid and intense daily changes of PA and NA, known as affective instability, was associated with BPD symptoms, such as anxiety and sadness, aversive tension, anger and hostility (Ebner-Priemer and Trull, 2009, Myin-Germeys et al., 2009, Nica and Links, 2009). Additionally, the same included reviews found people with BPD will experience higher variability of daily PA and NA than other clinical diagnosed groups or people without a mental disorder (Ebner-Priemer and Trull, 2009, Myin-Germeys et al., 2009, Nica and Links, 2009). Finally, one of these reviews found people with BPD may experience a different sequence of emotions throughout the day than other clinical and non-clinical groups (Ebner-Priemer and Trull, 2009).

2.3.2.2.2.2. Stress reactivity

Three included reviews reported on primary EMA studies that found an association between affective instability and daily stress and events in people with BPD (Ebner-Priemer and Trull, 2009, Myin-Germeys et al., 2009, Nica and Links, 2009). One included

review reported daily changes in affective states, such as PA and NA, appeared to be influenced by external triggers such as life events. In addition, changes to daily PA were also associated with interpersonal interactions during a life event (Nica and Links, 2009). Another included review found high aversion tension, rejection, and low esteem were associated with events that lead to high averse tension (Ebner-Priemer and Trull, 2009). Finally, one included review reported that high psychological distress and conflicts of emotion were associated with problems of identifying emotions among people with BPD (Nica and Links, 2009).

2.3.2.2.2.3. Behavioural associations with stress

Three included reviews reported on EMA studies that found an association between dissociative behaviours and daily stress or interpersonal stress in people with BPD (Ebner-Priemer and Trull, 2009, Myin-Germeys et al., 2009, Nica and Links, 2009). However, it was noted that the association between daily dissociation and affective instability had not been investigated previously by EMA researchers (Nica and Links, 2009). One included review also found people with BPD may show dominant, agreeable, and quarrelsome behaviours during daily measures of social interactions (Ebner-Priemer and Trull, 2009). Two included reviews reported on primary EMA studies that found day-to-day affective instability was associated with impulsiveness, and suicidal ideation and suicidal behaviours shown over the past year among people with BPD (Myin-Germeys et al., 2009, Nica and Links, 2009).

2.3.2.2.2.4. Physiological associations with affective instability

Two included reviews found associations between daily psychophysiological indicators and affective dysregulations (Ebner-Priemer and Trull, 2009, Nica and Links, 2009). The included review by Ebner-Priemer and Trull (2009) reported on one primary EMA study that found physical activity using an actigraphy device was associated with psychological distress among people with BPD. Both of these included reviews reported on primary EMA studies that found an association between changes in objective measures of heart rate and emotional responses in people with BPD (Ebner-Priemer and Trull, 2009, Nica and Links, 2009).

2.3.2.2.2.5. Biological associations with affective instability

Two included reviews found a relationship between biological changes of individuals with BPD and daily experiences of emotional dysregulation. Included reviews by Ebner-Priemer and Trull (2009) and Myin-Germeys et al. (2009) reported on one primary EMA study that found salivary cortisol were associated with hypothalamic-pituitary-adrenal (HPA) axis activity. Additionally, the included reviews reported on one primary EMA study that found people with BPD had high cortisol responses to awakening and high daily cortisol levels than people without BPD.

2.3.2.2.3. Psychosis

Two included reviews reported on findings of primary EMA studies on psychosis (Myin-Germeys et al., 2009, Oorschot et al., 2009). Included review findings were summarised into the following relevant themes; the positive and negative symptoms of psychosis, stress, substance use, paranoia and coping, biological mechanisms, and gene-environment interactions. These themes are reported from section 2.3.2.2.3.1 to 2.3.2.2.3.6.

2.3.2.2.3.1. Positive and negative symptoms

Positive symptoms such as delusions and daily hallucinations were reported in included reviews of primary EMA studies on people with psychosis. Included reviews reported on primary EMA studies that found people with psychosis experienced visual hallucinations, and intense auditory hallucinations in day-to-day life (Myin-Germeys et al., 2009, Oorschot et al., 2009). Furthermore, included reviews reported on primary EMA studies that found daily activity level and context of individuals with psychosis, such as social events, work activities, and leisure activities, were associated with positive psychosis symptoms (Myin-Germeys et al., 2009, Oorschot et al., 2009). Negative psychosis symptoms were reported in primary EMA studies of included reviews. Negative psychosis symptoms were associated with daily changes of emotions, and pleasures in deficits in consummatory and anticipatory pleasure (Oorschot et al., 2009). Included reviews reported on EMA studies that found depression and anxiety symptoms were associated with specific environments and social situations in people with psychosis (Myin-Germeys et al., 2009, Oorschot et al., 2009). Additionally, people who were prone to psychosis were socially withdrawn, and often inactive according to EMA measurements (Oorschot et al., 2009).

2.3.2.2.3.2. Stress

Two included reviews reported on daily stress reactivity in people with psychosis or people at risk of psychosis. Included reviews reported on primary EMA studies that found daily stress and stress sensitivity were associated with daily levels of psychotic experiences and changing levels of positive and negative symptoms in people with psychosis (Myin-Germeys et al., 2009, Oorschot et al., 2009). Furthermore, included reviews reported on primary EMA studies that found previous exposures to traumatic life events were associated with increases in emotional reactivity to small daily stressors (Myin-Germeys et al., 2009, Oorschot et al., 2009).

2.3.2.2.3.3. Substance use

Substances such as cannabis were reported in primary EMA studies of included reviews on psychosis. Included reviews reported on primary EMA studies that found cannabis use in people with psychosis were associated with onset, exacerbation, and recurrence of intense psychotic experiences (Myin-Germeys et al., 2009, Oorschot et al., 2009). Two included reviews reported on a primary EMA study that found cannabis use in people experiencing psychosis was associated with increase mood enhancing effects, and psychosis-inducing effects of cannabis compared with people without psychosis (Myin-Germeys et al., 2009, Oorschot et al., 2009). Other included review findings found cannabis use increased the subacute effects of hallucinations among people with psychosis, which suggests people may receive immediate rewarding effects of mood with the continued use of cannabis despite its long-term negative impacts.

2.3.2.2.3.4. Paranoia and coping

There was some evidence of the association between paranoia and self-esteem reported in the included reviews for people with psychosis; however, the included reviews findings of primary EMA studies on psychosis were inconsistent. People with higher paranoia were associated with daily fluctuations of self-esteem; however, included review findings also suggested that decreases in daily self-esteem were associated with daily increases of paranoia (Myin-Germeys et al., 2009, Oorschot et al., 2009). Included reviews reported on primary EMA studies on symptomatic and non-symptomatic coping with psychotic symptoms whereby coping strategies were measured using structured interviews and coping in daily life was measured using a three-item EMA assessment (Myin-Germeys et

al., 2009, Oorschot et al., 2009). The included reviews found symptomatic coping from structured interviews was not associated with coping in daily life measured using EMA, and non-symptomatic coping reported from structured interviews was associated with coping in daily life measured using EMA (Myin-Germeys et al., 2009, Oorschot et al., 2009).

2.3.2.2.3.5. Biological mechanisms

Two included reviews reported on primary EMA studies that investigated biomarkers in people with psychosis. Included review findings reported on a primary EMA study that found dopamine release from physical stressors was associated with psychotic reactions in response to daily stressors in people with first-degree relatives of patients with psychosis (Myin-Germeys et al., 2009, Oorschot et al., 2009). Also, included reviews reported on primary EMA studies that found the levels of cerebrospinal fluid, grey matter, and white matter were associated with daily stress reactivity, while white matter was not associated with emotional reactivity to daily stress using EMA, and grey matter was not associated with daily stress reactivity (Myin-Germeys et al., 2009, Oorschot et al., 2009).

2.3.2.2.3.6. Gene-Environment Interactions (G X E)

Included reviews by Oorschot et al. (2009) and Myin-Germeys et al. (2009) were reported in primary studies using EMA that found one form of Met/Met genotype (COMT VAL^{158}Met genotype) of patients with psychosis presented increases in psychotic symptoms and NA in response to daily stressors. However, in another primary EMA study reported in Oorschot et al. (2009) and Myin-Germeys et al. (2009), patients with COMT Val/Val carriers reported heightened feelings of paranoia in response to daily stress. Furthermore, both included reviews found patients with COMT Val carriers reported increases in daily hallucinations from cannabis use.

2.3.2.2.4. Eating disorders

Three included reviews examined primary EMA studies on eating disorders (Haedt-Matt and Keel, 2011a, Haedt-Matt and Keel, 2011b, Myin-Germeys et al., 2009). Of the three included reviews, one of the two included reviews was a revised meta-analysis study on purging and binge eating behaviours (Haedt-Matt and Keel 2011b). Included review findings were summarised under themes for each type of eating disorder; bulimia nervosa,

subtypes of bulimia, and anorexia nervosa. These themes are reported from section 2.3.2.2.4.1 to 2.3.2.2.4.3.

2.3.2.2.4.1. Bulimia nervosa

Included review findings of 56 primary EMA studies on bulimia nervosa showed associations between daily levels of NA, such as increased anger, and low self-esteem was associated with eating disorder behaviours, such as binge eating, purging, and dietary restrictions (Haedt-Matt and Keel, 2011a, Haedt-Matt and Keel, 2011b, Myin-Germeys et al., 2009). Changes in daily levels of PA and NA were found to be associated with the precedence of binge episodes for people with bulimia nervosa (Myin-Germeys et al., 2009). Meta-analysis findings, especially for daily levels of NA in people with bulimia nervosa, suggested that participants experienced significant increases of daily NA from pre-binge to post-binge episodes (ES = 0.50, 95% CI: 0.35 to 0.64; $p < .001$), and experienced higher levels of daily NA at compared with before they consumed a regular meal or snack (ES = 0.68, 95% CI = 0.40 to 0.95; $p < .001$) (Haedt-Matt and Keel, 2011b). Furthermore, people with bulimia nervosa experienced greater levels of daily NA at pre-binge episodes than average NA levels (ES = 0.63, 95% CI = 0.45 to 0.82; $p < .001$) (Haedt-Matt and Keel, 2011b).

Daily levels of NA were also associated with hunger or a desire to eat (Haedt-Matt and Keel, 2011a, Haedt-Matt and Keel, 2011b). The meta-analysis by Haedt-Matt and Keel (2011a) found hunger levels pre-binge binge episodes were significantly greater than the participant's mean hunger levels (d = 2.13, 95% CI = 0.38 to 3.87; $p < .05$). However, the authors also found hunger levels were significantly lower at pre-binge eating episodes than at pre-regular eating episodes (d = -0.68, 95% CI = -0.93 to -0.42; $p < .001$). Furthermore, other included review findings showed dietary restrictions, daily binge cravings and cravings were associated with actual binge episodes (Myin-Germeys et al., 2009).

Purging behaviours such as vomiting and extreme weight loss were also reported in included reviews on primary EMA studies on eating disorders. One included review reported on a primary EMA study that found people with bulimia nervosa experienced changes in affective states and increased anger after a post-binge or vomiting episode (Myin-Germeys et al., 2009). Of note, the meta-analysis results showed daily levels of NA were significantly lower at post-purge than pre-binge episodes for people with bulimia nervosa (ES = -0.46, 95% CI: -0.74 to -0.18; $p < .01$) (Haedt-Matt and Keel, 2011b).

Social experiences among people with bulimia nervosa were reported in one included review, indicating that self-esteem problems were associated with binge episodes (Myin-Germeys et al., 2009). Furthermore, day-to-day self-esteem issues experienced by individuals with bulimia nervosa in social interactions were related to regular binge episodes (Myin-Germeys et al., 2009).

2.3.2.2.4.2. Subtypes of bulimia

Primary EMA studies on subtypes of bulimia nervosa were reported in the findings of included reviews. The included review by Myin-Germeys et al. (2009) found two primary EMA studies on subtypes of bulimia nervosa. Findings showed that people with interpersonal-emotional subtypes experienced increased daily binge and purging behaviours. Additionally, people with multi-impulsive bulimia had more impulsive and self-damaging behaviours. Furthermore, childhood maltreatment, such as sexual abuse, was associated with purging and self-destructive behaviours, and emotional abuse was associated with anger. Lastly, the meta-analysis findings by Haedt-Matt and Keel (2011b) found higher daily NA at pre-binge episodes than regular eating episodes for people with Binge Eating Disorders (BED) than people with bulimia nervosa; however, these levels were not significantly different ($p < .01$).

2.3.2.2.4.3. Anorexia nervosa

The review by Myin-Germeys et al. (2009) was the only included review that reported on primary EMA studies of anorexia nervosa. Findings indicated that physical activity was associated with daily changes in emotion and weight issues among people with anorexia nervosa. Additionally, this review also reported on primary EMA studies that found Body Mass Index (BMI) was associated with daily levels of urge for physical activity.

2.3.2.2.5. Other psychopathological disorders

Only one included review reported on primary observational studies using EMA for other psychopathological disorders (Myin-Germeys et al., 2009). These included panic disorder, attention deficit hyperactivity disorders (ADHD), and pervasive developmental disorder with findings explored below. These mental disorders are reported from section 2.3.2.2.5.1 to 2.3.2.2.5.3.

2.3.2.2.5.1. Panic disorders

Panic disorder was examined in one included review. The findings indicated no difference in time spent in public places between people with panic disorder, with or without agoraphobia (Myin-Germeys et al., 2009). However, people with panic and agoraphobia spent more time alone (Myin-Germeys et al., 2009). Other findings showed the anticipation of panic attacks did not predict daily anxiety levels, threat, or experiences of control, while day-to-day panic attacks were associated with elevated danger, helplessness, avoidance, and catastrophic thoughts (Myin-Germeys et al., 2009).

2.3.2.2.5.2. Attention Deficit Hyperactivity Disorder (ADHD)

A single study examined ADHD (Myin-Germeys et al., 2009). This study reported on findings of primary EMA studies targeting children with ADHD and mothers of children with ADHD. First, hyperactive-impulsive symptoms were not associated with overall daily affective states and concentration; however daily symptoms were associated with lower sensitivity to the context of perceptions of situations. Another finding suggested that children with ADHD experienced child behaviour problems and mothers of children with ADHD experienced more daily levels of NA and argumentative interactions when day-to-day living tasks were perceived as challenging. Furthermore, Myin-Germeys et al. (2009) reported mothers of children with ADHD might experience lower parenting esteem and more anger in the company of their children. Finally, the author reported that people with ADHD might experience reductions in nicotine-related ADHD symptoms during the day.

2.3.2.2.5.3. Pervasive developmental disorder

Only one primary EMA study was reported in the review by Myin-Germeys et al. (2009) on autism spectrum disorders. The primary EMA study reported in the review examined a sample of three people with autism. Myin-Germeys et al. (2009) focused on inner experiences. They reported that two people in the primary EMA study described inner experiences, whereas one person described no inner experiences. Furthermore, inner thoughts were reported as images with no features of inner experiences.

2.3.3. Included review findings for primary evaluation studies

A total of six included reviews reported on results of primary evaluation studies on interventions that integrate EMA delivered on mobile technologies, which is also known

as Ecological Momentary Interventions (EMI) (aan het Rot et al., 2012, Ehrenreich et al., 2011, Heron and Smyth, 2010, Telford et al., 2012, Wenze and Miller, 2010, Whittaker et al., 2012a). Section 2.3.3.1 provides a summary of the characteristics of the evaluation study, including the target population. Section 2.3.3.2 provides a summary of the included review findings of the evaluation studies. Appendix C presents a table of a summary of the included review findings of primary evaluation studies on interventions using EMA.

2.3.3.1. *Evaluation study design*

Two included reviews reported on primary studies that examined the effects of interventions using EMA for mood disorders; however, the included reviews did not report on the specific study design (aan het Rot et al., 2012, Telford et al., 2012). Four included reviews reported on the efficacy of interventions using EMA for people with anxiety disorders using RCT designs (Ehrenreich et al., 2011, Heron and Smyth, 2010, Telford et al., 2012, Wenze and Miller, 2010). Furthermore, three included reviews examined primary studies on the effects of interventions using EMA for people with smoking addiction in which majority were RCT studies or pre-post studies (Ehrenreich et al., 2011, Heron and Smyth, 2010, Whittaker et al., 2012a). Two included reviews reported an intervention using EMA that targeted alcohol consumption in which the primary study reported to have employed an RCT design (Heron and Smyth, 2010, Wenze and Miller, 2010). Finally, one included review reported on interventions using EMA for people with eating disorders in which the reported primary studies employed pre-post study design (Heron and Smyth, 2010).

2.3.3.2. *Included review findings of primary evaluation studies*

Section 2.3.3.2.1 to 2.3.3.2.5 presents the included review findings of the evaluation studies on interventions using EMA delivered on mobile technologies. Relevant themes presented below include review findings on mood disorders, anxiety disorders, smoking addiction, eating disorders, and alcohol problems.

2.3.3.2.1. Mood disorders

Included reviews reported on two primary evaluation studies that examined interventions using EMA for mood disorders. One included review reported on a single primary study that found a PDA-based intervention delivering real-time personalised

health promotional messages to change behaviours showed a decrease in depression scores among people with bipolar disorder (aan het Rot et al., 2012). Another included review reported on a primary evaluation study that found college students who were given an EMA self-monitoring tool with mindfulness-based CBT showed that those with MDD gained greater awareness of negative thinking patterns and disengagement from ruminative cycles of depression (Telford et al., 2012).

2.3.3.2.2. Anxiety disorders

Included review findings on anxiety disorders were mixed. All included reviews that reported on primary evaluation studies of interventions using EMA for panic disorders found palmtop-computer based CBT treatment with therapist-delivered psychotherapy produced similar, or some superior, statistically significant reductions in symptoms when compared with usual care for people with panic disorders (Ehrenreich et al., 2011, Heron and Smyth, 2010, Telford et al., 2012, Wenze and Miller, 2010). Two included reviews reported on a palmtop-computer based CBT program for social anxiety with group face-to-face CBT sessions which showed the palmtop-computer based intervention did not significantly reduce symptoms when compared with a waitlist control group (Ehrenreich et al., 2011, Heron and Smyth, 2010).

2.3.3.2.3. Smoking addiction

All but one included review provided a meta-analysis of smoking cessation interventions using EMA, while the other two included reviews provided a descriptive summary of findings. The review and meta-analysis study by Whittaker et al. (2012a) found a mix of text and video messaging mobile phone interventions. The meta-analysis found mobile phone interventions increased long-term quit rates compared with control conditions (RR = 1.71, 95% CI: 1.47 to 1.99, P = .001, over 9000 participants total). The included review findings reported by Ehrenreich et al. (2011) found mobile phone interventions with personalised text messaging alone or personalised messages via the internet or other communication channels, such as emails, showed significant improvements on abstinence rates than control groups (ranged from 74.2% to 92%). Furthermore, the included review found high retention rates for mobile phone interventions and generally high user satisfaction for the use of mobile phone interventions. Similar conclusions were drawn by Heron and Smyth (2010). Authors reported EMIs targeting smoking behaviours showed superior improvements in

abstinence rates and quitting rates than standard cessation programs. However, they noted that little evidence of the effects of EMIs on objective measures, such as salivary cortisol levels, were found.

2.3.3.2.4. Eating disorders

Heron and Smyth (2010) reported on findings of a primary evaluation study on eating disorders. The pre-post study design was employed to understand the effects of mobile text message interventions for people with bulimia nervosa. At post-test, it was reported that 'after care' text messaging intervention showed some improvements in self-reported binge eating and purging behaviours for two participants; however, these participants experienced 'dysfunctional' levels of body dissatisfaction.

2.3.3.2.5. Alcohol problems

One primary evaluation study was reported in the included review study by Heron and Smyth (2010) that evaluated the effects of a palmtop computer intervention that monitored and delivered brief messages for college students that aimed to reduce negative consequences of alcohol consumption. The results of the primary evaluation study showed students receiving a palmtop computer intervention for 2 weeks reported reductions in the consumption of alcoholic drinks than students that only received EMA-based self-monitoring without feedback.

2.4. Discussion

Sections 2.4.1 to 2.4.4 provide a discussion of this meta-review of primary EMA studies on multiple mental disorders. Section 2.4.1 summarises main findings of the meta-review, including the relevance to current EMA research. Section 2.4.2 provides a discussion of the quality of included reviews. Section 2.4.3 provides a discussion of the limitations of this meta-review. Finally, section 2.4.4 provides recommendations for future research on the EMA approach for mental disorders, including implications for research and clinical practice.

2.4.1. Main meta-review findings and relevance to current research

Sections 2.4.1.1 to 2.4.1.3 summarise the primary findings of the reviews included in this meta-review, covering primary observational studies using EMA, and primary evaluation studies of interventions using EMA.

2.4.1.1. *Findings of included reviews*

This meta-review identified 14 included reviews of the use of EMA for mood disorders, borderline personality disorder (BPD), psychosis, eating disorders, panic disorders, smoking addiction, alcohol problems, attention deficit hyperactive disorder (ADHD), and pervasive developmental disorder. Of the 14 included reviews, the included reviews reported on primary observational studies using EMA and primary evaluation studies on interventions using EMA. As there were no systematic reviews on anxiety disorders identified in this meta-review, it was clear that further systematic reviews were needed.

2.4.1.2. *Findings of primary observational studies using EMA*

Details of the EMA protocols of primary observational studies using EMA were reported in the included reviews. Random and fixed-based interval sampling strategies were found to be used in primary EMA studies on mood disorders and BPD. While event-based sampling strategies were found to be used in primary EMA studies on eating disorders, the prime use of event-based strategies in observational studies using EMA on eating disorders suggests an event-based sampling approach seems intuitive for collecting data relating to the daily occurrence of rare or salient events, such as eating episodes (Kimhy et al., 2012). While the majority of the evidence indicated the use of P&P as the main delivery method for EMA assessments, there was a paucity of evidence for mobile technologies, such as smartphones and wearable devices, as a delivery method for EMA assessments for mood disorders, BPD, psychosis, and the mental health of aging adults. This shift from P&P to mobile technologies as a collection tool for outcomes in clinical research is unsurprising given the recent recognition of mobile technology (such as smartphones) for mental health assessments and treatments (Areán and Cuijpers, 2017). Dale and Hagen (2007) reviewed evaluation studies of personal digital assistants (PDA) and P&P methods used to measure chronic health outcomes. In their literature review, they found personal digital computers performed better than P&P in most of the selected

outcomes and compliance or adherence to be better than P&P methods. However, technical problems were a clear disadvantage of personal digital computers. The battery power of the mobile device is a known technical challenge for mobile-based EMA systems including other barriers such as software bugs (Kimhy et al., 2012, Ramanathan et al., 2012). Further investigation of these feasibility issues may be examined to identify what technical factors of the mobile technology may influence participant adherence or compliance with mobile assessments and possible real-time treatments.

The meta-review findings of primary observational studies using EMA for mood disorders showed there was an association between daily changes in the levels of PA and NA with daily stress and positive and negative events for people with mood disorders. Furthermore, daily changes in PA and NA levels were seen in people with bipolar and young people or older adults with mood disorders. While PA and NA in depression has long been characterised in *the Diagnostic and Statistical Manual of Mental Disorders (DSM)*, the findings of this meta-review strengthen existing research and psychological theories that suggest changes of levels of PA and NA are closely associated with the emotional regulation of people with mood disorders (Clark and Watson, 1991, Cohen et al., 2017, Gross and Jazaieri, 2014, Hofmann et al., 2012). One of the rationales for using EMA to investigate people with mood disorders over other research methods is to overcome some of the problems with existing retrospective assessments. In particular, people with mood disorders may experience cognitive difficulties when attempting to remember past psychological states or events (Clark and Beck, 2010). Thus, EMA may complement other research methods by studying psychological states, behaviours or events in real-time which may be useful in assessment and treatments of mood disorders (Wilhelm and Grossman, 2010). Lastly, there was some evidence in the meta-review of poorer daily mQoL, such as activity enjoyment, physical complaints, and mood levels associated with side-effects of psychopharmacology treatment and treatment drop-out for people with mood disorders. However, some evidence presented in the meta-review showed positive daily changes in PA and NA during the course of treatment, and mQoL which stabilised after receiving treatment. While other research has examined the effects and side effects of antidepressant for people with mood disorders, the meta-review findings suggest day-to-day function may be good indicators in examining the effects and side effects of medication for people with mood disorders (Santarsieri and Schwartz, 2015).

The findings of the meta-review also showed daily experience of affective instability was associated with BPD symptoms and daily stress and stressful events in people with BPD. While daily experiences of affective instability were associated with stress, results showed daily interpersonal stress was associated with behavioural factors, such as dissociation. Existing cross-sectional studies on depression have retrospectively measured affective instability at single time points using a self-reported instrument (Thompson et al., 2011). Employing EMA using event-sampling strategies may be beneficial for uncovering *dynamic* facets of affective instability that may be contingent on time and daily events (Larsen et al., 1986). Additionally, researchers and clinicians may also consider using EMA to assess the affective instability of people with BPD in which EMA can address some of the limitations of other assessments such as questionnaire reports (Solhan et al., 2009). Future work on novel analytical approaches and machine learning techniques can focus on the dynamic interactions (or networks) of affective states activated by daily events over time (Torous et al., 2015, Mohr et al., 2017, Cramer et al., 2016). Such findings may support the understanding of underlying processes of BPD symptoms that may be influenced by daily contextual factors of an individual, such as stressful events.

Positive and negative symptoms in people with psychosis were found to be associated with day-to-day social interactions. In the meta-review, daily stressors and sensitivity of stress were associated with psychotic experiences and symptoms. The meta-review also found daily stressors were associated with particular biomarkers in people with psychosis. These meta-review findings may suggest EMA could be particularly important in future research on specific biomarkers of psychosis which may support new classifications of psychosis and other mental disorders (Insel et al., 2010). For example, EMA can be used to generalise further data collected from laboratory-based research on brain activity using fMRI scans (Collip et al., 2013, Habets et al., 2012), or to directly study temporal changes in biological processes of individuals using saliva sampling kits (Kirschbaum and Hellhammer, 1989). The data collected from EMA may offer greater insights of current psychobiological and psychophysiological research on psychosis and other mental disorders. Of note, cannabis usage was also found to be associated with the intensity of psychotic symptoms, and the effects of cannabis were associated with increases in positive symptoms for people with psychosis. These meta-review findings support other EMA research on substance use in other populations. For instance, a feasibility study by Serre et al. (2012) found computerised ambulatory monitoring of daily substance use (tobacco,

alcohol, opiates, cocaine, amphetamine, cannabis, or other substances), mood, and context was feasible in a sample of people with varied substance dependencies. Furthermore, data collected using EMA on cannabis use may provide important insights to the maintenance of cannabis use among individuals with psychosis, especially antecedent facets of actual daily use of cannabis such as cravings, anxiety, and affective levels (Buckner et al., 2012).

The meta-review findings on eating disorders were perhaps one of the more notable findings of this study. Meta-review showed daily levels of NA were found to be associated with eating disorder behaviours, such as binge eating, purging, and dietary restriction. Furthermore, the quantitative meta-analysis reported in this meta-review demonstrates the potential of the EMA method in a treatment context. For instance, a recent study by Mason et al. (2016) used daily diaries to examine binge eating behaviours for 14 days in college women. As predicted, daily NA levels and dietary restrictions monitored by EMA seemed to predict daily binge episodes. Furthermore, other social factors such as perceived social isolation were associated with binge episodes. Furthermore, approximately 70% completed seven or more of the diary entries, and 22% completed all 14 days of diary entries. The study by Mason et al. (2016) and the meta-review findings seem to suggest daily diaries delivering EMA assessments could be feasible in clinical practice and may be suitable in self-monitoring possible daily predictors to determine appropriate delivery of digital or non-digital interventions for eating disorders, or possible dropout to the treatment. Furthermore, other researchers have suggested the potential of EMA in clinical practice that could empower patients to evaluate their own diagnosis and treatments in daily life (van Os et al., 2013).

2.4.1.3. *Findings of primary evaluation studies of interventions using EMA*

Few of the included reviews reported on primary evaluation studies that examined interventions using EMA with varied study designs. RCT study design was employed to evaluate interventions using EMA for anxiety disorders, smoking addiction, and alcohol problems. The pre-post study design was employed in evaluation studies on interventions for eating disorders, and some evaluation studies on interventions for smoking addiction. It was unclear what study design was employed to evaluate the interventions for mood disorders reported in the included reviews.

Although the study design was unclear for primary studies on mood disorders, the evaluation studies on interventions using EMA for mood disorders found a decrease in depressive symptoms and improvements in therapeutic skills. The meta-review findings of primary evaluation studies of interventions using EMA for anxiety disorders were mixed. Some of the findings of the meta-review showed interventions were superior to control group; however, others did not show a significant reduction of symptoms relative to the control group. From these meta-review findings, there was no study that investigated the effects of EMA and therapist-, online-, or mobile-based treatments targeting anxiety and depression. More work is needed to examine the development and evaluations of interventions that integrate the EMA protocol for anxiety and depression. Other researchers have previously noted new study designs are needed for treatments using EMA, especially mobile technologies that can possibly enhance existing treatments delivered face-to-face with a therapist (Schueller et al., 2017).

Meta-review findings of interventions using EMA for smoking addiction and alcohol problems were reported in the included reviews. In particular a meta-analysis on mobile phone-based smoking cessation interventions reported in the included reviews showed increased long-term quit rates than control conditions (Whittaker et al., 2012a), and a palmtop computer intervention for alcohol consumption that delivered brief messages for college students showed a reduction in the consumption of alcoholic drinks when compared with an intervention using EMA without any feedback (Heron and Smyth, 2010). Other researchers have noted the use of data collection via mobile phone and SMS text messaging in addiction research (Lukasiewicz et al., 2007) and SMS mobile phone interventions have shown positive short-term effects on smoking cessation outcomes (Fjeldsoe et al., 2009). There were no interventions using EMA delivered on smartphones. Further research can examine these types of interventions.

2.4.2. Quality of included reviews

Many of the included reviews yielded low 'Assessment of Multiple Systematic Reviews' (AMSTAR) quality scores. In particular, many of the included reviews did not report duplicate study selection and data extraction, did not report the status of publication as part of the inclusion criteria, did not provide necessary lists of included and excluded studies, did not outline the characteristics of included studies, did not formulate

appropriate conclusions regarding the methodological rigour of the reviewed studies, did not provide necessary graphs and statistical test for publication biases, or did not detail conflict of interest. The systematic reviews selected in this meta-review suggests potential sources of bias in the included reviews which may have an impact on the interpretation of meta-review findings. Therefore, caution should be taken in interpreting these results. Future review research should improve the quality of reporting of systematic reviews of EMA (or EMI) studies to allow accurate reporting of findings of primary EMA studies.

2.4.3. Limitations of this meta-review

A number of limitations are presented in this meta-review. First, due to resource constraints, only one reviewer (BLG) was used to screen, assess, and extract data from the included reviews. Two reviewers are considered optimal in order to reduce the risk of bias. Second, the use of the EMA approach for primary studies of mental disorders was frequently unclear. Among the included review findings, the EMA approach was used in various research settings. Therefore, it was difficult to synthesise the findings of primary EMA studies reported in the included reviews. Third, there was limited information reported in the primary observational studies and evaluation studies. Many of the included reviews did not report on quantitative findings, such as effects sizes. Lastly, this meta-review was conducted in 2013 at the beginning of the PhD candidature to assess the state of the field, which may have limited the framing of the research question and the reported results. Since this meta-review was conducted, systematic reviews of EMA studies for mental disorders have been published, such as Bos et al. (2015), Firth et al. (2017), Myin-Germeys et al. (2016), Versluis et al. (2016), and Walz et al. (2014). At the time this meta-review was conducted, the results of this study may have included more systematic reviews and primary EMA studies on anxiety, depression or other psychiatric disorders.

2.4.4. Future research

A number of implications can be drawn from this meta-review., primarily to the future work including EMA in research and clinical practice. Section 2.4.4.1 provides a discussion of the implications for future research, and section 2.4.4.2 provides a discussion of the implications for researchers, clinicians, and consumers.

2.4.4.1. *Implications for research*

Given many of the included systematic reviews in this meta-review were low quality, prospective reviews needs to improve the quality and reporting of primary observational studies using EMA, and evaluation studies of health interventions using EMA. Improvements in the reporting of primary studies, as outlined in section 2.3.1.1, will allow accurate reporting of associations between daily symptoms and other factors, or causational effects of an intervention using EMA to treat symptoms or improve adherence. Given there were few systematic reviews that reported on quantitative findings, more rigorous systematic reviews with meta-analyses are needed to interpret study effect sizes.

As there were a limited number of systematic reviews on anxiety disorders reported in the meta-review, more systematic reviews are needed for anxiety disorders. Since conducting this meta-review, a recent systematic review study by Walz et al. (2014) reported on the latest findings of observational studies using EMA on anxiety problems. The systematic review found variability of daily symptoms were associated with daily effect, behaviour, and situations in people with panic disorder, generalised anxiety disorder, social anxiety disorder, post-traumatic stress disorder, or obsessive-compulsive disorder. However, further systematic reviews on anxiety disorders may be needed to investigate the combination of EMA with the evaluation of interventions for mental disorders.

Overall, little is known in the research of the EMA approach in mental health treatments. More research on the EMA *protocol* is needed in order to understand how to integrate the EMA approach into existing mental health treatments. One recent systematic review by Bos et al. (2015) reported on observational studies using EMA to investigate the daily effects of psychopharmacology treatments. The review found the effects of medication on people with MDD, substance use, ADHD, psychosis, and anxiety (Bos et al., 2015). While the following systematic review by Bos et al. (2015) was focused on psychopharmacology treatment, little is known about the EMA approach in Internet-based interventions.

With the rapid advancement of mobile technology development, such as smartphones and wearable devices, future research is needed in primary evaluation studies of health interventions (EMIs) incorporating the EMA approach delivered on mobile technologies.

Particularly, further research is needed on the evaluation of the individual components of EMIs which includes EMA self-monitoring, mobile treatment notifications, tailored or random treatment message reminders, brief exercises, or intervention content. EMIs are distinct to research studies using EMA which focuses on the self-reporting personal thoughts, behaviours and environments in daily life in order to increase ecological generalisability of retrospective assessments. Systematic reviews on EMIs are needed to examine the clinical effects of EMIs on various mental disorders. Since conducting this meta-review, a number of recent literature reviews on EMIs have been published for depression and anxiety, and severe mental illnesses (Myin-Germeys et al., 2016, Versluis et al., 2016). Furthermore, a meta-analysis by Firth et al. (2017) found smartphone interventions reduced symptoms of anxiety relative to control conditions (g = 0.325, 95% CI: 0.17 to 0.48, p < .01); however, the meta-analysis by Firth et al. (2017) specifically focused on the effectiveness of downloadable smartphone mobile apps. While these literature reviews are relevant for understanding EMI for mental disorders, little research has been conducted on systematic reviews that are *specific* to EMIs for anxiety disorders and stress. Chapter 3 of this thesis provides a systematic review of the effectiveness of mobile technologies delivering EMIs specifically for anxiety and stress.

2.4.4.2. *Implications for practice*

Overall, the implications from this study suggest that researchers should consider using EMA to investigate daily symptoms of various or multiple mental disorders to inform clinical practice and advance knowledge of the development, course and treatment of mental disorders. Taking an EMA approach in investigating the associations of daily affective states across multiple mental disorders may be relevant for trans-diagnostic processes of psychological assessments and treatment (Clark and Taylor, 2009). EMA may provide a greater understanding of common processes of daily life (such as day-to-day emotions and thoughts) that may underlie a range of mental health problems. Additionally, the findings of this meta-review outline some of the potential technological applications of EMA into existing mental health care models. Indeed, the clinical application of EMA in the day-to-day lives of individuals with mental health problems may potentially detect early signs of daily symptoms and risk patterns before serious episodes of suicidal behaviour or psychosis. However, more research is needed in the application

of EMA into existing clinical practice, which outlines clear and safe protocol guidelines for clinicians and people with lived experience of mental illness.

2.5. Conclusion

The present meta-review reported on the systematic review findings of primary observational studies using EMA and primary evaluation studies of health interventions using EMA delivered via mobile technologies. Systematic reviews were found for mood disorders, borderline personality disorders, psychosis, eating disorders, specific psychological related addictions, and other psychopathological disorders. While the EMA approach was used for many mental disorders, included reviews reported a range of sampling strategies, data collection periods, and delivery modes for various mental illnesses. Primary observational studies found variability of daily levels of PA and NA were associated with psychological, behavioural, and environmental factors, such as daily levels of stress, activity levels, substance use, and social situations. Primary evaluation studies of interventions using EMA were mixed. Overall, the current meta-review highlights the need for more rigorous research including additional systematic reviews of studies on anxiety disorders and primary studies evaluating health interventions using EMA, also as known as EMIs.

3. CHAPTER 3
Effectiveness of Mobile Technologies Delivering Ecological Momentary Interventions for Stress and Anxiety: A Systematic Review and Meta-Analysis

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3.1. Introduction and Background

This chapter provides a systematic review of the effectiveness of mobile technologies for anxiety and stress. It follows from the previous chapter that provided a meta-review of systematic reviews of primary studies using EMA for multiple mental disorders (see chapter 2). The meta-review in chapter 3 highlighted a need for more high-quality systematic reviews on EMIs for anxiety and stress as there was a lack of systematic reviews on the topic. The aim of this systematic review is to understand what previous evaluation studies have been conducted on the effectiveness of EMIs to reduce anxiety and stress, and to understand the gaps in the existing literature. Section 3.1.1 provides background on anxiety disorders and stress, section 3.1.2 provides a description of Ecological Momentary Interventions (EMI), section 3.1.3 provides a background of mobile technologies for EMIs, section 3.1.4 provides a brief summary of existing research on EMIs for anxiety disorder and stress, section 3.1.5 provides the aims of the systematic review and meta-analysis.

3.1.1. Anxiety disorders and stress

Anxiety disorders are one of the most common mental disorders among adults (Alonso et al., 2004, Kessler et al., 2005a, Kessler et al., 2005b) with a 12-month prevalence of 14% among Australians aged 16-85 (Australian Bureau of Statistics, 2008), and an estimated annual and lifetime prevalence of 18 to 29% in the United States (Kessler et al., 2005b, Kessler et al., 2005a) and 13 to 14% in Europe (Alonso et al., 2004).

Although effective psychological treatments for anxiety disorders can be delivered face-to-face in a clinical setting (Høifødt et al., 2011), or online through a desktop computer (Reger and Gahm, 2009), changes in anxiety symptoms often arise in specific moment-to-moment real-life situations that only emerge outside the therapist's office within a real-world natural setting (Wilhelm and Grossman, 2010). Thus, the optimal treatment of

anxiety symptoms may require innovative approaches in which a person's anxiety symptoms are directly targeted in real-time.

3.1.2. Ecological Momentary Interventions [2]

A possible solution to treating anxiety symptoms in real-time is the employment of Ecological Momentary Interventions (EMI). EMIs are "momentary health treatments provided via hand-held mobile technologies that deliver psychological interventions while people are engaged in their typical routines in their everyday life" (Heron and Smyth, 2010). 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 (Shiffman et al., 2008, Heron and Smyth, 2010). When delivered as an adjunct, EMIs have the potential to reduce the amount of clinician contact required to treat anxiety conditions or to improve the effectiveness of clinician-delivered therapy. There is also the potential for EMIs to improve outcomes when used as a stand-alone intervention, although a priori it might be anticipated that EMIs would be most effective when delivered as an adjunct to clinical care (Newman et al., 2011). Newman et al. (2011) provide a four category framework of the level of human contact required for technology assisted therapies, such as EMIs. These descriptors are: 1) *self-administered therapy* (minimal contact with a human, such as therapist or mental health support worker), 2) *predominately self-help* (some human contact involving occasional check-ins, approx. no more than 1.5 hours of human contact), 3) *minimal-contact therapy* (some human contact that provides formal therapeutic guidance, approx. no more than 1.5 hours of human contact), and 4) *predominately therapist-administered treatments* (regular human contact with a therapist or support worker).

Also relevant to the categorisation of EMIs is the framework of interventions proposed by Mrazek and Haggerty (1994). Across a spectrum of mental health interventions, three types of interventions are used to prevent mental disorders in the community. These types include: 1) *universal* (interventions targeted to the general public), 2) *selective* (interventions targeted to individuals or a subgroup of the population whom are at risk of developing mental disorders), and 3) *indicated* (interventions targeted to high-risk

[2] "Ecological Momentary Interventions (EMI)" is defined here and repeated in other chapters of this thesis (Chapter 4, Chapter 5, and Chapter 6).

populations who are identified as having detectable signs of mental health symptoms). In a prevention context, differing types of EMIs (with multiple levels of complexities) can be classified across the three different types of mental health interventions. Mrazek and Haggerty (1994) distinguish prevention interventions from interventions that seek to treat existing health problems, such as mental disorders, and from interventions that aim to maintain or promote recovery and prevent relapse.

Carter et al. (2007a) described the differing complexities of EMIs through a multilevel classification framework. Firstly, EMIs can be a "simple low-level" informative intervention, providing either health information on a specific health issue or consumer support material at momentary periods. Secondly, EMIs can be "interactive" interventions allowing individuals to record their psychological, behavioural and contextual states at momentary periods, and to display this information on request. Thirdly, EMIs can incorporate a high-level "integrative" feature that computationally detects and interprets patterns of an individual's momentary input, and uses the resulting information to tailor the intervention to the individual. The three types of EMIs can be deployed on hand-held devices such as mobile phones, Portable Device Assistants (PDA), palmtop computers, ambulatory biofeedback devices, and portable digital media players.

Historically, pocket-sized ambulatory biofeedback and hand-held computers have been used in studies delivering EMIs for anxiety. Regular ambulatory biofeedback devices have shown promise in the context of panic disorders, especially in directing an individual's attention to physiological changes through continuous self-monitoring (Alpers, 2009). Additionally, hand-held computers such as PDAs and palmtop computers have enabled programmable capabilities for the ability to track symptoms, and to deliver relaxation training and Cognitive Behavioural Therapy (CBT) material for generalised anxiety (Newman, 1999, Dumont and Olson, 2012). However, since the early 2000s, some technologies such as PDAs and palmtop computers have become obsolete with the introduction of modern mobile phones (Liu et al., 2011).

3.1.3. Mobile technologies

Mobile phone technologies include regular mobile phones and smartphones (a specific mobile phone that contains many of the functions of a hand-held computer such as a touch interface, internet access, and an operating system). In the past decade, the

technical capabilities of mobile phones have advanced with the emergence of smartphones (Fiordelli et al., 2013). These portable devices incorporate a specific Operating System (OS) platform that enables more computing power and extra network connectively to various electronic devices and the internet (Liu et al., 2011, Fiordelli et al., 2013). Furthermore, smartphone technologies can wirelessly connect to wearable sensors to detect changes in physiological factors (such as heart rate) and to provide real-time feedback of sensor information or tailored therapeutic content (Morris and Guilak, 2009). Given these advances, such technologies have significant potential to improve health outcomes including mental health and are of particular utility for stress and anxiety disorders given the strong physiological component of these conditions.

A recent paper by Klasnja and Pratt (2012) provided a framework specifically for mapping features of modern mobile phones onto different health interventions strategies. They identified five mobile phone features including text messaging, cameras, automated sensing, Internet access, and native applications (such as programming libraries for Global Positioning System (GPS), accelerometer, graphics and audio, notification, contact list, and calendar functions.) They mapped these onto five health intervention strategies, which included tracking health information, involving the healthcare team, leveraging social influence, increasing access to health information, and using entertainment. Some mobile phone features were employed in each health strategy (e.g., text messaging); others were restricted to fewer strategies (e.g., cameras for tracking health information and involving the health care team). Although they provided a review of studies on mobile health interventions for various health conditions, Klasnja and Pratt (2012) did not specifically report on the effects of interventions for mental health problems.

3.1.4. Existing research

There have been a small number of reviews of studies on the effectiveness of EMIs for mental health problems (Donker et al., 2013, Ehrenreich et al., 2011, Heron and Smyth, 2010). However, to the author's knowledge, there have been no comprehensive systematic reviews of the effectiveness of EMIs for anxiety conditions. One previous narrative review assessed EMI for anxiety disorders (Alpers, 2009) but it focused on panic disorders and phobia, and it did not employ systematic identification and synthesis techniques. Accordingly, this study reports on a systematic review of the effectiveness of EMIs for

stress, anxiety symptoms and anxiety disorders. Further, this study examines the specific technical features of mobile technologies that deliver different EMIs for these conditions.

3.1.5. Objectives

The aims of the systematic review are to examine effectiveness of different types of EMIs. Moreover, the current review specifically examines randomised controlled studies that investigates anxiety or anxiety related outcomes for EMIs as a stand-alone intervention or EMIs as an adjunct to existing psychological therapies delivered by a therapist. In this review, the following research questions are addressed:

- *What are the study characteristics and quality of randomized controlled studies (including the outcome measurements) that examine EMIs for anxiety and stress?*
- *What are the intervention characteristics, types of technologies, and delivery methods or modes of EMIs for anxiety and stress?*
- *What is the effectiveness of EMIs on anxiety or anxiety-related outcomes, such as stress?*

3.2. Method

This systematic review conforms to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement (Moher et al., 2009). Section 3.2.1 to 3.2.6 provides a description of the methodology used in this systematic review. Section 3.2.1 describes the search strategy, section 3.2.2 describes the inclusion criteria, section 3.2.3 describes the exclusion criteria, section 3.2.4 describes the selection of studies, section 3.2.5 describes the data extraction, and section 3.2.6 describes the data analysis of the current systematic review.

3.2.1. Search strategy

The Cochrane Library, PUBMED, OvidSP (including MEDLINE and PsycInfo), and Science Direct databases were searched in January 2014 using search terms for a combination of the following three main concepts: *"ecological momentary intervention", "anxiety", and "mobile technologies"* (a list of specific search terms are available in Appendix D). MeSH and Subject Heading keywords from relevant databases were included. The search was restricted through limit functions on the databases to 'clinical trials', and 'randomised controlled trials'. No restriction was applied on publication date.

Additional studies were identified by manually searching the reference lists of relevant studies that were not identified by the database search.

3.2.2. Inclusion criteria

Studies were included if they 1) evaluated the effectiveness of an Ecological Momentary Intervention (as defined above); 2) examined anxiety symptoms or anxiety disorder or anxiety related outcomes such as stress or tension; 3) were published in English language in a peer-reviewed journal; 4) employed a randomised controlled trial (RCT) or randomised trial methodology and included at least one control group or second experimental/comparison; 5) examined an EMI with or without human support.

3.2.3. Exclusion criteria

Studies were excluded that 1) *only* measured the adherence to or usability of an intervention; 2) did not measure an anxiety or anxiety related outcome; 3) examined chemical and biological stress, such as oxidative stress and starvation-stress responses but not anxiety-related psychological symptoms; 4) examined interventions that were not undertaken within real-time and/or a real world setting (this included studies using biofeedback treatment confined to be laboratory as such interventions are likely to have low ecological validity); 5) used Ecological Momentary Assessment (EMA) with the sole aim of monitoring a particular psychological phenomenon over time; or 6) did not employ a mobile or hand-held electronic computer as part of the intervention or treatment.

3.2.4. Selection of studies

As shown in Figure 3, a total of 3145 records were retrieved from the database search and 35 references of two review papers on EMI for mental health which was identified in the chapter consisting the meta-review study (Ehrenreich et al., 2011, Heron and Smyth, 2010). A total of 1231 records were duplicate abstracts leaving 1949 unique records. Of these records, three raters [Brendan Loo Gee (BLG) and two PhD students, Rebecca Randall (RR), Kathina Ali (KA)] judged relevant records based on the titles and/or abstracts. From these, the full-text of 51 records were screened which yielded a total of 15 relevant papers.

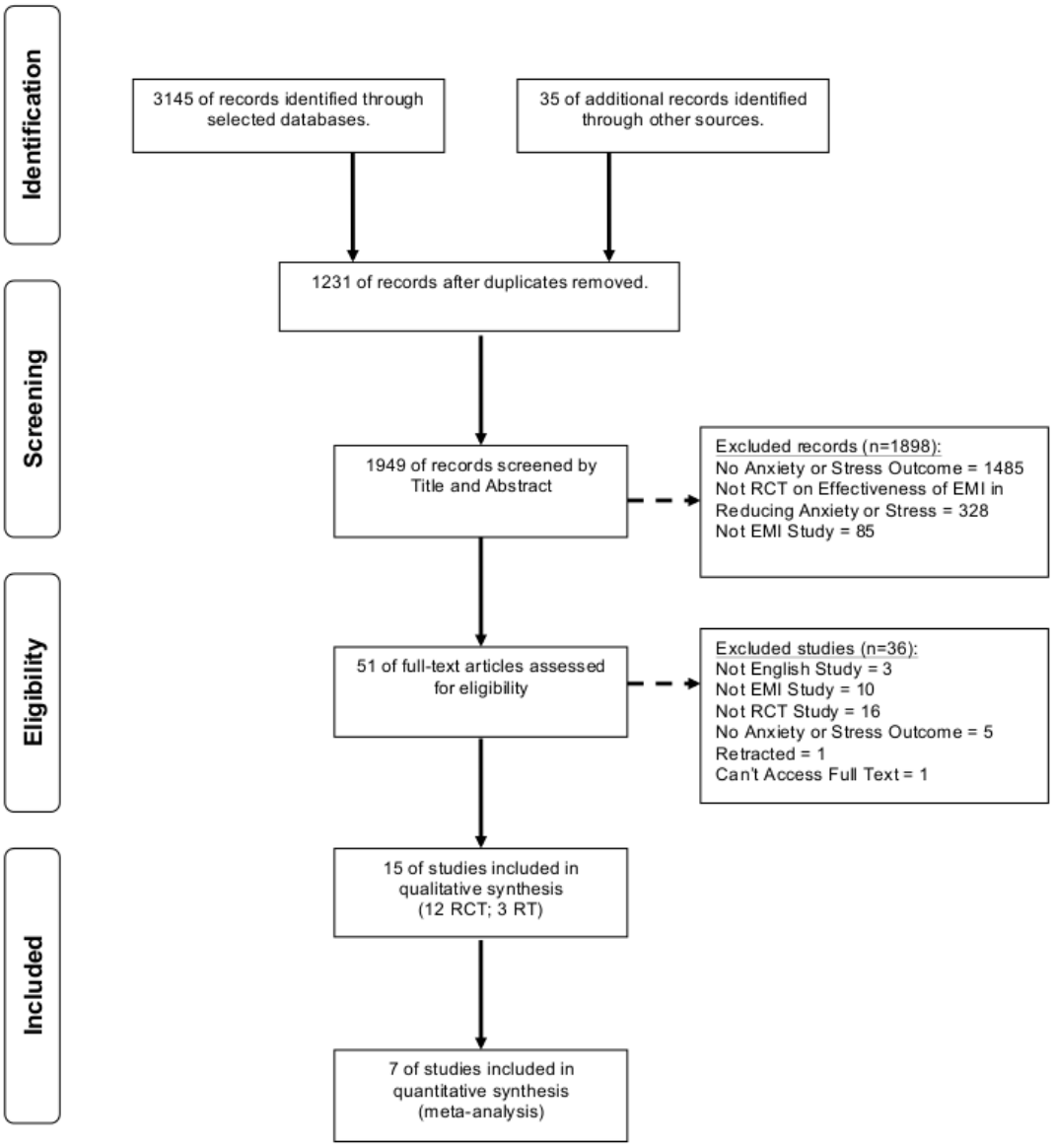

Figure 3. Flowchart of Systematic Review

3.2.5. Data extraction

Each of the 15 relevant papers was individually coded using a pre-formulated rating sheet by three raters. The following information was extracted: participant characteristics and recruitment method, demographics, description of study design, intervention details (including the intervention type as defined by Mrazek and Haggerty's (1994) framework, EMI type as defined by Carter et al. (2007a), the features of the mobile phone intervention as defined by Klasnja and Pratt's framework (Klasnja and Pratt, 2012), and level of human

contact coded based on categories defined by Newman et al. (2011), data analysis details, and qualitative information of treatment effects. EMIs were considered to be on-site or combined if the participant was required to travel to a physical location to receive face-to-face human support. Self-administered EMIs that required minimal travel for face-to-face human support was considered to be distal. Study quality was assessed using Cochrane Effective Practice and Organisation of Care Group criteria [EPOC, (Cochrane Effective Practice and Organisation of Care Group, 2012)] for each study, and the totals and percentage of studies that were of high risk or unclear were calculated across studies.

3.2.6. Data analysis

Study characteristics were summarised using descriptive statistics. The effect size was calculated based on the available Intention-to-treat (ITT) and/or completer analyses results. Cohen's *d* effect sizes were calculated to determine the between-group effects at post-test to provide an estimate of the intervention's effect. Where data was available, the intervention effect size was calculated based on the post-test mean and standard deviations from the study.

Given the heterogeneity of the included studies, an overall quantitative meta-analysis was not conducted. However, sufficient data were available to conduct a meta-analysis on the sub-group of studies examining generalised anxiety as an outcome measure. This meta-analysis was undertaken using the random effects model of the Comprehensive Meta-Analysis Software program (CMA; Version 2.2.064) (Borenstein et al., 2005). The between-group effect size (standardized mean difference) was calculated at post-test except for one study where the effect size was based on *F* for difference in change (Mosso et al., 2009) and a second study where the odds ratio was computed from reported improvement at post-test (Riva et al., 2007). Effect sizes were combined across conditions and measures within a study such that only one data point was incorporated into the meta-analysis for each study. The I^2 statistic was employed as a measure of heterogeneity between studies (Higgins and Green, 2011). Publication bias was investigated using visual inspection of funnel plots and the Tweedie trim and fill procedure (Duval and Tweedie, 2000).

3.3. Results

3.3.1. Study characteristics

The characteristics of each study are summarised in Appendix E. The 15 studies examined anxiety (*n* = 4) (Grassi et al., 2009, Riva et al., 2007, Riva et al., 2006, Mosso et al., 2009), generalised anxiety disorder (*n* = 3) (Newman et al., 2013, Pallavicini et al., 2009, Gorini et al., 2010), stress (*n* = 3) (Lemaire et al., 2011, Villani et al., 2013, Lappalainen et al., 2013), anxiety and stress (*n* = 2) (Proudfoot et al., 2013, Reid et al., 2011), panic disorder (*n* = 2) (Kenardy et al., 2003, Newman et al., 1997), and social phobia (*n* = 1) (Gruber et al., 2001). Three studies specifically targeted work-related stress (Lemaire et al., 2011, Villani et al., 2013, Lappalainen et al., 2013).

Studies were conducted in a number of countries including Italy (*n* = 6) (Villani et al., 2013, Riva et al., 2007, Riva et al., 2006, Pallavicini et al., 2009, Grassi et al., 2009, Gorini et al., 2010), United States (*n* = 2) (Gruber et al., 2001, Newman et al., 2013), Australia (*n* = 2) (Proudfoot et al., 2013, Reid et al., 2011), Australia and United States (*n* = 1) (Newman et al., 1997), Australia and Scotland (*n* = 1) (Kenardy et al., 2003), Canada (*n* = 1) (Lemaire et al., 2011), Finland (*n* = 1) (Lappalainen et al., 2013), and Mexico (*n* = 1) (Mosso et al., 2009).

The mean age of participants across studies ranged from 17 to 55 years. Seven studies examined adults (aged 18 and over) (Pallavicini et al., 2009, Proudfoot et al., 2013, Newman et al., 2013, Newman et al., 1997, Lappalainen et al., 2013, Kenardy et al., 2003, Gorini et al., 2010), and one study focused on the adolescent to young adult group (aged 14 to 24 years) (Reid et al., 2011). The remaining seven studies provided the average age of the sample but did not specify the age group targeted (Villani et al., 2013, Riva et al., 2006, Grassi et al., 2009, Mosso et al., 2009, Riva et al., 2007, Lemaire et al., 2011, Gruber et al., 2001). No studies targeted older people. Females represented the majority of participants in 12 (80%) of the studies; only three study samples were composed of more males than female participants (Lappalainen et al., 2013, Lemaire et al., 2011, Gruber et al., 2001).

The majority of studies recruited participants through patients at a health care facility (Reid et al., 2011, Pallavicini et al., 2009, Mosso et al., 2009, Kenardy et al., 2003, Gorini et al., 2010). Three studies recruited participants from the general community using newspaper advertisement and online media (Proudfoot et al., 2013, Lappalainen et al., 2013, Gruber et al., 2001). Two studies recruited staff of a health care facility (Villani et al., 2013,

Lemaire et al., 2011). A further two studies recruited participants from the general community at a public transport station (Riva et al., 2006, Grassi et al., 2009), and one study recruited participants from the general community and a mental health care facility (Newman et al., 2013). Only one study exclusively recruited participants from a university setting (Newman et al., 1997). Finally, one study did not report on where participants were recruited (Riva et al., 2007).

3.3.2. Study quality

The sample size of the studies ranged broadly from 13 to 720 (median 33.5). All included studies employed either an RCT or randomised trial design. Studies compared EMI groups with a wait-list control group (Gorini et al., 2010, Gruber et al., 2001, Kenardy et al., 2003, Lappalainen et al., 2013, Pallavicini et al., 2009), a group that deployed no intervention (Riva et al., 2006, Grassi et al., 2009, Mosso et al., 2009), an attention control group (Lemaire et al., 2011, Reid et al., 2011, Villani et al., 2013), no control group (Newman et al., 1997, Newman et al., 2013), both an attention and waitlist control groups (Proudfoot et al., 2013), or an unspecified control group (Riva et al., 2007). Nine studies compared EMIs with another intervention (Gorini et al., 2010, Grassi et al., 2009, Gruber et al., 2001, Kenardy et al., 2003, Newman et al., 1997, Newman et al., 2013, Pallavicini et al., 2009, Riva et al., 2007, Riva et al., 2006).

Table 3 presents the risk of bias assessment for each individual study. Most of the studies were unclear of high risk in study sequence generation, allocation concealment, the appropriate handling of incomplete data, and blinding.

Table 3. Risk of bias assessed by Cochrane Quality Rating Criteria [a]

Studies	Sequence generation	Allocation concealment	Baseline outcomes	Baseline factors	Incomplete data	Blinding	Contamination protection	Selection biases	Other biases
Newman et al. (1997)	?	?	✓	✓	✓	?	✓	✓	✓
Gruber et al. (2001)	?	?	✓	X	✓	X	✓	✓	✓
Kenardy et al. (2003)	?	?	✓	?	✓	?	✓	✓	✓
Riva et al. (2006)	?	?	?	?	X	?	✓	-	?
Riva et al. (2007)	?	?	?	?	X	?	✓	✓	?
Grassi et al. (2009)	?	?	✓	✓	X	?	✓	✓	?
Mosso et al. (2009)	?	?	✓	✓	X	X	✓	✓	✓
Pallavicini et al. (2009)	✓	✓	✓	✓	X	?	✓	✓	✓
Gorini et al. (2010)	?	?	?	?	X	?	✓	✓	?
Lemaire et al. (2011)	✓	✓	✓	X	X	X	✓	✓	✓
Reid et al. (2011)	✓	✓	✓	✓	✓	X	✓	✓	✓

Newman et al. (2013)	?	?	✓	X	✓	X	✓	✓	✓
Villani et al. (2013)	?	?	✓	?	X	?	✓	✓	?
Proudfoot et al. (2013)	✓	✓	✓	X	✓	?	✓	✓	✓
Lappalainen et al. (2013)	?	?	✓	X	✓	?	✓	✓	✓
Unclear and high-risk studies, n (%)	**11 (73.3%)**	**11 (73.3%)**	**3 (20%)**	**10 (66.6%)**	**8 (53.3%)**	**15 (100%)**	**0 (0%)**	**1 (6.66%)**	**5 (33.3%)**

[a] ✓ = low risk; ?= unclear information; X = high risk

3.3.3. Intervention characteristics

Six studies evaluated *treatment* interventions (Gorini et al., 2010, Gruber et al., 2001, Kenardy et al., 2003, Newman et al., 1997, Newman et al., 2013, Pallavicini et al., 2009), and a further five studies involved *universal* interventions delivered regardless of risk status and symptom levels (Grassi et al., 2009, Lemaire et al., 2011, Mosso et al., 2009, Riva et al., 2007, Riva et al., 2006). Four studies examined *indicated* interventions in those with high levels of symptoms (Lappalainen et al., 2013, Proudfoot et al., 2013, Reid et al., 2011, Villani et al., 2013). No studies evaluated *selective* interventions in those determined to be at risk for a disorder. There were a total of 18 EMIs evaluated in the 15 studies; eight of these were *integrative* EMIs (Gorini et al., 2010, Gruber et al., 2001, Kenardy et al., 2003, Lappalainen et al., 2013, Newman et al., 1997, Newman et al., 2013, Pallavicini et al., 2009, Proudfoot et al., 2013), seven were *simple* EMIs (Grassi et al., 2009, Mosso et al., 2009, Riva et al., 2007, Riva et al., 2006, Villani et al., 2013, Gorini et al., 2010, Pallavicini et al., 2009), and three were *interactive* EMIs (Lemaire et al., 2011, Newman et al., 1997, Reid et al., 2011).

3.3.3.1. *Generalised anxiety*

Of the seven studies examining EMIs targeting generalised anxiety symptoms (Grassi et al., 2009, Mosso et al., 2009, Riva et al., 2007, Riva et al., 2006, Gorini et al., 2010, Newman et al., 2013, Pallavicini et al., 2009), four studies evaluated universal interventions (Grassi et al., 2009, Mosso et al., 2009, Riva et al., 2007, Riva et al., 2006), and three studies examined treatment interventions (Gorini et al., 2010, Pallavicini et al., 2009, Newman et al., 2013). Six of the seven studies investigated simple EMIs, which employed relaxation training that adopted narrative and distraction techniques (Grassi et al., 2009, Mosso et al., 2009, Riva et al., 2007, Riva et al., 2006, Gorini et al., 2010, Pallavicini et al., 2009). The remaining study examined an integrative EMI using CBT and self-monitoring for treating Generalised Anxiety Disorder (GAD) (Newman et al., 2013). There were no indicated interventions for generalised anxiety. None assessed an interactive EMI.

3.3.3.2. *Stress*

Three studies evaluated interventions aimed at managing stress (Lappalainen et al., 2013, Lemaire et al., 2011, Villani et al., 2013); two of these examined indicated interventions (Villani et al., 2013, Lappalainen et al., 2013), and one evaluated a universal intervention (Lappalainen et al., 2013). Of these studies, one comprised a simple EMI employing relaxation training (Villani et al., 2013), one investigated an interactive EMI using heart-rate self-monitoring plus relaxation training sessions (Lemaire et al., 2011). Finally, one

study examined an integrative EMI that included CBT, Acceptance and Commitment Therapy (ACT), relaxation, and self-monitoring (Lappalainen et al., 2013). No studies examined treatment interventions for stress alone.

3.3.3.3. *Anxiety and stress*

Two separate studies examined indicated interventions aimed at reducing anxiety and stress (Proudfoot et al., 2013, Reid et al., 2011). Of these studies, one study examined an interactive EMI that included self-monitoring (Reid et al., 2011), and one study examined an integrative EMI that included CBT and self-monitoring (Proudfoot et al., 2013). No studies evaluated a universal intervention. None assessed a simple EMI.

3.3.3.4. *Panic disorder*

Two studies examined treatment interventions for panic disorder (Kenardy et al., 2003, Newman et al., 1997). Both of these examined integrative and interactive EMIs which included computerised CBT and individualised face-to-face CBT, in conjunction with self-monitoring of panic symptoms (Kenardy et al., 2003, Newman et al., 1997). One study examined the above treatment components with the addition of relaxation training (Newman et al., 1997). No studies evaluated a universal or an indicated intervention nor used a simple EMI.

3.3.3.5. *Social phobia*

Only one study examined a treatment intervention for social phobia, and it comprised an integrative EMI (Gruber et al., 2001). The intervention consisted of computerised CBT and group face-to-face CBT, in conjunction with symptom self-monitoring.

3.3.4. Types of EMI technologies

The 15 studies examined EMIs that deployed regular mobile phones (Grassi et al., 2009, Proudfoot et al., 2013, Reid et al., 2011, Riva et al., 2007, Riva et al., 2006, Villani et al., 2013), smartphones with or without sensors (Gorini et al., 2010, Lappalainen et al., 2013, Mosso et al., 2009, Pallavicini et al., 2009), hand-held computers (Gruber et al., 2001, Kenardy et al., 2003, Newman et al., 1997, Newman et al., 2013), and regular ambulatory biofeedback (Lemaire et al., 2011). The table presented in Appendix F shows the details of the technical

features of mobile technologies (including non-mobile phones) and related health intervention strategies as described by Klasnja and Pratt (2012). Native software features of the palmtop computer for diagnosed panic disorders and social phobia were used in a customised application that tracked health information via a diary module, and to assist in the clinician's care through guided CBT modules via palmtop software (Gruber et al., 2001, Kenardy et al., 2003, Newman et al., 1997, Newman et al., 2013). One study examined regular ambulatory biofeedback (Lemaire et al., 2011). This study monitored the heart rhythm pattern of individuals with stress while using this information to assist researchers in monitoring and documenting the participant's adherence to the intervention.

Seven studies examined EMIs using mobile phones, smartphones, and other portable devices that utilised graphics, audio, and video features of the device to deliver relaxation training (Grassi et al., 2009, Riva et al., 2007, Riva et al., 2006, Villani et al., 2013, Pallavicini et al., 2009, Mosso et al., 2009, Gorini et al., 2010). All of those studies examined interventional information targeting generalised anxiety or stress through an engaging virtual world simulation delivered on various mobile devices. Of these, one study used a smartphone and a portable virtual reality device to deliver relaxation content (Mosso et al., 2009). A further, two studies involved the delivery of similar relaxation content on touchscreen smartphones, gaming hardware, and wearable sensors (Gorini et al., 2010, Pallavicini et al., 2009). These interventions tracked psychophysiological symptoms via wearable sensors and smartphones to provide the therapist with the ability to monitor symptoms during the delivery of the entertaining relaxation content. Lastly, two studies examined portable digital media players that delivered relaxation training content via MP3 audio with no video capabilities (Riva et al., 2007, Grassi et al., 2009).

Three studies examined EMIs that tracked symptoms and delivered personalised therapeutic content via a mobile device (Reid et al., 2011, Proudfoot et al., 2013, Lappalainen et al., 2013). One study that examined an intervention targeting stress used native features of smartphones, internet access, and wearable sensors to track symptoms, and to deliver fitness and relaxation training content (Lappalainen et al., 2013). Lastly, two studies that examined EMIs for anxiety and stress utilised text messaging, native application features, and internet access (Proudfoot et al., 2013, Reid et al., 2011). Both interventions used text messaging for self-monitor psychological symptoms, and for sending motivational reminders to encourage adherence to the intervention. However, one of the latter interventions used native application features of a mobile phone and a website to further

facilitate doctor-client communication (Reid et al., 2011), whereas the other intervention used these features to deliver guided online CBT information (Proudfoot et al., 2013). No studies examined interventions using cameras on mobile phones.

3.3.5. Intervention delivery

Seven studies delivered interventions both on-site and distally (Gorini et al., 2010, Lappalainen et al., 2013, Lemaire et al., 2011, Newman et al., 2013, Pallavicini et al., 2009, Reid et al., 2011, Mosso et al., 2009), five were distal (Grassi et al., 2009, Proudfoot et al., 2013, Riva et al., 2007, Riva et al., 2006, Villani et al., 2013), and three involved on-site and combined on-site and distal delivery (Gruber et al., 2001, Kenardy et al., 2003, Newman et al., 2013).

3.3.6. Automation and human support

Six of the 18 EMIs were self-administered (SA) and fully automated using a standalone electronic intervention with low levels of human support (Grassi et al., 2009, Mosso et al., 2009, Proudfoot et al., 2013, Riva et al., 2007, Riva et al., 2006, Villani et al., 2013). Another four EMIs involved predominately self-help (PSH) interventions with no more than 1.5 hours of human support (Gorini et al., 2010, Lemaire et al., 2011, Pallavicini et al., 2009, Reid et al., 2011) while four EMIs were predominately therapist administered (TA), and required regular or high levels of human support (Gruber et al., 2001, Kenardy et al., 2003, Newman et al., 1997, Newman et al., 2013). The remaining EMIs were minimal-contact (MC) therapies, which involved more than 1.5 hours of human support (Lappalainen et al., 2013, Newman et al., 1997).

3.3.7. Outcome measures

Half of all studies used the State Trait Anxiety Inventory (STAI) as the primary outcome measure for either state or trait anxiety (Gorini et al., 2010, Grassi et al., 2009, Kenardy et al., 2003, Newman et al., 2013, Pallavicini et al., 2009, Riva et al., 2007, Riva et al., 2006, Villani et al., 2013). Two studies targeting anxiety, stress and depression used the Depression, Anxiety, and Stress Scale (DASS) (Proudfoot et al., 2013, Reid et al., 2011). Other measures of anxiety included the Hamilton Anxiety Rating Scale (HARS) (n = 3), the Penn State Worry Questionnaire (PSWQ) (n = 3), Beck Anxiety Inventory (BAI) (n =

2), and behavioural and cognitive assessment test on anxiety in social interactions (n = 1) (Gorini et al., 2010, Gruber et al., 2001, Newman et al., 2013, Pallavicini et al., 2009). Three studies targeting work-related stress used specific scales to measure distress induced by job demands, work burnouts and organisational pressures (Lappalainen et al., 2013, Villani et al., 2013, Lemaire et al., 2011). The two panic disorder studies used the Mobility Inventory (MI), the Agoraphobic Cognitions Questionnaire (ACQ), the Fear Questionnaire (FQ), the Body Sensations Questionnaire (BSQ), the Agoraphobia subscale, and the phobia subscales (Kenardy et al., 2003, Newman et al., 1997). The social phobia trial used Social Phobia Scale (SPS), and Social Phobia and Anxiety Inventory (SPAI) (Gruber et al., 2001).

3.3.8. EMI Effectiveness on anxiety outcomes

Section 3.3.8.1 to 3.3.8.4 presents the results of studies of EMIs for anxiety and stress. The meta-analysis on the sub-group of studies examining generalised anxiety as an outcome measure is presented in section 3.3.8.1.

3.3.8.1. *Generalised anxiety (n = 9)*

Most (n = 7) of the nine studies that evaluated EMIs specifically targeted generalised anxiety and used an anxiety measure (Gorini et al., 2010, Grassi et al., 2009, Mosso et al., 2009, Newman et al., 2013, Pallavicini et al., 2009, Proudfoot et al., 2013, Reid et al., 2011, Riva et al., 2007, Riva et al., 2006). These data were included in the meta-analysis (Grassi et al., 2009, Mosso et al., 2009, Newman et al., 2013, Pallavicini et al., 2009, Proudfoot et al., 2013, Reid et al., 2011, Riva et al., 2007). All but one of these studies incorporated a control group. This study instead employed two active comparison groups (Newman et al., 2013), comparing 6 weeks of group CBT plus EMI with (i) 6 weeks of group CBT; and (ii) 12 weeks of group CBT. Since the 12-week comparison intervention was not suitable for determining the effect of adding EMI to the 6-week group CBT, only the 6-week group CBT comparative data were incorporated into the analysis. The meta-analysis was run both with and without the inclusion of this study.

Table 4 and Figure 4 display the findings and forest plot of the meta-analyses of the 7 studies reporting generalised anxiety outcomes. Overall, EMI interventions were effective in reducing anxiety symptoms. The pooled effect size was 0.32 (95% CI = 0.12 to 0.53, p = .002) and heterogeneity among studies was low (I^2 = 8%). It is unlikely that publication

bias influenced the conclusions. The fail-safe N was 16 for the meta-analysis of all studies and after adjusting for publication bias using Duval and Tweedie trim and fill procedure the pooled standardised effect size for the combined interventions remained statistically significant (Adjusted effect size = 0.27; 95% CI = -.04 to 0.46).

Table 4. Meta-analysis of studies comparing the effects of EMI on generalised anxiety.

	N	d (95% CI)	Z	P	Q	p	I^2	Fail safe N
All Conditions								
All EMIs (FEM)	7	0.32 (0.15-0.50)	3.57	<0.001	6.52	0.37	7.96	16
All EMIs (REM)		0.32 (0.12-0.53)	3.12	0.002				
Excluding study with active control								
All EMIs (FEM)	6	0.31 (0.13-0.49)	3.34	0.001	6.08	0.30	17.78	10
All EMIs (REM)		0.31 (0.07-0.55)	2.54	0.011				

Note: FEM = fixed-effects model, REM = random-effects model

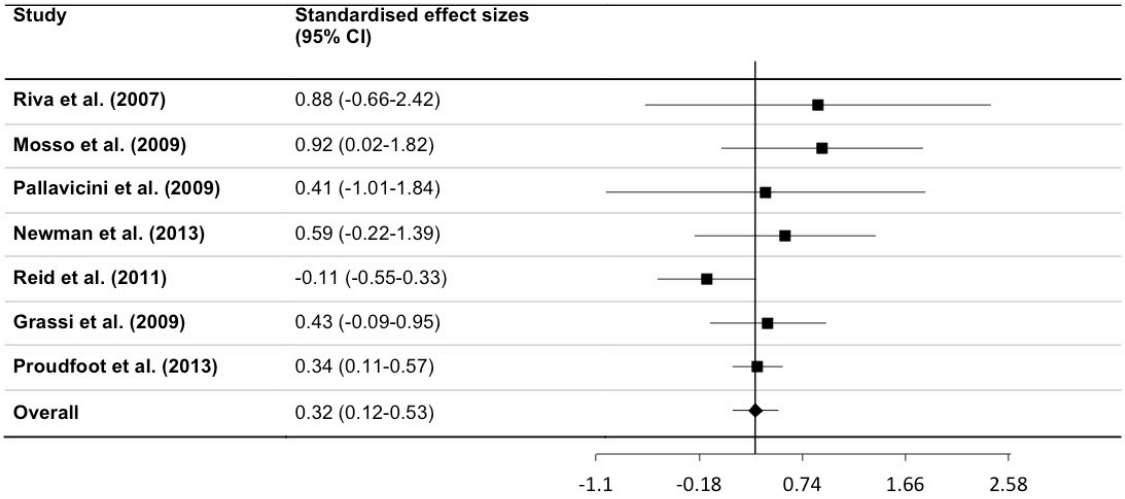

Figure 4. Forest plot showing the effect of EMI on generalised anxiety (random effects model; a positive effect signifies a decrease in anxiety symptoms)

There was little change in the pooled effect size after excluding data from the study by Newman et al. (2013) which employed an active comparison group (Pooled standardized effect size: 0.31; 95% CI: 0.07 to 0.55). Heterogeneity across studies was low (I^2=17.8%). Further, the fail safe *N* was 10, and after imputing potentially missing studies using the Duval and Tweedie procedure, the effect size remained statistically significant (Adjusted effect size=0.27, 95% CI= 0.006 to 0.50).

3.3.8.2. *Stress (n = 5)*

Studies examining EMIs in reducing stress demonstrated positive effects for EMI relative to controls (Lappalainen et al., 2013, Lemaire et al., 2011, Proudfoot et al., 2013). A study evaluating a transdiagnostic EMI comprising online CBT modules and SMS reminders for treating stress and anxiety was associated with lower stress levels than a waitlist control (*d* = 0.34 at post-test) (Proudfoot et al., 2013). Another study reported a reduction in work stress relative to waitlist control for an EMI that delivered CBT and ACT therapies (*d* = 0.21 to 0.63 at post-test) (Lappalainen et al., 2013). Further, a study evaluating an EMI consisting of multimedia relaxation training reported a reduction in work anxiety and stress relative to an attention control (Villani et al., 2013). Additionally, a study evaluating an EMI consisting of portable heart rate monitoring accompanied by breathing and positive emotion exercises was associated with decreased work stress compared with an attention control (0.19 at post-test) (Lemaire et al., 2011). However, an EMI using self-monitoring on mobile phones was not effective relative to an attention control in reducing stress (*d* = -0.08 at post-test) (Reid et al., 2011).

3.3.8.3. *Panic disorder (n = 2)*

The two studies on panic disorders yielded inconsistent findings. One study compared 6 weeks of individual face-to-face CBT with EMI including psychotherapy and self-monitoring with 6 weeks or 12 weeks of individual face-to-face CBT without EMI, and a waitlist control condition (Kenardy et al., 2003). Although the 6 weeks of CBT (with EMI) was effective in reducing panic symptoms relative to a waitlist control (d = 2.00 at post-test), the 6 weeks of CBT with EMI was not significantly superior to 6 weeks (d = 0.43) or 12 weeks (d = -0.23) of CBT without EMI. At follow up, the three active treatments did not statistically differ in reducing symptoms relative to control, but treatment gains were sustained. The only other study of panic disorder compared 4 weeks of individual face-to-face CBT with EMI including therapy and self-monitoring with 12 weeks of individual face-to-face CBT with EMI including self-monitoring only (Newman et al., 1997). The combined 4 weeks of CBT with EMI using therapy and monitoring was significantly superior to the 12 weeks of CBT with EMI using monitoring only (d = -0.92 to 0.81 at post-test). At follow up, there was no statistical difference between the two treatment conditions.

3.3.8.4. *Social phobia (n = 1)*

The single study on social phobia reported 12 sessions of group face-to-face CBT without EMI improved symptoms relative to the waitlist control (Gruber et al., 2001). However, the eight sessions of group face-to-face CBT with EMI including psychotherapy and self-monitoring did not significantly reduce symptoms relative to the waitlist control. Furthermore, the comparison of eight sessions of group CBT with EMI and 12 sessions of group CBT without EMI found no significant difference. Lastly, there were no comparisons done between the EMI intervention and waitlist control at follow up.

3.3.9. Outcomes for different levels of automation and human support

Four of the six studies that examined SA interventions found EMIs to significantly reduce anxiety and stress relative to controls (Riva et al., 2006, Riva et al., 2007, Proudfoot et al., 2013, Mosso et al., 2009). Similarly, three of the four studies that examined PSH interventions found EMI to significantly reduce anxiety or stress relative to controls (Pallavicini et al., 2009, Lemaire et al., 2011, Gorini et al., 2010). Finally, one of the four studies that examined TA interventions found EMIs to significantly reduce anxiety

symptoms relative to controls (Kenardy et al., 2003). However, another study that compared a TA intervention against control reported no significant reduction in anxiety symptoms (Gruber et al., 2001). Only one study that compared a TA against an MC intervention found the TA intervention to be significantly superior in reducing panic symptoms (Newman et al., 1997).

3.4. Discussion

This systematic review identified 15 randomised controlled trials and randomised trials of the effectiveness of EMIs for generalised anxiety, stress, panic disorders, and social phobia. The majority of these studies (n = 7) targeted generalised anxiety. The meta-analysis results demonstrated that EMIs are associated with a small, but significant reduction in generalised anxiety symptoms (d = 0.31). There was also some encouraging evidence that EMIs targeting stress may be effective. However, only a few studies have examined EMIs targeting other anxiety-related conditions with all of those studies showing mixed results. Overall, a majority of studies evaluated integrative EMIs that involved self-monitoring of symptoms, and the delivery of automated or therapist-delivered psychotherapy content.

To the author's knowledge, this is the first quantitative meta-analysis of the effectiveness of EMIs for generalised anxiety. The review findings suggest that EMIs may be a promising treatment for generalised anxiety. The effect size appears lower than reported previously for internet-delivered cognitive behavioural therapy (iCBT) for anxiety (Mewton et al., 2014). Given many of the EMIs included in the meta-analysis were predominately self-administered and unguided by a therapist, it is possible EMIs with therapist support would have yielded larger effect sizes (Spek et al., 2007, Palmqvist et al., 2007). Further, the EMIs included in the meta-analysis were on average briefer and less intensive than iCBT. Overall, the present results are comparable to findings of a recent systematic review of mental health interventions delivered using mobile phones (Donker et al., 2013). This review concluded that mobile application treatments targeting anxiety are effective. Furthermore, the present effect size appears to be similar to the effect size reported for smartphone interventions for anxiety (g = 0.325) (Firth et al., 2017). Similar findings have been identified in EMI studies for depression, smoking, and other addictive behaviours (Heron and Smyth, 2010, Telford et al., 2012).

The current review findings also suggest that EMIs may be effective for reducing stress. All but one study targeting stress found EMIs demonstrated significant reductions in stress compared with controls. In the present research, the study conducted by Reid et al. (2011) was the only study evaluating an interactive EMI using mobile phones which failed to yield significant effects in reducing stress relative to an attention control. However, the negative findings of this study may have been due to nature of the attention control, which closely resembled the intervention (Donker et al., 2013). Given the scarcity of studies on stress, more research is needed to examine the effects of EMI in various stressful environments that may induce high levels of anxiety.

Currently, there is no convincing evidence that EMIs are effective for other anxiety disorders. Two of three studies did not find EMIs to be associated with a reduction in the required number of face-to-face psychotherapy sessions for panic disorders or social phobia (Gruber et al., 2001, Kenardy et al., 2003). Although EMI and face-to-face CBT combined was more effective than receiving no treatment for panic disorders, EMI did not enhance face-to-face CBT, there being no significant difference between 6 weeks of CBT with and without EMI (Kenardy et al., 2003). Clearly, further research is required to investigate EMIs for panic and social phobias and whether EMI can enhance the effectiveness of face-to-face treatment. Other broader reviews have previously noted that more trials are needed on the effectiveness of EMI (Ehrenreich et al., 2011, Heron and Smyth, 2010). Despite this, no new studies targeting social phobia or panic disorder were located in the present study since the review conducted by Ehrenreich et al. (2011) in June 2010.

The majority of the studies in this review assessed integrative EMIs consisting of features that allow individuals to self-monitor symptoms and to receive appropriate in-situ electronic psychotherapy. Many of these integrative EMIs included therapy delivered through programmed computer modules. It is possible that mobile phones delivering therapy exercises and self-monitoring will prove useful as a *technology adjunct* to enhance the efficacy of existing web-based psychotherapies (Clough and Casey, 2011). Current psychotherapies for anxiety can be delivered online using a website (Cuijpers et al., 2009, Griffiths et al., 2010), and evidence suggests that psychotherapies for anxiety disorders delivered through the Internet demonstrate comparable effects to treatments delivered by a therapist (Christensen et al., 2014). Further research is warranted to investigate whether

EMIs can enhance existing psychotherapy treatments such as Internet-based interventions.

In this review, only two studies examined the effects of the individual features of mobile technologies that delivered EMIs for anxiety (Pallavicini et al., 2009, Gorini et al., 2010). Neither study found that adding automated sensors to tailored therapeutic content delivered via smartphones significantly reduced anxiety symptoms. Further, no study examined EMIs using in-built cameras. However, many of the recent advances in smartphones have enabled the use of automated sensors and in-built cameras (Luxton et al., 2011). These features can be accessed through native OS programming libraries, which can be used to develop smartphone applications (apps) (Liu et al., 2011). Generally, smartphone apps are designed to deliver specific therapeutic activities, such as self-monitoring, facilitating skills acquisition, or to provide information about a particular health condition (West et al., 2012, Martínez-Pérez et al., 2013, Harrison and Goozee, 2014). In comparison to other delivery modalities (such as face-to-face and desktop apps), smartphone apps have the advantage of delivering media-rich, personalised therapeutic content directly on the mobile device at all times of the day (Liu et al., 2011). However, further work is required to determine if and how EMIs can take full advantage of the smartphone app platform to optimise the delivery of particular therapeutic components of anxiety interventions. For example, more research is needed to evaluate the effectiveness of specific Human-Computer Interaction (HCI) mechanisms of smartphones and other portable devices in alleviating anxiety-related symptoms (Klasnja et al., 2011).

Overall, it is difficult to draw reliable conclusions on the effects of EMIs on reducing anxiety symptoms and stress. Many of the included studies yielded low EPOC quality scores. In particular, a number of studies failed to treat missing data appropriately and provided inadequate documentation of randomisation procedures, sequence generation, and allocation concealment. These issues are also coupled with the small sample sizes in many of the trials. It is important to improve the quality and reporting of prospective randomised controlled trials using EMI for anxiety and stress to allow accurate evaluation of the effectiveness of EMIs for these conditions.

3.4.1. Limitations

Several limitations are presented in this review. Firstly, the review included studies that examined EMIs with varying levels of therapist support. Therefore, the combined studies that evaluated EMIs with different forms of treatments may have impacted on the reported pool effect size of the meta-analysis, with results not necessarily generalisable to all types of EMIs. There are very few studies directly investigating the relative effectiveness of EMIs with and without human support or if EMI adds to face-to-face therapy or online human support. Further research is required to investigate these questions. Secondly, the main search concept "Ecological Momentary Intervention" was used in the search strategy. It is possible that the terms used to identify papers relevant to this concept did not capture all relevant studies. Thirdly, studies were only included if they measured an anxiety-related outcome. Thus, studies observing other related measures such as cost-efficiency and protocol adherence were not incorporated into this analysis. These studies may have provided further insights into the value of EMIs. Fourth, the overall indication of quality using the EPOC quality score (i.e., high medium, and low) was not included. This indication may have identified the potential impact of the study quality of the review findings. Specifically, removing low quality studies may have changed the estimated effect sizes. Finally, a more standardised definition for EMI would have reduced the ambiguity of included interventions. The current definitions for EMI are broad, and there are insufficient models describing these types of interventions in detail. It is difficult to meaningfully compare different EMIs that deploy a wide range of mobile and self-tracking technologies.

3.4.2. Future research

Given the paucity of RCT studies on the effects of EMIs for social anxiety, more research into social anxiety is needed. Furthermore, little is known about the technical implementation of mobile technologies that support the delivery of EMIs for social anxiety. Further research is needed in the design and development of EMIs, especially for researchers in understanding how EMIs can take full advantage of the mobile app platform. This may require further investigation of the available development tools and processes required to achieve the development and evaluation of EMIs for anxiety disorders, such as social anxiety. Chapter 4 will provide a case study that demonstrates the

conceptual design and development of an EMI for social anxiety using software engineering methods.

3.5. Conclusion

This systematic review found a small significant positive effect of EMIs on generalised anxiety. Studies targeting stress found EMIs to be significantly superior to controls. EMIs for panic disorders and social anxiety demonstrated mixed results. Although overall the findings are promising, more high quality randomised controlled trials are required, particularly to examine the effectiveness of EMIs for anxiety disorders such as panic and social anxiety disorder and the utility of EMIs as an adjunct to face-to-face and online web-based programs.

4. CHAPTER 4
Conceptual Design and Development Process of Ecological Momentary Interventions for Mental and Behavioural Health: A Software Development Perspective

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4.1. Introduction and Background

This chapter presents research on the design and development of an evidence-based Ecological Momentary Intervention (EMI) for mental and behavioural health. It reports a case study on the development of an EMI for social anxiety, which will form the intervention for the trial in Chapter 5. The present chapter builds on the previous chapter of a systematic review of the effectiveness of mobile technologies delivering EMIs for anxiety and stress (Chapter 3) by developing an EMI that addresses the key components of psychotherapy (such as self-monitoring, psychoeducation material, guided psychotherapy modules) and mobile technologies (such as text messaging, automated sensors, internet access, and native application programming libraries) for social anxiety found in the systematic review presented in Chapter 3.

Sections 4.1.1 to 4.1.13 provide a background of the research for the design and development of software for EMIs. Section 4.1.1 introduces the concept of EMIs. Section 4.1.2 provides a background of exposure therapy and the therapeutic components underpinning an EMI. Section 4.1.3 provides a background of the design and development of EMIs. Many of the concepts in Chapter 4 are software engineering concepts, and Chapter 4 will be used to provide a software engineering foundation for the proposed development process. Sections 4.1.4 to 4.1.12 present a background of software engineering concepts for the research on the design and development of EMIs. Section 4.1.4 provides a background of software development processes for EMIs. Section 4.1.5 provides a description of agile methods and principals. Section 4.1.6 gives a background on a software development process called Rational Unified Process (RUP) in which RUP can be used to model the software for an EMI. Section 4.1.7 provides background on modelling the problem domain for an EMI. Section 4.1.8 gives a background on the development of software artifacts using software development modelling approaches. Section 4.1.9 provides a background of Unified Modelling Languages (UML) which is a type of

modelling approach for software development. Section 4.1.10 provides background on the use of software views when using UML to model a software system for an EMI. Section 4.1.11 provides background on the agile modelling process for EMIs. Section 4.1.12 provides background on Model-Driven Development (MDD) for EMIs. Finally, section 4.1.13 provides a summary of the background of the development of EMIs.

4.1.1. Ecological Momentary Intervention (EMI) [3]

Ecological Momentary Interventions (EMIs) are "momentary health treatments provided via hand-held mobile technologies that deliver psychological interventions while people are engaged in their typical routines in their everyday life." (Heron and Smyth, 2010). Hand-held mobile technologies include smartphone apps and wearable devices. EMIs are also sometimes referred to as "Just-In-Time Health Interventions" (Danaher et al., 2015), that may use methods of dynamic tailoring, and intelligent real-time therapy (Nahum-Shani et al., 2016). EMIs can be delivered as stand-alone mental health interventions, or delivered as an adjunct to enhance other forms of treatment with a clinician, such as a therapist (Shiffman et al., 2008, Heron and Smyth, 2010). EMIs have been developed to improve various mental health problems such as anxiety disorders (Loo Gee et al., 2016), which involves employing evidence-based content (such as Cognitive Behavioural Therapy (CBT) involving cognitive restricting and exposure therapy), validated questionnaires, and reliable self-monitoring methods (Klasnja and Pratt, 2012). This thesis will focus developing an EMI that optimize the delivery of exposure therapy components for social anxiety, which may increase the accessibility of therapeutic content to people who faces barriers in seeking professional help.

4.1.2. Exposure therapy and EMI components [4]

Exposure therapy is a type of evidence-based CBT used in treating anxiety disorders that require a person to expose themselves to a fearful or challenging situation (Hofmann et al., 2013, Huppert et al., 2003, Ponniah and Hollon, 2008). As stated by Craske (2015) and Craske et al. (2014), the *inhibitory learning model* is the central mechanism of exposure

[3] "Ecological Momentary Interventions (EMI)" is defined here and repeated in other chapters of this thesis (Chapter 2, Chapter 5, and Chapter 6).

[4] "Exposure Therapy and EMI Components' is defined here and repeated in other chapters of this thesis (Chapter 5)

therapy for fear and anxiety. The model involves *fear extinction* (i.e., weakening of previous learned associated between a social situation and the aversive experiences of the social situation during exposure) with additional mechanisms, such as *habituation* (i.e., a reduction of the physiological arousals or physical reactions, such as elevated heart rate, associated with the repeated exposure of a fear provoking stimuli, such as the social situation). A range of therapeutic strategies can be delivered to people with social anxiety which can enhanced inhibitory learning process during exposure therapy, and to enhance its retrieval following completing exposure therapy. As noted in Chapter 1, use of these strategies may be optimised through EMI to sequence, schedule, support and deliver exposure therapy in real time.

Linguistic processing involving *affective labelling* can be used to enhance the inhibitory regulation process during fear extinction of an actual social situation, or it can be used independently but in complementary ways for fear extinction. Furthermore, cognitive strategies may be used to increase awareness the barriers of confronting a fear. Individual strategies can be implemented as therapeutic exercises facilitated through an standalone or EMI adjunct to other treatments. One of the beneficial factors of delivering ecologically valid exposure therapy exercises directly to a person's smartphone is that exercises are accessible in various environments, such as at home, at school, or at work. This benefit could overcome fears of seeking professional support, or other informal support, such as friends and family. This also can make the design of EMIs to be "complex" (Schueller et al., 2017). A complex EMI may require modern software design and development approaches to distil the core elements of psychological and behavioural change strategies, such as exposure therapy, and to formulate the software design of an EMI into small, meaningful, self-contained, and repurposable modules or components (Hekler et al., 2016).

4.1.3. Design and development of EMIs

Recently, there has been an increased interest in how to design EMIs for various mental health problems (Bakker et al., 2016, Mohr et al., 2014). Particularly, it has been argued that the software that delivers the content of an EMI have focused more on examining the device or system of the EMI software, known as the *black box*, rather than the internal software structures, functions, and features of the EMI design (Danaher et al., 2015). An

example of examining the *black box* of an EMI is the investigation of the EMI in which the internal mechanics and software design (i.e., source code, components, architecture, algorithms etc.) are hidden or unknown to researchers and clinicians. Instead of inspecting the black box of EMIs, design research approaches in software development could be used to examine the internal parts of EMIs for different mental health problems.

The field of *design research* is intended to understand the design processes, techniques, principals, and language used through the practice of purposefully developing software for an area of interest (Faste and Faste, 2012, Zimmerman et al., 2007, Hevner et al., 2004). It integrates scientific knowledge with engineering knowledge of technical solutions to real problems (Zimmerman et al., 2007). Hence, one of the purposes of design research is to better "understand and document knowledge that is generated from a design research process" through the creation of a working product (Zimmerman et al., 2010). For example, design research of an EMI aims to investigate how a particular design approach, such as user-centred design, is applied to develop an EMI that can deliver exercises to increase physical activity for people with depression. Further, design research includes understanding the various design processes (i.e., interviews or focus groups with end-users or rapid prototype sessions) that researchers may undertake to achieve the EMI design for people with depression.

The knowledge of the development processes of EMIs for mental health can vary. User participatory approaches can be used to invite people with lived experiences to contribute to the development of EMIs (Orlowski et al., 2016). There are also approaches that focus on the development of the theory-based material of EMIs (Mummah et al., 2016). However, the knowledge of software design practices in a development process of EMIs for mental health is mainly unknown which raise questions in the development of complex EMIs. Researchers can investigate the design and development process of an EMI software, and uncover knowledge of various design activities involved in the implementation of the EMI (Zimmerman et al., 2010). Design activities are often iterative and are part of a software development process (Zimmerman et al., 2007, Zimmerman et al., 2010). For example, a design activity can involve researchers repeatedly engaging with clinicians to design the functionality of a mobile app screen that displays personal recordings of a person's anxiety levels. Some design activities of an EMI may require the support of documentation that can facilitate the software development process as well as

communicate and critically evaluate the design process itself (Bardzell et al., 2016). Design documents can vary in forms, which includes workbooks, journals, engineering diagrams, sketches, project management reports, and rough prototype models (Bardzell et al., 2016). Researchers can examine a design of an EMI by critically *reflecting* on the design decisions, dialogues and pathways captured in the design documents (Bardzell et al., 2016, Bardzell et al., 2015). For instance, diagrams that show a mobile app screen of an automated message on relaxation exercises can contain annotated design notes that captures brief conversations between software developers and clinicians. These written communications can be used to clarify ambiguities concepts between software developers and clinicians. For example, software developers may provide clarity on the design of an automated message that sends weekly reminders to do mindfulness exercises or the design of operational rules for automated messages sent to users.

4.1.4. Software development process

A multi-disciplinary Research and Development (R&D) team conducts software development for EMIs. The development process consists of a series of *design and development activities* relating to the creation of a specific software system. An R&D team is made up of mental health researchers, policy advisors, mental health consumers, clinicians and software developers (Van Velsen et al., 2013). Often, these design and development activities are encapsulated in a sequence of distinct *steps* or *phases* (Davis et al., 1988, Behforooz and Hudson, 1996, Schmidt, 2013). The *System Development Life Cycle* (SDLC) is a specific development process that is used to facilitate the design and development of software through iterative development phases (Behforooz and Hudson, 1996, Davis et al., 1988, Pew et al., 2007). Steps or phases of the SDLC process include; 1) capturing user requirements (from domain expects such as clinicians, mental health researchers, and consumers); 2) system implementation; 3) and evaluation (Davis et al., 1988, Schmidt, 2013, Kendall and Kendall, 2014). Based on the characteristics of a project, additional methodologies, such as *agile methods*, can also be deployed with the SDLC process in designing and developing complex software systems (Jiang and Eberlein, 2009, Dybå and Dingsøyr, 2008). Furthermore, the SDLC process can be extended to address specific types of software development projects.

4.1.5. Agile methods and principals for EMIs

Agile methodologies in software development can be used to extend the SDLC process. Agile methods and principles are a subset of iterative and evolutionary development approaches based on continuous and responsive design of software products. Furthermore, agile methods are focused on different aspects of the SDLC. Several literature reviews that compare agile methods over traditionally software development methods have identified several common areas between each methodologies, which includes; *goals/objectives*, *development process*, *technology development*, *usability*, *project management*, *requirements elicitation*, *communication*, *stakeholders*, and *documentation/design artifacts* (Moniruzzaman and Hossain, 2013, Dyba and Dingsoyr, 2009, Nerur et al., 2005, Boehm, 2002). Section 4.3.2 uses areas of concerns when comparing development approaches of EMIs. Some agile methods focus on technology development, usability, and development process (such as agile modelling), while others focus on software development project management practices (such as Scrum approaches) (Moniruzzaman and Hossain, 2013).

Scrum is an agile method for managing software development projects that are unpredictable and flexible to adopt to continuous changes imposed by the environment (i.e., user requirement changes, financial pressures etc.). Particularly, the method consist of a series of small, flexible and self-contained work units called *'sprints'* (Vlaanderen et al., 2011). No new user requirements can be introduced during sprints, however, a '*backlog*' is used to as a repository to log and prioritise user requirements for a software product (Vlaanderen et al., 2011). An example of sprints could be the development of content for a self-contained module that delivers breathing exercises for an EMI for social anxiety. This sprint can be place in the Scrum backlog with other sprints relating to developing other components of the EMI for social anxiety. For example, setting up usability interviews with stakeholders, developing a psyhoeducation module, constructing automated surveys and other potential work units. Recently, Hekler et al. (2016) have broaden the use of agile methods within behavioural change interventions, such as EMIs. "*Agile science* is a process for creating useful and usable behaviour change interventions using relevant evidence for supporting decision-making of consumers, practitioners, and policy-makers" (Hekler et al., 2016). Other elements such as *intervention content* require additional consideration when developing EMIs, especially using agile methods and principles.

4.1.6. Rational Unified Process (RUP) for EMIs

The Rational Unified Process (RUP) is another extension of the SDLC process. RUP is a unified design framework that represents the dynamic aspects of software development (Anwar, 2014, Jacobson et al., 1999). Further, RUP consists of four lifecycles phases; 1) *inception*, 2) *elaboration*, 3) *construction*, and 4) *transition*. Additionally, RUP consists of static aspects of software development, such as design activities, diagrams and models (or *artifacts*), and defined worker roles (Anwar, 2014).

Figure 5 shows a diagram of these static aspects. A key aspect of RUP is to control the complexity of the design and development process (Jacobson et al., 1999). Managing the complexity allows a much simpler design of the software with various degrees of *reuse* or *repurpose*. It is thought that a series of iterative *design stages* or lifecycle *phases*, a software system begins to develop, evolve and mature, which potentially leading to better usability of the software (Jacobson et al., 1999, Anwar, 2014). During this process, software developers confront several challenges in design and development of software for EMIs.

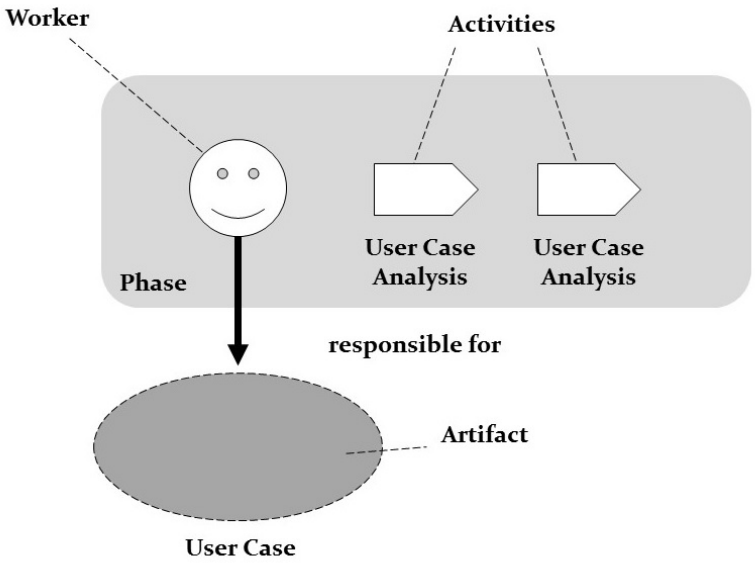


Figure 5. Static aspects of Rational Unified Process (RUP) (i.e., activities, worker role, and artifact)
(Anwar, 2014)

RUP originated from a software development process called *Objectory,* which developed during the 1990's (Kruchten, 2004, Anwar, 2014). Over the years, RUP and similar processes have evolved with the support of Object Orientation (OO) techniques

in the development of software. *OO* programming is a software development paradigm that supports the implementation of software systems based on the OO design framework (Meyer, 1997). The OO technology is grounded in a representation of items, phenomena, or systems in the real world, called *objects*. An essential feature of OO design is the ability to apply changes to software objects without impacting the entire structure of the software.

Examples of the use of the RUP process and OO techniques for the development of EMIs is not well known in the literature. However, clinicians or mental health researchers interested in the technical implementation of an EMI can use OO techniques to develop and design EMIs for mental health problems. For instance, software developers select clinical concepts (i.e., therapy exercises, positive reappraisal messages etc.) that translate clinical concepts into OO objects. These OO objects can be part of the RUP design process in which they are rearranged to formulate modules of an EMI, such as identifying anxiety levels or safety behaviours of the user. Therefore, the RUP process involves modelling OO objects grounded in the therapeutic parts of the mobile app which delivers the psychological content of the EMI.

4.1.7. Modelling aspects of the problem domain

One of the critical challenges for many software developers who are developing software for EMIs is the challenge of understanding the problem domain. The *problem domain* is the expert knowledge of the area of problems to be solved by a technical solution (Jackson, 1995, Jackson, 2005, Cheng and Atlee, 2007). The problem domain has explicit *constraints* or *boundary conditions* in which the development of software solutions can occur (Ross and Schoman, 1977, Nuseibeh and Easterbrook, 2000, Cox et al., 2005, Cheng and Atlee, 2007). Therefore, the problem domain disregards other areas of interest and focuses on a set of interrelated problems. In mental health, a specific problem domain could be a specific or series of mental health problems, such as depression and anxiety. Furthermore, an EMI is one particular form of psychological intervention (i.e., solution) that is part of the problem domain. Examples of psychological interventions could be acceptance and commitment therapy, behavioural activation therapy, or interpersonal psychotherapy. Particularly, software developers will have limited knowledge of mental health problem and psychological interventions, which may require them to extensively

research these domains, or engage with domain experts, such as clinical psychologists, that has extensive knowledge of these areas of interest.

During the early stages or phases of the SDLC, the R&D team will deliberate on the *scope* of the problem domain and identify possible technical solutions or products (Cheng and Atlee, 2007, John et al., 2006). In the context of EMI, R&D teams will collaboratively derive the evidence-based content or theory-driven requirements of the health intervention (i.e., exposure therapy material) in which the technical specification can then be established (Schueller et al., 2017, Hekler et al., 2016). Especially in the beginning phases, the problem domain and the EMI are ill-defined and require clarity from key stakeholders, such as mental health researchers, policy advisors, mental health consumers, clinicians and software developers (Van Velsen et al., 2013). *Modelling* in software development can be used to understand unclear or an ill-defined problem domain (Gonzalez-Perez and Henderson-Sellers, 2007). Specific models can be constructed to determine the technical solution that addresses the underlying problem domain (Dieste et al., 2001). *Software models* are formal abstract representations of the solution domain (i.e., EMI), with properties of the problem domain (Dieste et al., 2001, Gonzalez-Perez and Henderson-Sellers, 2007). An example of a software model can be the clinical workflow to teach people with anxieties about breathing exercises. The software model can encapsulate aspects of the clinical workflow that describes the process of clinicians teaching people to apply breathing exercises in their daily routines at home or workplace. The development of software models can be constructed from a full understanding of the EMI to be designed (i.e., top-down), or from the direct design of the EMI on an existing technology platform or program (i.e., bottom-up) (Pizka and Bauer, 2004).

Bottom-up development begins with the design of software from a legacy system or existing functional software (Pizka and Bauer, 2004). A fully defined (or "complete) functional system is used to gain the requirements of the technical solution (Jackson, 2012). This case study on the development of an EMI for social anxiety shows an example of the bottom-up approach. The case study integrates the bottom-up approach with other software development techniques. The bottom-up design process differs from a top-down approach. The top-down approach begins by describing the general requirements of software and then refining the design through consecutive steps until the software

program is completely defined (Jackson, 2012, Wirth, 1971). This process is called *stepwise refinement*. Essentially, software development involves bridging the gaps between the system requirements (i.e., "top"), and the technology platform (i.e., "bottom") (Jackson, 2012, Pizka and Bauer, 2004). While there are many ways of bridging these gaps, it appears using a mixture of bottom-up and top-down approaches (such as *stepwise refinement*) may improve the greater use of architectural styles and patterns in software development process (Bagheri and Sullivan, 2013). An example of a top-down approach is an R&D team that begins gathering minimal requirements of a viable EMI that delivers mindfulness exercises followed with the R&D team getting more detailed requirements of the mindfulness content (i.e., images, animation, sound, type of material etc.) to build the EMI. Notwithstanding the particular approach (top-down or bottom-up), the use of documents and diagrams in the modelling of the problem domain can simplify the software models complexity of an EMI.

4.1.8. Development of the software artifacts

Through modelling, a series of documented *software artifacts* can be produced to assist in communicating and understanding the problem and solution domains, especially between different stakeholders of an R&D team. Software artifacts are defined as any technology-related items that formally describes the functionality, architectural structure, and design of a software application (Hevner et al., 2004, Fowler and Scott, 1997). The construction of a software artifact is developed through a shared understanding and consensus of the underlying problem space across all key stakeholders including domain experts (Lindberg et al., 2011, Evans, 2004). Specifically, the language shared by the software developer and other stakeholders (such as mental health researchers, mental health consumers, and clinical psychologists) conveys the common understanding of the problem domain.

A series of different software artifacts contains expressions of a *shared* and *common language* of the problem domain (Damyanov and Sukalinska, 2015, Evans, 2004, Evans, 2014). Software artifacts are transformed into implementable programming code using software development tools. *Integrated Development Environment* (IDE) is a platform that fully integrates various tools to facilitate the software development process. An example of a software artifact for an EMI can be an artifact that describes the workflow of a clinical

process for performing exposure therapy, or an artifact that describes the mobile app screen displaying visual graphs of a person's mood levels over weeks. From a single development environment, and IDE is used to compile programming code into machine code used to assist in the transformation process of different software artifacts (desRivieres and Wiegand, 2004, Jarvensivu et al., 2006). Common IDE for mobile app development includes XCode for Apple smartphones (Apple, 2017b), or Android Studio for Android smartphones (Google, 2017). While the IDE may be useful tools for software developers, non-technical stakeholders in an R&D team may find the associations between the software artifact and the programming code to be useful to understand the technical feasibility of the software platform for a specific EMI. Compiled code can be executed on a device simulator for prototype testing, or on a device such as a smartphone, web application, or mobile device.

4.1.9. Unified Modelling Language (UML) artifacts

General-purpose software engineering modelling languages and tools are deployed to express a complex problem domain, and design of the software application, using standardised modelling notations. For instance, *Unified Modelling Language* (UML) can be used to capture and express the underlying model of a software application delivering a health intervention (Fowler and Scott, 1997, Guizzardi et al., 2006, Object Management Group, 2015). Previous development of health information systems for hospitals used visual modelling languages, such as UML (Blobel, 2000). In the context of mental health, UML and other similar modelling languages can be used to construct software artifacts that can document the software design of EMIs (Fowler and Scott, 1997). UML diagrams are a type of software artifact that can be used to communicate the *multiple aspects* of a software application of an EMI for various stakeholders, such as mental health consumers, researchers, clinicians, and software developers (Fowler and Scott, 1997). From section 4.5.3 to 4.5.7 of this chapter, the case study will demonstrate the use of several UML diagrams that builds the multiple perspectives of the software model of EMI for social anxiety.

4.1.10. Software views using UML

Multiple views can describe the design of the EMI from different perspectives of stakeholders of the R&D team, which can improve the comprehension of the software

design for specific stakeholders (Kruchten, 1995). For example, clinicians and mental health consumers can develop UML diagrams to demonstrate a function of an EMI for sending daily smartphone notifications that contain mindfulness content. Similarly, software developers can use UML diagrams to show the schematic layout of software components of functions that send daily or weekly smartphone notifications that contains mindfulness content. Different *views* of a software application are important in examining the architectural design of components and structures of a software system (Perry and Wolf, 1992). Software views can be used to further exploit the underlying software architecture of an EMI by identifying architectural patterns and styles that can potentially promote the reuse of software components for the given problem domain (Frakes and Kyo, 2005, Kruchten, 1995, Perry and Wolf, 1992). For example, software views of an EMI delivering mindfulness exercise can show the multiple uses of smartphone notifications in different aspects of the EMI, such as reminders to do mindfulness exercises or reminders to plan a mindfulness exercise before the anticipation of a social event perceived as stressful.

Kruchten (1995) proposed the "4+1" view model framework for describing software applications. It consists of five main *views* or *perspectives* of a software system. Figure 6 shows the 4+1 view model for describing software systems. The four main views of the model exemplify a series of *use cases* or *scenarios*, which signifies the fifth view of the model (i.e., "+1"). Use cases or scenarios are views that describe important requirements of a given software system through scripts that describe the sequence of interactions between abstract *elements* and *processes* of the problem domain (Jacobson, 2004). Use cases are frequently used to understand the conceptual representation of a software application or computer program, also known as the "*mental model*" (Staggers and Norcio, 1993, Storey et al., 1999). The case study presented in this chapter will demonstrate the use of use cases and scenarios in phase 4 of the design process for an EMI for social anxiety (section 4.5.4).

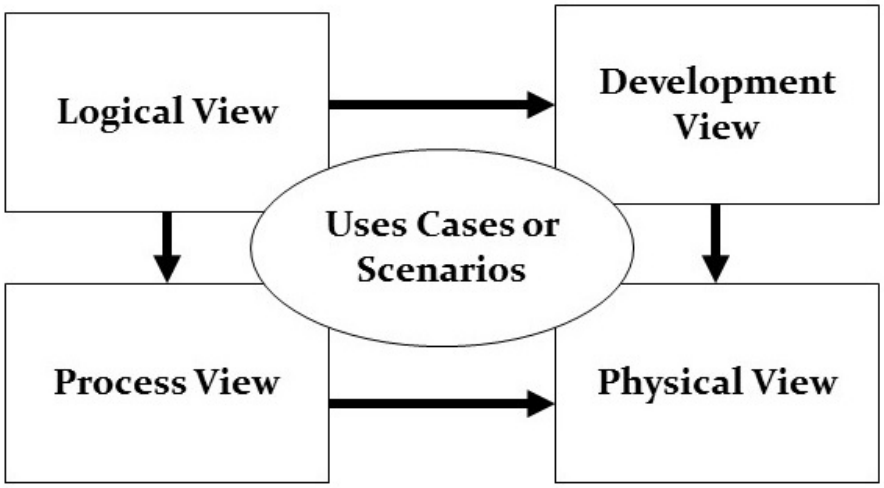


Figure 6. 4+1 view model
(Kruchten, 1995)

Next, Kruchten (1995) proposes the *decomposition* of the system into the four remaining views of the 4+1 view model centred on the use cases ('scenarios'). First, a *logical view* is derived to represent the functional requirements of a software system through a set of key abstractions of the problem domain. Abstractions encapsulate *data objects* and *classes* of data objects also known as *elements*. An example of an element of EMI can be psychotherapy modules, mental health consumers or mindfulness notification messages. Second, a *process view* can be derived to represent the changing states of elements known as *processes*. An example of an EMI process can be the order of psychotherapy modules that a mental health consumer would require to complete before receiving a reward of completion. Third, a *development* view can be derived to represent the static structures of the software through a series of program *layers* and *libraries*. An example of libraries of an EMI is animation programming libraries on the mobile app platform used to display a moving image of a person confronting their fears of public speaking. Finally, a *physical* view is used to represent the mappings of the software onto hardware of a specific device. Different design phases of the SDLC process involves developing the different views of the software application of an EMI. In this chapter, the case study demonstrates the logical, process, and development views via the different phases of the design process of an EMI for social anxiety (section 4.5.3 to 4.5.8).

4.1.11. Agile modelling for EMIs

The SDLC phases can incorporate rapid development approach called *agile modelling* to construct the different views of software for EMIs as described in the Kruchten (1995) model. Agile modelling involves the development of programming code (or software system implementation) alongside the continual documentation of the software, which can be used to communicate the design of EMI software among the domain experts (such as a clinical psychologist and mental health researchers) of an R&D team (Ambler, 2006). Agile modelling is a set of values, principals, and practices for *modelling* and *documenting* software (Ambler, 2002, Ambler, 2006, Erickson et al., 2005). Modelled artifacts are produced using standard notation of Unified Modeling Language (UML) 2.x or other modelling techniques (Ambler, 2004). Principally, the initial model of the software application is developed, followed by a process where the initial model evolves through gradual iterations on the architecture (Matinnejad, 2011). In this project, agile modelling was used to guide the development of UML artifacts of the software for the EMI. Section 4.3.1 of this chapter uses agile modelling with other software development methods into a single development framework for an EMI for social anxiety.

4.1.12. Model-Driven Development (MDD) for EMIs

Agile modelling practices integrate with the Model-Driven Development (MDD) approach, which can complement each other in rapidly developing model-centric software delivering EMIs. (Matinnejad, 2011, Ambler, 2006). MDD is a development approach that relies on the use of *models* for the development of software (Daniluk, 2012, Raghupathi and Umar, 2008, Mens and Van Gorp, 2006). Furthermore, MDD models can assist R&D teams to understand complex problems and potential solutions through different architectural views of a mobile app software for an EMI. For instance, one UML diagram can present the data *structures* of the software model of an EMI, such as the types of anxieties or users of the EMI. Another UML diagram can present the view of the system *behaviours* of the software model of the software of an EMI, such as the steps of doing exposure therapy in a real-life situation. Figure 7 shows the agile-based MDD approach to software development. Principally, MDD focuses on constructing abstract models that are independent of the implementation or programming code of the specific software platform delivering an EMI (Daniluk, 2012). UML is often used in MDD models to allow models to be portable across multiple technology-specific platforms (Raghupathi and

Umar, 2008). This project adopts MDD design principals to develop the initial architecture of the EMI software for social anxiety.

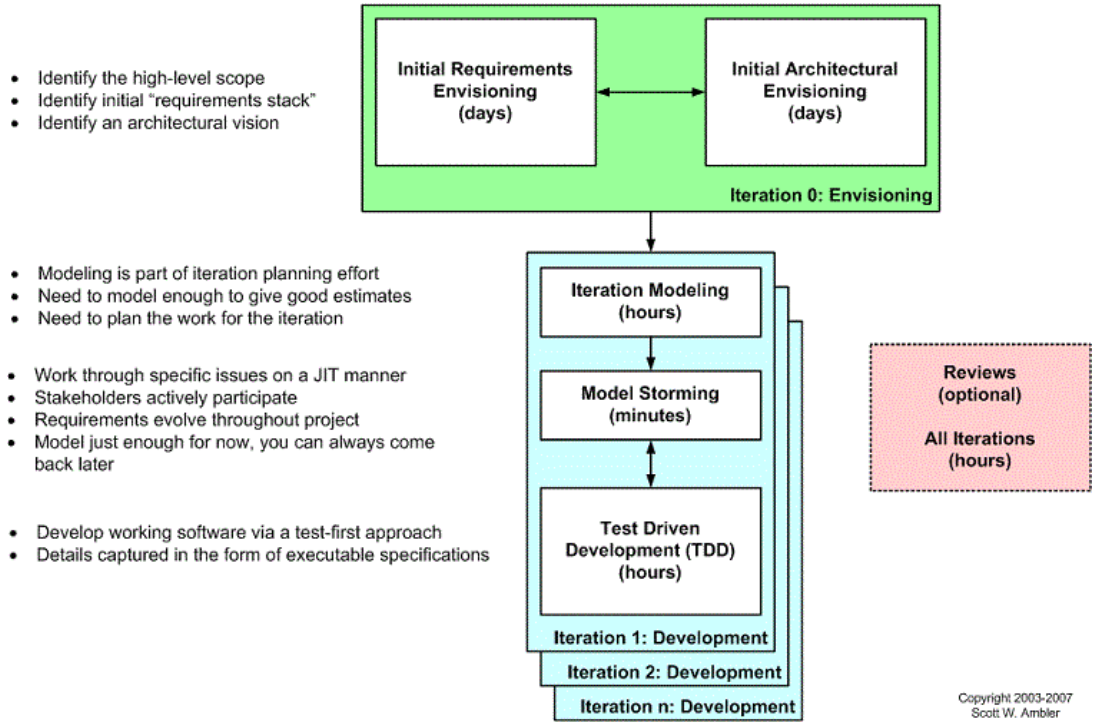


Figure 7. Agile-based MDD approach to software development (Ambler, 2006, Matinnejad, 2011)

The generation of software programming code is related to the underlying models represented in various UML diagrams. *The model transformation* consists a mixture of automated or semi-automated approaches that generates a target model (i.e., programming code) from a source model (i.e., UML diagram) (Mens and Van Gorp, 2006). Traditional MDD approaches involve the use of model-driven engineering toolkits that automatically generate and compile software programming code through the transformation of UML software artifacts (Mens and Van Gorp, 2006). While the use of these tools can automate the development process, the semi-automated process can be used to partially generate the programming code of a mobile app software (Mens and Van Gorp, 2006). Furthermore, the manual transformation is needed to address unresolved ambiguity, incompleteness, and inconsistency of software requirements. For example, a series of UML software artifacts that represents an EMI for depression can be used to present the individual software components, structures, and functions of the software delivering behavioural activation content for mental health consumers with depression. However, manual methods are needed to add mobile app features to the UML models

representing the behavioural activation content, such as notification reminders to do behavioural activation exercises or mobile sensors to detect activity levels to trigger notification reminders.

4.1.13. Background summary

An EMI is a real-time momentary health intervention delivered on mobile technologies. The design process of EMIs can inform all members of an R&D team on the internal mechanics of EMIs (i.e., the software architecture, algorithms etc.), especially when evaluating the EMI for the target population, such as social anxiety. Furthermore, the SDLC and RUP is a design process that facilitates an understanding of the problem domain (i.e., anxiety problems), possible solutions (i.e., the EMI delivering exposure therapy), and software artifacts (i.e., design documentation of the EMI design). UML is a form of a software artifact used in software development process, which can be used to articulate views of the EMI software for different stakeholders, such as the clinicians, researchers, consumers, and software developers. Using agile modelling and MDD approaches can produce UML artifacts that can represent relevant views of the EMI (i.e., the clinical process for developing fear hierarchies for exposure therapy) in which an R&D team can reflect, communicate, and evaluate on particular design decisions made during the development process. The case study presented in section 0 will use agile modelling, MDD, and bottom-up approaches to demonstrate how the views of an EMI for social anxiety via UML artifacts which are important learning tools for understanding the challenges of the iterative design process, development of components, stakeholder engagement and communication, documentation and time management.

4.2. Related Research to Development of EMIs

Following on section 4.1 which provided a background of EMIs and software development concepts, sections 4.2.1 to 4.2.7 will provide a review of the related research to the design and development of EMIs. This review outlines some of the gaps in the current research on the design and development of EMIs and similar digital interventions for mental and behavioural health.

E-Health researchers have explored multiple approaches to creating digital interventions, such as EMIs, targeting mental health problems. Some have focused on

designing software focused on user participation, such as user-centred design (Section 4.2.1) (Orlowski et al., 2016, Eyles et al., 2016, Schnall et al., 2016, Yardley et al., 2015, Doherty et al., 2010). Others have focused on the design of the behavioural-theory of the content of the intervention, such as instructional design (Section 4.2.2) and interventional mapping (Section 4.2.3) (Crutzen, 2014, Hilgart et al., 2012). Some researchers have proposed combined user-centred and behavioural-theory driven approaches, such as Integrate, Design, Assess and Share framework (IDEAS) (Section 4.2.4) (Mummah et al., 2016). Models such as the Health Behaviour Change Support Systems (HBCSS) (Section 4.2.5) and Behavioural Intervention Technology (BIT) model (Section 4.2.6) are hybrid integrative approaches for content design and technology design (Mohr et al., 2014, Oinas-Kukkonen, 2013). Finally, section 4.2.7 provides a summary of each of these design approaches.

4.2.1. User centred design

User-centred design approaches focus on the participation of both the end-user and the domain experts in the development of software for digital interventions for mental health (Eyles et al., 2016, Schnall et al., 2016). These approaches aim to empower mental health consumers (the end-users of an EMI) by inviting them to contribute to the development of software delivering a mental health intervention for their needs (Orlowski et al., 2016, Doherty et al., 2010). Additionally, user-centred design approaches may involve other experts including behavioural scientists and clinical psychologists in the development process (Orlowski et al., 2016, Roth et al., 2014, Coyle et al., 2013, Mark et al., 2008). Qualitative methods to collect data to inform the development of the intervention includes workshops, focus groups, and surveys. These user-centred design approaches elicit user needs and preferences to influence the design of the digital interventions for mental health delivered via a mobile app or internet website (Yardley et al., 2015). Furthermore, participatory methods can collect data on usability, acceptability, privacy, and potential software features of a mental health intervention. This additional data can enhance theory-based and evidence-based approaches to the development of digital interventions, such as an EMIs (Bradbury et al., 2014, Hekler et al., 2011).

Bradbury et al. (2014) propose a methodological process that combines the identification of existing evidence and theory with usability testing to inform the

development of digital interventions, such as EMIs. Researchers proposed a two-phase development process for the development of digital interventions. The first phase called "Intervention Planning", involved the combination of *deductive* or *inductive* approaches. Deductive approaches include the review of existing quantitative and qualitative literature, especially RCTs, and qualitative research studies on the user experience of behavioural change techniques or entire health interventions. Data from deductive approaches may inform the components to include in a digital intervention for mental health. Inductive approaches include interviews and focus groups on users or clinicians. Data from inductive approaches can highlight the components of digital interventions, identified using inductive methods, which are acceptable (or unacceptable) to end users. Inductive approaches are particularly useful in the planning stages if limited qualitative literature is available. For example, there were no qualitative research studies on EMI for depression and anxiety. Early qualitative interviews can be done on clinicians and consumers with anxiety and depression to repackaged EMI content to better *appeal* or *engage* consumers with social anxiety. After conducting deductive or inductive approaches, the final version of the program is prioritised to refine the design of the intervention. The second phase called "Intervention Development", involves the employment of usability testing methods to evaluate digital interventions on the desired target groups. Think-Aloud and Retrospective Interviews are employed to understand the feasibility of the digital intervention. Data from interviews can inform future iterations on the design of the digital intervention. Essentially, user-centred design approaches, such as Bradbury et al. (2014), can be orientated towards designing the content of digital interventions, such as EMIs, for mental health.

4.2.2. Instructional design

Instructional design is also an approach to developing digital mental health interventions. Instructional design models are prescriptive models that describe a set of design activities that involve the planning, implementation, and evaluation of instruction-based learning programs (Burns et al., 2013, Hilgart et al., 2012). In the context of digital interventions for mental health, the instructional design model focuses on three key activities or phases of the design process: 1) *analysis,* 2) *strategy and* 3) *evaluation* (Hilgart et al., 2012). Similar to the SDLC process, a series of iterative stages or lifecycles are used to develop the instruction-based learning content of a digital intervention for mental

health. The instructional design model contains various process models. Each process model encompasses a set of design activities that aims to design instructional learning material for mental well-being. Design activities include identifying specific information about the user, identifying specific needs of the user, and translating the user needs into technical requirements for product development (Burns et al., 2013). Similar to other design approaches, the instructional design model is best suited in conjunction with other design processes that can formulate a software application or operations.

4.2.3. Interventional mapping

Interventional mapping is a development protocol similar to the instructional design model. However, a range of theory- and evidence-based interventions can be developed using the interventional model (Crutzen, 2014). Intervention mapping has been used to apply empirical data and theory into the design of health promotion programs (Eldredge et al., 2016, Kok et al., 2004). Furthermore, intervention mapping is rooted in the systematic development of health promotion interventions. The instructional mapping design approaches encompass six steps: 1) needs assessment, 2) establishing program objectives, 3) identifying the theory-based methods and application, 4) program development, 5) planning program implementation, and 6) planning evaluation (Crutzen, 2014). Developing digital interventions for mental health, such as EMIs, can use intervention mapping and other design methods.

4.2.4. Integrate, Design, Assess, and Share (IDEAS)

Researchers have recently proposed design approaches that combine behavioural theory-driven approaches for the design of content with user- participatory approaches in the development of digital interventions (Hekler et al., 2011, Whittaker et al., 2012b, Mummah et al., 2016). Recently, Mummah et al. (2016) introduced the Integrate, Design, Assess, and Share (IDEAS), which is a step-by-step design and development process that integrates a "user-centred design approach with the use of behavioural theory-driven strategies" (page 3). The IDEAS framework consists of 10 phases; 1) empathise with target users, 2) specify target behavior, 3) ground in behaviour theory, 4) ideate implementation strategies, 5) prototyping potential products, 6) gather user feedback, 7) build a minimum viable product, 8) pilot potential efficacy and usability, 9) evaluate efficacy in RCT, and 10) share intervention findings. Four overarching categories of the 10 phases include; 1)

integrating the user and theory of users; 2) design through iterative cycles including the feedback of users; 3) assessing the intervention; and 4) sharing research with others. IDEAS is based on the development frameworks developed by Hekler et al. (2011) and Whittaker et al. (2012b).

Whittaker et al. (2012b) established a development and evaluation framework for digital interventions. The process involves six steps: 1) conceptualisation, 2) formative research, 3) pretesting, 4) pilot study, 5) Randomised Controlled Trial (RCT), and 6) Qualitative Follow-Up. *Conceptualisation* step involves R&D teams to identify the theoretical basis of the digital intervention. Theories may include behaviour change strategies, such as intervention mapping or Behavioural Change Wheel (Smith et al., 2016). The other five steps are *formative research*, *pretesting*, *pilot study*, *Randomised Controlled Trial (RCT)*, and *qualitative follow-up* which predominantly evaluate the acceptability and engagement of digital interventions. In the five steps, Smith et al. (2016) also included the Health IT Usability Evaluation Model framework to support the user-centred design, which included focus groups, prototype walkthroughs, and app usage analysis. Each stage of the process by Whittaker et al. (2012b) can deploy measures to understand specific health outcomes or satisfaction of intervention content. The development process can deploy agile software development and optimisations strategies (Jacobs and Graham, 2016). Importantly, the IDEAS and other related development frameworks address the design of the content for a digital intervention for mental health with some focus on the technology platform that delivers the content of an e-intervention.

4.2.5. Health Behavioural Change Support Systems (HBCSS)

Kelders et al. (2016) recently proposed an integrative framework for the development and evaluation of Health Behavioural Change Support Systems (HBCSS). HBCSS shares similar properties to EMIs, such as the use of mobile technologies that deliver evidence-based content for behavioural change, however, EMIs are more potent interventions that emphasise on the real-time delivery of evidence-based content for behavioural change in a person's natural environment. HBCSS systems address the technical implementation of digital interventions for mental health. The framework consists of three constructs. First, *content* is parts of an HBCSS that intends to change the behaviour of the user, such as behaviour change theories or therapeutic approaches. Implementable parts of content can

be a mixture of text and video of an HBCSS. Second, the *system* is parts of an HBCSS related to the specific technology platform delivering the content. Third, *context* is the part of an HBCSS related to the contextual aspects of the system, such as organisational factors, therapist alliance and peer support, and environmental factors. A Single integrative approach contains a combination of HBCSS constructs. The HBCSS model draws on the Persuasive Systems Design (PSD) principals (Fogg, 2009, Kelders et al., 2016). The PSD framework is a set of design principals that support *primary task*, *dialogue*, *system credibility*, and *social context* (Fogg, 2009, Oinas-Kukkonen, 2013, Oinas-Kukkonen and Harjumaa, 2009, Torning and Oinas-Kukkonen, 2009). Essentially, HBCSS and PSD are technical frameworks that can potentially automate the personalisation of the content of digital interventions for mental health, or provide support to therapist assisted mental health care.

4.2.6. Behavioural Intervention Technology (BIT) model

Similarly, the Behavioural Intervention Technology (BIT) design model developed by Mohr et al. (2014) provides a design framework that allows the conceptual definition of mental health interventions from its clinical aims to technology delivery. This model addresses the limitation of the design models for behaviour change proposed by Oinas-Kukkonen (2013), Ritterband et al. (2009), and Fogg (2009). Schueller et al. (2017) argue that the BIT model can understand the components of EMIs. Especially, the delivery of a BIT treatment via the design of EMIs. BIT is a hybrid design model that provides a comprehensive framework for the translation of evidence-based content into implementable technology-based elements. Furthermore, the same research group has developed Purple Robot to complement the BIT model (Schueller et al., 2017), which is a set of programming libraries for the Android mobile app platform. It was constructed to provide modular, reusable programming libraries for the development of context-aware BIT interventions. While there has been previous research on specific technology frameworks (Zens et al., 2017, Eckhoff et al., 2015), the investigation of the use of these platforms for digital mental health interventions remains.

The overall BIT model by Mohr et al. (2014) is made up of two parts; *theoretical* and *instantiation*. The theoretical aspect of an intervention consists of "why" the intervention is important in changing health behaviours, and conceptually "how" changes in health

behaviours of a person can occur and maintained. Goal setting, self-monitoring, and motivational enhancements can be particular clinical strategies used to satisfy the clinical aims of the intervention. The instantiation aspect of an intervention consists of; "what" technical instantiations are used for a mental health intervention (such as multimedia, push notifications, or passive data collection), "how" these clinical strategies are delivered using technology features, and "when" are the clinical strategies delivered over a period.

4.2.7. Summary of related research to the development of EMIs

As a summary of the related research, user-centred design approaches have been used to empower end-users of EMIs to contribute to the development of EMIs for mental health. Theory-centric development approaches such as instructional design and interventional mapping have been used to design the instructional-based and evidence-based material of EMIs. Integrated approaches of user-centric and theory-centric development approaches, such as IDEAS, are design processes that can ensure an EMI meets the theory-driven requirements, such as the therapeutic basis of an intervention, and the end-user requirements. Furthermore, HBCSS and BIT are technical frameworks that integrate the evidence-based content of an EMI and technical aspects of a technology platform into a single approach. These approaches focus on the technical design of EMIs. While the HBCSS and BIT models are suitable high-level models for the development of multiple mental health interventions, the model is limited in understanding the relevant design activities of software development practices involved in the implementation of the mobile app that delivers the EMI.

4.3. Materials and Methods

Following section 4.2 which outlined the related research, section 4.3 provides a description of the material and methods of a case study on the development of an EMI for social anxiety. Section 4.3.1 describes the research aims of the case study, and section 4.3.2 describes the participants, or the members of the R&D team, of the case study.

4.3.1. Research rationale

This case study uses existing software development approaches to design and develop an EMI. The case study aims to apply existing software development practices to

investigate the key learnings of the development of an EMI for social anxiety. Using modelling techniques and existing software development principals, we want to examine and reflect on the design activities of the development process. The case study findings can potentially address the implications of the development process on the iterative design process, the development of software components, the challenges of stakeholder engagement and communication, the challenges of documentation and time management.

4.3.2. Research and Development (R&D) team

Qualified and experienced software developers [Brendan Loo Gee (BLG) and Arjun Rajshekhar (AR)], mental health researchers [Kathleen M Griffiths (KMG), Amelia Gulliver (AG), Philip J Batterham (PB), and Andrew White (AW)], and qualified clinical psychologists/researchers [Julia Reynolds (JR), Lou Farrer (LF) and Dominque Kazan (DK)] were involved in the development process. All but AW are from the Research School of Population Health at the Australian National University. A qualified clinical psychologist [Les Posen (LP)] from Melbourne, Australia with experience of integrating information technology into clinical practice assisted in the development of the EMI.

4.4. Development Framework

This section describes the development framework used for the design of the EMI for social anxiety. Section 4.4.1 describes the proposed development approach used for the development of the current EMI for social anxiety. Lastly, section 4.4.2 provides a comparison of the proposed development approach over other development approaches described in section 4.2.

4.4.1. Proposed development approach

Agile modelling was used to produce UML based software artifacts for an EMI for social anxiety. These artifacts were interrelated to represent various views of the software mobile app delivering the EMI, especially the 4+1 software architectural model by (Kruchten, 1995). Software artifacts included the use of user stories, UML activity diagrams, UML object diagram, UML class diagram, UML sequence diagram, and UI wireframe. Table 5 provides a description of the software artifacts used in the current development process.

System requirements and were captured using user stories, UML activity diagram, and UML wireframes. However, logical and physical architecture of the software app delivering the EMI were mainly captured using UML object diagrams, UML class diagram, and UML sequence diagram.

Table 5. Descriptions of the software artifacts in the development process.

Software Artifact	Software Artifact Description	4+1 Software Architecture Model
User Stories	User stories are tools for capturing high-level requirements of a software system, such as a mobile app, for an EMI (Cohn, 2004). It can be used to explore the high-level system structures, behaviours, and decision rules of an EMI with non-technical stakeholders of an R&D team. A natural language, such as English, is used to write system requirements in user stories. In this case study, the Connextra user story template was used to capture *who*, *what*, and *why* of a psychotherapy user through concrete scenarios and personas (Hudson, 2013). Connextra templates are similar to the BIT model proposed by Mohr et al. (2014). However, they have been widely adopted in other industries such as social media and digital news platforms (Lucassen et al., 2016).	Scenarios
UML Activity Diagram	Activity diagrams are diagrams that can represent the logic of actions of a software process of an EMI (Ambler, 2002, Ambler, 2004). They can articulate the therapy and EMI processes and goals that achieve the intended reduction of social anxiety symptoms. An R&D team can produce a series of UML activity diagrams that describe the logical flow of therapeutic activities or actions of the therapy and EMI from user story modelling. UML activity diagrams use modelling language notations to describe the individual actions of a therapy process, decision rules of a therapy process, and the flow of actions of a therapy process.	Process View
UML Object Diagram	Object diagrams are diagrams that *partially* represent the data (and information) structures of a user scenario of an EMI (Ambler, 2002, Ambler, 2004). The concrete instances of associated data and objects in the software of an EMI shown through the partial representation of objects in diagrams. Object diagrams present the structures and relationships of data and objects of a given user scenario in an EMI at a point in time. Predominately, software developers of an R&D team use object diagrams to articulate complex relationships of classes of objects in the software of EMIs to better communicate abstract models. UML object diagrams utilise modelling language notations to describe the storage of data (and information), the value	Logical View

	of data (and information) stored, and the relationship of different data (and information).	
UML Class Diagram	UML Class Diagrams is a graphics tool to *fully* represent the data (and information) structure and behaviours of a user scenario of an EMI (Ambler, 2002, Ambler, 2004). Contrast to UML Object diagrams; class diagrams represents the full representation of data and objects structure and the relationship between data and objects. Full representation hide details of concrete instances of objects. Additionally, class diagrams represent integral rules between different classes whereby rules constrained the operation of objects. Rules could include whether a relationship between various data structures is *mandatory* or *optional*. Or, a rule that indicates the *number of times* an instance of a particular object associated with another object. Fundamentally, the software developer's utilises UML class diagrams to design the storage and function of objects. It uses specific modelling language notations to convey concise information structure and functions of the domain.	Logical View
UML Sequence Diagram	UML sequence diagrams are depictions of a model that represents the flow of data between objects in a given order (Ambler, 2002, Ambler, 2004). They are used to implicitly or explicitly represent the collaboration and interactions of objects in the software. The software developer can use standard notations of UML sequence diagram to design a complex process of a system. For instance, a system process can be a procedure to handle the storage of data for a domain object of the EMI. Lastly, the UML sequence diagram can show the dependencies of objects among the architectural layers of the software.	Process View, Development View, Physical View
UI Wireframe	UI wireframe diagrams are mock-ups of a UI of an application. They are intended to provide a visual skeleton of the UI for a range of applications such as website, desktop applications, or mobile apps for healthcare such as mental health (McCurdie et al., 2012, Rudd et al., 1996). Wireframe diagrams are low-level mock-ups of the static layout of UI components (such as the simple representation of buttons, text, and lists of contents) on the mobile app screens (Rudd et al., 1996). Unlike UML, UI wireframe diagrams do not utilise standard language notations to describe the design of the software of the EMI. Low-fidelity prototyping uses wireframes whereby non-functional aspects of software communicates to all stakeholders of an R&D team (Yasar, 2007). The software developer will utilise UI wireframes to gain feedback from domain expects during the walkthroughs and usability testing of the software for an EMI (Rudd et al., 1996).	Scenarios

MDD principals were applied to this development process whereby a UML modelling tool, Graphical UI (GUI) prototyping tool, and IDE tool generated the EMI design and programming code of the prototype. In this project, some tools were used to facilitate the MDD process for the development of the EMI for social anxiety. First, an open-source modelling tool called ArgoUML was used to develop UML models and to automatically generate programming code templates for the problem domain of the EMI for social anxiety (CollabNet, 2009). Second, a GUI prototyping tool called Pencil and Microsoft Word was used to create the UI models and wireframe diagrams (Evolus, 2012). Lastly, XCode IDE was used to develop, generate, test, and simulate the programming code for the various models of the prototype of the EMI (Apple, 2017a).

The bottom-up approach was predominately used to gain the initial user requirements of the software system of the EMI for social anxiety. An existing Internet-based mental health intervention, called eCouch (ecouch.anu.edu.au), was used to develop the system requirements of this EMI. Based on the requirements of the legacy system, top-down techniques were then applied to develop new software models of the EMI on the mobile app platform. New models included a series of software artifacts, such as UML diagrams. A sequence of steps was used to refine the underlying software models and artifacts of the EMI for social anxiety. Selected aspects of the reliable material of the given treatment protocol (or problem domain) formed the basis of these software models. New features (such as mobile app elements) were used to enhance the underlying model. Overall, the bottom-up approach encouraged R&D teams to implement certain aspects of software of an EMI in well-formulated components.

The scope of the design project was discussed among all stakeholders of the R&D team (described below) before the eight phases began. Design phases were *not all* carried out linearly throughout the development process. Each phase consisted of design activities that produced separate views of the software architecture of the EMI. Similar to SDLC and RUP, this development process consisted of *iterative* lifecycles of design and development activities that involved analysing the existing evidence-based material, translating the evidence-based material into models, and transforming models into implementable software mobile application features. Each phase of the development process produced a series of UML software artifacts, which various stakeholders of the R&D team utilised for the development of the EMI.

4.4.2. Comparison of proposed development approach over other development approaches

The proposed develop approach is inspired by software development practices that are commonly used in other industries. Software development approaches have the potential to build on the existing understanding of how the technical instantiation of eHealth interventions for mental health, such as EMIs, can be communicated, documented, implemented, and adopted over extended periods of time. Distinct characteristics of the proposed approaches includes an exploratory development process, the use of object oriented and component-based technologies, and the reuse of an existing software system to build on new components of the EMI. However, shortcomings include the limited focus on including mental health consumers as stakeholders, usability of end-users, and formal communication and documentation. Table 6 provides a comparison of the proposed development approach over other development approaches of EMIs discussed in section 4.2.

Table 6. Comparison of development approaches over other development approaches of EMIs (discussed in Section 4.2).

	User-centre Design	**Instructional Design**	**Intervention Mapping**	**Integrate, Design, Assess, and Share (IDEAS)**	**Health Behavioural Change Support Systems (HBCSS)**	**Behavioural Intervention Technology (BIT) model**	**Agile modelling, MDD, bottom-up development**
Objectives/Goals	Develop software involving end-users of the EMI to identify barriers of adoption, and improve engagement with consumers.	Develop instruction-based learning material and content by identifying learning needs/goals	Developing a theory-based evidence-based intervention to educate and promote health and well-being	Developing a digital intervention using behavioural theory and user participatory approaches	Developing complex Health Behaviour Change Support Systems that integrate technical and other approaches.	Developing mHealth and eHealth interventions from theory to application.	Rapid develop software models of the expert domain using principals of continuous development through rapid feedback and adapting the software to change.
Development process	Iterative, and research study driven	Linear, systematic, prescriptive	Linear, systematic, prescriptive	Stepwise, design thinking, theory-driven	Iterative, and holistic.	Stepwise, and evolutionary	Iterative, evolutionary, exploratory, context-centre, and flexible.
Intervention content	End-user knowledge driven.	Domain/ theoretical knowledge driven.	Domain/ theoretical knowledge driven.	Domain/theoretical knowledge driven.	End-user and domain/theoretical knowledge driven.	Domain/theoretical knowledge driven.	Domain/ theoretical knowledge driven.
Technology development	UI design and prototype. Focus is placed on developing usable software	Web design and prototype. Focus on developing learning	Multiple technologies. Don't necessary need to use technology.	Multiple technologies and platforms depending on user's needs.	Technology neutral but emphasis on systems	Multiple technologies; mobile phones, web, and sensors	Object oriented and component-based software. Focus on developing software architecture aligned

	aligned with consumer needs.	material and activities.					with domain/theoretical knowledge.
Usability	Emphasis on usability of the EMI for *consumers*.	Emphasis on usability of the EMI for *consumers*.	Emphasis on usability of the EMI for *domain/theory* experts.	Emphasis on usability of the EMI for consumers and *domain/theory* experts.	Emphasis on usability of the EMI for *consumers* and *domain/theory* experts.	Emphasis on usability of the EMI for *consumers* and *domain/theory* experts.	Emphasis on usability of the EMI for *consumers* and *domain/theory* experts.
Project management	Product-centric, and research and development.	Learning content and material development.	Task-based activities, and program development.	Product-centric, and research and development.	Multidisciplinary project management.	Product-centric.	People-centric, leadership and collaborative.
Requirements elicitation	Knowledge upfront; elicited from perspectives of end-users of the EMI (mainly consumers).	Knowledge upfront; requirements focus on learning needs of *consumer* of the EMI.	Knowledge upfront; requirements focus on psychological theory and evidence-based health intervention.	Knowledge upfront; elicited from perspectives of end-users of the EMI (mainly consumers) with theory and evidence-based basis.	Emergent; requirements from multiple stakeholders.	Emergent; start from small requirements and evolving over time.	Emergent; elicited from an existing system or software application, and evidence-based material of expert/ theoretical domain.
Communication	Formal.	Formal.	Formal.	Formal/Informal.	Informal.	Informal	Informal.
Stakeholders	Collaboration between researchers, and consumers	Collaboration between researchers and consumers.	Collaboration between researchers and consumers.	Collaboration between researchers and consumers.	Collaboration between software developers, researchers and consumers.	Collaboration between software developers, and researchers	Collaboration between software developers, researchers, and clinical staff.

Design artifacts	Explicit knowledge; think aloud and retrospective interviews, focus groups and prototype.	Explicit knowledge; pedagogy plan, needs assessments, website prototype.	Explicit knowledge; brainstorming sessions, and needs assessments	Explicit and tacit knowledge; interviews, questionnaires, hand sketches, mockups, and clickable prototypes.	Explicit and tacit knowledge; user requirements, prototype, and business modelling.	Explicit and tacit knowledge; workflow, finite state machine, and prototype.	Tacit knowledge and lightweight; User stories, UML diagrams, wireframes, and prototype.

4.5. Case Study: Prototype Development of an EMI for Social Anxiety

Section 0 presents the results of a case study of the development of an EMI prototype for social anxiety using the development framework proposed in section 4.4. Sections 4.5.1 to 4.5.8 describe the phases 1 to 8 of the development process.

4.5.1. Phase 1: Requirements elicitation for prototype development

In the early stages or phases of development, an experienced software developer (the current author, BLG), a mental health researcher (KMG), and practising clinical psychologists (JR and LP) collaborated to discuss the design constraints of the mobile app software that delivered an EMI for social anxiety. Design constraints were discussed and agreed upon to understand the overall health intervention aims of the EMI. Table 7 provides a summary of ideas for the EMI that were discussed among the mental health researchers and clinical psychologists but not implemented due to barriers that prevented implementation. These discussions also included identifying the boundaries of the problem domain and general requirements of the EMI. These design constraints were used to understand the underlying theoretical strategies underpinning the EMI.

Table 7. A summary of possible ideas for the EMI that were discussed but not implemented due to barriers.

Possible ideas for EMI	Reasons for not implemented due to barriers
Using embedded sensors on a smartphone to track behavior	There was insufficient knowledge about the use of embedded sensors in smartphone, especially using them as part of an EMI for social anxiety. At the time of development, there were not many tools for developers and researchers to acquire these signals specifically for health interventions. The R&D team believed that the tools that were available required more testing, sufficient expertise and knowledge to configure, and sufficient time to invest in development. There were concerns on the battery consumption levels of the smartphone device when all sensors are active on the device, and privacy concerns with passive sensors (Hsieh et al., 2013).
Wireless wearable sensors to track physiological measurements, such as sleep patterns	At the time of development, the R&D team were concerned with the validity of wearables. More research was required to invest in the use of wearables for a standalone EMI for social anxiety. There were particular concerns on issues relating to synchronizing wearables with smartphone or personal computer desktop systems.
Using smartwatches to deliver EMI	At the time of development, smartwatches were expensive. Additionally, the market for smartwatches was small and niche. The tools to develop apps for smartwatches were not mature and not easily accessible

	for developers and researchers. While this appeared attractive for the R&D team at the time, considerable time and investment in the technology was needed to conduct a sufficiently powered study.
Using existing gaming technologies (such as Wii Fit) to encourage physical exercise for people with social anxiety or eating problems	The R&D team believed that gaming technology, such as Wii Fit, needed sufficient expert knowledge to configure the device to meet requirements of the EMI. Therefore, considerable time was needed to invest in the development of the technology to deliver an appropriate EMI for social anxiety.
Using home monitoring cameras to measure the gait of people with anxiety and depression	Cameras installed at the home, work, or other environments can measure the gait of people with social anxiety. This was feasible in smaller lab studies, however developing and implementing the technology for a sufficiently powered study was not feasible.
Using the embedded cameras of smartphone to capture and record photos and videos of a person social anxiety.	Use of embedded smartphone cameras was the most feasible solution to implement for an EMI for social anxiety. Given the limited knowledge of the smartphone app platform at the time of development, the R&D team decided to work on a stable system (using a basic software architecture) before exploring the integration of embedded cameras. This design decision was made to reduce the risk of failing to deliver a functional EMI for the evaluation study.

The R&D team agreed upon some design constraints. First, the EMI must target the reduction of social anxiety symptoms (i.e., clinical aims of the EMI). Second, the content and structure of the EMI must be based on exposure therapy (i.e., the clinical strategy of the EMI), which is an evidence-based treatment for social anxiety (Craske et al., 2014). Third, the EMI must be a standalone health intervention (without therapist support). Forth, the iOS software platform must deliver the EMI on a native mobile app for Apple smartphone devices. Hence, this restricted the development of the EMI to a platform-specific mobile app framework.

During a period of 18 months, the development process continued to guide the development of the iOS mobile app software for the delivery of an EMI for social anxiety. Appendix G presents a timeline of each of the design phases. Sections 4.5.2 to 4.5.8 provide detailed discussions of the remaining design phases used to complete the EMI prototype. The appendices contain the relevant software artifacts produced at each design phase. These software artifacts and diagrams in the appendices provide the detail designs of the EMI through each of the conceptual design phases of the development process.

4.5.1.1. *Key learnings from phase 1*

Phase 1 of the development process allowed space for all stakeholders of the R&D team, such as the software developer, mental health researcher, and clinical psychologists to brainstorm ideas and critically discuss the scope of the project. Many of the ideas discussed were difficult to implement because of technical and resource constraints of the project. An example of a technical constraint included validity issues of wearables, or financial constraints of purchasing expensive mobile devices, such as smartwatches. Phase 1 of the design process assisted the R&D team in narrowing the scope of the project and eliminating any uncertainty of the EMI design. Estimating the feasibility of ideas were difficult in phase 1 (i.e., time to develop) for the R&D team because there were a lot of uncertainties in ideas proposed by different stakeholders. For instance, the software developer with limited knowledge of psychotherapy could not determine the time needed to develop a particular EMI concept proposed by the clinician. Similarly, the researcher and clinical psychologist had limited knowledge of software development process to understand the technical proposals by the software developer. However, some general parameters were agreed upon, which include the technology platform, the support of the therapist, and the clinical strategy. In the subsequent phases of the design process, these parameters became the starting point to formulate and build on the design of the EMI through iterations.

4.5.2. Phase 2: Evidence-based material into user stories

The early phases of the design process involved capturing aspects of the mental model of the domain experts. The domain experts of this project included qualified clinical psychologists (JR, LF, and LP), and a mental health researcher (KMG). The mental model of this EMI was described through a series of user scenarios, or use cases, employing user story modelling techniques. User stories are tools for capturing high-level requirements of a software system (Cohn, 2004). User stories were used to articulate the mental model of the clinical psychologist (i.e., domain expert) administering a given clinical strategy (the theoretical aspect of the EMI) to reduce social anxiety symptoms. In this case, the underlying clinical strategy of this EMI was exposure therapy. In this phase of the process, the goal of the R&D team was to ensure the problem domain of the software for the EMI met the evidence-based theory of exposure therapy. Sections 4.5.2.1 to 4.5.2.3 describe the construction of user stories through the analysis of existing evidence-based material.

4.5.2.1. *The analysis of existing evidence-based material for EMI*

The R&D team adopted bottom-up development principals to elicit requirements of the EMI. The analysis and translation of evidence-based material informed the design of the software structures and functions that delivered the EMI content. Appendix F presents a table of technical features and mobile-related health intervention strategies used in previous studies on EMIs for anxiety and stress. This table was generated from the systematic review in Chapter 3, and was used to inform the initial design of the EMI. Native application libraries and automated sensors were technical features of smartphone that were used for EMIs (Klasnja and Pratt, 2012). Increasing the access to health information was the intervention strategy that was used in all EMIs delivered on a smartphone followed by a mixture of the other intervention strategies, such as tracking health information, involving the healthcare team, leveraging social influence, and using entertainment (Klasnja and Pratt, 2012). Relevant elements were extracted from an existing evidence-based Internet program developed by researchers from eHub at Australian National University (Bennett et al., 2010). The eCouch website (ecouch.anu.edu.au) is a web-based application that delivers CBT material for people with a variety of mental health problems, including social anxiety. The eCouch program contains self-guided modules with psychoeducation material, exercises, and quizzes for practising exposure therapy. Additionally, published self-help treatment manuals on exposure therapy assisted the software developer (BLG) to understand and capture key aspects of the mental model (Bourne, 2005, Antony and Swinson, 2008).

As planned, the eCouch program was only used to inform the design and development of the mobile app's internal structure and logic (or software architecture). The plan was not to re-adapt the entire eCouch program into the mobile app and EMI, however, to use a pre-existing internet intervention as a basis to developing the software architecture of the EMI. Based on the recommendation provided by the mental health researchers and clinicians, the R&D team planned to re-adapted only certain aspects of the eCouch program into the EMI which improved the safe use of the EMI for people with social anxiety. The R&D team adopted two types of re-adaption. *Full re-adaption* involved using eCouch text-based material in the EMI. For example, majority of the instructional content on "what is exposure therapy?" from eCouch was used in the current EMI. *Partial re-adaption* involved minor amounts of the eCouch text-based material and user online

inputs to be used in the EMI, with additional iOS smartphone features added onto the pre-existing structure of these elements. For example, user online inputs that captured a list of safety behaviours from eCouch were used in the current EMI with additional iOS smartphone automated alerts that delivered brief messages delivering brief affective labelling and positive reappraisal strategies. Table 8 provides a product comparison table that compares the features, components and content of eCouch program (social anxiety toolkits), and the EMI for social anxiety (Lee et al., 2012).

Table 8. A product comparison table that compares the features, components, and content of the eCouch program and the EMI for social anxiety (include types of re-adaption of eCouch content used for the EMI).

	EMI for social anxiety	**eCouch program (social anxiety toolkits)**
Pyschoeducation	• What is exposure therapy?* • How graded exposure works?* • Why exposure therapy works.* • Tips before starting exposure practice.* • Rehearsal and roleplay.* • Stepping up exposure practice.* • Evidence on exposure therapy?	• Social anxiety armchair (psychoeducation on social anxiety disorders). • What is exposure?* • How graded exposure works?* • Why exposure therapy works.* • Tips before starting exposure practice.* • Rehearsal and roleplay.* • Stepping up exposure practice.*
Treatment planning exercises	• Identify my situations (fears) with automated smartphone-based alerts for anchoring situations. ** • Identify my reaction to fears with automated smartphone-based alerts for affective labelling and positive reappraisal. 1) Safety behaviours. ** 2) Physical sensation. • Identify unhelpful thoughts with automated smartphone-based alerts for affective labelling and positive reappraisal (not cognitive restructuring). • Relaxation exercise. • Breathing control exercise.* • Self-coaching strategy.	• Identify my situations (fears). ** • Identify my safety behaviors. ** • Modifying your thinking exercise (cognitive restructuring). • Relaxation exercise. 1) Breathing control exercise.* • Attention practice exercise. • Social skill training.

	1) Share coping statement with friends using SMS, social media, or email on the smartphone. • Regulate emotions during exposure. • Building a exposure plan (fear hierarchy). 1) Schedule smartphone reminders for exposure practice.	
Self-monitoring and exposure practice exercise	• In-situ exposure practice and automated monitoring. 1) Smartphone-based alerts for challenging situations. 2) Momentary smartphone-based assessments and alerts for Subjective Unit of Distress (SUD), situation, coping strategy, and safety behaviours. ** 3) Smartphone-based alerts for inhibitory learning exercises and feedback. 4) Reward system for in-situ exposure practice. 5) Smartphone-based alerts for in-situ stepping exposure practice. **	• Internet-based 6 steps exposure practice. 1) Internet-based assessments for Subjective Unit of Distress (SUD), situation, coping strategy, and safety behaviours. ** 2) Stepping up exposure practice exercises. ** • Internet-based assessment and monitoring. 1) Depression and Anxiety Quiz. 2) Quiz Feedback. 3) Social Phobia Inventory (SPIN). 4) SPIN feedback.

Note: *=EMI content *fully* re-adapted from eCouch, **=EMI content *partially* re-adapted from eCouch

Key aspects of the mental model requiring consideration included the way a clinical psychologist administered exposure therapy, mental health consumers doing exposure therapy, and mental health researchers evaluating the effects of exposure therapy. Throughout this phase of design, the clinical psychologist (JR and LF) and mental health researcher (KMG) provided informal advice through the analysis and translation of the evidence-based material. Specifically, the clinical psychologist provided the software developer (BLG) clarity and insight to certain clinical concepts of exposure therapy to produce high-quality translations of appropriate software design of the EMI. The analysis of evidence-based material on exposure therapy produced a series of user stories. The software developer utilised user stories to demonstrate to the clinical psychologist and mental health researcher the operations of the EMI in reducing anxiety symptoms of a mental health consumer.

4.5.2.2. *Employing user stories to analyse evidence-based material for EMI*

The software developer used user stories to design the overall exposure therapy *logic* of the EMI for social anxiety from the perspective of the domain expert. Specifically, they used user stories to capture the high-level *steps* and *role* of a person doing exposure therapy in the context of treating their social anxiety symptoms. Additionally, the software developer used the user stories of the EMI to make the initial key design decisions on aspects of the software architecture of the iOS mobile app. For instance, user stories were used to extract software architectural elements from "*nouns and nouns phrases"*, and processes and constraints from "*verbs and attributes"* identified from the "informal English descriptions" of the underlying treatment protocol of exposure therapy prescribed in the evidence-based material (Abbott, 1983). For example, common nouns of exposure therapy included elements such as "consumer", "workbook", and "exercises". Furthermore, the software developer extracted common verbs such as "read" and "learn*"* that described the operations of the treatment protocol of exposure therapy and included verbs in the user stories.

Figure 8 presents an example of the analysis and extraction of the verb and noun elements from eCouch. The software developer used the analysis of the eCouch program via user stories to develop the initial version of the EMI software model for social anxiety.

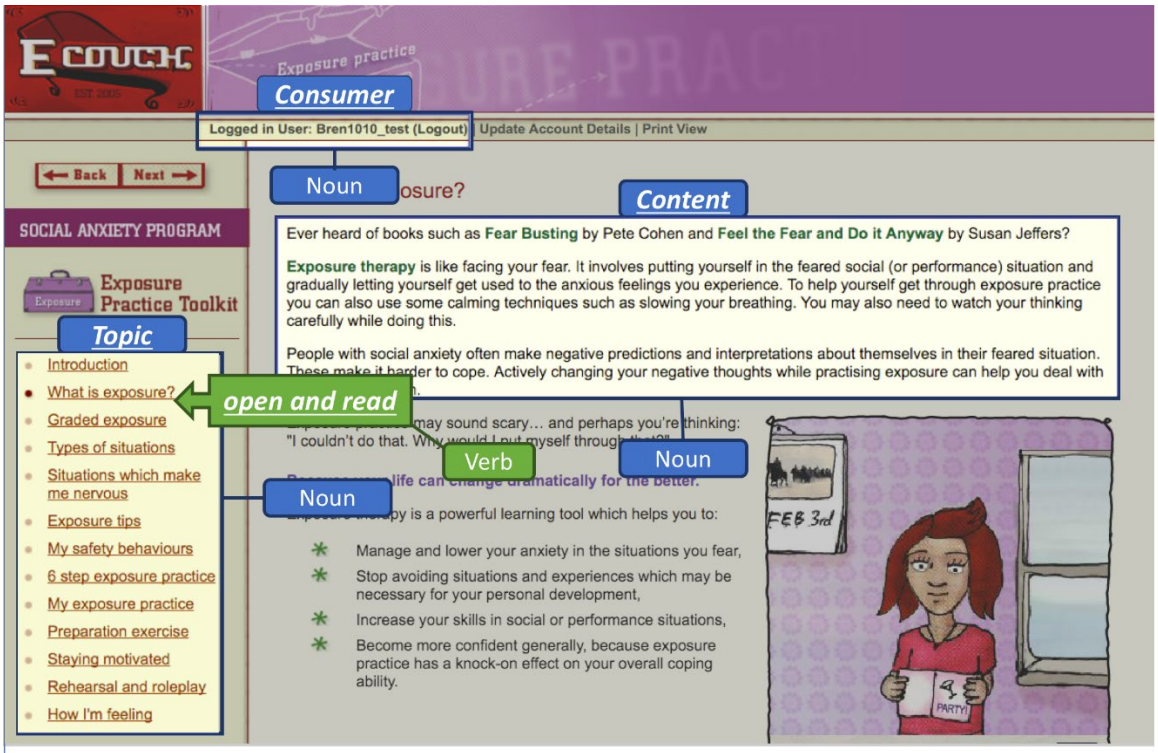


Figure 8. An example of analysis and extraction of verbs and nouns from the eCouch program

The Connextra user story template employed in personas created an understanding of the *role*, *goals*, and *benefits* in the practice of exposure therapy to reducing social anxiety symptoms (Hudson, 2013). Personas created concrete examples of factitious end-user using the EMI for reducing their social anxiety. For example, a persona could be the name of a consumer, such as "Jerry", and their identification number, "123". Figure 9 describes the user story templates used in the development process:

User Scenarios Description: A description of the task that a user will perform to achieve a particular goal in the system
As a: [User Role] **called/named/represented**: [User] The [User Role] is the label of the user who is performing the given user scenarios The [User] is the description of the label that represents the user
List of steps/tasks to achieve the given user scenarios **Step 1 Description:** Describe the step/task of the step to perform. Highlight common [Verbs] in red and underline all common [Nouns] in the descriptions of each step. [Screenshot of user interface]. A screenshot can be provided to illustrate the given step. **Step 2:** **Step 3:** **…**
Benefits of the given user scenarios (optional) You can optionally provide the benefits of "why" the user wants to achieve this user scenario. Benefit section was not included in this project because the software developer (BLG) had prior knowledge of these steps.

Figure 9. User story templates used in the development process of the EMI for social anxiety

The user story template shown in Figure 9 was employed to capture the high-level requirements of the system. Five user stories (with personas) constructed the high-level software architectural structures of the EMI for social anxiety. Table 9 presents the description of the user stories used for the EMI for social anxiety, and the appendices containing each of the user stories.

Table 9. Description of user stories used for the EMI for social anxiety with related appendices.

User Stories	Description	Appendix
Exposure Practice Steps	This user story encapsulates the individual steps of exposure therapy.	**H.1**
Learn about Exposure Practice	This user story encapsulates psychoeducation, text-based material related to exposure therapy.	**H.2**
Identify my Social Anxieties	This user story encapsulates instructions on how to monitor challenging social situations, reactions to fears, and unhelpful thought patterns during a challenging situation. The EMI mobile app contained some of the material of the eCouch program.	**H.3**
Get ready for Exposure Practice	This user story is comprised of brief exercises to allow users to; learn about and practice self-coping and emotional regulation techniques; rehearse exercises; and schedule exposure practice. The EMI mobile app contained some of the material of the eCouch program.	**H.4**
Perform Exposure Now	This user story contains step-by-step instructions on how to conduct exposure in real situations.	**H.5**

4.5.2.3. *Key learnings from phase 2*

During phase 2, the clinical psychologists provided clinical input in the early designs of the prototype. The clinical psychologists and researcher engaged more in phase 2 than subsequent phases of the design process because they better understood the design artifacts of phase 2 than artifacts in later phases of the process. The language used in the user stories were simple and clear for the clinical psychologist to understand design decisions made by the software developer. Furthermore, the software developer gained further insights on exposure therapy from the clinical psychologists via the use of the user stories. Annotated comments in a word document containing the user stories provided contextual information on complex structures of the EMI. For example, annotated notes described the clinical concept of "anchoring" to software developers when the R&D team began designing the fear hierarchy process of the EMI. The annotated comments provided in the user stories allowed the software developer to reflect and understand the clinical concepts and re-examine the EMI design before making further changes to the EMI design for the clinical psychologist to re-review. Phase 3 of the development process was to

transform these user stories into UML activity diagrams. UML activity diagrams can represent the flow and control of activities and actions of exposure therapy or EMI processes.

4.5.3. Phase 3: User stories into UML activity diagrams

This design phase aimed to understand the underlying exposure therapy protocol of the EMI. This design phase allowed the software developer (BLG) to focus on making clear to all stakeholders of the R&D team the flow of therapeutic activities involved in exposure therapy in the EMI. Specifically, the software developer (BLG) used UML activity diagrams to communicate the logical processes of exposure therapy of the EMI to non-technical stakeholders of the R&D team, such as the clinical psychologists (JR, LF, and LP) and the mental health researcher (KMG). Section 4.5.3.1 to 4.5.3.3 describes the transformation of user stories into UML activity diagrams with the relevant examples.

4.5.3.1. *Transformation of user stories into activity diagrams for EMI*

The software developer transformed the user stories developed in phase 2 into the appropriate UML activity diagrams. It involved transforming scenarios and steps described in the user stories into activities and actions described in the UML activity diagrams. For each scenario or step in the user stories, an associated activity or action was relatively modelled in the related UML activity diagrams. When possible, particular steps in the user stories were decomposed into a finer series of activities or actions in the UML activity diagrams. The breakdown of an individual step of a therapy process described in the user stories reduced the complexity of a therapy process making it easier for stakeholders of the R&D team to understand the therapy process.

4.5.3.2. *Example of developing UML activity diagrams for EMI*

A single UML activity diagram was used to describe a set of actions that aimed to achieve a particular goal of exposure therapy. For example, actions included 1) learning about planning how to conduct exposure practice, 2) recording a plan to conduct exposure practice, and 3) finding a challenging situation to the planned practice exposure. In most cases, the UML activity diagram contained the logical flow and decisions of actions of exposure therapy. Common nouns identified in the user stories were used in the

descriptions of the activities and actions used in a UML activity diagram. For example, nouns included “consumer” and “instruction” which were described in the user stories. Nouns were modelled as a description of the actions in the UML activity diagrams, such as “consumer read and open instruction”. Similarly, common verbs described in the user stories were modelled into the control flow and decision of actions in the UML activity diagrams. For example, common verbs included “choose”, “read”, and “open”. An example of these verbs was used in the user stories to describe a behaviour of a person learning about exposure therapy described in a UML activity diagram. Appendix I provides a description and name of the UML activity diagram notation used for the modelling of this EMI for social anxiety.

Appendix J presents the UML activity diagram that represents all of the high-level steps to achieve exposure practice for the proposed EMI for social anxiety. For each activity or step represented in Appendix J, Appendix J.1 to J.4 represents the UML activity diagrams that represent the activities and actions relating to; learning about exposure therapy (Appendix J.1), identifying a person’s social anxiety (Appendix J.2), preparing a person to get ready to practice exposure practice (Appendix J.3), and encouraging a person to do exposure therapy in a real challenging situation (Appendix J.4). These diagrams or software artifact formed the basis for the next phases of development.

4.5.3.3. *Key learnings from phase 3*

In phase 3 of the development process, the mental health researcher (KMG) provided further clarity on the EMI design. Particularly, the mental health researcher gave clarity to larger and complex UML activity diagrams during the review of diagrams with researchers. Indeed, software developers inserted the “Note” UML notation to provide contextual information on segments of the diagram that contained complex logic and multiple decision nodes. The mental health researcher found the UML activity diagrams easy to understand because of its similarities to flowcharts. In particular, the mental health researchers and clinical psychologists ease of understanding of the activity diagrams allowed the mental health researchers to propose changes to the EMI design. This feedback from the domain experts assisted the software developer in detecting changes and improving the clarity to the EMI design early in the process, especially before implementing the software components of the EMI. Phase 4 of the design process was to

transform the following UML activity diagrams into UML object diagrams. Object diagrams represented the structure, values, and relation of data and information used in exposure therapy.

4.5.4. Phase 4: UML activity diagrams into UML object diagrams

At this design phase of the development process, the rationale was to understand the structure and relationships of data (and information) used to deliver exposure therapy. The software developer (BLG) began to examine the static structure of information of the iOS mobile app that delivered the EMI for social anxiety. A series of UML object diagrams were produced to *partially* represent the data *structures*, *values,* and *relationships* of exposure therapy prescribed in the EMI software. Partial representation included concrete values of data and information used in the EMI for social anxiety. The software developer extracted concrete values from personas formulated in the user stories identified in phase 1 of the development process. The transformation of the UML activity diagrams (and aspects of the user stories) into UML object diagrams are described below with examples.

4.5.4.1. *Transformation of activity diagram into object diagrams for EMI*

The transformation of the UML activity diagrams into UML object diagrams involved the transforming nouns described in the activities and actions described in the UML activity diagrams into objects described in the UML object diagrams. Specific nouns are names of objects. These types of nouns described in the user story were transformed into the properties of objects represented in the UML object diagrams. Properties included descriptions such as the name of a therapy object. For each noun identified in the activity diagrams (and user story), an associated object was modelled in the related UML object diagrams. Similarly, flows and decisions described in the UML activity diagrams were transformed into associations or relationships of objects in the UML object diagram.

4.5.4.2. *Example of developing UML object diagrams for EMI*

A UML object diagram contains objects (or elements) of an EMI required to achieve a therapy process or goal of exposure therapy. For example, objects in an exposure therapy workflow can include elements, such as “consumer” and “exercise”. Furthermore, objects described in a UML object diagram can pertain to properties that describe characteristics

of an object. For instances, a “consumer” or “exercise” object can pertain to particular properties, such as “name”. Specific values were assigned to each of these properties. For instance, the value “Jerry” was assigned to the “name” of the “consumer“ object, or the value “breathing exercise” can be assigned to the “name” of an “exercise” object. These values were directly modelled into these partial structures represented in the UML object diagrams to understand emerging repeated patterns or architectural styles within the exposure therapy model.

Furthermore, a UML object diagram contains the association of different objects of an EMI. These associations are important in describing the relationship of objects, and the operations of a therapy workflow. For example, associations in an exposure therapy process can include operations, such as “open” or “read”. In an object diagram, an association of an object can be modelled multiple times between two different objects. For example, a specific consumer object with the name “Jerry” can “choose” a specific manual object with the title “Exposure Therapy”. Furthermore, a consumer object called “Jerry” can also “choose” another specific manual object with the title “Cognitive Restructuring”. While the manual objects may have separate titles, a single consumer will choose either one or the other, or both, of the manual objects. These associations are essential to articulate the relationships between different individual objects or elements of exposure therapy for a specific therapy process. Appendix K provides a description and name of the UML object diagram notation used for the modelling of this EMI for social anxiety.

Appendix L presents the UML object diagrams that represent the high-level steps to achieve exposure practice for the proposed EMI for social anxiety. Furthermore, Appendix L.1 to L.4 represents the UML object diagrams that represent the activities and actions relating to; learning about exposure therapy (Appendix L.1), identifying a person’s social anxiety (Appendix L.2), preparing a person to get ready to practice exposure practice (Appendix L.3), and encouraging a person to do exposure therapy in a real challenging situation (Appendix L.4). These diagrams formed the basis for the next phases of development.

4.5.4.3. *Key learnings from phase 4*

The software developer was more engaged in phase 4 than the mental health researchers and clinical psychologists. In particular, the software developer used the UML object

diagrams to construct the specifications of the software components based on translations of concepts in the user stories and UML activity diagrams. Indeed, the UML object diagrams appeared to be difficult for the mental health researcher and psychologist to understand. Many objects and associations overloaded one or more UML objects diagrams which made the diagrams large and complex to understand for domain experts. The diagrams occasionally confused and overwhelmed the researchers and psychologists. The software developer found a way to overcome this problem by extracting segments of the UML object diagram and present only relevant elements that expressed a particular EMI feature or function. Additionally, the software developer inserted notes that described the links between parts of a UML object diagram and parts of the UML activity diagram. Phase 5 of the design process was to transform these UML object diagrams into UML class diagrams. Class diagrams are next steps to implementing the design of the EMI directly on to a technology platform.

4.5.5. Phase 5: UML object diagrams into UML class diagrams

This phase of development aimed to formulate abstract structures and behaviours of the iOS mobile app delivering the EMI for social anxiety. This design phase involved the software developer (BLG) producing a series of UML class diagrams that represented groups of one or more common therapy objects. While UML class diagrams represent the full representation of objects in exposure therapy, these diagrams do not represent specific implementation details or concrete values of those objects. For example, this could include the specific name of a single consumer, or the specific title of a single manual object. By hiding these values or details, the software developer can focus on the design of software implementation, or programming code, of an iOS mobile app of the EMI.

There is a number of clear distinctions between UML object diagrams (described in section 4.5.4) and UML class diagrams (described in the following section 4.5.5). First, UML classes are *groups* of different UML objects. For example, a UML class for "consumer" can represent a group of unique UML objects, such as "Jerry", "Annie", and others. Second, the relationship of UML classes with other UML classes contains more *contextual* information compared to the relationship of UML objects with other UML objects. For example, the relationship of a UML object called "Jerry the Consumer" and UML object called "Workbook for Exposure Therapy" can include *contextual* information that

describes the type of relationship (i.e., "Jerry choose the Workbook for Exposure Therapy"). However, the relationship of a UML class for "consumer" and UML class for "workbook" can include *contextual* information on the relationship type (i.e., "consumer choose the workbook"), the number of times the relationship occurs (i.e., "consumer choose 1 or 3 workbooks"), and the conditions of a relationship (i.e., "consumer can only choose 1 workbook but not 3"). UML classes simplify the relationships of UML objects by aggregating them and including more meta information on those relationships. The transformation of the UML object diagrams into UML class diagrams are described below with examples.

4.5.5.1. *Transformation of object diagrams into class diagrams for EMI*

The software developer transformed the objects in UML object diagrams into classes modelled in UML class diagrams. Groups of common objects or concepts that are modelled in UML object diagrams were transformed into distinct classes in UML class diagrams. While UML objects were grouped into UML classes, the associations of similar objects in UML object diagrams were transformed into a single *aggregated* class association in UML class diagrams. Furthermore, the occurrence of the associations of similar objects in UML object diagrams was transformed into specific rules for classes in UML class diagrams.

4.5.5.2. *Example of developing UML class diagrams for EMI*

A UML class diagram represents classes of objects used in EMI to achieve a goal or process in exposure therapy. Classes represent groups of exposure therapy objects with similar or overlapping data properties and types, such as the "name" of consumer or the "type" of exercise. For example, a particular consumer object with the name "Jerry" may be separately associated with two psychological exercise objects. One of the exercise objects can be of a type of "Breathing Exercise" whereby the other exercise object can be a type of "Roleplay Exercise". Given the objects representing the two exercise objects carry similar data types (but distinct data values), these objects can be grouped into one single class. Therefore, a group of exercise objects can be transformed into a single class called "Therapy Exercise". Similarly, a group or a single consumer object, such as "Jerry", can be transformed into a single class called "Consumer".

Conversely, the *aggregated* association of classes in a UML diagram represents the associations of similar objects of an EMI or exposure therapy process. For instance, a class called "Consumer" can have an aggregated association called "learn" with a class called "Therapy Exercise". The association can be elaborated by applying specific rules between the "Consumer" and "Therapy Exercise" classes. These rules can be modelled into a UML class diagram for an EMI process using specific modelling notation rules. For example, a consumer may only be able to "learn" one or more psychological exercises for their social anxiety at a given time. Furthermore, a consumer must be doing exposure therapy to "learn" a psychological exercise for their social anxiety. Appendix M provides a description and name of the UML class diagram notation used for the modelling of this EMI for social anxiety.

Appendix N presents the class diagrams that represent the high-level steps to achieve exposure practice for the proposed EMI for social anxiety. Furthermore, Appendix N.1 to N.4 presents the class diagrams that represent the data structure and functions relating to; learning about exposure therapy (Appendix N.1), identifying a person's social anxiety (Appendix N.2), preparing a person to get ready to practice exposure practice (Appendix N.3), and encouraging a person to do exposure therapy in a real challenging situation (Appendix N.4). These diagrams formed the basis to the next stages/phases of development.

4.5.5.3. *Key learnings from phase 5*

Similar to phase 4, the software developer engaged more with the phase 5 part of the design process than the mental health researchers and clinical psychologists. Similar to UML object diagrams, the UML class diagrams were difficult for the researcher and psychologist to comprehend. While smaller UML class diagrams (such as learning about exposure therapy) were easier to understand than larger UML class diagrams (such as preparing for exposure practice), the software developer still found it difficult for the researcher and psychologist to understand UML class diagrams. However, the UML class diagrams simplified the UML object diagrams for the software developer. The software developer was able to directly construct the software components of the EMI from details outlined in the UML diagram. While these diagrams may be idiosyncratic to the software developer, they were useful software artifacts to reflect on the software architectural

elements of the EMI design, to isolate concerns, and to make the EMI more *modular*. Phase 6 of the development process was the beginning phase of transforming the design of the EMI from the development of a model into implementable programming code.

4.5.6. Phase 6: UML class diagrams into programming code

This design phase aimed to implement the iOS mobile app modules based on UML class diagrams. This phase of development consisted of design activities that translated formal models into programming code which implemented the domain model of the software for the EMI. A *domain model* is a type of software model that represents the level of the software that contains *domain-specific* elements of the underlying problem domain (i.e., the therapeutic elements of the EMI) (Evermann and Wand, 2005, Lotz et al., 2010). The domain model of a software application is separate from the underlying technical parts of the mobile app software platform (i.e., the operating system libraries to display a message box) (Brown, 1998, Lotz et al., 2010). The software developer (BLG) interpreted the UML class diagrams and directly implemented the classes and functions of the EMI into the IDE. As a result of this translation process, the software developer transformed the conceptual model into implementable programming code.

4.5.6.1. *Transforming UML Class Diagrams into implementable code*

The software developer used a programming environment, or IDE, to implement the system or mobile app for the EMI. Depending on the type of mobile app implementation, the programming code is implemented to execute the mobile app on a specific operating system platform, such as iOS. This project delivered a mobile app whereby the Objective-c programming code was developed using XCode IDE to implement the mobile app that delivered the EMI for social anxiety. The programming code of the iOS mobile app was intended to reflect all aspects, and features of the EMI captured in the user stories, UML activity diagram, UML object diagram, and UML class diagrams. In particular, the UML class diagram was the closest representation of the programming code and software implementation.

4.5.6.2. *Example of implementing the domain of EMI*

A UML class diagram, such as exposure practice steps (Appendix O), was used to begin the implementation of the programming code. For each of the class in the UML class diagram, an objective-c class was created in XCode IDE. For instance, a "Consumer" class in the UML class diagram was directly translated into an objective-c class name called "Consumer" with the appropriate objective-c header and implementation file in XCode IDE. Furthermore, for each aggregated association between two classes in the UML class diagram, an objective-c class method was implemented in XCode IDE. For instance, in the UML class diagram, a "Consumer" UML class may have an association called "learn exercise" with an "Exercise" class. Therefore, the "Consumer" objective-c class will have an objective-c class method called "learnExercise()" with a direct method call to the "Exercise" objective-c class.

This phase of development completed the conceptual design of the iOS mobile app of the EMI. The next phase of the development process required the implementation of the back-end of the iOS mobile app. The back-end development required the development of functionality relating to data access layer of the iOS mobile app.

4.5.6.3. *Key learnings from phase 6*

In phase 6 of the design process, the software developer was able to write programming code that directly reflects the UML class diagrams developed in phase 5. The software developer found the UML class diagrams useful in guiding the construction of multiple objective-c classes of the EMI. Hence, the programming code of the EMI became modular during this phase of the design process, which made the EMI design more easy to modify in the subsequent phases of the process. In particular, the software developer found the UML class diagrams useful when the clinical psychologists introduced changes at later phases of the development process.

4.5.7. Phase 7: UML sequence diagrams for the back-end and data storage

This design phase of development aimed to separate the development of the domain model of the iOS mobile app from the development of the back-end software components. *Back-end development* is usually referred to layers of software relating to the data services of a software system (Sharma et al., 2015). Back-end development in EMIs involves the

specific implementation (or programming code) relating to persistent data storage of an EMI. For instance, the mobile app contained iOS-specific functionality that provided features that allowed data of a person's anxiety symptoms to be serialised into various data storages on the device, such as Core Data and SQLite a DataBase Management Systems (DBMS) (Liu et al., 2011). One of the reasons for constructing the domain model of the EMI was to develop the therapy treatment protocol into the iOS mobile app, thus distilling the programming code of the therapy treatment from other parts of the system (Brown, 1998, Lotz et al., 2010). Furthermore, a clear domain model represented a decomposition of elements of the therapy treatment protocol whereby customisation of the iOS mobile app may be applied to tailor parts of the EMI.

4.5.7.1. *Employing UML sequence diagrams*

Appendix O presents the UML class diagram of the data access layer for the iOS mobile app delivering an EMI for social anxiety. The UML sequence diagrams are not included in this thesis because these diagrams were not used in the design process with the domain experts. During this phase of development, the software developer (BLG) developed a series of UML sequence diagrams. The software developer used sequence diagrams to design the communication of data between the domain model and data layers. Using the iOS Core Data programming libraries, a set of objective-c classes and methods were constructed to handle the persistent storage of information on the mobile device. A similar study has suggested the mobile app of an EMI should store data on the device, then the data on the device should sync to a remote web server when an Internet connection is available to avoid data loss (Burke et al., 2017). Objective-c classes and methods implemented the data access layer wrapped in classes separate from the classes of the domain model. Furthermore, a series of programming interfaces was developed and integrated with the iOS mobile app that managed the user access logs of the iOS mobile app. PHP with a MySQL DBMS provided the web service backend system of the EMI. Overall, the development of the back-end system on the device and web service took 6 months to develop and test. BLG developed the mobile device backend, and AR developed the web service backend with the integration of the system with the iOS mobile app assisted by BLG.

4.5.7.2. *Key learnings from phase 7*

Phase 7 of the design process was one of the longest phases of the design process compared to other phases (approximately 5-6 months). Particularly, the software developer found it difficult at times to maintain the integrity of the domain model while adding new code that stored and sync data with the back-end of the mobile device and the web server. The two software developers (BLG and AR) used the UML sequence diagrams to communicate with each other in coordinating the development of the back-end of the EMI. Although the mental health researcher and clinical psychologist were not involved in this phase of the design process, they were regularly updated on the progress to ensure the project was on schedule.

4.5.8. Phase 8: UI wireframes for the front-end and User Interface (UI)

During this phase of development, the R&D team refined the design of the User Interface (UI) for the iOS mobile app of the EMI. The software developer developed the front-end software components and the programming code for the UI separate from the implementation of the domain model and back-end software components. *Front-end development* is usually referred to layers of the software relating to the User Interface of a software system (Sharma et al., 2015). In the context of EMIs, front-end development involves the specific implementation of mobile app screen(s) or embedded device sensors that capture the user interactions engaged with an EMI. Front-end software components contain programming code that depends on the iOS-specific functionality of the UI of the mobile device, such as iOS UIKit programming libraries (Liu et al., 2011). This phase of development aimed to implement the front-end of the iOS mobile app with the intention to refine the information architecture of the iOS mobile app. A series of UI wireframe documents were produced to communicate the design of the iOS mobile app to a qualified clinical psychologist with interest in mobile apps in clinical practice.

4.5.8.1. *Employing UI wireframes to design the front-end and User Interface (UI)*

The software developer (BLG) developed a series of UI wireframe diagrams. The UI wireframe diagram was used to design the flow of the mobile app screens for the iOS mobile app delivering the EMI. Additionally, the UI wireframe was used to design the

layout of psychological material and buttons on the mobile app screens. The modelling language notation of UI wireframes provided a visual representation of the EMI design. The software developer used the Pencil (GUI prototype tool) to express aspects of the conceptual design and front-end aspects of the EMI mobile app to the domain experts, such as the clinical psychologist and researchers. The UI wireframe diagrams created by the Pencil tool were placed in a single word document to record feedback from the clinical psychologists regarding changes to the prototype design via walkthroughs of the EMI features.

4.5.8.2. *Conducting walkthrough sessions with domain experts*

Over the course of 1-2 months, a series of 1-hour video conference sessions were undertaken with BLG and LP to review the iOS mobile app content. LP is a qualified clinical psychologist with experience of integrating information technology into clinical practice. The aim of these sessions was to ensure the therapeutic content designed on the iOS mobile app were of high quality and safe to use (Light et al., 2016). Each session involved an extensive walkthrough of the UI wireframe document with a simulation of the prototype of the iOS mobile app. Feedback and proposed modifications of the design were recorded on the UI wireframe document and recorded on digital video file via a recording software. Some of the proposed changes include changes to the psychoeducation content on exposure therapy, changes to the information structures displayed on each iOS mobile app screen, changes to the flow of iOS mobile app screens, and changes to the content displayed on messages prompted to the user during the course of exposure therapy. Figure 10 presents a set of screenshots of the videos conferences conducted with LP.

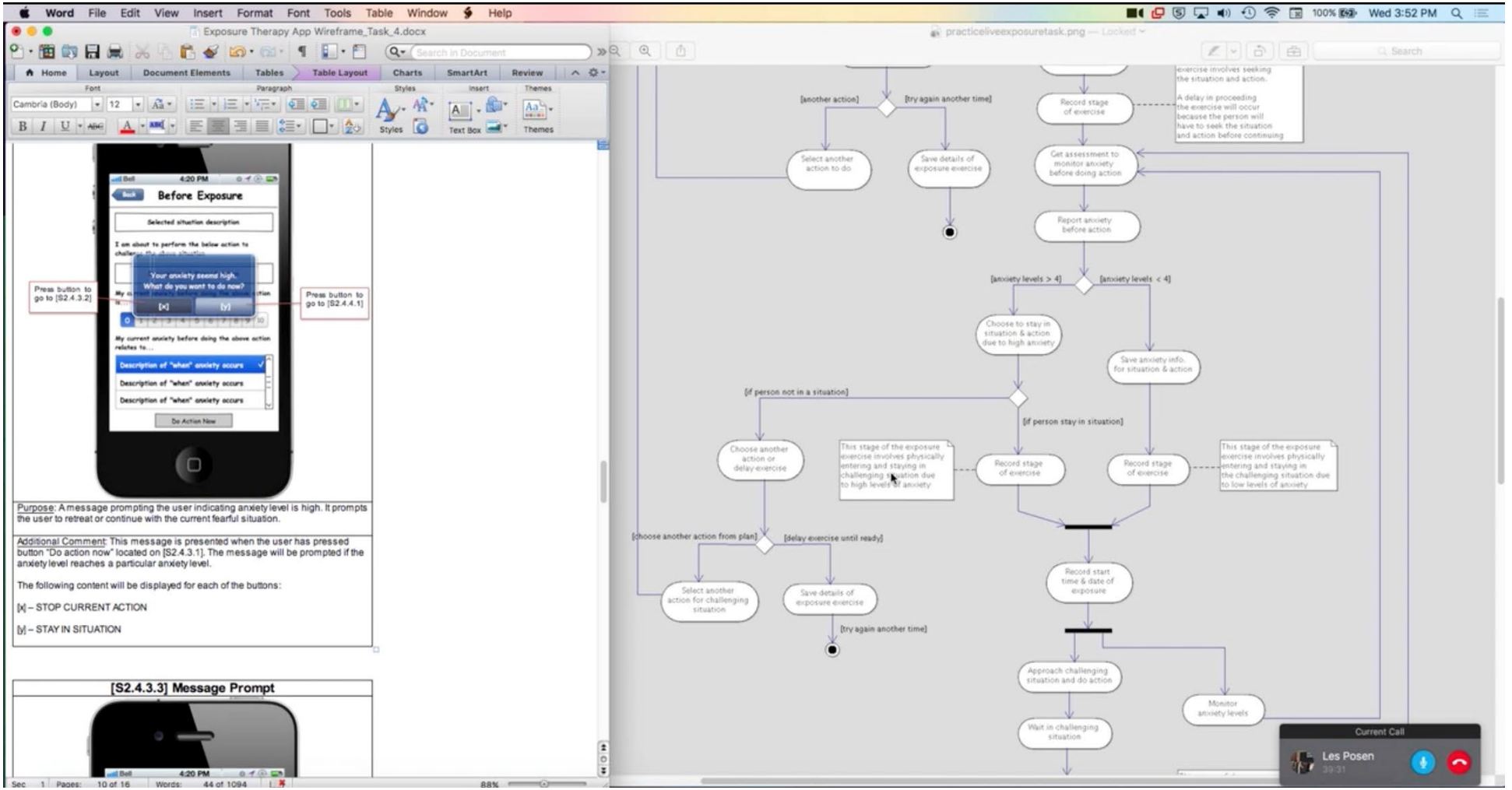


Figure 10. Screenshot of video conference with the clinical psychologist (LP)

4.5.8.3. *Refinement of usability design of EMI*

Another course of 1-2 months was used to refine the usability of the UI for an iOS mobile app delivering an EMI for social anxiety. Changes to the font, colour icons and animation were applied in the final version of the mobile app with input from KMG, PB, AG, and DK. Many of these programming changes were completed on the presentation layer of the iOS mobile app. Studies on the effects of the colour of website on mood, memory, and readability found the use of chromatic colours, such as green and yellow hues, for the background and foreground supported memorising website content compared to a website with achromatic colours (Pelet and Papadopoulou, 2012). In this instance, the UI of the EMI mobile app used green and blue as the main colour scheme for the entire mobile app. Moreover, a study by Hall and Hanna (2004) found that greater contrast in colour ratio in text and background lead to the greater readability of content on an educational website. Similar findings were found on mobile websites (Pelet and Taieb, 2016). Hence, we applied the above principals by using a darker green colour on the text and toolbar buttons over a lighter green background on the mobile app navigation toolbar. Furthermore, this same colour principal was applied to the text of the main psychoeducation content presented in each of the therapy modules of the iOS mobile app. Similarly, white was applied to the text and toolbar buttons over a dark blue background on the iOS mobile app navigation toolbar. Figure 11 presents the iOS mobile app screens demonstrating colour usability principles.

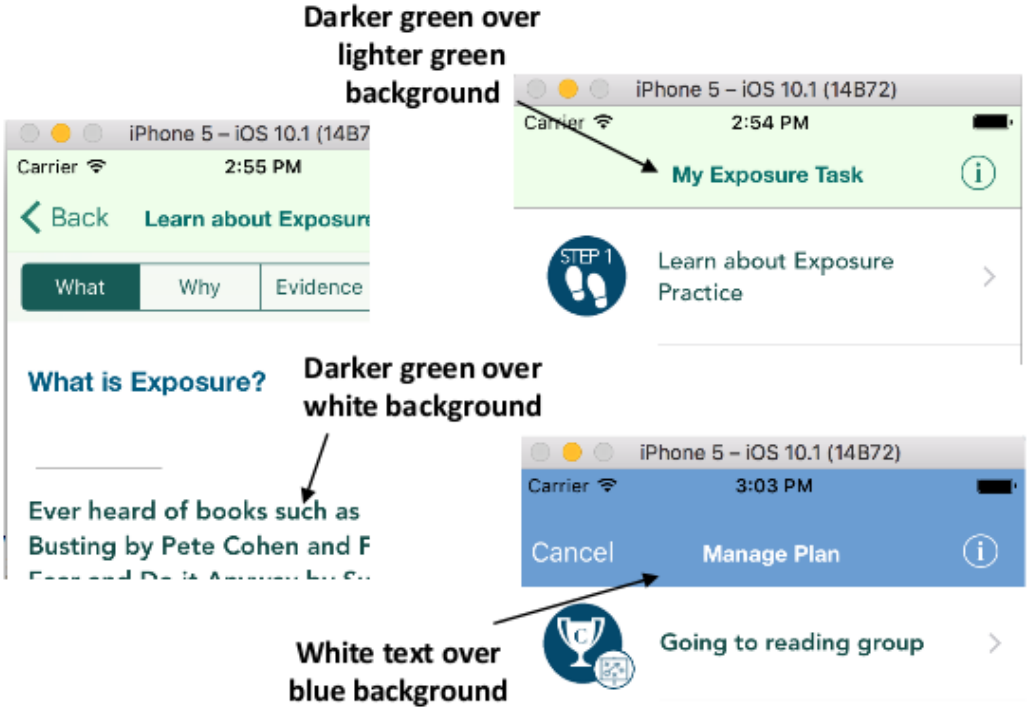


Figure 11. iOS mobile app screens demonstrating colour usability principals for EMI

High colour contrast between the text, background, and other UI components was one of the main usability principals suggested in literature reviews of mHealth usability studies and mHealth mobile apps (Zapata et al., 2015, Franklin and Myneni, 2018, Morey et al., 2017). Further changes to the usability of the mobile app delivering the EMI were also applied to improve usability, accessibility, and consumer engagement (Franklin and Myneni, 2018). In particular, usability is a key factor in the adoption of mHealth applications, especially among end-user who may have limited experience using mobile technologies (Morey et al., 2017). For example, the R&D team carefully applied and tested various *font sizes* for the EMI psychotherapy content presented on the iOS mobile app based on the Apple Human Interface Guidelines (Apple, 2018b). This particular usability design principal is consistent with usability studies of mHealth apps that improved *understandability* of mobile app content (based on ISO9126-1 quality model of usability), and with many existing mHealth apps for older people (Zapata et al., 2015). Furthermore, attempts were made to improve the *learnability* of the mobile app (based on ISO9126-1 quality model) (Zapata et al., 2015). For instance, help/documentation and 'tips' to use the

mobile app for social anxiety were included on most screens of the EMI to provide extra guidance for people to use the EMI for their social anxiety.

Other usability features were also considered in the EMI design to improve *understandability* and *operability* (based on ISO9126-1 quality model), such as using consistent navigation and easy management of navigation (Zapata et al., 2015). For example, a main menu was implemented to guide the end-user to practice each of the individual therapeutic components of the EMI, 'pop up' menus were designed and implemented to provide consistent and easy management of planning exercises for exposure practice, and large icons and buttons were used to improve the operability of the EMI. Icons and some custom-made images used in the EMI that were carefully designed and chosen based on the Apple Human Interface Guidelines for iOS mobile apps (Apple, 2018a). These guidelines are used to *standardise* the 'look and feel' of iOS mobile apps. Given the shortfall in graphic design skills, the R&D team could not invest in improving *attractiveness* which is an usability criteria of the ISO9126-1 quality model, however, other criteria from the quality model were mostly addressed during the development of the EMI (Zapata et al., 2015).

4.5.8.4. *Key learnings from phase 8*

In phase 8 of this development process, the emphasis of development was on the UI of the mobile app. The software developer and mental health researchers, and clinical psychologists engaged most in this phase of the design process compared to other phases of the process. This may have been due to the emphasis on the development of the UI and improvements on the exposure therapy content of the EMI, especially, the walkthrough sessions with the clinical psychologist using the UI wireframe tools. During the walkthrough sessions, the software developer inserted annotated comments in a word document containing the UI wireframes while talking to the clinical psychologist in Skype teleconference sessions. These comments were mainly focused on the wording of the content, such as the instructional text-based material about exposure therapy. There was less focus on actual mobile app structure; however, the clinical psychologists did make suggestions to changes to aspects of the mobile app structure during this phase of the process. In some cases, the UML activity, object, and class diagrams from phase 2 to 6 were repeated again to make the necessary changes to parts of the EMI model. In hindsight,

these changes took longer than expected which extended the time frames of the development of the EMI. Phase 8 was by far the longest phase of this development process which took approximately 7-8 months to complete. Especially during the last 2-3 months of phase 8, the R&D team felt there appeared to be a "sprint" to rapidly ship the EMI mobile app to the user and to test the EMI on the target users (Noordman et al., 2017).

The limited resources and time available to the R&D team at the time of development led to the inability to conduct usability testing with end-users of the EMI (i.e. mental health consumers). Usability testing is a critical factor in the development of eHealth programs and interventions (van Gemert-Pijnen et al., 2011, Lilford et al., 2009). In particular, these evaluation approaches are able to gain insight on usability factors relating to the end-user environment, and other sociocognitive aspects of the EMI. The current development process was intended to examine the intersect between mental health researchers, clinicians, and developers during prototyping of an EMI. Therefore, mental health consumers were intended to be excluded from the current development process. While most well-conducted usability studies of eHealth programs and interventions are often qualitative and formative, the inclusion of qualitative end-user data in the current development process may have also introduced validity issues when combined with quantitative data collected from the pilot Randomized Controlled Trial (RCT) outlined in Chapter 5 and 6. Especially, there are possible validity issues that may arise when combining (or triangulating) qualitative and quantitative end-user data within the same context, especially if the end-user evaluation of the EMI is conducted in both development and deployment settings (Lilford et al., 2009).

4.6. Exposure Therapy iOS Mobile App Delivering an EMI for Social Anxiety

Based on the given development process, the R&D team implemented an iOS mobile app delivering exposure therapy for social anxiety. The content of the iOS mobile app consisted of psychoeducation, text-based material related exposure therapy, instructions on how to monitor reactions to fears, and unhelpful thought patterns that occur when a challenging situation. Furthermore, the iOS mobile app is comprised of brief exercises to allow users to; learn about and practice self-coping and emotional regulation techniques; rehearse exercises, and schedule exposure. The R&D team adapted some of the

psychoeducation and instructional material on exposure therapy in the iOS mobile app from the eCouch program by modifying the content to fit the iOS mobile app format. For instance, the R&D team translated the eCouch material on exposure therapy for social anxiety into the iOS mobile app format. Finally, the iOS mobile app contains step-by-step instructions on how to conduct exposure in real situations. Figure 12 presents a sample of the mobile app screenshots of the EMI for social anxiety. Appendix P presents how the different software architectural layers of the iOS mobile app constructed the EMI for social anxiety.

Figure 12. iOS mobile app screens of the EMI.

(a) exposure therapy steps, (b) learning about exposure therapy, (c) identifying challenging situations (fears), (d) practice exercises before live exposure, (e) assessment before exposure to a social situation, and (f) reward after exposure to the social situation.

4.7. Discussion

The eight-phase development process resulted in several key learnings from the challenges of applying existing software development approaches in the development of an EMI for social anxiety. These included the iteration of prototype development of the EMI (Section 4.7.1), managing the uncertainties of ongoing changes to EMI design (Section 4.7.2), software components and reuse (Section 4.7.3), stakeholder engagement and feedback on software artifacts (Section 4.7.4), communication with domain experts (Section 4.7.6), well-documented software design for EMI (Section 4.7.7), and time management (Section 4.7.8). Sections 4.7.1 to 4.7.8 discuss the key learnings from this development process of designing and developing an EMI to inform the future development of EMIs for mental health and to place it in the context of previous research on designing EMIs.

4.7.1. Iteration of the development of EMI prototype

The development process demonstrated an iterative approach to the design and development of the EMI for social anxiety. An iterative approach provided the ability to design the EMI in incremental steps, or in small manageable parts. Results from a similar mHealth study for smoking cessation found iterative design phases expanded functionality and value of the intervention (van Mierlo et al., 2014). This development process allowed the R&D team to initially focus on developing the core parts of the EMI and mobile app, especially during phase 1 to 3 of the design process using user stories and UML activity diagrams (took up to approximately 2-4 hours to complete over 194 days, approximately 27 weeks). The domain model of the EMI provided the maximum therapeutic value for the end user. Therefore, the EMI contained software components that resembled real-world elements of the therapy workflow of exposure practice (such as consumers, therapists, workbook modules, exercises). Phase 4 to 6 of the design process iteratively modelled the therapy elements and clinical decision rules of the EMI (took up to approximately 298 days to complete over 42 weeks). From phase 7 onwards, the EMI expanded with additional back-end and front-end features which improved both function and style of the EMI mobile app (took up to approximately 440 days to complete over 62 weeks). As a result, this design process allowed the design of the EMI to evolve and expand from the early phases of development through to the initial release and shipping of the

EMI prototype. Notably, this design process differed from other design models which may place less emphasis on developing the domain model of the EMI in beginning phases of the development process which consequently can be difficult to manage (Davis et al., 1988).

Incremental modifications to the mobile app achieved the technical enhancements to the domain model of the EMI. These modifications supported the overall intervention goals of the EMI delivered through the mobile app. As the initial domain model of the EMI was constructed in the early phases of the design process (phase 1 to 6), the R&D team began to progressively integrate new mobile app features that improved the overall mobile app functionality and usability of the EMI. These specific features of the EMI supported the domain model, whereby features were implemented separately from the domain model of the EMI. An example of particular features included the functionality of the storage of EMI data on the mobile device, the functions for the font and colour schemes of the UI of the mobile app, and other iOS platform-specific functions. This design approach of this development process is unique from other approaches because other design methods may not separate the domain of an EMI from specific mobile app features, which could ascend to complex designs of the EMI implementation which can cause difficulties to enhance or maintain over time (Evans, 2004). While new mobile app features were refined and added along with regular feedback from stakeholders in the EMI for social anxiety, there were challenges with the validity of the feedback gained through small and iterative tests that validated the EMI design. Thus, a set of micro-scale randomised studies on different components of an EMI may improve the validity of evaluating and refining the EMI based on on-going effects (Klasnja et al., 2015, Schueller et al., 2017).

4.7.2. Managing uncertainties of changes to EMI design

The iterative approach managed the possible uncertainties of late requirement changes to the EMI design throughout the development process. The R&D team identified many risks and uncertainties early phases of the development process (especially during phase 1 and 2) and progressively throughout the lifecycle, in particular, the risks to changes which came from uncertainties identified in the area of interest. User stories and UI wireframe documents were the primary tools to engage with domain experts that identified those risks. Uncertainties included the discovery of new knowledge or scientific evidence on the

practice of exposure therapy, the accounting for a broad range of characteristics of potential users of the EMI, or environmental and organisational factors. This development process allowed the design of the EMI to mitigate and control some of these uncertainties by adjusting the design of the EMI in incremental phases to fit current or new circumstances. However, in a study by Noordman et al. (2017), they developed a web-based preparatory communication tool for cancer patients. This study by Noordman et al. (2017) noted that the iterative approach was found more useful for software developers in gathering requirements for the development of the technical system of the intervention. However, the study by Noordman et al. (2017) also found the approach did not always coincide with the scientific requirements of researchers that required content and material to develop at the same time.

Uncertain changes to an EMI design are unavoidable; therefore the design of this EMI for social anxiety was designed to be adaptable to possible external factors that may influence its implementation and impacts. It is common for an EMI to adapt and adjust its design based on new information gathered during the development process (Schueller et al., 2017). In this case study, it was especially the case in the diverse perspectives held by the software developer, mental health researchers and clinical psychologists in the R&D team. New information or insights from results of the use case tests with the mental health researcher and psychologists resulted in further changes to the EMI design at later stages/phases of the development lifecycle. For example, when the clinical psychologist raised last-minute modifications to the EMI design based on clinical safety concerns.

4.7.3. Software components and reuse

This development process facilitated the application of software components into the design of the EMI for social anxiety, which made this aspect of the mobile app reusable for further development and evaluation of the EMI. Software components may encourage further investigation into specific architectural styles and patterns for EMIs. Software *architectural styles* can play a vital role in the design of EMIs because they describe the structure, composition, and behaviour of the software system (Perry and Wolf, 1992). Reusable software architectural patterns and styles are important for adapting and adjusting the design of the EMI because they are used to solve reoccurring design problems and to make the software of EMI more modularised (Frakes and Kyo, 2005,

Oduor et al., 2014, Parnas, 1972). Software components and reuse may also improve the overall productivity of testing and redesign of the EMI for people with mental health problems, such as social anxiety (Blaauw and Emerencia, 2015).

Software architectural styles and components discovered through this development process draw on similar patterns investigated in software *case studies* on behaviour change support systems. In particular, the logical and process view of this software architecture of the EMI draws on similar software elements and patterns found in PSD case studies by Alahäivälä et al. (2013). For instance, common software elements include "user", "goal" and "story" in the PSD model. Furthermore, the development view of the software architecture of this EMI resembles similar architectural layers proposed by Blaauw and Emerencia (2015). The five-layer architecture by Blaauw and Emerencia (2015) provides the analysis of two case studies (HowNutsAreTheDutch and Leefplezier). Common software layers include a "presentation layer" that encapsulates UI features (similar to the development of the front-end of this EMI described in section 4.5.8), an "application layer" that contains study and treatment features, and a "service and data layers" that encompasses back-end features of the systems. While there are many similarities and overlaps, there also appears to be subtle differences in the architectural styles and patterns in the above models. Further investigation into the synthesis of design styles and patterns of EMIs and other similar models may improve the reusability of EMI designs for mental and behavioural health.

While software reuse was encouraged in this development process, implementing reuse in complex domains, such as exposure therapy and social anxiety, became difficult to achieve. Identifying the levels of reuse for the domains of the EMI was problematic at times. The limited knowledge of the domains held by individual team members led to issues with abstracting some aspects for reuse. The software developers did not have the equivalent clinical expertise to the mental health researchers and clinical psychologists about exposure therapy; therefore, the software developer could not always identify patterns of reuse. Nevertheless, the software developers did eventually gain more knowledge on exposure therapy during the design process which improved the software developer's ability to apply reusable elements into the design of the EMI for social anxiety.

4.7.4. Usability of the EMI

Usability is a critical factor for the successful adoption of EMI and similar e-interventions (Zapata et al., 2015, van Gemert-Pijnen et al., 2011). However, the project was constrained by the available resources and time available to the R&D team at the time of development. In hindsight, the R&D team would have preferred to conduct more *formative* assessments of the EMI design to gain *qualitative* insights of end-users (i.e., mental health consumers). Formative assessment is used to evaluate the EMI during the early stages of development to provide timely feedback of any implementation issues and needs of various stakeholders, including health researchers, clinicians, and consumers (van Gemert-Pijnen et al., 2011, Lilford et al., 2009). Therefore, this development process deployed formative assessments to examine the interactions between mental health researcher, clinical psychologist, and software developer during the prototyping of an EMI. Furthermore, formative assessments of end-users views during the iterative development of the EMI prototype may have informed the R&D team of possible end-user adoption failures, and possible areas of improving usability, accessibility and consumer engagement of the mobile app delivering the EMI (Franklin and Myneni, 2018). Despite the absence of formative assessments of the end-users, this development process instead examined literature reviews of usability studies of mHealth applications, and mobile apps in the app stores to maximise the engagement of the EMI for the end-user (Zapata et al., 2015, Franklin and Myneni, 2018, Morey et al., 2017). Lastly, the pilot study evaluating the EMI (explained in Chapter 5 and 6) will be used to provide *quantitative* feedback of end-users to inform further enhancements to the EMI design. This quantitative feedback of the end-user for the EMI will be more *formative* rather than *summative*.

Summative assessment is used to evaluate the effects of the EMI on longer term outcomes, such as health outcomes and cost reduction, quality of health care, benefits, and performance (van Gemert-Pijnen et al., 2011, Lilford et al., 2009). Therefore, this development process did not deploy summative assessments to assess the EMI. Instead, the quantitative results of the pilot study in Chapter 5 and 6 will be used to provide immediate feedback to the R&D team to begin summative research on the EMI. Lilford et al. (2009) have noted that well-conducted formative studies on eHealth programs are often devoid of any generalisable (or quantitative data) results even though the feedback is immediate. However, potential issues are raised when combining formative and

summative results of end-users within the same context, especially if evaluation is taken in both development and deployment settings. Further investigation is needed to understand the facets of the implementation of EMIs in various complex settings to provide robust evaluations, and to identify methods to best engage end-users in the development process.

4.7.5. Stakeholder engagement and feedback on UML artifacts

During the development of the EMI, software developers, mental health researchers, and clinical psychologists of the R&D team appeared to lack understanding of the modelling task. In particular non-technical stakeholders, such as researchers and clinical psychologists, found that producing the various UML artifacts hindered the development process. Indeed, some UML research suggests the use of standard notations, such as UML, increases the cognitive processing to differentiate ambiguous concepts of any complex problem domain (Moody and van Hillegersberg, 2009). Hence, this process may slow down the comprehension of specific domain concepts when formulating the design of the mobile app with domain experts. Many of the stakeholders involved in this design process preferred reviewing the product of the mobile app delivering the EMI content for social anxiety. The lack of consistent engagement with the design process created problems of communicating the model with the domain experts and non-technical stakeholders.

While it was unclear what the causes were for the lack of engagement in the design process and UML artifacts with stakeholders, future research can examine the reasons behind the issues with using UML for mental health researchers and clinical psychologists. Furthermore, more research is required to examine the potential for training for mental health researchers and psychologists in UML notation and agile modelling practices to increase engagement with the design process. Due to project constraints, many of the stakeholders in the R&D team were not able to familiarise with the agile modelling techniques, which may have reflected on the poor engagement from researchers and psychologists. Lastly, research into simplifying the modelling notation for mental health researchers and psychologists is recommended to assist with comprehension of software artifacts during the design process.

Software engineers can improve engagement with stakeholders by collaborating with them to readapt existing modelling languages to form a new language that is truly

common and familiar to only the R&D team. From the case study, it was clear that imposing an existing modelling language from one discipline may have hindered the nature or dynamic process of designing the EMI with diverse stakeholders. Indeed, much of the effort was placed on the process rather than delivering a product that engaged with the mental health consumer while also meeting the requirements of the clinicians and researchers. Future design research of EMIs may consider a more democratic approach to the use of modelling languages and design. By considering the context of the stakeholders, an appropriate modelling language may evolve naturally. Furthermore, this collaborative approach to modelling may allow the R&D team gain more ownership to the design process and the end product, therefore improving productivity.

4.7.6. Communication of UML artifacts

Communication difficulties arose during the discussion of the UML artifacts for the mobile app delivering an EMI for social anxiety. For instance, the clinical psychologists and mental health researchers preferred specific modelling notations and tools to communicate and understand the design of the EMI for social anxiety. The domain experts (mental health researchers and clinical psychologist) found that user stories, UML activity diagrams, and UI Wireframes were the preferred tools to understand the conceptual design of the EMI. These experiences were similar in a case study on the development of a mobile app for generalised anxiety in which user personas and scenarios assisted in the effective dialogue between the psychologist and software developers (Topham et al., 2015). Particularly, the user stories of the EMI used natural language, such as English, to convey complex features of the mobile app to the clinical psychologists. Similarly, UML activity diagrams were preferred tools for communicating aspects of the EMI design to the domain expert, such as the clinical psychologist, because of the similarities to flowcharts. Interestingly, the design process also found domain experts preferred using UI Wireframe documents to communicate with software developers on most aspects of the EMI design including technical parts relating to the information architecture of the EMI. Software developers frequently refer back to the class and object diagrams to make changes or enhancements to the EMI design based on changes to the UI wireframe documents.

Despite some of the difficulties of communicating the design of the EMI using certain diagrams, the use of annotated notes in a Word Document or the 'Note' notation of UML

activity diagrams overcame these difficulties by making complex features of an EMI more clearer to software developers and domain experts. Notes in a UML activity diagram written in plain English allowed software developers to communicate with the clinical psychologist and mental health researchers on complicated features of the EMI. An example of an annotated description written in English is "The plan of a challenging situation assumes consumer XYZ has recorded XYZ in module X of the EMI" at the beginning of a workflow for planning a challenging situation for exposure practice. These types of annotated design notes provided clarity to the mental health researchers or the clinical psychologists when they were confused on particular EMI features that were described using UML notation.

4.7.7. Documenting the software design of EMIs

This development process produced a series of documents that reflected the design process of the EMI. The R&D team anticipated that this type of documentation could be used to enhance or maintain the mobile app in future development iterations. There is some evidence of the use of UML documents in industry. However, software developers are known to primarily use UML modelling during the early designs of software rather than during the implementation of programming code (Petre, 2013). Furthermore, there is evidence that suggests development teams will use certain types of UML diagrams more than other types of UML diagrams, and different diagrams are suitable for particular design activities than other UML diagram types, such as communication (Dobing and Parsons, 2008). Despite the different uses of documentation in other areas, this project used the development of documents and other artifacts to research the design process of an EMI. Given the number of documents produced over the course of developing the EMI for social anxiety, it appears that many of these documents were redundant with a few of the most relevant documents of the mobile app (such as the UML Class diagrams) being important to update and maintain. Therefore the documents of this design process should serve the purpose of understanding the development process and reflect on the learnings of the actions or activities taken to achieve the desired EMI for social anxiety (Bardzell et al., 2016, Bardzell et al., 2015, Pierce, 2014). Overall, system documentation was important artifacts for the design research process of the EMI for social anxiety, because it provided a *reflexive* account of the development of the EMI for social anxiety which may potentially

be relevant design knowledge for future researchers and practitioners wishing to develop EMIs for other mental health problems.

4.7.8. Time management

It is known that the construction of a mobile app is time-consuming and costly to develop because of the lack of support for automated software development processes (Joorabchi et al., 2013). The timeframes reported in the research study by van Mierlo et al. (2014), which employed similar agile methods for a smoking cessation mHealth program, were longer (714 days) than the timeframes reported in this case study (700 days). However, the case study on the EMI for social anxiety did not have a fixed budget or timeframe as opposed to van Mierlo et al. (2014) study in which organisational resources were based per fiscal year, and multiple developers were assigned to their project. Numerous other factors had major constraints on time, such as the availability of R&D team members or key stakeholders of the project. Similar issues were found in the study by Noordman et al. (2017) whereby the "busy schedule" of the oncologists involved in the agile development process became a challenge. Furthermore, technical issues also delayed the development of the present EMI for social anxiety. For instance, daily consultation with the clinical psychologist on the design of the EMI was a constraint with the busy schedule of the psychologist. This resulted in irregular weekly consultation meetings with the clinical psychologist. Furthermore, there were delays in the development of the data storage of the EMI. For instance, technical difficulties were integrating the domain model of the mobile app with the features to manage data on the mobile device.

4.8. Future Research

Further investigation is needed to understand the extensibility of the development process and related artifacts for future research of EMIs for mental health. In particular, the knowledge gained from the software artifacts can be useful research data for improving the design process. Technical tools and techniques that can automate the generation and testing of programming code on different mobile app platforms which can enhance this design process. As a result, the EMI is portable and scalable across various technology platforms. Therefore, the R&D team could ship future software releases of the EMI on a

cross-platform mobile app framework that supports Android devices, or cloud computing services that supports web-based mobile apps.

With this development process, the software of the EMI can further evolve and change based on the discovery of new research outcomes through regular evaluations of the EMI. As future research into EMIs and similar interventions progress, timely delivery of EMIs will be necessary. Particularly, the timely delivery of the entire EMI or individual parts of the EMI requires a flexible technology infrastructure that supports rapid and dynamic changes to the programming code. Engineering methods that can analyse and optimise the internal structure of the software's programming code could be employed to assess and refine the complexity of EMI features.

Finally, the software artifacts of the EMI for social anxiety may be used to transfer the knowledge of EMIs for social anxiety to the community of design practitioners who may be interested in developing EMIs for mental health. Particularly, the software artifacts could potentially be a useful contribution to the open-source community. Common software elements identified in the software artifacts can be communicated to other R&D teams to extend the known design patterns of the EMI to the wider research community. Therefore, the development of the EMI is intended to broaden the scope of these designs with the intention of standardising the development of EMIs for future evaluations.

4.9. Conclusion

This eight-phase development process demonstrated a structured approach to the design of a mobile app delivering an EMI for social anxiety. Unlike existing design approaches for EMIs or similar eHealth interventions, it drew on existing development approaches and design principals from the software engineering discipline. Furthermore, the development approach applied these principles into the context of EMIs for mental health problems. Feasibility was demonstrated by adopting the various approaches into a single systematic development process and by documenting key learnings from the application of these approaches to this development context. Advantages included the iterative approach to the design of the EMI and the use of comprehensive documentation to reflexively understand the design of the EMI for future iterations. Disadvantages

included the long timeframes of development and deployment and the difficulties of the software developer engaging with domain experts and stakeholders.

5. CHAPTER 5
A Standalone Self-Help Ecological Momentary Intervention Delivering Exposure Therapy for Social Anxiety Disorders: Study Protocol for a Randomised Controlled Trial

5.1. Introduction and Background

This chapter describes a study protocol of a Randomised Controlled Trial (RCT) to test the effects of a new intervention for social anxiety. The conceptual design and development of the intervention for social anxiety were described in the previous chapter (Chapter 4). Sections 5.1.1 to 5.1.5 provide background for the RCT protocol. This chapter includes background for social anxiety (Section 5.1.1), help-seeking for social anxiety (Section 5.1.2), Cognitive Behavioural Therapy (CBT) for social anxiety (Section 5.1.3), self-help and therapist guided e-interventions (Section 5.1.4), Ecological Momentary Interventions (EMIs) (Section 5.1.5). Section 5.1.6 provides a description of the related research of the RCT on EMIs for social anxiety, and Section 5.1.7 describes the objective of the RCT study. Chapter 6 will present the results of the RCT.

5.1.1. Social anxiety

Social anxiety disorder, also known as social phobia, is one of the most commonly diagnosed anxiety disorders (Kessler et al., 2005a, Stein and Stein, 2008). Social anxiety disorder has a 12-month prevalence of 4.7% among Australians aged 16-85 (Australian Bureau of Statistics, 2008), and lifetime prevalence of 2.8 to 13% in the United States and Europe (Alonso and Lepine, 2007, Kessler et al., 2005a). More females (71-70%) are diagnosed with the disorder than males (21%) (Cottraux, 2005, Westenberg and Liebowitz, 2004). The Diagnostic and Statistical Manual of Mental Disorders, 5th edition, defines social anxiety 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" (American Psychiatric Association, 2013). Symptoms include palpitations, dizziness, tingling sensation, abdominal distress, dry mouth, sweating, and blushing (Jakatdar and Heimberg, 2010). Individuals with social anxiety may experience symptoms during social situations or through the anticipation of these situations (Heimberg et al., 2010). Social situations are often feared and avoided due to embarrassment and perceived negative

judgments from others in anticipation of and during any social interactions (Kashdan et al., 2014).

5.1.2. Help-seeking for social anxiety [5]

While it is a highly debilitating condition for many individuals, social anxiety disorder is frequently associated with critically low levels of help-seeking (Ormel et al., 2008, Wang et al., 2005). Published studies have investigated help-seeking mechanisms for individuals with social anxiety (Buckner and Schmidt, 2009, Chartier-Otis et al., 2010, Olfson et al., 2000). Moreover, a recent study by Griffiths et al. (2017) investigated an online text-based self-help intervention program designed to increase help-seeking intentions for social anxiety disorders. Participants in the study were randomised to either the shyness intervention program which aimed to promote help-seeking, or to an online attention control group. The study found the intervention program to show more favourable attitudes in seeking help for participants' social anxiety with a high perceived need for treatment. Furthermore, the study found participants showed greater knowledge of social anxiety relative to the control group at post-test. Researchers suggest these types of interventions may have the potential to encourage individuals to seek help with a therapist or an evidence-based online program that delivers psychotherapy for social anxiety.

5.1.3. Cognitive Behavioural Therapy (CBT) for social anxiety [6]

Currently, one of the most effective treatments for social anxiety is Cognitive Behavioural Therapy (CBT) (Hofmann et al., 2013, Huppert et al., 2003). Typically, a trained therapist delivers this therapy (consisting of cognitive restructuring, exposure therapy, and homework exercises) face-to-face individually or in a group setting (Huppert et al., 2003). There is evidence *exposure therapy* (a component of CBT) alone can be effective in treating anxiety symptoms (Ponniah and Hollon, 2008). Exposure therapy is a type of evidence-based CBT used in treating anxiety disorders that require a person to expose themselves to a fearful or challenging situation.

[5] This section on Help-seeking for Social Anxiety is repeated in Section 6.1.1 in Chapter 6 of this thesis.

[6] This section on Cognitive Behavioural Therapy for Social Anxiety is similar to Section 6.1.1 in Chapter 6 of this thesis. Some of the content on exposure therapy and therapeutic components are defined here and repeated in other chapters of this thesis (Chapter 4).

As stated by Craske (2015) and Craske et al. (2014), the *inhibitory learning model* is the central mechanism of exposure therapy for fear and anxiety. The model involves *fear extinction* (i.e., weakening of previous learned associated between a social situation and the aversive experiences of the social situation during exposure) with additional mechanisms, such as *habituation* (i.e., a reduction of the physiological arousals or physical reactions, such as elevated heart rate, associated with the repeated exposure of a fear provoking stimuli, such as the social situation). A range of therapeutic strategies can be delivered to people with social anxiety which can enhanced inhibitory learning process during exposure therapy, and to enhance its retrieval following completing exposure therapy. As noted in Chapter 1, use of these strategies may be optimised through EMI to sequence, schedule, support and deliver exposure therapy in real time. Linguistic processing involving *affective labelling* can be used to enhance the inhibitory regulation process during fear extinction of an actual social situation, or can be used independently but in complementary ways for fear extinction. Furthermore, cognitive strategies may be used to increase awareness the barriers of confronting a fear. Individual strategies can be implemented as therapeutic exercises facilitated through a cost-effective standalone intervention or as an adjunct to other treatments, such as therapist supported CBT or an internet-based health intervention.

Due to the chronic symptoms of social anxiety, ongoing treatment may be needed in the long-term in order to avoid relapse (Westenberg and Liebowitz, 2004). While it has been suggested CBT with a therapist is cost-effective in the long-term (Huppert et al., 2003), the cost of treatment may be increased with the relapse of symptoms which may require more CBT sessions with a therapist, generally more than 20 sessions (Lazar, 2014). Additionally, the cost of CBT with a therapist can be a barrier for people to get professional help with a therapist (Chartier-Otis et al., 2010). This increased cost of receiving face-to-face help with a therapist can be possibly offset by translating CBT content into self-help or therapist guided interventions which can be delivered through an electronic platform (Donker et al., 2015, Ophuis et al., 2017). Such self-help or therapist guided interventions are known as e-Interventions.

5.1.4. Self-help and therapist guided e-interventions

Self-help or therapist guided e-interventions for anxiety disorders can be delivered via online or a portable hand-held device, which could be an effective way to treat symptoms with minimal therapist contact (Cuijpers and Schuurmans, 2007). A review study conducted by Christensen et al. (2014) suggested that online self-help e-interventions are as effective as face-to-face psychotherapy delivered by a therapist. Furthermore, additional advantages may be gained by delivering e-interventions through a portable hand-held device, such as smartphones (Proudfoot, 2013). Firstly, such devices enable self-help or therapist guided therapeutic content to be delivered ubiquitously to an individual in different locations or time periods directly targeting mental health symptoms in a naturalistic setting (Harrison et al., 2011). Secondly, context and environmental user data may be collected to tailor self-help or therapist guided therapeutic content potentially improving the efficacy of treatment (Burns et al., 2011, Carter et al., 2007a). The level of tailoring can be applied either by a therapist or another automated electronic system, such as an evidence-based internet intervention. Ecological Momentary Interventions (EMIs) can be potential psychological and behavioural treatments that can support tailored self-help or therapist guided e-interventions.

5.1.5. Ecological Momentary Interventions (EMI) [7]

EMI is "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" (Heron and Smyth, 2010). EMI is also sometimes referred to as "Just-In-Time Health Interventions" (Danaher et al., 2015, Schueller et al., 2017), that use methods of dynamic tailoring, and intelligent real-time therapy (Nahum-Shani et al., 2016). EMIs are designed to be more *ecologically* valid because the treatment is directly available for people anywhere or anytime (that is, in the course of their everyday lives rather than in a consulting room) (Heron and Smyth, 2010). Therefore, EMI provides real-time support to people when they really need it. Smartphone mobile apps are appropriate tools to deliver EMIs because they are ubiquitous, and they are personal devices that people usually carry around with them every day (Schueller et al., 2017). Furthermore, one of benefits of

[7] "Ecological Momentary Interventions (EMI)" is defined here and repeated in other chapters of this thesis (Chapter 3, Chapter 4, and Chapter 6).

delivering ecologically valid exposure therapy exercises to a person's smartphone is that exercises are accessible in various environments, such as at home, at school, or at work. This benefit could overcome fears of seeking professional support, or other informal support, such as friends and family.

5.1.6. Related research evaluating EMIs for social anxiety [8]

A systematic review of randomised controlled trials (RCT) has found promising results for EMIs aimed at reducing symptoms of anxiety and stress (Loo Gee et al., 2016). Since the review search by Loo Gee et al. (2016) which was conducted in January 2014, two RCTs have examined the efficacy of EMIs for social anxiety (Dagöö et al., 2014, Enock et al., 2014b). A recent study that compared CBT and Interpersonal psychotherapy (IPT) via smartphones demonstrated CBT to be superior to IPT (Dagöö et al., 2014). Additionally, a trial by Enock et al. (2014b) showed cognitive bias modification on smartphones to be superior to waitlist control at post-test. However, Enock et al. (2014b) did not evaluate exposure therapy alone on smartphones against waitlist at post-test. To date, no study has examined the efficacy of *a standalone self-help EMI delivering exposure therapy only* for social anxiety via hand-held smartphones.

5.1.7. Objectives

The aim of this thesis is to improve the delivery of EMIs using mobile technologies for people with social anxiety. Specifically, the current study aims to examine a new standalone or self-guided EMI using mobile technologies, which encourages the use of the EMI in moments when a person experiences anxiety. The self-guided or standalone intervention allows a person to learn strategies to cope with social anxiety in different settings or time periods directly targeting symptoms in a naturalistic setting, potentially leading to better outcomes on anxiety and mental wellbeing. In addition, we anticipate that brief self-help therapeutic content on the mobile phone will benefit people whom may not seek professional help for their anxiety due to a number of barriers. Such barriers include a person's lack of knowledge about to where to seek help, the belief of not having social anxiety, the belief of treatment being not effective, the belief of not being able to

[8] This section of Related Research to EMIs for Social Anxiety is the same as in Section 6.1.3 in Chapter 6 of this thesis.

cope in social situations, inability to take medication, stigma, financial barriers, long waiting times to get help from a health professional, long travel times to health professional, personal commitments preventing a person accessing help, avoidance behaviours associated with social anxiety that may be barriers to seek help, and poor detection of social anxiety by general practitioners (Chartier-Otis et al., 2010, Griffiths et al., 2017, Olfson et al., 2000, Wagner et al., 2006).

The purpose of the RCT described in the current study protocol is to investigate the effectiveness of an indicative public health EMI program aimed at reducing subclinical and mild symptoms of social anxiety and to compare the EMI against a waitlist control group. Immediate outcomes and mobile app usage will be measured. The content of the EMI is designed to deliver exposure therapy for people with social anxiety symptoms. It is hypothesised that the EMI will be significantly more effective in reducing symptoms of social anxiety and stress than a waitlist control group. Effects on social anxiety may also translate into reduced symptoms of generalised anxiety and depression and reduced stress. In addition, it is hypothesised that the EMI will increase help-seeking intentions and behaviours. Lastly, user satisfaction of the EMI for social anxiety and the usage of the mobile app will be examined.

5.2. Methods/Design

5.2.1. Design

The randomised controlled trial in this protocol was registered in the Australian New Zealand Clinical Trials Registry (ACTRN12617000060347) and received approval from the Australian National University Human Research Ethics Committee in Canberra (approval number: 2016/607).

Participants will be recruited from the general community and randomised to one of two study groups; 1) one group receiving access to download a mobile app program with therapeutic content for iPhone, iPad, or iPod touch, or, 2) a waitlist control group. Participants will be randomly allocated via computer script to each of the study arms, stratified by age, gender, and level of social anxiety symptoms (participants who score above or below the cut off of 10 on the Social Phobia Screener (SOPHS) will be allocated to one of either group). Similar to other e-interventions, blinding allocation of participants

to the study arms was not possible. Hence, participants knew when they would receive the intervention, which may potentially impact the results. However, assessments will all be self-reported ensuring that researchers did not influence assessments. The waitlist control group will receive the same e-intervention as in group 1. A wait-list control group is a control condition that delays administering the EMI to participants. Attrition will be measured using download status and usage logs of the mobile app with the EMI program. This study will not include a comparison between groups at follow-up measurements after post-test due to logistic reasons. Figure 13 presents the study flowchart for the RCT.

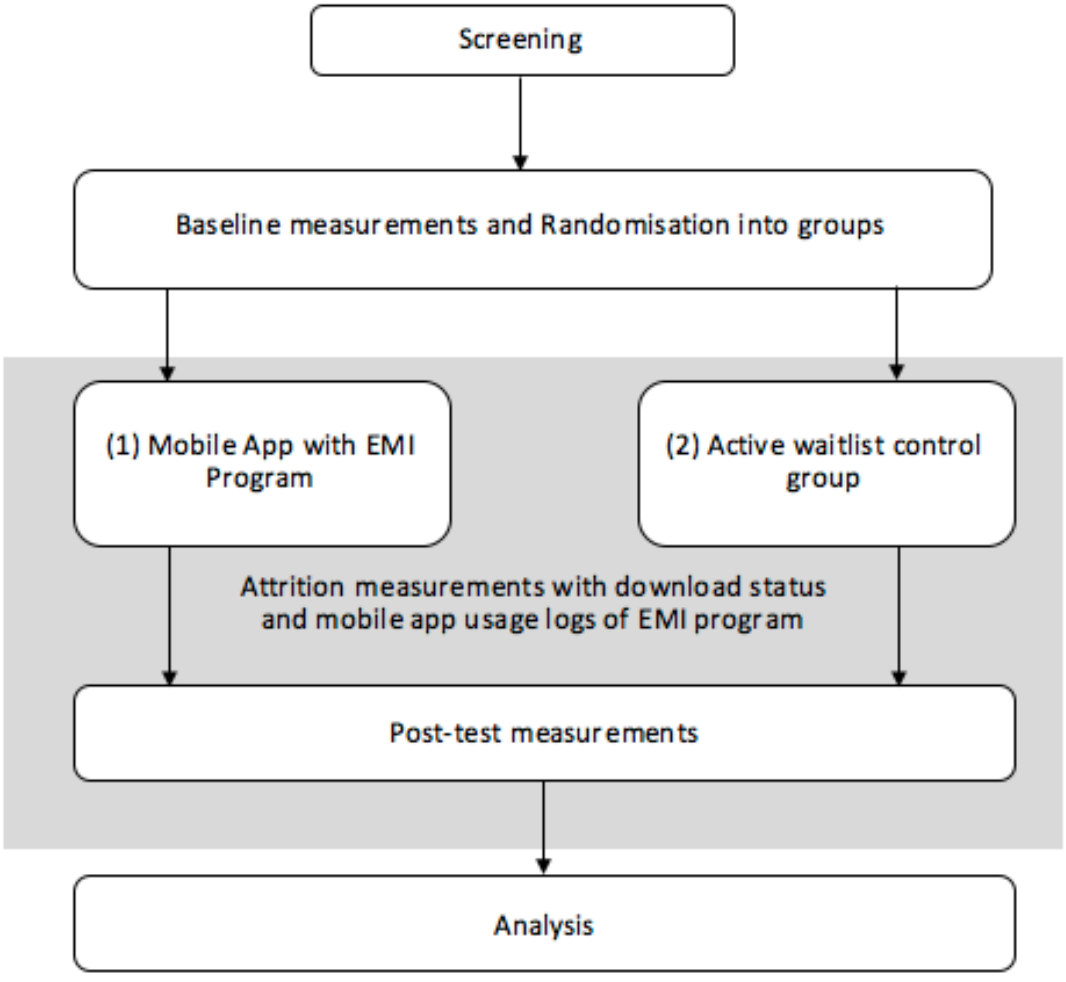


Figure 13. Flowchart for the RCT

5.2.2. Study setting

This RCT examined a community, a sample of adults aged 18 years and older living in Australia with subclinical symptoms. This research was conducted entirely online, with participants recruited in online communities and social media platforms such as Facebook.

5.2.3. Procedure

5.2.3.1. *Recruitment*

The study will recruit people to participate in the study via Facebook. Paid Facebook advertisements will be used to promote the study and reach a greater diversity of people than traditional recruitment methods such as mail and phone (Thornton et al., 2016). The Facebook advertisement will be worded in a way that attracts individuals with 'shyness' to participate in a 4 weeks study testing an iOS mobile app, and it will include an image of hands reaching out. Advertising will be delivered broadly to adults in Australia, without targeted to specific user characteristics. Additionally, researchers will ask other organisations and Facebook pages to share the Facebook post, which is a way to increase the reach of the promotion without cost.

Facebook advertisements will direct participants to a web page featuring links to the study information sheet, consent form, and an online screening assessment. Recruitment will be restricted in distributing 100 beta versions of the mobile app via TestFlight, however was not used as method to calculate the target sample size. TestFlight is a beta testing system on iTunes Connect that invites people to test beta mobile apps (Apple, 2017a). Beta testing rules for beta mobile apps will limit the distribution of no more than 100 mobile apps to 100 participants. Therefore, the study is limited in sample size to a total of 100 participants (50 participants per condition). However, it is anticipated that more participants are needed to be screened to achieve 100 randomised participants. Interested people are able to respond to the advertisement via clicking or accessing the link on the Facebook advertisement. Respondents who click the YES checkbox on the online consent webpage and respondents who meet the eligibility criteria for the online screening test will be immediately directed to baseline assessments.

5.2.3.2. *Screening and baseline assessment*

Consenting participants will be immediately directed to complete an online screening and baseline assessment prior to randomisation. The online screening survey will ensure the participant is aged 18 and over, have a valid email, have a working mobile device with internet access, and is currently not receiving treatment for their anxiety problems nor depression, and have no self-reported history of schizophrenia and bipolar disorder. This is followed by the administration of the Social Phobia Screener (SOPHS) to assess social anxiety symptoms (Batterham et al., 2016a). Eligible respondents with a total score of 4-16 on the SOPHS and who met other requirements will be invited via email to participate in the study. Participants who reported higher levels of SOPHS, who are aged less than 18, did not have a working mobile device with internet access, and who are currently on treatment for their anxiety or depression problems will be excluded from participating at the beginning of the screening survey and they will be provided with a link to help-seeking resources in Australia (such as Lifeline, BeyondBlue, SANE, etc.).

Eligible participants will be immediately directed to a 15-minute baseline online survey about their demographic details, social anxiety symptoms, and mental wellbeing. This includes brief assessments on age, gender, education level, employment status, living region, language, mobile phone usage, and email. Additionally, this include outcome measurements and scales: social anxiety (SOPHS and Mini-SPIN scales) (section 5.2.5.2.1), anxiety sensitivity (ASI scale) (section 5.2.5.3.2), generalised anxiety and depression (PHQ4 scale) (section 5.2.5.3.3), psychological distress (DQ5 scale) (section 5.2.5.3.4), and help-seeking attitude and behaviours (AHSQ and GHSQ scales) (section 5.2.5.3.1) will be used to evaluate outcome measures. Participants will receive a reminder to complete the survey if they did not complete it after one week.

5.2.3.3. *Randomisation and allocation*

Participants meeting inclusion criteria will be randomised and allocated via automated computer scripts in a database software to study arms either to receive an immediate email about instructions to download the mobile app on their mobile device from TestFlight to begin the intervention (group 1) or to receive the same instructions after a 4 week delay (group 2). Participants will be stratified and allocated to each of the study arms based on age, gender, and level of social anxiety symptoms (a score above or below the cut off of 10

on the Social Phobia Screener (SOPHS) will be allocated to one of either group). Randomisation and stratification of participants will be carried out electronically by the researcher using a computer-generated script that uses a predetermined randomisation schedule.

A reminder email will be sent to participants in the intervention group (group 1) to check if they have been able to download the mobile app from TestFlight mobile app distribution system. As some participants may only use the mobile app once or twice or not at all, researchers will provide an e-mail reminder to participants three weeks after inviting them to install the mobile app on their device. This reminder message will be used to encourage participants to adhere to the intervention. These reminders will be automatically triggered using a custom-built database system and an email account set up by the university.

Participants allocated to the control group will be notified via email within 4 weeks to continue with the study. This information will be presented on a web page after completing the baseline assessment. After 4 weeks, the participant will receive an email invitation to complete the post-test survey. After completing this survey, participants will be sent a further email containing instructions to download the mobile app on their device from the TestFlight mobile app distribution system, and instructions to use the mobile app.

5.2.4. Intervention

5.2.4.1. *Ecological Momentary Intervention (EMI)*

All participants will receive the same EMI program. The intervention consists of four brief modules that encapsulate steps for learning and conducting exposure therapy at moments when a person experiences symptoms. The EMI design of exposure therapy is similar to the study by Gruber et al. (2001); however, additional self-help modules will be added to compensate the therapist supported aspects of the EMI. Table 8 in Chapter 4 provides a product comparison table that compares the features, components and content of eCouch program (social anxiety toolkits), and the EMI for social anxiety (Lee et al., 2012). In order to successfully complete all modules, a participant is required to complete the modules in chronological order. It is estimated each module would take 10-15 minutes

to compete; however, it requires participants to engage in the exercises daily. Automated push notification to prompt users were considered in the development of the EMI, however, users were required to self-initiate the use of the iOS mobile app in order to receive the content of the EMI. Furthermore, users were able to setup their reminders on the mobile app to receive push notifications on the phone at certain times.

The first module consists of text-based material about exposure therapy. The second module requires participants to identify personal factors relating to their social anxiety. The module consists of text-based material about how to identify these factors with the ability to record these factors into the mobile app. The third module requires participants to prepare and plan for exposure therapy. The fourth module consists of a step-by-step guide to practising exposure therapy in a variety of situations and settings with the mobile app device. An orange dot will appear on the far right of the main icon to indicate to the participant a therapy module or step has started. Figure 14 presents screenshots of the main screen of the mobile app delivering the EMI.

Figure 14. Screenshots of the main screen of the mobile app delivering the EMI.

(a) Enter participant id for study. (b) Display information on shyness and mobile app once the app is loaded. (c) Choosing task for exposure practice. (d) Display information on shyness and mobile app from main.

The psychological content of the EMI is based on an existing evidence-based internet program developed by eHub at Australian National University (Bennett et al., 2010). eCouch.anu.edu.au is a web-based application that delivers CBT material for people with a variety of mental health problems, including anxiety. The eCouch program contains a number of self-guided modules with psychoeducation material, exercises, and quizzes for

practising exposure therapy. Additionally, a number of published self-help treatment manuals on exposure therapy were used to help the development of the intervention content and decision logic of the EMI (Bourne, 2005, Antony and Swinson, 2008). Modifications of the eCouch content were adapted to fit the iOS mobile app format, which included material from the exposure practice toolkit, and material from breathing control exercise of the relaxation toolkit. Additional psychotherapy content and decision logic were added from the clinical psychologist and researchers in the field [Georgia Tayler (GT), Kathy Griffiths (KMG), Julia Reynolds (JR), and Les Posen (LP)]. Most of the content of the EMI is based on evidence-based CBT principals, and it was designed to be brief and minimally invasive. A software developer developed the mobile app for the EMI (Brendan Loo Gee). Chapter 4 discusses in depth the development process of the EMI with the researcher, clinical psychologist, and software developer. It also includes a discussion on the technical implementation of the EMI.

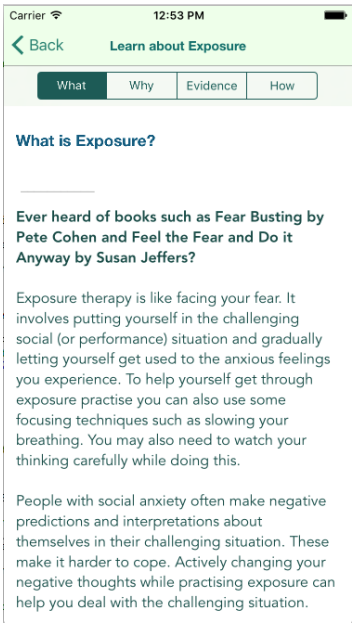
5.2.4.2. *Mobile app content for the EMI*

The core content of the mobile app of the EMI contains a series of instructional material and complementing self-help psychotherapy exercises for practising exposure therapy with the iOS mobile app. Features are similar to the mobile challenger app for social anxiety by Miloff et al. (2015). However, the EMI in this protocol emphasised clinical and cognitive-behavioural aspects of exposure therapy designed into the mobile app. Sections 5.2.4.2.1 to 5.2.4.2.4 briefly discuss some of the clinical content and aspects that were included in each of the EMI modules.

5.2.4.2.1. Content for learning about exposure therapy

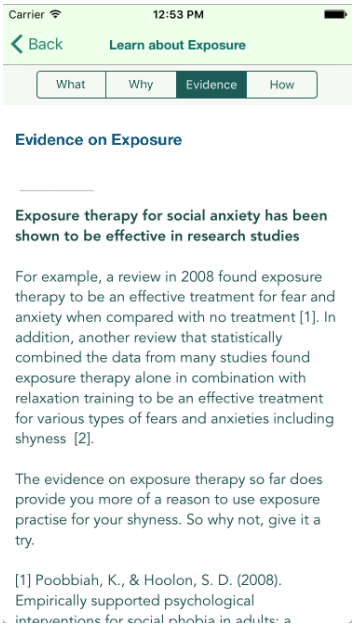
Participants are able to select a number of options to read and learn about exposure therapy. A series of self-help material will be provided to the participants. This self-help material includes; educational information on “what is exposure therapy?”, “why use exposure therapy for social anxiety?”, the evidence of using exposure therapy, and a brief description of how exposure therapy works. Upon finishing the modules, participants are able to move to the next stage of the intervention. Figure 15 presents screenshots for this module of the EMI.

(a)



(b)

(c)



(d)

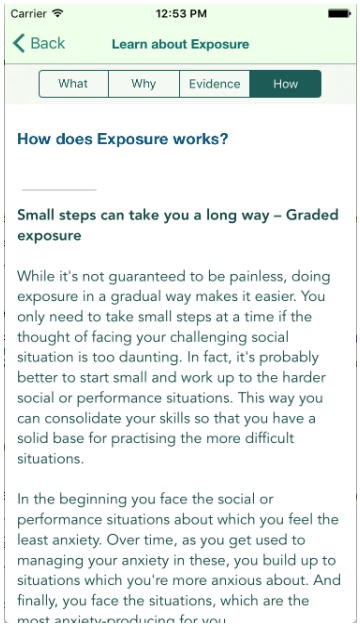


Figure 15. Screenshots of the module for learning about exposure therapy.

(a) Display information on what is exposure therapy (b) Display information on why use exposure therapy (c) Display information on evidence on exposure therapy (d) Display information on how exposure therapy works.

5.2.4.2.2. Content for identifying situations, reactions, and thoughts

The aim of this content is to enable participants to be able to read and learn to recognize challenging situations, physical reactions to fear, and unhelpful thoughts about the fear. The participant will be able to learn about a challenging situation with examples of different types of situations, such as “easy”, “hard”, “difficult”, and “very difficult”. The

mobile app will prompt participants to indicate if a challenging situation is doable after they save a challenging situation in the app. Additionally, the mobile app checks if a challenging situation is stored for each type of situation before saving the information into the app.

Participants will be able to learn and identify reactions to fear, such as physical sensations and safety behaviours. The mobile app allows participants to identify and describe physical sensations, safety behaviours, or unhelpful thoughts. Participants will be able to indicate using a graphical scale from "Not at all" and "Very Much"; the levels of how a sensation bother them, the use of a safety behaviour in a challenging situation, and the occurrence of a particular unhelpful thought. Additionally, participants will be given a list of predefined labels to describe their feelings and thoughts towards a specific physical sensation, safety behaviour, and unhelpful thought. After the participant saves their physical sensations, safety behaviours, or unhelpful thoughts into the mobile app, feedback messages from the app will be prompted back to the participant.

Feedback messages included mechanisms to assist participants in learning about the reactions of physical sensations, safety behaviours or unhelpful thoughts. For instance, affective label messages include feedback messages such as "My sensation of <physical sensation> I want to… <list of selected labels>" and "My behaviour of <safety behaviour> Made me feel… <list of selected labels>. While the labels used in the EMI have not been fully validated, the use of "affective labelling" on the emotional experience of sensations, behaviours, and thoughts are based on a technique developed by Craske et al. (2014). Affective labelling allows participants to challenge situations by enhancing the inhibitory learning process during exposure practice. Furthermore, a positive reappraisal message will be displayed after the participant saves a physical sensation, safety behaviour, or unhelpful thought in the mobile app. The positive reappraisal message is used as a coping strategy to begin preparing for exposure therapy (Garland et al., 2009). An example of this message includes "These feelings can be overwhelming but have you tried to…" with specific strategies containing messages relating to how to accept, neutralize, and perform activities to manage a physical sensation, safety behaviour, or unhelpful thought. Figure 16 presents screenshots of this module of the EMI.

Figure 16. Screenshots of the module for identifying situations, reactions, and thoughts.

(a) Choose to learn and identify to recognize situations, reactions, and thoughts. (b) Display list of situations with learning material. (c) Display affective labelling message with an input form to enter information. (d) Display positive reappraisal message with an input form to enter information.

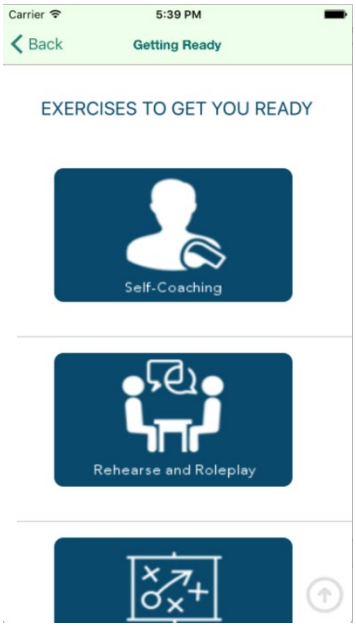
5.2.4.2.3. Content for preparing for exposure practice

The mobile app consists of a series of exercises that prepare participants before beginning exposure practice in a real situation with the mobile app. Exercises include

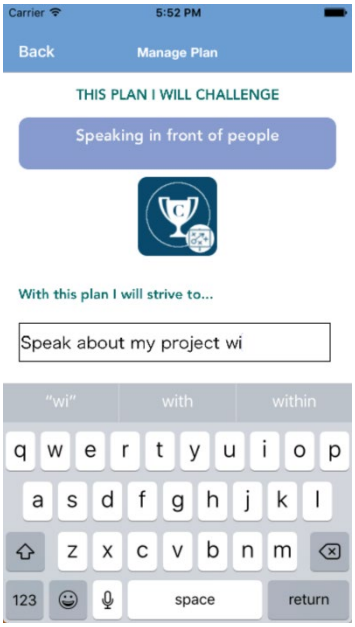
writing and saving a coping statement to self-coach a participant in trying exposure practice, instructions on rehearsal and roleplay which were extracted from eCouch, planning specific actions for exposure practice for a challenging situation, and breathing exercises for regulating emotions during exposure practice which were extracted from eCouch. Planning actions for exposure practice is a mandatory exercise to begin the next module or step for exposure practice.

The exercise for planning exposure therapy requires participants to plan an exposure practice in a given challenging situation. Participants are required to select a challenging situation previously identified in the previous therapy module. Next, participants are required to describe a goal for the challenge, set a mobile phone reminder to complete exposure practice, and enter a list of specific actions to complete the goal and challenging situation. Participants are asked to describe the specific action and further break down this description. For instance, they are asked to describe "who" might witness this action, describe "when" they might predict their anxiety would peak, describe "where" the action may occur, and describe "what" strategies they will do to cope with the action. Once the participant finished a plan, they are able to review the plan using the mobile app (similar to a hierarchy plan) and continue with performing this exposure practice in an actual real-world situation. Figure 17 presents screenshots of this module of the EMI.

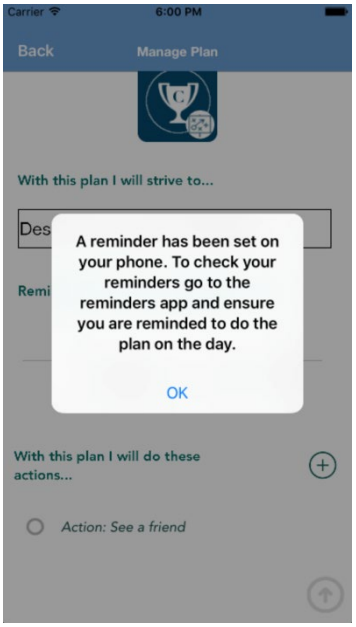
(a)



(b)



(c)



(d)

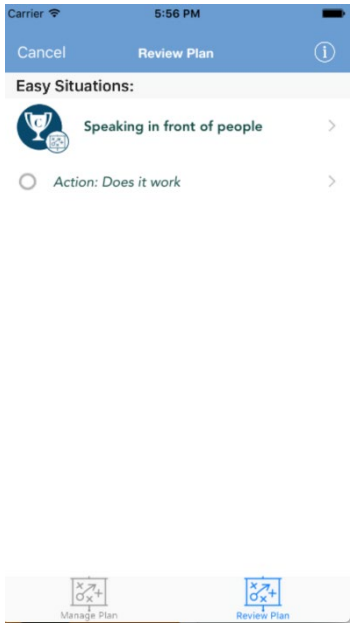


Figure 17. Screenshots of the module for preparing for exposure practice.

(a) Choose preparation exercise (b) Enter a plan for challenging situation (c) Save reminder to do plan (d) Display plans to do for challenging situation (hierarchy plan)

5.2.4.2.4. Content for performing in-situ exposure practice

The last main feature of the mobile app allows participants to use the mobile app in a real-life situation. A series of step-by-step instructions are used to guide the participant to do exposure practice for a challenging situation. They are able to select a challenging situation from a list of challenges they identified in the earlier modules. Next, they are able

to seek an action for a challenging situation, such as attending a friend's birthday party. The mobile app prompted assessments before and after an exposure practice to monitor participant's anxieties during the exposure practice. Each assessment includes a Subjective Unit Distress (SUD) scale which is a scale that measures the current level of subjective distress experienced by the participant (Bourne, 2005). Furthermore, the mobile app will check for high levels of anxiety before entering a challenging situation to ensure they received the appropriate messages to recover from any discomfort during the exposure of the challenging situation. While it is unclear on the exact threshold level for high anxiety during exposure practice (Craske, 2015), the mobile app will prompt an alert for participants in case of high levels of anxiety with supportive information to encourage the participant to continue with the exposure practice or seek further help with their anxieties.

Feedback information will be given to the participant after the exposure practice. Participants will be given the Subjective Unit Distress (SUD) scores of the assessments before and after exposing themselves to a challenging situation with the mobile app. This is part of the learning and recovery process of the exposure practice. A graphical badge will be given to participants after completing exposure practice, and a message will be displayed on the mobile app to congratulate the participant for trying exposure practice and encouraging them to keep trying exposure therapy to see improvements. Next, the participants will be able to decide to repeat the same situations, choose different situations, or finish the exercise. Figure 18 presents screenshots of this module of the EMI.

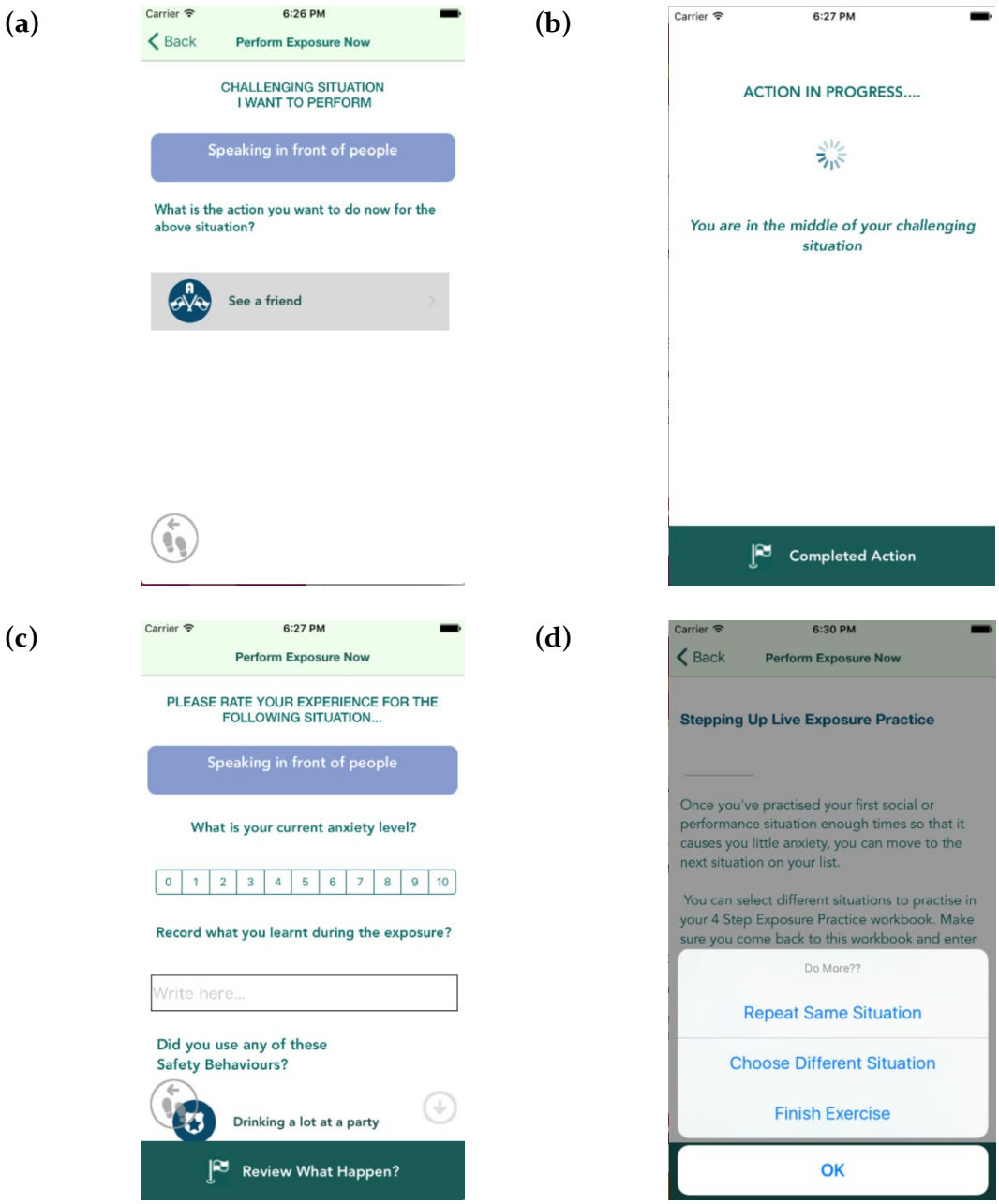


Figure 18. Screenshots of the module for performing in situ exposure practice.

(a) Select action of the challenging situation to do. (b) Waiting screen for a person to complete exposure to the situation. (c) Enter information about exposure to the situation (d) Continuing exposure therapy.

5.2.4.3. *Clinical support*

A qualified clinical psychologist will be used to provide clinical support for participants during the trial. Dominique Kazan is a PhD candidate at the Centre for Mental Health Research and is also an experienced registered psychologist in Canberra. She has

qualifications in a Master of Clinical Psychology (University of Canberra) and is a registered Clinical Psychologist (PSY0001676464). She will address any participant concerns over the study period (although technical issues will be addressed by BLG). Furthermore, help-seeking resources will be given to all participants during the study.

5.2.5. Measurements

Demographic measurements will be taken prior to randomisation and assignment. At 4 weeks after assignment, participants in both groups will be invited to participate in a 15 minutes post-test survey containing the primary and secondary outcome measurements. Participants would receive a reminder to complete the survey if they did not complete after one week. No follow-up assessment will be provided. The post-test survey will assess the effectiveness of the mobile app program relative to control. These surveys contain identical scales in the baseline assessment alongside demographic measurements. Participants in the intervention group (who used the mobile app) will compete for a separate survey that will assess the acceptability of using the mobile app for their social anxiety including a retrospective question on the number of times the mobile app was used during the study period.

5.2.5.1. *Demographic measurements*

Participants will be asked to complete a brief demographic online assessment that will take approximately 3 minutes to compete. Participant age will be measured based on the age of 18 or over. Gender will be measured based on the participant identifying as a male, female, other, or prefer not to answer. Education level will be measured based on the level of education completed (primary school, some secondary school, year 10 or equivalent, year 12 or equivalent, certificate level I-IV, diploma/associate degree, bachelor degree, graduate diploma/graduate certificate, master degree, doctoral degree, or prefer not to answer). Employment status will be measured based on the current employment level of the participant (full-time, part-time, unemployed, not in the labour force – not employed or unemployed, or student). Living region will be measured based on the best description of the area the participant lived in (a metropolitan capital city, an urban metropolitan city with an urban population more than 100,000, rural township, or remote township). Average mobile app usage will be measured based on the number of times the participant used their mobile app per day (5-10, 10-20, or 20 times a day).

5.2.5.2. *Primary outcome measurements*

The primary outcome will evaluate the reduction of social anxiety symptoms in participants. Section 5.2.5.2.1 will provide a brief discussion of the scales used to measure the primary outcome.

5.2.5.2.1. Social anxiety

The Social Phobia Screener scale (SOPHS) will be used to self-report a measure of social anxiety (Batterham et al., 2016a). SOPHS is a five-item screener scale for social anxiety. Participants will be shown examples of fearful or embarrassing social situations, such as "speaking in public" and "eating in public". Each item will assess social anxiety symptoms in the last four weeks, such as "To what extent have you felt fearful or embarrassed of any social situation in the past 4 weeks" and "Was the fear or embarrassment you experienced during the past 4 weeks excessive or unreasonable?". The scale will be rated from 0 to 4 using a 5-point Likert-type scale ("not at all" to "extremely"). Participants who do not respond to the first item will not need to complete item 2, 3, 4, and 5 as these are irrelevant and equate to zero. The total severity score range from 0 to 20 whereby higher scores indicate the high severity of symptoms. SOPHS yield reliable and valid results for severity of social anxiety symptoms (Batterham et al., 2016a). Furthermore, SOPHS is accurate in identifying social anxiety disorder as identified in Diagnostic and Statistical Manual of Mental Disorders 5th edition in population community-based sample. It has been reported to have good internal consistency (Cronbach alpha = 0.93) and univariate factor structure (Batterham et al., 2016a). Furthermore, sensitivity to detect social anxiety disorder is comparable (78% sensitivity, 72% specificity) to the 17-item Social Phobia Inventory (77% sensitivity, 71% specificity) and the 3-item Mini-SPIN (74% sensitivity, 73% specificity) relative to clinical criteria in the trial sample.

The Mini-Social Phobia Inventory (Mini-SPIN) is also used to measure social anxiety as a contingency scale to SOPHS (Connor et al., 2001). The Mini-SPIN will also be used because the SOPHS has been used in few interventions and therefore it was not clear whether it would be sensitive enough to detect changes in social anxiety symptoms following from the intervention. Mini-SPIN is a three-item brief self-reporting screening tool for diagnosing generalised social anxiety disorder. The scale is derived from the Social Phobia Inventory (SPIN) which is a 17-item self-reporting scale. Each item assesses social

anxiety in the last 4 weeks and includes items such as "Fear of embarrassment causes me to avoid doing things or speaking to people in the past 4 weeks" and "I avoid activities in which I am the centre of attention in the past 4 weeks". Furthermore, each item measures social anxiety based on a 5-point Likert-type scale from 0 to 4 ("not at all" to "extremely"). Mean scores are derived from each item, and a total score is derived from 0 to 12. A cut-off score of 6 is used to identify participants with social anxiety disorder. Mini-SPIN has been demonstrated to yield accurate results and is efficient in detecting social anxiety in a managed care setting (Connor et al., 2001). In a study on an online treatment sample, Mini-SPIN has shown to have good internal consistency (Cronbach alpha = 0.90) (Fogliati et al., 2016). Additionally, The Mini-SPIN has been shown to detect change over time (Dear et al., 2015).

5.2.5.3. *Secondary outcome measurements*

Secondary outcomes included help-seeking behaviours, anxiety sensitivity, generalized anxiety and depressive symptoms, and psychological distress. Furthermore, participants in the intervention group will be assessed on how satisfied they were using the mobile app for their social anxiety. Section 5.2.5.3.1 to 5.2.5.3.4 will provide a brief discussion of the scales that measured the secondary outcomes.

5.2.5.3.1. Help-seeking attitudes and behaviours

The Actual Help-Seeking Questionnaire (AHSQ) is used to measure help-seeking behaviours (Rickwood and Braithwaite, 1994). The AHSQ is a 19 item scale derived from the General Help-Seeking Questionnaire (GHSQ). Participants will be given a list of help-seeking sources and asked to select a source of help that "you sought for your anxiety problems in the last 4 weeks". For each item, the participant is provided with a "yes" or "no" answer. Items include formal sources such as "Doctor/GP and "Mental Health Professional (e.g., school counsellor, psychologist, or psychiatrist)", and informal sources such as "friend (not related to you)", and other sources of support including online websites. Participants are able to provide a textual description of a help source that is not listed. The scale has good predictive and construct validity (Rickwood and Braithwaite, 1994, Wilson et al., 2005) and it has been validated in three help-seeking interventions (Costin et al., 2009, Gulliver et al., 2012).

5.2.5.3.2. Anxiety sensitivity

The Anxiety Sensitivity Index (ASI) is used to measure the beliefs of the negative implications of social anxiety (Reiss et al., 1986). The ASI is a 16 item scale for identifying anxiety sensitivity in participants with an anxiety disorder. Participants will be asked to rate beliefs based on "How often have you felt the following in the past 4 weeks?" using a 5-point Likert-type scale from 0 to 4 ("very little" to "very much"). Each item specifies a possible negative consequence to the experience of social anxiety or generalised anxiety, such as "It is important to me not to appear nervous" and "when I cannot keep my mind on a task, I worry that I might be going crazy". Individual's score will be calculated as the sum of all items with a total score ranging from 0 to 64. Higher scores indicate greater anxiety sensitivity. ASI is a reliable and valid scale that has shown to have good psychometric properties and high internal consistency (Cronbach alpha = 0.83) in a sample of young adults (Vujanovic et al., 2007).

5.2.5.3.3. Generalised anxiety and depression

The Patient Health Questionnaire-4 (PHQ-4) is used to measure depression and anxiety symptoms. PHQ-4 is a four-item scale (Löwe et al., 2010). Participants will be asked to rate items based on "In the past 4 weeks, how often have you been bothered by the following problems?" using a 4-point Likert-type scale from 0 to 3 ("not at all" to "nearly every day"). Each item describes problems relating to depression and generalised anxiety, such as "Little interest or pleasure in doing things" and "Feeling down, depressed, or hopeless". The total score is a sum of all items with a score ranging from 0 to 12. A cut-off score of more or equal to 3 will be used to detect cases of depression and anxiety among participants in a general population sample. PHQ-4 has acceptable internal consistency in general population (Cronbach alpha = 0.78) (Löwe et al., 2010).

5.2.5.3.4. Psychological distress

The Distress Questionnaire-5 (DQ5) will be used to measure psychological distress. DQ5 is a five-item that identifies distress related to common mental disorders. Participants will be asked the following "In the past 4 weeks…" and asked to rate items using a 5-point Likert-type scale from 1 to 5 ("never" to "always"). Each item screens for common mental disorders, such as "My worries overwhelmed me" and "I felt hopeless". Total scores will be calculated as the sum of all items with scores ranging from 0 to 20.

Higher scores indicate greater psychological distress and greater risk of common mental disorders. In a population sample, the DQ5 has been shown to be reliable and valid with good internal consistency (Cronbach alpha = 0.86) (Batterham et al., 2016b).

5.2.5.4. *Intervention measurements*

5.2.5.4.1. User satisfaction and acceptability

Participants will be asked to rate how satisfied they were using the mobile app after 4 weeks. They will be asked to read ten statements and to provide a rating from 1 to 10, where 1 means the participant completely disagree and 10 means the participant completely agree. Statements will include "I enjoyed using the program", "I found the program to be helpful", "The program as easy to understand", "I would use the program in the future", "I would recommend the program to other people who might benefit from it", and "The skills I learned from the program helped me a lot in my everyday life". Total scores will be calculated as a mean of all items. Higher scores will indicate greater satisfaction with the mobile app and EMI. This scale has not been validated or used in a previously published study.

5.2.5.4.2. Mobile app download and usage measurements

Mobile app download status will be used to measure the number of times the mobile app was installed since invited to download the mobile app from TestFlight. Download status will be measured based whether the mobile app was installed, or not installed on the participant's mobile device. Mobile app usage will be measured based on the number of time a participant interacted the EMI and mobile app during the study. For each time the participant used the mobile app, participant usage information about the date and time of use, and the module name (Module 1, 2, 3, or 4) will be recorded. Furthermore, participants will be asked to provide the "estimate of how many times have you used the mobile app in the last 4 weeks" on the online post-test survey after 4 weeks of using the mobile app.

5.2.6. Data management

5.2.6.1. *Data storage*

Personal information collected during screening, baseline, and post-test will be securely stored on a remote server located in Utah, United States. Data will be uploaded from Australia via a secure portal managed by Qualitrics. Data collected on the mobile phone while doing the intervention will be stored on the participant's own device. Information such as the number of times a person using the mobile app will be de-identified and stored separately on a custom-built secure online database. The secure online database will be designed and developed by two trained software developers (Brendan Loo Gee and Arjun Rajshekhar). Records of emails sent to participants will be retained in a spreadsheet separate from survey responses.

5.2.6.2. *Data monitoring*

To participate in the study, participants will need to provide a valid email address which made them potentially identifiable. Email addresses will be used only for the purposes of contacting participants for the assessments and access to the intervention. Participants who did not consent to participate in the study will remain anonymous. Only participants who consented to participate in the study will be assigned a unique user token (ID). All survey responses will be stored separately in a secure online survey database only accessible to the researchers, and user data will be linked by the assigned unique user ID, allowing monitoring of completion of assessments and intervention.

5.2.6.3. *Data privacy*

Ethical issues include managing the privacy of personal information to reduce the risk of threats when collecting and transmitting personal data, protecting the identification of data from third parties, obtaining informed consent in obtaining personal data for research, providing the right to rescind the agreement to participate, and communicating valid clinical information via mobile device in order to reduce harm (Carter et al., 2015). The project will ensure the privacy of personal information will be managed by ensuring all data stored via the mobile app is encrypted and password protected. De-identified data about the number times users accessed the mobile app will be encrypted, sent and stored on a remote server in Australia.

The identification of personal information will be protected by the unique token that will be assigned to each participant after giving consent to participate in the study. The token will be used to track participants in the study. The token and any identifiable data of participants will be stored in a separate location. Informed consent will be obtained via a web page. This web page will invite participants to participate in the study, and it will include information about the study (including a printable version of the information sheet), as well as an online consent form for participants. The online consent will require the participant to click a box indicating that they have understood the provided information with "Yes" as a response to be involved in the study. Participants who did not complete this online consent will not progress and will be directed to a thank you page with help-seeking resources.

In order to address participants' right to rescind the agreement to participate, the project information sheet will state that participants will be able to withdraw at any time without giving a reason. If a researcher receives an email request to withdraw, the researcher will disable users access/progress of the mobile app. If the participant asks for the existing data to be removed from the database, then the principal investigator will action this request.

5.2.7. Statistical analysis

A power calculation was conducted using the G*Power software (Faul et al., 2007). Previous evaluations on standalone self-help EMI for anxiety disorders have shown small to medium range effects on symptoms (Cohen's d = 0.31). This study protocol will intend to recruit 130 participants to the point of randomisation in order to detect an effect size of d = 0.31. However, the sample size will be restricted to a total of 100 participants (50 participants per condition) because of the beta testing rules for distributing beta mobile apps to participants. Therefore, the planned sample size will be based on invited and eligible participants who completed the online baseline survey, and successfully installed the mobile app on their own device. It is expected that approximately 30% will not proceed to randomisation leaving approximately 100 participants in the trial. The expected drop out of 30% is based on the studies identified in the systematic review in Chapter 3.

Data analysis will be carried out using IBM SPSS Statistics for Windows, Version 22.0 (IBM, 2013). Primary outcomes will be tested using a mixed-model approach repeated

measures approach, which is an intention-to-treat analysis that uses all available data under the missing-at-random assumption (Molenberghs, 2000). Hedges' g will be used to calculate the effect sizes. Between-group effect sizes will be computed by subtracting baseline between-group Hedges' g from the between-group post-test Hedges' g.

Between-group comparison of baseline demographics and outcome measures and post-test attrition results will be undertaken using an independent samples *t*-test for continuous data, or chi-square tests for categorical variables. Descriptive statistics will compare demographic, user satisfaction, and mobile app download and usage measurements. Means and standard deviations will be calculated for demographic and user satisfaction. Descriptive analysis of download and usage data will be used to examine the percentage of participants that downloaded the mobile app after allocation, the number of times participants used each module, and the number of times a module was used.

5.3. Discussion

Smartphone mobile apps delivering EMI for anxiety disorders are promising treatments to reduce symptoms. This study protocol described an RCT aimed at evaluating the effectiveness of a new EMI for social anxiety that was developed in the case study in chapter 4. Additionally, the RCT aims to examine the effectiveness of EMIs to reduce social anxiety symptoms more generally. Studies so far have focused on the effects of EMIs for generalized anxiety. However, very few studies have examined the effectiveness of EMIs for social anxiety.

This RCT study will plan to compare a standalone self-help or self-guided EMI via smartphone versus waitlist control group. Therefore, the trial will not include a study arm that receives a different intervention or different components of the EMI. However, such trials can be undertaken if the EMI proves effective compared to control. A strong feature of this protocol is the analysis of the download and usage data of the mobile app. This is different to another similar protocol by Lindner et al. (2013) who do not consider these types measurements. These results can address important questions of the use of the EMI on anxiety symptoms.

If the EMI is found to be effective, then standalone self-help or self-guided smartphone application may be evaluated in a sufficiently powered RCT to test the EMI efficacy. Such an outcome will encourage further investigation to optimise the intervention, such as tailoring the intervention to accommodate the needs of the individual and investigating how best to scale up the intervention to maximise public health impact.

5.3.1. Future research

While this study design is underpowered to find a small effect, the author's intention was to evaluate the effects of the EMI on social anxiety symptoms, which could inform the design of a fully powered trial that could examine the individual EMI components. While the expected drop out of 30% was calculated based on mainly *human-supported* EMIs, future research on *standalone* EMIs will expect a higher drop out rate than human-supported EMIs. Particularly, some researchers have suggested the use of new trial designs to evaluate the delivery of EMIs at the right times and location of an individual (Schueller et al., 2017). Micro-randomised trials have been suggested in modelling the causal effects and time-varying effects for components within an EMI (Klasnja et al., 2015). Future RCTs and use of other study designs on the EMI, such as Multiphase Optimization Strategy (MOST) and the Sequential Multiple Assignment Randomised Trial (SMART), may be designed to investigate the causal and time-varying effects of each module of the intervention (Collins et al., 2007).

6. CHAPTER 6
Ecological Momentary Intervention for Social Anxiety: Study Outcomes from a Pilot Randomised Controlled Trial

6.1. Introduction and Background

This chapter describes the results of a pilot Randomised Controlled Trial (RCT) on the effects of a new Ecological Momentary Intervention (EMI) for social anxiety. This chapter follows from the previous chapter which provided the study protocol for the RCT (Chapter 5).

Sections 6.1.1 to 6.1.4 provide a background of the RCT study evaluating an EMI for social anxiety. Section 6.1.1 provides a background of psychotherapy interventions for social anxiety, including background on previous research examining in electronic interventions (e-interventions) for social anxiety. Section 6.1.2 provides background on Ecological Momentary Interventions (EMI) for social anxiety, which is a type of e-intervention for social anxiety. Section 6.1.3 gives a brief description of the research related to EMIs for social anxiety. Finally, Section 6.1.4 provides the objective of the RCT for evaluating an EMI delivering exposure therapy for social anxiety which was developed in a case study in Chapter 4.

6.1.1. Psychotherapy interventions for social anxiety [9]

Social anxiety is defined as the persistence of fear or anxiety of social situations and performance, the scrutiny of others, and the corresponding withdrawal from interpersonal interactions (American Psychiatric Association, 2013). One of the most effective treatments for social anxiety is exposure therapy, which is a component of Cognitive Behavioural Therapy (CBT) (Hofmann et al., 2013, Huppert et al., 2003, Ponniah and Hollon, 2008). Typically, a trained therapist delivers CBT (consisting of cognitive restructuring, exposure therapy, and homework exercises) face-to-face individually or in a group setting (Mayo-Wilson et al., 2014, Huppert et al., 2003). Therapist-delivered CBT

[9] This section on Psychotherapy Interventions for Social Anxiety is similar to Section 5.1.2 and 5.1.3 in Chapter 5 of this thesis.

is one of the most well-known psychotherapy interventions for treating social anxiety (Mayo-Wilson et al., 2014) and is recommended as a first-line treatment for social anxiety disorder. However, social anxiety disorder is also associated with low levels of help-seeking which may hinder individual's from receiving professional help from a therapist (Chartier-Otis et al., 2010, Olfson et al., 2000). Alternative approaches to delivering CBT or other psychotherapy interventions include self-help or therapist guided e-interventions for anxiety disorders delivered via a web application or a portable hand-held device, which may be effective in treating symptoms with minimal therapist support (Christensen et al., 2014, Cuijpers and Schuurmans, 2007). Self-help web applications have the potential to increase help-seeking intentions for social anxiety and encourage individuals to seek help with a therapist (Griffiths et al., 2017). However, there appears to be mixed evidence around the use of self-help applications for social anxiety, especially the poor attrition rates (high drop-outs) that are attained in most efficacy trials.

Barriers to adoption for e-interventions is an under-explored area in mental and behavioural health research (Mohr et al., 2014). Other areas of e-Health have explored adoption however these studies are often confined to technologies relating to electronic medical records and clinical decision support systems (Ross et al., 2016). Factors associated with adoption can be measured in multiple ways, including examining attrition and adherence rates of e-Health applications in RCT studies. Usage metrics can be used to measure the extent to which a user is engaged with the e-intervention (Eysenbach, 2005). Attrition rates in RCTs can refer to participants not completing follow up assessments, or a decline in the usage of an e-intervention over time, or the converse of adherence (Eysenbach, 2005, Geraghty et al., 2013). Attrition is important factor for adoption of a self-help application for social anxiety, especially when determining the efficacy of the intervention or treatment.

6.1.2. Ecological Momentary Interventions (EMI) for social anxiety [10]

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" (Heron and Smyth, 2010). EMIs also sometimes refer to as "Just-In-Time

[10] "Ecological Momentary Interventions (EMI)" is defined here and repeated in other chapters of this thesis (Chapter 3, Chapter 4, and Chapter 5).

Health Interventions" (Danaher et al., 2015, Schueller et al., 2017), that use methods of dynamic tailoring, and intelligent real-time therapy (Nahum-Shani et al., 2016). 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 (Heron and Smyth, 2010, Schueller et al., 2017). EMIs may be suitable for treating social anxiety symptoms that may return before, during or after receiving an intervention or treatment from a therapist (Schueller et al., 2017). Furthermore, EMIs may be suitable for treating symptoms of depression, generalised anxiety, and stress (Schueller et al., 2017). While many people do not seek help for their social anxiety (Ormel et al., 2008, Wang et al., 2005), a standalone self-help EMI using mobile technologies such as mobile apps may facilitate help-seeking intentions and behaviours for an individual with social anxiety symptoms.

6.1.3. Related research to EMIs for social anxiety [11]

A systematic review of randomised controlled trials (RCT) has found promising results for EMIs aimed at reducing symptoms of anxiety and stress (Loo Gee et al., 2016). Since the review search by Loo Gee et al. (2016) which was conducted in January 2014, two RCTs have examined the efficacy of EMIs for social anxiety (Dagöö et al., 2014, Enock et al., 2014a). A recent study that compared CBT and Interpersonal psychotherapy (IPT) via smartphones demonstrated CBT to be superior to IPT (Dagöö et al., 2014). Additionally, a study by Enock et al. (2014a) showed cognitive bias medication on smartphones to be superior to waitlist control at post-test. However, Enock et al. (2014a) did not evaluate exposure therapy alone on smartphones against waitlist at post-test. To date, no study has examined the efficacy of a standalone self-help EMI delivering exposure therapy alone for social anxiety via hand-held smartphones.

6.1.4. Objectives

The aim of this study is to investigate the effects of a standalone self-help EMI delivering exposure therapy for social anxiety. Specifically, this study aims to examine a new standalone or self-guided EMI which allows a person to learn strategies to cope with social anxiety in different settings or time periods. Therefore, the EMI can directly target

[11] This section of Related Research to EMIs for Social Anxiety is the same as in Section 5.1.6 in Chapter 5 of this thesis.

symptoms in a naturalistic setting, which can potentially lead to better outcomes on anxiety and mental wellbeing (such as reducing psychological stress, anxiety sensitivity, and generalised anxiety and depression). Additionally, the author anticipates that brief self-help therapeutic content on the mobile phone will benefit people whom may not seek professional help for their anxiety due to barriers seeking help. It is hypothesised that the EMI will be significantly more effective in reducing symptoms of social anxiety and stress than a waitlist control group. Effects on social anxiety may also translate into reduced symptoms of generalised anxiety and depression and reduced stress. Additionally, it is hypothesised that the EMI will increase help-seeking behaviours. Lastly, user satisfaction of the EMI for social anxiety and the usage of the mobile app will also be examined.

6.2. Methods

Data collection for the study began on 7th of March 2017 as part of an RCT study on the impacts of an EMI targeted at reducing social anxiety symptoms. Post-test assessments were completed on 25th of July 2017. A full description of the RCT design and methods of the trial is described in a previous chapter (Chapter 5). Data analysis began on the 26th of July 2017.

6.2.1. Participant recruitment

The Facebook research advertisement posts were delivered to a total of 6,096 people. Of these people, a total of 368 Facebook users clicked on the posts that contained a short description of the study with a website link to the participant information sheet, screening assessment, and baseline survey. Three separate Facebook posts were published on 7th of March 2017, 17th of March 2017, and 2nd of May 2017 and were boosted by paid advertising across a period of three months.

6.2.2. Participant flow

A total of 180 people consented to participate in the study, of whom 160 participants were assessed for their eligibility to participate in the study (20 were lost to screening for eligibility). Of these people, 88 participants did not satisfy the inclusion criteria, and were excluded, due to living outside Australia (n = 3), being under 18 years of age (n = 2), not having an valid email address (n = 3), not owning an Apple iOS 8.2 or later mobile device

(*n* = 13), not being proficient in English (*n* = 2), currently receiving medication for anxiety problems (*n* = 23), currently seeking professional help for problems with anxiety or depression (*n* = 28), having a diagnosis of schizophrenia or bipolar disorder (*n* = 2), having a SOPHS score that was either minimal (less than 4) or severe (more than 16) (*n* = 11), or having not finished screening (*n* = 1). After exclusion, 72 participants completed the online baseline survey. Following the completion of the online baseline survey, 17 participants did not finish baseline survey. 55 participants were randomised and allocated to the trial study arms. However, 6 people (10%) formally withdrew from the study. 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 analyses of download, mobile usage, and outcome measurements. The 49 participants (23 intervention and 26 waitlist control) who completed the baseline assessment, were randomised into the study, and did not actively withdraw during the study were retained in the trial, and their outcomes are reported in the present analyses. Figure 19 shows a consolidated Standard of Reporting Trials (CONSORT) diagram of the flow of participants in the study.

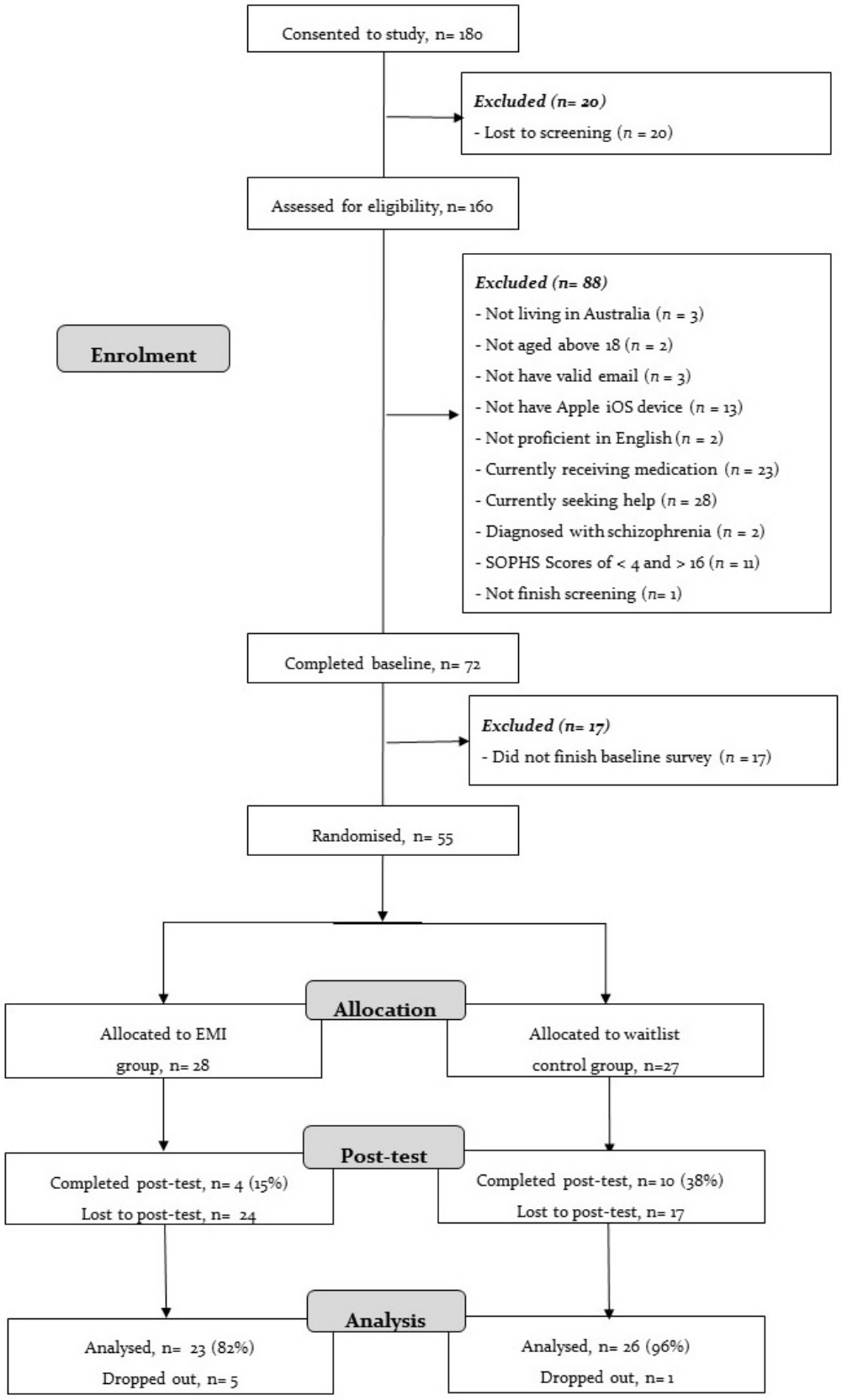


Figure 19. Flow diagram of participants in RCT

6.3. Results

6.3.1. Baseline characteristics

The majority of the 49 participants was female, *n* = 40 (81%). The most common education level of participants was year 12 or equivalent (34.7%), followed by bachelor's degree (24.5%), certificate level I-IV (12.2%), diploma/associate degree (12.2%), graduate diploma/graduate certificate degree (8.2%), year 10 or equivalent (2.0%), master degree (4.1%), and doctoral degree (2.0%). 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%). These figures are largely consistent with the Australian population (Australian Bureau of Statistics, 2015). Most participants used their mobile phones frequently, with one-half reporting use 20 or more times per day (46.9%), and the remainder reported using their phone 10 to 20 times per day (28.6%), and 5 to 10 times per day (24.5%). The age of participants ranged from 18 to 60 years old (mean age = 28.7, standard deviation (SD) = 12.4 years). The average severity of social anxiety at baseline fell in the moderate range, based on the SOPHS (mean score = 8.98, SD = 3.24) and Mini-SPIN measures (mean score = 6.47, SD = 2.11). At baseline, there were no differences between study groups in education, employment, living region, average use of participant's mobile phone per day, social anxiety symptoms, anxiety sensitivity, generalised anxiety and depression, or psychological distress. Table 10 shows the baseline demographics of participants who satisfied the inclusion criteria and the study measures as a function of the group.

Table 10. Baseline characteristics of participants by the group and statistical comparisons between groups.

Demographics	**EMI Group (n = 23)**	**Control Group (n = 26)**	**Comparison Between Groups**
Age (years)			
Mean age (SD)	29 (11.1)	29 (13.7)	$t(47) = -0.078$, $p = .938$
Range	18-54	18-60	
	n (%)	**n (%)**	
Gender			
Female	19 (82.6%)	21 (80.8%)	$\chi^2(1, n = 49) = 0.028$, $p = .863$
Male	4 (17.4%)	5 (19.2%)	
Education			
Year 10 or equivalent	1 (4.3%)	0 (0%)	$\chi^2(1, n = 49) = 7.039$, $p = .425$
Year 12 or equivalent	10 (43.5%)	7 (26.9%)	
Certificate Level I-IV	2 (8.7%)	4 (15.4%)	
Diploma/Associate Degree	2 (8.7%)	4 (15.4%)	
Bachelor Degree	4 (17.4%)	8 (30.8%)	
Graduate Diploma/Graduate Certificate	2 (8.7%)	2 (7.7%)	
Masters Degree	2 (8.7%)	0 (0%)	
Doctoral Degree	0 (0%)	1 (3.8%)	

Employment status			
Full-time	5 (21.7%)	8 (30.8%)	$\chi^2(1, n = 49) = 3.997, p = .262$
Part-time	11 (47.8%)	8 (30.8%)	
Unemployed	0 (0%)	3 (11.1%)	
Not in the labour force	0 (0%)	0 (0%)	
Student	7 (30.4%)	7 (26.9%)	
Living region			
Metro Capital City	10 (43.5%)	13 (50.0%)	$\chi^2(1, n = 49) = 1.632, p = .442$
Urban Metro City (population > 100,000)	6 (26.1%)	9 (34.6%)	
Rural Region	7 (30.4%)	4 (15.4%)	
Average mobile phone usage			
5 to 10 times per day	4 (17.4%)	8 (30.8%)	$\chi^2(1, n = 49) = 1.834, p = .400$
10 to 20 times	6 (26.1%)	8 (30.8%)	
20 or more times	13 (56.5%)	10 (38.5%)	
Outcome measurements			
SOPHS			
Mean score (SD)	9.65 (3.6)	8.38 (2.7)	$t(47) = 1.378, p = .175$

Mini-SPIN			
Mean score (SD)	6.78 (2.3)	6.19 (1.8)	$t(47) = 0.976$, $p = .334$
ASI			
Mean score (SD)	24.61 (11.8)	21.62 (9.5)	$t(47) = 0.978$, $p = .333$
PHQ-4			
Mean score (SD)	5.39 (2.7)	4.26 (1.5)	$t(33) = 1.728$, $p = .093$
DQ5			
Mean score (SD)	12.96 (3.7)	12.0 (3.2)	$t(47) = 0.974$, $p = .335$

Note: SD: standard deviation; SOPHS: Social Phobia Screener Scale; Mini-SPIN: Mini- Social Phobia Inventory; ASI: Anxiety Sensitivity Index; PHQ-4: Patient Health Questionnaire-4; DQ5: Distress Questionnaire-5

6.3.2. Primary analysis

Primary analysis involved examining all primary and secondary outcomes. These outcomes investigated the mental health impacts of the EMI for social anxiety.

In total, 14 participants (28.5%) completed the post-test assessments. A statistically significant interaction between group and time would be indicative of a differential change in the effect of the intervention relative to the control condition on primary or secondary outcomes. Table 11 shows a summary of the results for outcome measures for social anxiety symptoms, anxiety sensitivity, general anxiety and depression, and psychological distress.

Table 11. Estimated means and standard errors for each group at pre-test and post-test measurement points, including the group x time interactions for the intention-to-treat analysis.

Outcome Measures	*Group*	*Pre-test, EM (SE)*	*Post-test, EM (SE)*	*Group x time interaction*	*Between-group effect size (Hedges' g) at post-test*
SOPHS	EMI Group	9.6 (0.67)	10.3 (1.80)	$F(1, 11.6) = 0.280$, $p = .606$	*EMI vs Control* = 0.38
	Control	8.4 (0.63)	7.9 (1.08)		
Mini-SPIN	EMI Group	6.8 (0.44)	7.1 (1.07)	$F(1, 13.1) = 1.447$, $p = .250$	*EMI vs Control* = 1.19
	Control	6.2 (0.41)	4.0 (0.59)		
ASI	EMI Group	24.6 (2.23)	33.0 (4.75)	$F(1, 11.2) = 4.646$, $p = .054$	*EMI vs Control* = 1.28
	Control	21.6 (2.09)	20.2 (2.96)		
PHQ-4	EMI Group	5.4 (0.46)	7.6 (1.22)	$F(1, 14.2) = 3.510$, $p = .082$	*EMI vs Control* = 3.12
	Control	4.3 (0.43)	3.6 (0.67)		
DQ5	EMI Group	13.0 (0.71)	14.7 (1.67)	$F(1, 11.5) = 0.812$, $p = .386$	*EMI vs Control* = 0.35
	Control	12.0 (0.67)	12.0 (0.99)		

Note: EM: Estimated Means; SE: Standard Errors; Mini-SPIN: Mini- Social Phobia Inventory; ASI: Anxiety Sensitivity Index; PHQ-4: Patient Health Questionnaire-4; DQ5: Distress Questionnaire-5

6.3.2.1. *Primary outcome: Social anxiety symptoms*

The primary outcome of social anxiety symptoms was measured using the SOPHS and Mini-SPIN. Mixed model repeated measures estimates were used to test whether SOPHS and Mini-SPIN scores had differential changes in the EMI group relative to the waitlist control group. Pre-test and post-test mean scores and standard deviations were used to determine the effect sizes. On the SOPHS scores, the mixed-model analysis did not yield a significant main effect of time on all measurement time points ($F(1, 11.6) = 0.006$, $p = .938$) and did not yield a significant main effect of group ($F(1, 17.3) = 2.070$, $p = .168$). Furthermore, there were no significant interaction effects between group and time on the SOPHS outcome measurements ($F(1, 11.6) = 0.280$, $p = .606$, hedges' $g = 0.38$). However, there were non-significant increases in SOPHS scores for the EMI group from pre-test ($M = 9.6$) to post-test ($M = 10.3$), and non-significant decreases in the control group from pre-test ($M = 8.4$) to post-test ($M = 7.9$).

On the Mini-SPIN scores, the mixed-model analysis did not yield a significant main effect of time across all measurement points ($F(1, 13.1) = 0.471$, $p = .504$) and no significant main effect of group ($F(1, 18.0) = 3.525$, $p = .076$). Furthermore, there were no significant interaction effects between group and time on Mini-SPIN outcome measurements ($F(1, 11.6) = 1.447$, $p = .250$, hedges' $g = 1.19$). There was a non-significant increase in Mini-SPIN scores for the EMI group from pre-test ($M = 6.8$) to post-test ($M = 7.1$), and a non-significant decrease in Mini-SPIN scores for the control group from pre-test ($M = 6.2$) to post-test ($M = 4.0$), consistent with outcomes on the SOPHS.

6.3.2.2. *Secondary outcomes*

The ASI, PHQ-4, and DQ5 scores were examined to identify whether there were differential effects of the EMI group relative to the waitlist control group on secondary outcomes of anxiety sensitivity, generalised anxiety and depression, and psychological distress respectively. Pre-test and post-test mean scores and standard deviations were used to determine the effect sizes.

6.3.2.2.1. Anxiety sensitivity (ASI)

On the ASI scores, the mixed-model analysis did not yield a significant main effect of time on all measurement time points ($F(1, 11.1) = 2.487$, $p = .143$). However, there was a significant main effect for group, which indicated that the EMI group showed greater ASI scores across both time points compared to the control group ($F(1, 28.3) = 5.041$, $p = .033$,

η_p^2 = 0.10). There were no significant interaction effects between group and time on ASI outcome measurements (F(1, 11.2) = 4.646, p = .054, hedges' g = 1.28). There were non-significant increases in ASI scores for the EMI group from pre-test (M = 24.6) to post-test (M = 33.0), and non-significant decreases in ASI scores for the control group from pre-test (M = 21.6) to post-test (M = 20.2).

6.3.2.2.2. Generalised anxiety and depression (PHQ-4)

On the PHQ-4 scores, the mixed-model analysis did not yield a significant main effect of time (F(1, 14.2) = 0.471, p = .327) However, there was a significant main effect for group, which indicated that the EMI group had greater PHQ-4 scores across both time points compared to the control group (F(1, 13.8) = 11.478, p = .004, η_p^2 = 0.19). There were no significant interaction effects between group and time on PHQ-4 scores (F(1, 14.2) = 3.510, p = .082, hedges' g = 3.12). There were non-significant increases in PHQ-4 scores for the EMI group from pre-test (M = 5.4) to post-test (M = 7.6), and non-significant decreases in PHQ-4 scores for the control group from pre-test (M = 4.3) to post-test (M = 3.6).

6.3.2.2.3. Psychological distress (DQ5)

On the DQ5 scores, the mixed-model analysis did not yield a significant main effect of time (F(1, 11.5) = 0.876, p = .369) and did not yield a significant main effect of condition (F(1, 24.1) = 2.122, p = .158). Furthermore, there were no significant interaction effects between group and time on the DQ5 (F(1, 11.5) = 0.812, p = .386, hedges' g = 0.35). There were non-significant increases in distress scores for the EMI group from pre-test (M = 12.0) to post-test (M = 14.7), but no change in distress scores for the control group from pre-test (M = 12.0) to post-test (M = 12.0).

6.3.2.2.4. Help-seeking behaviours (AHSQ)

A total of 13 participants (26.5%) completed the AHSQ score at post-test measurement time point. These included three participants from the EMI group and 10 participants from the control group. A Pearson's chi-square test of contingencies (with a standard alpha level of 0.05) was used to evaluate whether there were differences in the proportions participants who sought any help or did not seek any help in the past 4 weeks between the EMI group and the control group at post-test. On the AHSQ score, the chi-square test did not show a statistically significant difference between the EMI and the control group (χ^2(1,

n = 13) = 2.359, p = .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%).

Four of the 13 participants provided data for seeking help from a doctor/GP or a mental health professional (e.g., school counsellor, psychologist, or psychiatrist) at post-test. A chi-square test did not show a statistically significant interaction when comparing the difference in the proportions of participants who sought help or did not seek help from a doctor/GP between the EMI group and the control group at post-test (χ^2(1, n = 4) = 1.333, p = .25). One of the participants in the EMI group sought help from a doctor/GP (n = 2) compared to none in the control group. Similarly, a chi-square test showed no significant effect of group on seeking help from a mental health professional at post-test (χ^2(1, n = 4) = 1.333, p = .25), with one participant in the EMI group (n = 2) reporting seeking help from a mental health professional, compared to none in the control group.

6.3.3. Secondary analysis

Secondary analysis examined two types of attrition: 1) attrition from the follow-up assessments and 2) attrition from the EMI for social anxiety (Eysenbach, 2005). Attrition was examined to understand participants interest in the EMI, and the frequency of using the EMI for their social anxiety (Geraghty et al., 2013). Furthermore, user satisfaction was examined to understand participants acceptance of the EMI for their social anxiety.

6.3.3.1. *Attrition from follow-up assessments*

Attrition from follow-up assessments was examined in terms of participants not completing the post-test assessment, or participants formally (actively) withdrawing from the study.

Of the 55 participants randomised, a total of 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). Six participants formally withdrew from the study and were not included in the analyses due to the requirements of the ethics protocol.

Consistent with the ethical protocol, researchers did not obtain a reason from participants for their withdrawal.

There were no significate differences in age ($t(47) = 0.822$, $p = .415$), gender ($\chi^2(1, n = 49) = 0.105$, $p = .746$), education ($\chi^2(1, n = 49) = 6.398$, $p = .494$), employment status ($\chi^2(1, n = 49) = 2.978$, $p = .395$), living region ($\chi^2(1, n = 49) = 3.115$, $p = .211$), or average mobile phone usage ($\chi^2(1, n = 49) = 4.290$, $p = .117$) between participants who completed the post-test assessment and those who did not. Furthermore, there were no significant differences in social anxiety symptoms (Mini-SPIN: $t(47) = -2.428$, $p = .190$), anxiety sensitivity (ASI: $t(47) = -1.576$, $p = .122$), generalised anxiety and depression (PHQ4: ($t(47) = -1.380$, $p = .174$), or psychological distress (DQ5: $t(47) = -0.736$, $p = .465$) among completers and non-completers of post-test assessment.

6.3.3.2. *Attrition from the EMI mobile app*

Attrition from the EMI mobile app was firstly assessed based on participants downloading and installing the mobile app on their device across each study group. Attrition was further investigated on the basis of the average number of times a participant accessed the mobile app (by post-test), and the usage logs of the mobile app that were passively recorded on the system.

6.3.3.2.1. Mobile app downloads

Mobile app downloads were determined by whether participants downloaded and installed or not downloaded and installed the mobile app on their device, tracked through the Testflight portal. Of the 49 participants that were analysed, 16 participants (33%) downloaded and installed the mobile app from both study groups. Of those who downloaded and installed the mobile app, 13 participants were in the EMI group, and three participants were in the control group (and therefore downloaded the mobile app after the waiting period). Only two of the participants in the EMI group who installed the mobile app also completed the post-test assessments. A total of 33 participants (67%) did not download and install the mobile app on their device from both groups, 10 participants in the EMI group and 23 participants in the control group.

6.3.3.2.2. Mobile app usage

Mobile app usage was determined both by participant self-report of an estimate of the number of times the mobile app was accessed (at post-test) and by usage logs that were passively recorded on the system. Two participants in the EMI group who installed the mobile app on their device provided the number of times they used the mobile app in the 4 weeks after being allocated to the study arm. The estimated average number of times that participants self-reported to access the mobile app was 3.0, (median = 3.0, *SD* = 1.4). This appeared to be consistent with the actual usage logs that were passively recorded in the system. Of the 49 participants that were analysed, a total of 15 participants from both groups (30%) logged at least one or more uses of the mobile app during the study. Overall, the average number of uses that were recorded in the logs was 6.0, (median = 6.0, *SD* = 3.07). Specifically, 14 participants in the EMI group passively logged at least one or more uses while using the mobile app during the study. The average 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).

A total of 90 usage logs were passively recorded on the system through the participant's use of the mobile app in both groups. 15 participants from both groups individually logged into Module 1 (25 usage logs), Module 2 (26 usage logs), Module 3 (22 usage logs), and Module 4 (17 usage logs). Furthermore, a total of 15 participants accessed module 1, 13 participants accessed module 2, 11 participants accessed module 3, and 8 participants accessed module 4. **Error! Reference source not found.** shows the number of usage logs of each EMI module that were accessed by participants relative to each study group.

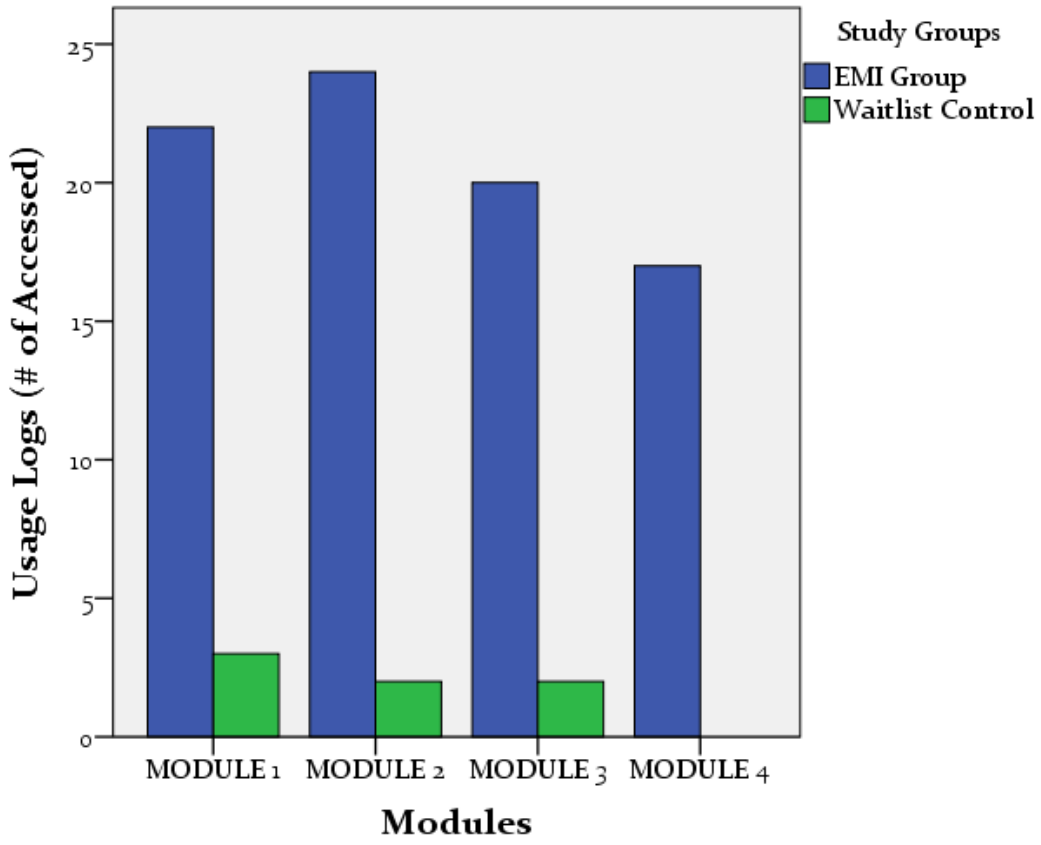


Figure 20. The number of times each module was accessed by participants in each study group, based on usage logs.

6.3.3.3. *User satisfaction*

A total of two participants (4.0%) in the EMI group who downloaded and installed the mobile app provided data on the post-test user satisfaction items. Items were rated from 1 to 10, where 1 indicated they completely disagreed and 10 indicated they completely agreed with the item. The average 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 average user satisfaction rating scores (out of 10) for finding the mobile app to be "interesting", and to be "useful in the future", were 6.0, (SD = 1.4). The average rating for finding the mobile app to be "helpful", was 5.0, (SD = 0.7). Furthermore, the average ratings to "recommend the mobile app to other people who might benefit from it", was 7.0, (SD = 1.4). Finally, all participants agreed that the mobile app was easy to understand (mean score = 8.0, SD = 0).

6.4. Discussion

The aim of the pilot RCT study was to compare the effects of a new standalone self-help EMI based on exposure therapy delivered on a smartphone with a waitlist control condition. This section summarises and contextualises the overall findings (including primary and secondary analysis), the lessons learnt, implication for future EMI development and evaluation, and limitations of the research.

6.4.1. Overall findings

The study showed that the EMI group had no statistically significant benefits any of the primary and secondary outcome measurements compared to the waitlist control group. These results were divergent from other studies testing EMIs for anxiety and depression (Loo Gee et al., 2016, Schueller et al., 2017). A systematic review and meta-analysis study conducted by Loo Gee et al. (2016) found a small significant effect of EMIs in reducing generalised anxiety when compared to control and/or comparison group (Effect Size (ES) = 0.32). Furthermore, a review conducted by Schueller et al. (2017) found a meta-analysis of studies of EMIs on depression to have a small-to-medium significant effect on depressive symptoms (Hedge's g = 0.48) (Versluis et al., 2016). Despite the negative findings, results on the effectiveness of the current EMI for social anxiety are inconclusive due to only four participants in the intervention group completed the follow-up assessments at 4 weeks. The negative results are in context of several factors that are common in many eHealth intervention studies.

A common phenomenon in many e-intervention trials is when a substantial proportion of participants who drop-out before the completion of a trial. Attrition is a common and natural characteristic of self-help e-interventions and it can impact on the validity of results (Eysenbach, 2005). Particular factors that may influence drop-out include relative advantage, compatibility, complexity, trialability, and observability (Eysenbach, 2005). Particularly, fully-automated e-interventions often report drop-out rates of up to 80% (Geraghty et al., 2013). This study provides some quantitative analysis of drop-out rates for mobile-based interventions, such as EMIs.

The current study found many of the participants in the EMI group did not complete follow-up assessments. Of the 55 participants who were randomised (including the six who

formally withdrew from the study), 83% of the participants did not complete the post-test assessment, 4 weeks after being allocated to the study arm. A more recent study of fully-remote mobile apps to treat depression in Hispanic and Latino population in the United States revealed participation decreased by 50% from week 1 to week 4, with 14% of participants dropping out by the end of 12 weeks (Pratap et al., 2018). A similar study showed high usage during the first 2 weeks of the mobile-based intervention, however falling to 44% adherence by the 4th week of the mobile-based intervention (Anguera et al., 2016).

Of the four participants in the EMI group who completed the post-test assessment, only two participants downloaded the mobile app. This is similar to a fully remote clinical trial on two active mobile apps for depression reported by Arean et al. (2016) who found 57.9% of participants did not download their assigned mobile-based intervention for depression. Furthermore, they found there was no significant difference in participant demographics between users who downloaded the mobile app and those who did not. Additionally, most users of the mobile apps tended to use the intervention no more than 2 weeks. While the adherence rates were poor, they suggest that mobile apps may be more useful for people with moderate levels of depressive symptoms.

Among the participants who installed the mobile app, the self-reported results showed participants on average used the mobile app for their social anxiety 3-6 times over the 4 weeks that they were allocated to the EMI group, which is likely to be considerably less than the dosage that might be required to have an impact. While the sample of participants usage logs was small (15 participants), the percentage of the mobile app usage of the EMI fell as participants progressively used the 4 modules. Indeed, the findings from this study coupled with recent qualitative analysis on drop-out rates on a web-based intervention, suggest the loss of motivation for eHealth interventions may be related to participant frustration with the technology, perceiving the content as irrelevant and incomprehensible, choosing not to use the technology because of other life priorities, and lack of face-to-face encounter (Lie et al., 2017).

Despite the poor attrition and usage of the EMI, it appears that participants who used the mobile app for their social anxiety were generally satisfied with it. Overall, the mean of the user satisfaction rating out of 10 for participants in the EMI group ranged from 5-8,

which indicated participants appeared to have moderate levels of satisfaction in terms of using the mobile app, using the mobile app to improve everyday skills, and finding the mobile app helpful, interesting, and easy to use. However, it is important to note that these results on user satisfaction are from the responses of only two of the four participants who downloaded the mobile app and completed the post-test assessment at 4 weeks. While the response rate was low, the current results show some evidence to suggest that participants who engaged with the mobile app were satisfied with the current mobile app.

6.4.2. Lessons learned

To our knowledge, this study is the first to investigate the effects of a *standalone self-help* EMI delivering exposure therapy on social anxiety outcomes. Although there was a poor uptake of the EMI in the study, a number of lessons can be learnt from conducting the current study. These lessons can be important for implementing future EMIs for people with social anxiety.

- **People with social anxiety may benefit from additional personal support to assist in using the EMI for their needs.** While many participants did not complete the post-test assessments, some participants were satisfied with using the EMI. This indicated some people did find the app useful however users may have required more assistance to gain benefits from the mobile app. Personal support may include remote or face-to-face support provided by peers, trained lay people or professionals to assist people with social anxiety requiring additional support to use the EMI for their personal needs.

- **People with social anxiety must be approached to use the EMI to maintain training goals of the EMI.** The current study took a passive stance to maintain therapy goals during the RCT. A more active approach would have encouraged people with social anxiety to use the EMI more. Proactive strategies include regular monitoring of downloads and survey responses, assisting participants with using the app, use of push notifications, and sending regular reminders to complete follow-up surveys.

- **Content of the EMI must be aligned close with people's attitudes, behaviors, and cultural values embedded in their environment.** Our study was conducted online and remotely delivered in multiple environments. This is challenging setting for delivering a standalone EMI, as it is unclear whether the intervention aligns to various attitudes, behaviors, and cultural values of users. Perceptions of the usefulness of the EMI may have been superseded by other factors related to the person's life (i.e., work commitments, or relationship problems). Adoption to EMIs will require addressing person, technology, and contextual barriers to improve the uptake of these types of mobile-based interventions (Cajita et al., 2018).

- ***People must be offered adequate training before given the EMI to use for their social anxiety.*** No formal training was provided to participants before given the app to use for their social anxiety, which prevented the ease of use or encouraged users to learn how to use the EMI for their social anxiety symptoms. Furthermore, the low rates of download and poor app usage may have been due to technical challenges of downloading and installing the mobile app on the participant's device. It may have been only the most highly motivated or technologically savvy users that engaged in this study. Participants must be given adequate training to download and engaging instructions to use the app to understand the perceived usefulness of the EMI for their symptoms. Furthermore, the current study used text and images to display the download and installation instructions of the mobile app. The use of video instructions may increase the installation and uptake of the mobile app. Additionally, alternative methods for download and installation can be explored for future EMIs. For instance, HTML5 mobile web apps, and other mobile cross-platforms may improve the accessibility of the mobile app's content with much easier installation procedures.

6.4.3. Implication for future EMI development and evaluation

A number of implications for the future design of EMIs can be drawn from the lessons learnt from the current study. These implications are discussed in the next sections.

6.4.3.1. *Developing and evaluating EMIs for engagement*

Considering the motivation of the user of the EMI is important to consider while conducting data collection for the RCT study. Theories from the Human-Computer Interaction (HCI) literature suggest fundamental factors of engagement comprise a number of discrete phases or stages through which engagement can progress (Peters et al., 2009). Another important factor is the artefact (i.e., mobile app) in which the user is engaged with, and the measurable factors of user *interest* and *attention* to the artefact (Peters et al., 2009). For example, identifying early decreases in interest and attention to an EMI could be managed using cohort maintenance strategies, such as live telephone contact and participant incentive schemes (Geraghty et al., 2013). Furthermore, introducing more appealing pictures and videos (with less text) into the content of the EMI mobile app may increase engagement. Alternatively, novel user interface features could have been deployed in the mobile app to increase engagement. For instance, the use of the mobile phone's embedded accelerometers and cameras could be deployed to make content more interactive for participants. Future EMIs could be developed and evaluated with these strategies in mind before beginning participant recruitment.

6.4.3.2. *Integrate the development of EMIs with study infrastructure*

Some researchers have proposed new evaluation methodologies to evaluate EMIs. In particular, current RCT designs cannot provide all the necessary data to identify context, personalisation, and tailored experiences (Schueller et al., 2017). Micro-randomised trials (MRTs) have been proposed as an alternative study design for EMIs whereby multiple decision points and randomisations are applied in order to accommodate the dynamics of a person's changes in symptoms, cognitive functioning, and behaviours (Klasnja et al., 2015). The current EMI and the study infrastructure implemented the baseline assessments, follow-up assessments, and randomisation algorithm on a separate platform. Assessments and group randomisation were disconnected from the EMI, so participation in the RCT was not a seamless experience for participants. Better integration of assessments into the mobile app may have made the study less burdensome for participants, leading to lower attrition rates, although this was not possible within the context of the test platform.

6.4.3.3. *Developing and evaluating EMIs holistically*

Examining the EMI as a whole and the interrelations of its parts may improve uptake and impacts of the EMI for people with social anxiety. A holistic approach would comprise of fitting the EMI mobile app to human and contextual factors. For instance, instead of developing a complete EMI followed by a RCT study, a mixed-method study design may address some of the limitations of assessing the added value of the EMI for the population (van Gemert-Pijnen et al., 2011). By including all stakeholders from multiple disciplines coupled with continuous and systematic evaluation on the EMI, a research study can demonstrate the impacts of the EMI more effectively (van Gemert-Pijnen et al., 2011). Future EMI designs and evaluations may include a more holistic approach when examining effects on the population.

6.4.4. Limitation

One of the main limitations of the current study was the small sample size and high attrition. The study provided an underpowered sample to detect the differential effects of the EMI group relative to the control group. This was partly due to challenges in recruitment and partly due to high rates of attrition from the assessment and intervention (low adherence). Due to resource restrictions of the research project, certain aspects of the study and features of the intervention were difficult to implement. Indeed, this study demonstrates the complexities and difficulties of implementing this type of intervention and study design. In particular, the time required to develop the EMI for the study was underestimated in terms of complexity and size. A final limitation of the study relates to the long-term effects of the EMI. An extended follow-up on symptoms may have determined whether the EMI was effective on the proposed outcomes after an extended period of using the mobile app. However, given the high attrition after four weeks, better retention strategies would be required before testing long-term outcomes. The four-week period may have nonetheless been too short, restricting dosage and time to have an impact in terms of changes in social anxiety symptoms. Further reminders and incentivisation of assessment completion may be required to reduce the high attrition seen in the present study.

6.5. Conclusion

This pilot RCT study is the first study to evaluate a standalone self-help EMI for social anxiety. The results of the study showed that the EMI did not improve social anxiety symptoms, anxiety sensitivity, psychological distress, or generalised anxiety and depression. Effect sizes suggested that the intervention was associated with non-significant deterioration in anxiety symptoms and secondary outcomes. Therefore, modification of the EMI and trial design is warranted before conducting a fully powered RCT study to evaluate whether an EMI can reduce social anxiety. In particular, further investigation of the role of support in increased efficacy and adherence to the EMI may be warranted.

6.6. Trial Registration

The current study was registered through the Australian New Zealand Clinical Trials Registry (ACTRN12617000060347).

7. CHAPTER 7
Concluding Remarks

Chapter 7 concludes this thesis on the development and evaluation of an Ecological Momentary Intervention (EMI) for social anxiety. Section 7.1 provides brief summaries of the findings from each study of this thesis. Section 7.2 identifies major parallels and differences of this thesis with previous research on EMA and EMI for social anxiety. Section 7.3 poses a theoretical position of the research presented in this thesis within the context of development and evaluation of EMIs for social anxiety. Section 7.4 outlines the limitations of the research presented in this thesis. Section 7.5 recommends a future direction for EMI research on social anxiety. Finally, Section 7.6 and 7.7 conclude Chapter 7 by describing the practical implications of this research to software developers, mental health researchers, and clinicians.

7.1. Summary of Study Findings

In Chapter 2, the meta-review of EMA and EMI studies identified systematic reviews examining general psychopathology (including addiction), mood disorders, eating disorders, mood disorders and borderline personality disorders combined, borderline personality disorder, smoking addiction, and psychosis. The focus of the identified reviews included observational studies using EMA and interventions using EMA. Of the included reviews reported in the meta-review, only four systematic reviews conducted a meta-analysis to determine the effect size of the associations between activity levels and depression, hunger and eating episodes, and mobile phone interventions increasing long-term quit rates. From the results of the meta-review, gaps in the EMA and EMI literature for specific mental disorders were identified, including the need for reviews on EMIs that reduce daily stressors associated with the negative experiences of day-to-day anxiety levels.

Chapter 3 described a systematic review of the effectiveness of EMIs for stress and anxiety. The review identified 15 RCTs examining generalised anxiety, stress, anxiety and stress, panic disorders, and social anxiety. The majority of the EMIs evaluated in the included RCTs were *integrative EMIs* comprising self-monitoring and CBT or other forms

of psychotherapy using a range of mobile technologies, followed by RCTs examining simple EMIs comprising of multimedia content and RCTs evaluating interactive EMIs comprising self-monitoring only. The meta-analysis demonstrated a reduction in generalised anxiety outcomes when EMIs were compared to a control and/or comparison group. Furthermore, the review findings suggested EMIs were effective in reducing stress when compared to a control group. The review findings found a lack of evidence for the effects of EMIs on panic disorders or social anxiety. The review concluded that further research was warranted to investigate the effectiveness of EMIs for anxiety disorders such as panic and social anxiety and the usefulness of EMIs as an adjunct to existing psychotherapy treatments. Moreover, the review indicated that further work is required to determine how EMIs can be implemented on a mobile app platform to deliver components of an EMI targeting anxiety disorders, such as social anxiety.

A case study was presented in Chapter 4 on the conceptual design and development of an EMI for social anxiety. The case study demonstrated an eight-phase design process. Agile modelling, model-driven development, and bottom-up development were synthesised into a single development process. Key learnings were identified, which included: designing the EMI in iterative steps by implementing parts of the exposure therapy protocol into the software first before implementing technical elements, managing uncertainties and changes to the EMI design through the engagement of multiple stakeholders during the design process, developing the EMI software to be modular and repurposable, engaging and communicating the EMI designs to multiple stakeholders of an R&D team during all phases of the design process, documenting the software design of the EMI throughout the process in order to reflect on design decisions taken to achieved the solution, and finally managing timelines in developing the mobile app without automated software development tools and processes. Lastly, the design of modular EMIs encourages the optimisation of EMI components and the possible scaling up of the EMIs to maximise public health impacts.

In Chapter 5, the protocol for the design of an RCT that aimed to examine the effects of an EMI for reducing social anxiety symptoms was presented. This RCT aimed to fill a gap in the research evidence, as many existing RCTs have focused on the effects of EMIs in reducing generalised anxiety symptoms. Furthermore, the RCT was the first single study to investigate a *stand-alone* EMI delivered via smartphone versus waitlist control group.

The protocol also described the analysis of download and usage data of the EMI mobile app.

Chapter 6 presented the results of a pilot RCT on the effectiveness of a standalone EMI for reducing social anxiety symptoms. After excluding six participants who formally withdraw from the study, a sample of 49 participants was recruited and analysed. A large proportion of the participants did not complete the post-test assessment, and many of the participants did not download or use the mobile app during the trial. The EMI was not associated with a significant improvement in social anxiety symptoms relative to waitlist control group. Furthermore, the EMI was not associated with significant improvements in anxiety sensitivity, psychological distress, or generalised anxiety and depression relative to the waitlist control group. Furthermore, there were no significant improvements in help-seeking behaviours between the EMI and waitlist control. However, participants who used the mobile app were largely satisfied with the EMI.

7.2. Comparison with Previous Research

To the author's knowledge, the meta-review in Chapter 2 of this thesis is the first meta-review of EMA and EMI research on mental disorders. The meta-review highlighted the need for further investigation into the use of EMA and EMI for anxiety and stress. EMA research on anxiety disorders can generate insight into associations between daily symptoms of anxiety and everyday environments (Walz et al., 2014). Additionally, the meta-review presented the findings of EMI studies. EMI studies for mental disorders showed mixed results for the efficacy of EMIs for mood disorders, borderline personality disorders, psychosis, and eating disorders. Indeed, the meta-review suggested more systematic reviews of EMI studies for mental disorders are needed to directly investigate the effects of EMIs on anxiety symptoms compared to control or comparison groups. Given the heterogeneity of EMA and EMI research, more research on which components of EMA and EMI that have the most impact on symptoms outcomes may progress the field. Furthermore, there is also a need for greater rigour and innovation in the design of future research testing EMA and EMI. Overall, the meta-review provided an overview of EMA and EMI research for mental health problems and demonstrated the methodological potential in observational studies of mental disorders and interventions using EMA for mental disorders delivered in real-time.

The systematic review in Chapter 3 of this thesis suggested that EMIs can be a promising treatment for generalised anxiety. The small effect size on generalised anxiety symptoms reported in the meta-analysis (Hedges' g = 0.32) is comparable to the small to medium effects of EMIs on mental health and positive psychological well-being outcomes (Hedges' g = 0.47) (Versluis et al., 2016), and the effects of smartphone app interventions on anxiety symptoms (Hedges' g = 0.32) (Firth et al., 2017). The mixed results of the review findings of EMIs for panic disorders and social anxiety are consistent with those reported by Heron and Smyth (2010) and Ehrenreich et al. (2011). In particular, the present review in Chapter 3 found a promise for EMI in increasing the efficiency of face-to-face therapy for social anxiety, with similar symptom reductions obtained using few sessions when EMI was implemented (Gruber et al., 2001). Nevertheless, this systematic review suggests more work is needed to directly investigate the relative effects of EMIs with and without human support, and whether EMI enhances existing treatments.

In the case study presented in Chapter 4 of this thesis, the development of an EMI for social anxiety was demonstrated using an eight-phase design process. This case study is the first design research study of an EMI for social anxiety using existing software development approaches. The design process in Chapter 4 builds on technology-driven design models for mental and behavioural health proposed by Mohr et al. (2014) and Kelders et al. (2016). The iterative design phases and long timeframes presented in this case study are similar to the study by van Mierlo et al. (2014) in which agile methods allowed the expansion of the functionality and value of their intervention; however, van Mierlo et al. (2014) also reported challenges to overcoming their limited budget and meeting timelines while developing their intervention. Similarly, this case study presented comparable experiences to those of Noordman et al. (2017) who found agile development approaches to be useful in the early phases of development, although found the approach challenging within the restricted timeframes of a project. Lastly, the case study presented new insights on the construction of the EMI software components, and it highlighted the particular barriers to the design process using software development approaches to engage and communicate the EMI designs to clinical psychologists and mental health researchers. Overall, the design artifacts produced from this case study address *how* EMI can utilise the mobile app platform to optimise the delivery of EMI components.

The considerable effort placed on the development process described in Chapter 4 of this thesis resulted in obstacles of engaging and communicating the design of the EMI with relevant stakeholders, managing documentation and managing timeframes. Some of the author's experiences of using UML and other software artifacts appear to support some of the evidence of design artifacts and system documentation in other industries (Dobing and Parsons, 2008, Petre, 2013). For instance, user stories and scenarios are effective design tools used between psychologists and software developers (Topham et al., 2015). This is perhaps unsurprising because user stories are often written in a natural language understood by both the psychologist and software developers. Of note, the software developer in the R&D team would use annotated notes written in a natural language to describe complex features within a UML diagram for a clinical psychologist or mental health researcher. Design notes described in a natural language could be supplemented with appropriate training on modelling notations, modelling techniques, and design artifacts to improve communications with stakeholders. This training could overcome some of the barriers of engaging stakeholders in the modelling process due to challenges in understanding the modelling tools used in the design process.

The RCT protocol for the evaluation of an EMI for social anxiety presented in Chapter 5 is one of the first to examine a standalone EMI delivering exposure therapy for social anxiety. The protocol paper by Lindner et al. (2013) presents a similar study design to the RCT protocol presented in Chapter 5. However, the Lindner et al. (2013) study protocol examined a mobile application as an adjunct to face-to-face therapy, while the present study aimed to deliver exposure therapy via the EMI app alone. An additional strength of the protocol was the inclusion of an analysis of the mobile app download and usage data of the mobile app. Furthermore, the RCT protocol presented in chapter 5 was designed to determine further investigation of tailoring the EMI to accommodate the relative needs of individuals with social anxiety. Finally, the study results of RCT protocol was designed to inform the design of future RCTs evaluating the causal and time-varying effects of each module of the EMI (Collins et al., 2007, Klasnja et al., 2015, Schueller et al., 2017).

In Chapter 6, the study outcomes of the pilot RCT of an EMI for social anxiety did not show significant reductions in social anxiety symptoms relative to the waitlist control group (p = .606). The results on social anxiety symptoms are largely consistent with previous studies that examine EMI with therapist support, which also did not find

significant effects (Gruber et al., 2001, Loo Gee et al., 2016). Furthermore, the results of the RCT were divergent from other studies examining EMIs targeting generalised anxiety and depression. This divergence may partly be because the EMI in this pilot study was designed to specifically target social anxiety symptoms rather than other forms of anxiety (Schueller et al., 2017, Versluis et al., 2016), and the exposure approach used to treat social anxiety may be less amenable to delivery without guidance in a standalone app. Additionally, the majority of participants did not engage in the study and EMI. While low engagement is typical of e-interventions (Eysenbach, 2005), the poor engagement identified in the pilot RCT in Chapter 6 suggests considerable changes to the study design and delivery of the EMI may be required to determine whether there are meaningful effects of the EMI components.

7.3. Theoretical Implications of Findings

This thesis provides evidence to support the feasibility of EMA and EMI research for mental disorders, with a focus on anxiety disorders. The meta-review findings provide evidence to support EMA as a valid research methodology to investigate the daily lives of individuals experiencing mental illnesses. Observational studies using EMA have shown an association between daily affective states, and everyday behaviours in multiple environments. This is perhaps different from retrospective methods which require people to recall these daily changes of affective states, behaviours and environments upon assessments of their symptoms. Furthermore, the meta-review and systematic review of this thesis support EMA and EMI as promising real-time approaches to treat mental health problems directly in real-time, or to aid the facilitation of medication or psychotherapy treatments delivered by a therapist. In particular, real-time approaches, such as EMI, can benefit people who experience generalised anxiety symptoms.

Psychotherapy treatments can potentially be delivered in real-time during challenging social situations, which can potentially improve the ecological validity of existing treatments for people with social anxiety. The meta-analysis provided in Chapter 3 of this thesis provides some evidence for EMIs in reducing generalised anxiety symptoms compared to a control or comparison group. Although the systematic review in this thesis did not found EMIs to be effective in reducing social anxiety symptoms, no new RCT studies on EMIs for social anxiety were identified in the review since the most recent

literature review conducted by Ehrenreich et al. (2011) covered research completed up to June 2010. Furthermore, the majority of EMIs for anxiety disorders assessed in the systematic review were integrative EMIs that delivered self-monitoring and in-situ computerised psychotherapy exercises using various mobile technology features, such as sensors, text messaging, and native programming libraries. In the literature review, integrative EMIs using mobile technologies of smartphones and other wearables were found to deliver personalised therapeutic content targeting anxiety symptoms, such as social anxiety, directly on a smartphone device at all times of the day.

While some EMIs are simple to design, other EMIs that integrate self-monitoring with electronically delivered psychotherapy content are complex to develop. In Chapter 3, the systematic review identified EMI studies that examined three types of EMIs based on the framework of Carter et al. (2007b). Although the literature review in Chapter 3 used this framework to review studies on the complexity of existing EMIs, questions were raised about how mobile technologies are used to deliver EMIs. This thesis addressed the questions of how EMI is developed through the design of an EMI from a software development perspective. In the case study presented in Chapter 4, the employment of software development techniques to understand the complexities of developing EMI components for social anxiety was demonstrated. Complexity was examined through the synthesis of the software development approaches into a unified eight-phase design process. The development process was intended to study the design activities, processes, and design artifacts of the construction of a mobile app prototype, and its underlying components, delivering the EMI content targeting the reduction of social anxiety symptoms.

In the case study, the eight-phase design process allowed the R&D team to distil parts of the behavioural change theory underpinning an EMI implementation from the technical specification of the target mobile app platform. Furthermore, the design process allowed the EMI to be built in "small, meaningful, self-contained and repurposable" software components through continual iterations on the overall design of the EMI (Hekler et al., 2016). As predicted, this design process in the case study resulted in the development of the software architecture that supported the behavioural change theory of the EMI. Furthermore, the agility of the iterative design processes allowed the R&D team to identify risks and uncertainties of possible requirement changes in the early

phases of the design process. Overall, this type of EMI design may be suitable for complex and adaptable EMIs, which require regular feedback from domain experts (e.g., mental health researchers and clinical psychologists) during the development process (Schueller et al., 2017).

While the design theory used in this thesis was rigorous and systematic, there remained some limitations of the theory that emerged during the eight-phase design process. In particular, the UML artifacts to construct the components of the EMI with mental health researchers and clinical psychologists were difficult to use to communicate designs, which it may have slowed down the design process. Indeed, certain strategies (such as annotated design notes) were adopted by the software developer to overcome some of these communication challenges; however, it seems supplementary training may be required for mental health researchers and psychologists to understand the UML modelling process properly. Perhaps some aspects of the design process, such as the simplification of the UML modelling notation, or fewer UML artifacts, may require some compromise to account for both the limitations in the understanding of the software developer in the evidence-based content, and the limited understanding of the mental health researchers and psychologists in the design process of the mobile app delivering the EMI.

The results of Chapter 6 suggest that EMIs for social anxiety may require the better engagement of individuals with social anxiety in order to observe improvements in symptoms or greater efficiency of treatment. While the evaluation study contained in this thesis did not show that the EMI significantly reduce social anxiety symptoms or other related outcomes relative to waitlist control group, it is clear that there are potential factors that may have influenced these poor results. First, many of the participants in the study did not complete post-test assessment after 4 weeks, which weakened statistical power to detect a significant result. Second, critically, many participants in the intervention group did not download the mobile app. The low rate of downloads may indicate technical or computer literacy challenges involved in downloading and installing the mobile app. Third, the mobile app usage of the EMI fell as individuals engaged with the EMI. While the current evidence in this thesis suggest that the present EMIs was not effective in reducing social anxiety, any future designs of EMIs may need to incorporate additional components that can enable participants to obtain the intervention, and subsequently sustain the engagement of participants during the trial. For example, the use

of video instructions may have increased the installation and uptake of the mobile app, or the implementation of HMTL5 mobile web apps may improve the accessibility of the EMI's content with much easier installation procedures. Incorporation of potential users (mental health consumers experiencing symptoms of social anxiety) as an additional key stakeholder in the development of a future EMI would likely provide substantial benefit in adherence and outcomes (Bovaird, 2007). User-led design can be particularly time- and resource-intensive and was not feasible in the current research program, but would be strongly recommended for future research in this area.

Given parts of this thesis elaborate on the development of the EMI, the research presented in this dissertation also contributes to our knowledge on the *design* aspects of the research of EMIs for social anxiety. While existing studies on EMIs and other similar e-interventions have emphasised on the *evaluation* aspects of research (Pagliari, 2007), this thesis provides evidence of how activities of development and evaluation of EMIs can run in parallel with each other. For instance, the dynamic development of an EMI in real-time based on continual evaluation of the EMI in multiple contexts may result in more tailored EMI designs for people with social anxiety. Indeed, the dynamic aspects of daily experiences of social anxiety can be explored to infer day-to-day triggers that can directly push EMI content that is personalised to an individual's context. However, one of the first steps is to understand how the complex design of EMIs can be aligned with the research aims of EMIs for social anxiety.

7.4. Limitations of the Research

There were several limitations with the research presented in this thesis. First, due to financial constraints, only one reviewer was used to screen, assess, and extract data from the included reviews of the meta-review in Chapter 2. Two reviewers are considered optimal in order to reduce the risk of bias. Second, the systematic review in Chapter 3 included studies that examined EMIs with varying levels of therapist support. There were very few studies in the systematic review that directly investigated the relative effectiveness of EMIs with and without human support or whether EMIs added to face-to-face therapy or online human support. Further research is required to investigate these questions. Additionally, the meta-review and systematic review may have missed studies that were not reported in the peer-reviewed literature or non-English language studies.

Third, the development methods employed in the case study in Chapter 4 were time-consuming, and communication with stakeholders was challenging as noted, especially given the restrictions of delivering a functional mobile app that is ready to evaluate for a research study. Indeed, more work can be done on improving the modelling notations of design artifacts and improving the time estimates of an EMI research project. Fourth, a major limitation of the RCT evaluation study was the small sample size. This was partly due to challenges in recruitment and partly due to high rates of attrition, along with poor adherence. More work is needed on the design of the RCT study. For instance, the study design could have included fewer selection criteria or better integration of the pre- and post- assessments into the mobile app. Finally, the engagement of the EMI content in the mobile app and download of the mobile app was very low. Engagement may be improved introducing more appealing multimedia content (with less text) or making the content of the EMI briefer and working with consumers to optimise the design and flow of the EMI. Furthermore, alternative methods for download and installation can be explored to improve download rates of mobile apps.

7.5. Future Research

Section 5 provides recommendations for future research on the development and evaluation of EMIs for social anxiety. Section 7.5.1 discusses directions for future studies of EMIs for social anxiety. Section 7.5.2 covers broader issues to be addressed in future studies.

7.5.1. Where to from here?

Following the pilot evaluation study of the EMI, the next phase of the project would require a sufficiently powered RCT to test the EMI efficacy. However, before a fully-powered study, design changes to the EMI and its delivery are likely to be required, as noted above. Smaller studies could be conducted prior to the RCT study to ensure various therapeutic components of the EMI are effective, such as factorial experiments to identify active components. Continuous refinement of the EMI may require software developers to assess new tools and methods that may address problems with developing the EMI. Researchers may experiment with various design approaches that bridge the silos of interdisciplinary collaborations between software developers, mental health researchers,

clinicians, and consumers in future research projects (Pagliari, 2007). Furthermore, future RCT studies of EMI for social anxiety may evaluate whether additional face-to-face support by a therapist or the use of a supplementary internet-based intervention might improve adherence to the EMI, thereby improving effects on social anxiety symptoms. This may require further development of the content and technology delivering the EMI.

7.5.2. Broader issues

Broader issues of adherence need to be addressed in EMIs for social anxiety. These issues can be investigated empirically with methods that can better engage with the end-users of EMIs for social anxiety. There is growing interest in user involvement in the design of e-interventions for mental health and other similar health problems, including an emphasis on user-led or participatory design (Blanchard et al., 2013). More work can be done on the involvement of software developers and clinicians in the design process. In particular, the perspectives of clinicians in the design process may be relevant when examining the impacts on existing clinical workflows or using technology to facilitate parts of the therapeutic care of their patients. Additionally, software developers need the extensive knowledge and experiences of practising clinicians to design EMIs better to improve outcomes and maximise safety for end-users. More research on tools and methods may be needed to address the development of EMIs in order to increase the efficiency of the development process, while also ensuring the technology solution of EMIs meet the goals of the intervention. Finally, EMIs must align with underlying behavioural change theories, and EMIs must meet the ethical standards of current clinical practice.

7.6. Practical Implications

This thesis provides software developers with a guide to the development of EMIs for mental health problems with domain experts, such as mental health researchers and clinical psychologists. It provides key learnings reflected from a design process that is oriented towards the perspectives of software design and engineering. Software developers could use this thesis to understand how the implementation of the software of an EMI for social anxiety and well-being can be constructed with the collaboration of an interdisciplinary team. Furthermore, mental health researchers and clinical psychologists could use this thesis to identify ways to engage with software developers to develop EMIs

for social anxiety or other mental health problems. Lastly, this thesis could be used by domain experts of EMIs to engage with software developers who require translating the requirements of a system into formal technical specifications for delivering the EMI to end-users.

7.7. Conclusion

Overall, the research presented in this thesis found that more research is needed on EMA and EMI to examine and potentially modify the symptoms of mental disorders in real time within everyday settings. The current research also found EMIs to be a promising treatment for generalised anxiety. However, there was no consistent evidence for the effectiveness of EMIs for panic disorder and social anxiety disorder. Despite this outcome, this thesis suggests more investigation of EMIs for panic and social anxiety disorders, with or without face-to-face human support, is needed. The research presented also found that EMIs are complex to develop within a multidisciplinary team of developers, clinicians and researchers.

The EMI developed within this thesis was not found to be effective in a pilot evaluation study for reducing social anxiety symptoms; however, this research was markedly limited by low uptake and adherence and high attrition in the RCT pilot study. Future RCT studies with larger sample sizes and additional face-to-face support, along with further refinements to improve adherence to the EMI, may lead to better outcomes. Given the growing interest in mobile technologies for clinical care to improve mental health outcomes, EMIs may emerge as promising tools to treat a variety of mental disorders such as social anxiety. However, further EMI development and rigorous evaluations are required. EMIs have the potential to be more potent in targeting symptoms than other interventions that are not delivered in real-time. Developing these interventions requires sufficient knowledge, time, resources, and financial support to produce high-quality mental health interventions. Future research into EMIs requires collaboration between diverse stakeholders with various expertise around the challenges of treating social anxiety. This collaborative process involving varied disciplines may allow space for new methods that can address the problems of social anxiety, which a single discipline may not be able to achieve. A shared and respectful understanding of each discipline's methods

should be fostered in order to create purposeful tools that can be agreed upon from all stakeholders involved in the design process.

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9. APPENDIX A

Findings Relating to EMA Protocol and Feasibility Issues

Review Studies	**Subgroup**	**Targeted Population**	**Summary of the EMA protocol details**			
			Sampling Contingency	***Data Collection Periods***	***Delivery Mode***	***Feasibility Issues***
Wenze & Miller (2010)	General Population	Mood Disorder	**X**	**X**	Pen and Paper (P&P) and beeper was the simplest method for people with remitted Bipolar and depression. Also, it was found that P&P visual mood charts to be simple to record depressive symptoms. Other methods include answer-only mobile calls and wrist actigraph for young people. Other methods include salivary cortisol sensors and electroencephalographic sensors and heart rate monitors.	Reviewers found EMA to be feasible for mood disorders with good adherence, low dropouts, and high completion rate for people with mood disorders. People with bipolar completed fewer assessments than healthy control. There was no relationship between the severity of symptoms and the compliance with EMA protocol. No strong relationship between the severity of symptoms and the intensity of assessments
aan het Rot et al. (2012)	General Population	Major Depressive	Most studies used random-	Average number of days was 11	Studies used P&P and Personal Device	EMA was feasible for people with bipolar. Individuals with

		Disorder (MDD) and Bipolar Disorder	based interval sampling. Some studies used fixed-based interval sampling.	(range of 3-54 days). Average number of repeated assessments per day was 7 (range of 2-10 messages). Total number of repeated assessment was 70 (range of 12-420 messages).	Assistants (PDA) method and blood pressure monitors. Some EMA studies used lab-based measures such electroencephalography (EEG) and functional magnetic resonance imaging (fMRI). These methods were used young people with depression and adults with remitted bipolar.	bipolar would tend to adhere better to the EMA protocol if clinicians were given insights of the progress of treatment. The feedback provided by EMA reports, such as the progress of data collection, found to determine the efforts of completing assessments and changing behaviour for clinicians.
Telford et al. (2012)	General Population	Major Depressive Disorder (MDD)	**X**	**X**	Wristwatch signals, mobile phone, Personal Digital Assistance (PDA), pager signals, portable saliva testing, and blood pressure monitor were used in EMA studies.	The review reported on one study showed 95% completed at least 50% of assessments, and 70% completed 95% of assessments.
Burton et al. (2013)	Adults between the age of 18-85	Major Depressive Disorder (MDD)	**X**	Day-time monitoring using actigraph range between 3-30 days. Night-time monitoring using actigraph range	EMA studies used wrist actigraph devices to monitor activity.	**X**

				between 2-14 nights.		
Ebner-Priemer & Trull (2009)	General Population	Mood Disorder or Borderline Personality Disorder (BPD)	One study on bipolar used fixed-based interval sampling. Two studies on BPD used fixed and event-based interval sampling.	Reviewers found changing the time for the data collection period of EMA study can change the diagnosis of the mental illness.	Reviewers had reported that most studies on bipolar disorder used P&P method with some software are now available. A few studies on mood disorders and BPD reported to use mobile phones. EMA studies on depression used mobile phones and actigraph. Some of the studies that used actigraph were used for depression treatment. Across both mood disorder and BPD studies, blood pressure and heart rate monitors were used. Reviewers reported a high risk of confounding variables when using physiological recording such actigraphs.	**X**

Nica & Links (2009)	General Population	Borderline Personality Disorder (BPD)	Random or event-based sampling was used in reported studies.	Study periods range from 24 hours to 1 month with an interval ranging from 15 minutes to once per day. No average rate of assessments was reported	Reviewers reported the transition of P&P to electronic formats such as mobile phones and PDAs. One study for BPD in the review reported the use of heart rate monitors and skin conductance sensors.	**X**

Haedt-Matt & Keel (2011a) ** Haedt-Matt & Keel (2011b)	General Population	Eating Disorder including Bulimia Nervosa and Binge Eating Disorder and including subtype of Anorexia Nervosa	78% or a majority of EMA studies used event-based sampling. It was suitable for assessing before and after binge or purging episodes. Studies that used fixed and random-based sampling were associated with the Effect Size (ES). Larger ES was found with random-based interval sampling, and smaller ES were found with fixed or random-based sampling.	Average EMA recording periods ranged from 6-14 days with an average length of 7.71 days. Event-based sampling ranged from 1 eating period to 5 weeks. Fixed or Random-based sampling averaged 7.8 times a day. Longer periods and greater frequency rate were associated with smaller Effect Size (ES).	**X**	Adherence rate for random-based sampling ranged from 76%-92%, average of 84.1% of random signals, and fixed-based sampling showed an average of 91.5% of interval ratings.
Oorschot et al. (2009)	General Population	Psychosis	**X**	**X**	EMA study on psychosis reported the use EEG to measure dopamine levels.	Reviewer reported one study showed 90% of individuals with schizophrenia completed over 2/3 of assessments. Compared to

						other studies, it was lower than studies in non-psychiatric populations (90-96%) and higher than studies on people with severe symptoms.
Myin-Germeys et al. (2009)	General Population	Psychopathology	EMA study on BPD used event-based sampling.	**X**	Devices include a blood pressure monitor to measure cortisol levels, a prefrontal cortex electroencephalography (PFC EEG), and a pupilometer.	**X**
Cain et al. (2009)	Participants of the age of 50 years and over	General Psychology and Behavior	Many EMA studies used fixed-based sampling. Only a few studies used random- or event-based sampling	Recording periods ranged from 1-365 days with a median of 2 weeks.	Majority of EMA studies on elderly used P&P with beeper or pager. Only one study used a PDA device. A couple of studies used wrist actigraph, blood pressure monitor, and heart rate monitor.	Reviewers found the compliance rate to be high in many EMA studies. Only 4 studies reported compliance rates under 18%. The attrition rate was 25%, and the reasons for drop out were because participants did not fully understand what to do.

10. APPENDIX B

Summary of Review Findings of Observational Studies using EMA

Review Studies	*Included Observational Studies*	*Population Characteristics*	*Findings of Observational Studies (under themes)*
aan het Rot et al. (2012)	48 studies: 48 controlled studies	Major Depressive Disorders (MDD) and Bipolar Disorders Age: Not Specified Gender: Not Specified	Affective States: Reviewers found low PA and high NA was associated with high stress and positive and negative events in people with MDD. This association may explain the possible links between low PA and high NA with poorer mQoL for people with MDD. Reviewers found inconclusive results for the association of PA and NA with sleep quality. Reviewers found in one study that physical activity may be influenced by changes in the PA and NA. However these results only reflect subjective measures of physical activity. Bipolar: The number of studies on bipolar patients was small. Many studies compared EMA data from people with bipolar and people with MDD. Reviewers did find differences in PA and NA between people with bipolar and people with MDD, but these differences are based on their clinical status. Reviewers reported studies that examined people with only bipolar, in which reviewers found people experienced less PA and more NA, and spent more time alone. Young People: Reviewers found high NA may occur in specific contexts. Reviewers reported the changes of PA might be associated with sleep activity and NA maybe associated with wakefulness. Reviewers concluded that sleep hygiene practices might be beneficial for young people with MDD than in adults with MDD. Reviewers found young people with MDD to have poor sleep quality. Biological Processes: Reviewers reported on a study that found an association of HPA system function with experiences of daily hassles. The HPA system function is measured by salivary levels of cortisol. Reviewers found associations between the strength of EEG signal with everyday cognitive symptoms, such as rumination and self-esteem. Reviewers found an

			association of PA and striatal activity, but no association of NA with striatal activity. Lastly, reviewers reported on a study that found less pronounced pupil dilation with more NA and less PA for young people with MDD. Remitted patients*:* Reviewers found EMA studies compared people with MDD in remission with healthy control. Reviewers found people with MDD to continue to experience high NA and stress after treatment, which may have contributed to relapse of symptoms. Reviewers found no association of physical activity with NA, but increases in PA for individuals in remission. Overall, reviewers suggest daily symptoms may remain over time after recovering from treatment. Treatment Progress: Reviewers found increases in PA and decrease in NA after receiving medical treatment for depression. Reviewers also found side-effects of treatment were positive predictors to treatment drop-out because of the negative effect on QoL. Reviewers found an association of NA and PA with pleasant activity, which may be positive predictors for completing treatment such as psychotherapy. Reviewers found PA and NA and affective responses to emotional events all normalized in treatment responders but not in non-responders. In psychotherapy treatment, reviewers found higher NA than control at baseline, subsequently, NA decrease over the course of the treatment, however, younger people with MDD did not experience less nervousness, and they did not spend more time with others. However, reviewers found that young people with MDD who spent more time with close peers were more likely to recover than young people with MDD who spent more time with general peers.
Telford et al. (2012)	19 studies: 14 controlled studies, 5 non-controlled studies	Major Depressive Disorders (MDD) Age: Not Specified Gender: Not Specified	Affective States: Reviewers found people with MDD to experience higher NA and lower PA than healthy control. Reviewers found people with MDD to experience increases of PA during the course of the day followed by reductions, and increases of NA during the course of the day followed by decreases. Reviewers found changes in PA and NA with negative or positive events. Reviewers found people with MDD reported more stress with ongoing activities and social environments. Reviewers found greater NA was associated with negative events; however, reviewers were unclear in the difference between an event and activity-related stressors.

			Reviewers found sleep quality were associated with PA and NA levels of people with MDD and healthy control. Reviewers found PA and activity enjoyment to be associated with high mQoL, and NA and physical complaints to be associated with lower mQoL. Reviewers found caffeine consumption with NA and nervousness among young people with MDD. Work Performance: Reviewers found depression to be associated with absenteeism and a reduction in work productivity. Biological Processes: Reviewers found cortisol changes to have some association with negative events among men with MDD and people with a history of mood disorders. Reviewers found more erratic patterns of cortical secretion throughout the day. Overall, reviewers found little association between cortical secretion with stressful or social events in people with MDD. Genetic Factors: Reviewers found PA acts as a protective factor in NA reactivity, this may indicated shared genetic vulnerabilities to depression matters less among people who experience more PA. Reviewers found genes may be associated heightened NA from everyday stress and accelerate stress-sensitization. Treatment Progress: Reviewers found that PA and NA with events were predictors to treatment effects. Reviewers found side effects of medication treatment was associated with lower mQoL among people with MDD, especially among people who drop-out of the study. Reviewers found mQoL did not increase after receiving treatment, but the treatment stabilized. Reviewers found mQoL takes longer to return after treatment. Reviewers found stress was a predictor of rewarding experiences of activity before and after treatment for people with MDD.
Burton et al. (2013)	18 studies: 18 controlled studies	Major Depressive Disorders (MDD)	Physiological Mechanisms: Reviewers found a significant difference in objective measures of daytime activity (using actigraphy) between people with MDD and control (standardized mean difference: -0.76, 95% CI, -1.05 to -0.47).

		Age: Adults aged 18-65 years Gender: Not Specified	Treatment: Reviewers found a significant increase in objective measures of daytime activity (using actigraphy) following treatment (standardized mean difference: 0.53, 95% CI, 0.2 to 0.87). Reviewers found a small reduction in overnight activity following treatment (standardized mean difference: -0.36, 95% CI, -0.65 to -0.06). Reviewers found small improvements on sleep efficiency (standardized mean difference: 0.19, 95% CI, -0.38 to 0.76).
Ebner-Priemer & Trull (2009)	Not Reported	Mood Disorders and Borderline Personality Disorders (BPD) Age: Not Specified Gender: Not Specified	***Mood Disorders:*** Affective States: Reviewers found changes in NA to be associated with negative events for people with depression. Reviewers reported on one study that found people with MDD experience increases of PA during the day with later peaks, but more peaks of NA during the mornings. In a study on MDD, bipolar, and healthy control, reviewers found an increase NA and decrease PA in people with bipolar, but increase NA and decrease PA in people with bipolar or MDD with affect levels associated with stressful situations compared to healthy control. Bipolar: Reviewers reported one study found a significant inverse correlation between sleep or bed rest and the changes of mood, whereby sleep loss was followed by a move towards hypomania/mania on the next day, and sleep gain was followed by a shift towards depression on the next day. Work Performance: Reviewers reported a study on the economic effects of people with MDD which found reported impaired performance was associated with a reduction in work productivity. Biological Processes: Reviewers reported no differences in cortisol or heart rate variability between people with depression and people without depression. Reviewers reported a study on MDD that found an association of psychosocial factors with cortisol levels, but changes may occur during mild to moderate episode of clinical depression.

Genetic Factors: A study on female twins with or without MDD, reviewers found cotwins with depression showed larger mood response to stress than cotwins without MDD, which may indicate a potential endophenotype for depression.

Physiological Mechanisms: Reviewers reported on a study that found lower motor activity levels during wake time and high motor activity levels and decreases in immobility during sleep periods of people with MDD. Reviewers reported on a study of people with MDD that found a reduction of bright light exposure and change in heart rate during physical activity, especially the differences between day-time and night-time activity. In a study on Unipolar Depression, reviewers reported on a study that found less motor activity and less awaked to be associated with more depression in the morning compared to the evening. In a study on bipolar, reviewers reported the findings of a study that found circadian physical activity level to be unstable and more variable during inactive periods of the illness.

Treatment Progress: Reviewers reported on EMA studies that found high variability of QoL among people with depression, with a decrease in enjoyment of activities, more physical complaints, and increase mood before perceiving medication treatment, after receiving treatment QoL among people with depression improved. Reviewers found EMA findings relating to predicting treatment progress. Reviewers reported on a study that found daily stress was associated with early treatment response to cognitive therapy. Reviewers reported on studies that found side-effects of medication treatment were associated with decreases in QoL, with strong associations of side-effect and QoL with treatment dropout. Reviewers reported on a study that examined bright light therapy for people with MDD. It was reported that motor activity increased at treatment onset. Reviewers also reported in another study on MDD that found diurnal hypoactivity and 24-hr rhythm amplitude decreased at treatment onset.

Borderline Personality Disorder:
Affective Instability: Reviewers found there was an association between affective instability and BPD symptoms. High variability of PA and NA were reported significantly more in people with

			BPD than people with other mental illnesses or healthy individuals. Emotions such as hostility, fear and sadness were reported more by people with BPD. Reviewers also found a study on sequences of daily emotions among people with BPD. The review findings found emotions such as sadness, anxiety, and anger was regularly changing and persistent among people with BPD. Stress Reactivity: Reviewers also found changes in affective instability were related to changes in emotional valence and psychological distress. Reviewers reported on an EMA study that found aversion tension was high and frequent, rejection and low esteem were accounted for events that lead to high aversive tension. Reviewers found some association between stress and dissociation among people with BPD than people with other clinical and healthy groups. Reviewers found stress was associated with daily events and changes in PA and NA among people with BPD. Behavioural relationships: Reviewers reported on an EMA study that found high variability of interpersonal behaviours in social interactions, such as dominant, agreeable, and quarrelsome behaviours. Biological relationships: Reviewers found studies that examined people with BPD were investigating the relationship of emotional dysregulation and physiological indices of BPD. For instance, reviewers reported on a study that found high salivary cortisol levels than healthy control. Reviewers also found associations of heart rate with emotional changes. Physiological relationships: Reviewers reported on one study that found physical activity using actigraph were associated with psychological distress. Reviewers found associations between daily psychophysiological indicators and affective dysregulation in people with BPD.
Nica & Links (2009)	19 studies: 19 controlled and uncontrolled	Borderline Personality Disorders (BPD)	Affective Instability: Reviewers reported on EMA studies that found people with BPD experienced more frequent and intense NA and more aversive tension than people without symptoms. However, reviewers reported little difference of PA for people with BPD than people

observational studies	Age: Not Specified Gender: Not Specified	without a mental illness. It was also reported that people with BPD experiences more variability of PA and NA than other clinical diagnosed groups or people without a mental illness. Other review findings found changes of NA was associated with increases of NA independent of a BPD diagnosis. Stress Reactivity: Reviewers reported on EMA studies that found associations between changes in NA and PA and daily interpersonal stressors. Reviewers found 30% of affective states, such as PA and NA, were influenced by external triggers such as life events and interpersonal interactions. Reviewers found daily changes in affective states were triggered by external events, and changes of PA were associated with interpersonal interactions during events. Reviewers reported on studies that found an association between problems identifying emotions with high psychological distress and the experience of conflicting emotions. Behavioural relationships: Reviewers reported changing patterns of psychological and behavioural changes with affective instability. Reviewers also found interpersonal stress was related to rejection, self-esteem, and dissociative behaviours, however, some association were drawn between dissociative behaviours and changes in affective states. Reviewers also reported on the association of affective instability and BPD symptoms. Reviewers reported on an EMA study that found changes in affective instability were significantly related to daily suicidal ideation. Physiological relationships: Reviewers found in a couple of studies the relationship of heart rate with emotional responses. Treatment: Reviewers reported on a study found people with BPD experienced difficulties with identifying emotions during dialectical behaviour therapy than people who were more advanced in the course.

Oorschot et al. (2009)	Not reported	Psychosis Age: Not Specified Gender: Not Specified	<u>Positive and Negative Symptoms:</u> Delusions (a part of positive symptoms) and daily hallucinations were reported in the review study. Reviewers found people with psychosis experienced more visual hallucinations and intense auditory hallucinations. Furthermore, the context was found to be associated with daily hallucinations, including the withdrawal to social events, work activities and low activity levels. Other findings found people with psychosis that attended social activities or passive leisure activities were associated with increases in hallucinations. Reviewers found environmental factors, such as being in the presence of family members, were associated with variations in delusions. Reviewers found the social company to be strong predictors of psychotic experiences. *Studies on negative symptom*s were found to be associated with changes in emotions over time. In particular, reviewers found people with psychosis experienced a decrease in positive emotions, lower levels of pleasure, and small deficits in consummatory pleasure (pleasure from enjoyable activities) and larger deficits in anticipatory pleasure (pleasure from future events). Several behaviours have been explored in relation to negative symptoms. Reviewers found people who are prone to psychosis were not more socially withdrawn, and be often doing nothing. Results suggest anxiety and depression were associated with specific environments. <u>Stress:</u> Reviewer reported on studies that found daily hassles were associated with symptom severity. Reviewers found changes in stress sensitivity may be associated with changing levels of positive and negative symptoms in people with psychosis. Reviewers found previous exposures to life events (such as childhood trauma) were associated with increases of emotional reactivity (variability of PA and NA levels) to small daily stressors. <u>Substance Use:</u> Reviewer found cannabis use was associated with the onset, exacerbation, and recurrence of psychotic experiences. Reviewers found associations between cannabis use and psychotic experience. Cannabis use was found to be associated with increased intensity of psychotic experiences. Reviewers found patients with psychosis were more sensitive to mood-enhancing effects and psychosis-inducing effects of cannabis than healthy control. Reviewers

			reported on a study that found cannabis use increased hallucinations, which results may suggest immediate rewarding effects of mood were associated with cannabis use. Paranoia and Coping: The reviewers a study that found the association between paranoia and self-esteem were inconsistent results. Reviewers found higher psychosis liability was found to be associated with rapid changes of self-esteem, while decreases in self-esteem were associated with increase paranoia, which may indicate fluctuations in self-esteem may induce paranoia. Symptomatic coping that happen in daily life were negatively associated with coping symptoms measured in the clinic, and non-symptomatic coping was positively associated with coping symptoms measured in the clinic. Results may suggest effective coping is associated with the urge to develop conscious appraisal of psychotic symptoms. Biological Mechanisms: Reviewers reported on a study that found a relationship of dopamine release from physical stressor were associated with psychotic reactions to daily stressors in a patient with first degree relatives of patients with psychosis. Furthermore, review studies found values of cerebrospinal fluid, grey matter and white matter were associated with stress reactivity, whereas white matter was not associated with emotional reactivity to stress and the grey matter was not associated with stress reactivity. Gene-Environment Interactions (GXE): One study was found Met/Met genotype of patients with psychosis showed increases in psychotic symptoms and negative affect in relation to daily stressors. However, reviewers also found patients with Val/Val carriers reported feelings of paranoia in response to stress. Lastly, reviewers also found patients with COMT Val carriers reported an increase in hallucinations in response to cannabis use.
Haedt-Matt and Keel (2011a)	7 studies: 7 controlled and uncontrolled studies	Eating Disorder including Bulimia Nervosa and Binge Eating Disorder	Bulimia Nervosa: The meta-analysis study by Haedt-Matt and Keel (2011a) found hunger levels pre-binge binge episode was significantly greater than the average hunger levels (d = 2.13, 95% CI = 0.38 to 3.87; $p < .05$). However, authors also found hunger levels to be significantly lower

		and including subtype of Anorexia Nervosa Age: Not Specified Gender: Not Specified	pre-binge eating episodes than pre-regular eating hunger episode (d = -0.68, 95% CI = -0.93 to -0.42; p < .001).
** Haedt-Matt and Keel (2011b)	36 studies: 36 controlled and uncontrolled studies	Eating Disorder including Bulimia Nervosa and Binge Eating Disorder and including subtype of Anorexia Nervosa Age: Not Specified Gender: Not Specified	<u>Bulimia Nervosa</u>: The revised study meta-analysis by Haedt-Matt and Keel (2011b) found NA was greater at pre-binge episode compared to average NA levels (ES = 0.63, 95% CI = 0.45 to 0.82; p < .001). The same meta-analysis found NA was higher at pre-binge episodes than before a person consumes a regular meal or snack (ES = 0.68, 95% CI = 0.40 to 0.95; p < .001). The review also reported on the consequences of binge eating. In the same review paper, people with bulimia nervosa experience significant increase of NA from pre-binge to post-binge episodes (ES = 0.50, 95% CI: 0.35 to 0.64, p < .001). <u>Purging Behaviours</u>: the study by Haedt-Matt and Keel (2011b) presented findings on purging behaviours in people with eating disorders, including vomiting and extreme weight loss gains. It was found that NA was significantly lower at post-purging episodes than pre-purging episodes (ES = -0.46, 95% CI: -0.74 to -0.18, p < .01). Furthermore, results showed NA did not differ between post-purging and pre-binge episodes (ES = 0.10, 95% CI: -0.09 to 0.30, p = .29). <u>Subtypes of Bulimia:</u> More NA at pre-binge episodes than regular eating episodes for people with Binge Eating Disorders than people with bulimia nervosa, however, these differences were not significant (p < .01).

Myin-Gemeys et al. (2009)	Not reported	Psychopathology Age: Not Specified Gender: Not Specified	***Mood Disorders:*** Affective States: Reviewers reported on studies that found changes of diurnal rhythm was associated with changes to NA and PA for people with MDD. Reviewers also found QoL were mediated by changes to PA and NA, physical complaints, and pleasant activities. Reviewers reported on a study that found mood fluctuations was associated with the incidence of casual attributions and perception of controllability; however, there was no supporting evidence on the association between uncontrollability attributions and anxious mood for people with depression. Reviewers found that patients with MDD experienced few positive events but the same frequency of negative events. Reviewers reported on study findings that suggest people with depression showed large increases in NA than people with healthy control, people with bipolar experienced larger decreases in PA than healthy control, and people with psychosis showed larger increases in NA and larger decreases in PA than healthy control. Bipolar: Reviewers reported people with bipolar spent more time in passive leisure activities and were spent more time alone, and showed strong variability in affect levels and self-esteem. Young People: Reviewers reported on a study on young people with MDD, in which they found caffeine use was associated with sleep problems. Furthermore, young people with depression were more likely to smoke, have urges to smoke, and drink alcohol. Reviewers also found problem behaviour has been associated with emotions and emotion regulations. Work Performance: Reviewers reported study findings of people with MDD and they found depressive symptoms to be associated with work performance, such as decreases in task focus and productivity. Remitted patients*:* Reviewers reported on a study that found daily hassles were associated with stressful events in people with remitted bipolar.

Biological Processes: Reviewers reported on EMA studies that found associations between cortisol responses with daily PA and NA changes and daily activities. Reviewers reported on a study that found an association between rumination and self-esteem with patterns of alpha activities recorded by Prefrontal Cortex Electroencephalography (PFC EEG) in a laboratory. Another study found pupil dilation was associated with changing levels of PA and NA among children with MDD. There have been reported a study on Gene X Environment (G x E) in people with MDD. Reviewers found daily mood and stress were more prevalent in co-twins with MDD than co-twins without MDD.

Treatment Progress: Reviewers found increases in physical activity levels, such as household activities, active leisure time and changes in PA and NA, were found after people with depression were given anti-depressant treatment. Another study found anti-depressant treatment did not associate with changes in mQoL and decreased activity levels. However, reviewers also found increases in reward experiences of activities after treatment.

Borderline Personality Disorder:
Affective Instability: Reviewers found an association between rapid changes of NA and PA, aversive tension, and persistent of anxiety and sadness among people with BPD than people without BPD. It was reported that high variability of PA and NA, and unstable levels of hostility, fear and sadness were experienced among people with BPD.

Stress Reactivity: Many of the reported studies found an association between affective instability with the experience of daily stress and increases of dissociative behaviours. Reviewers also found NA were significantly related to impulsiveness, and self-reports of suicidal ideation and behaviours over the past year in people with BPD.

Biological relationships: In a study on BPD, reviewers found salivary cortisol were associated with hypothalamic-pituitary-adrenal (HPA) axis activity. The study found high cortisol responses to awakening and high daily cortisol levels among people with BPD.

Psychotic Disorders:

Positive and Negative Symptoms: Reviewers found people with psychosis experienced more visual hallucinations and intense auditory hallucinations. Reviewers found hallucinations were associated with contextual factors, such as social context and activity level. Delusional moments (a part of positive symptoms) and changes in PA and NA were associated with social factors and activity levels. Reviewers also found social company to be strong predictors of psychotic experiences in persons at risk of psychosis. *Reviewers found negative symptoms* were associated with people who spend time alone, a greater preference for solitude and less PA among people with schizophrenia. More time spent alone was associated with depression and anxiety in specific environments and social situations.

Stress: Reviewers found small stressors were predictors in increases in emotional reactions in people with an increased liability to psychosis, which was more pronounced in females. Reviewers also found levels of psychotic experiences were associated with daily stress. Reviewers also found people with psychosis that have previous exposures to severe stress, such as life events, were associated with sensitivity to daily stress, which may give rise to lasting behavioural liability.

Substance Use: Reviewers have reported on EMA studies that found cannabis use among people with psychosis immediately increase psychotic episodes and decrease pleasure in people who were vulnerable to psychosis. Other review findings suggest cannabis used increased hallucinations and were sensitive to mood-enhancing effects of cannabis among people with psychosis. One study in the review found cannabis use was not associated with daily state anxiety.

Paranoia and Coping: The reviewers a study that found the association between paranoia and self-esteem were inconsistent results. Reviewers also found changing levels of daily self-esteem were associated with daily experiences of paranoia. Studies on coping behaviours of people with

psychosis found symptomatic coping, using retrospective assessments, were negatively associated with coping in daily life; however, non-symptomatic coping was positively associated with coping in daily life.

Biological Mechanisms: Reviewers reported on several investigations on biomarkers among people with psychosis. Reviewer reported on the associations of daily stress and increase levels of cerebrospinal fluid and reductions in white-matter volumes in patients with psychosis. Another study reported on findings related to a study that found dopamine release induced by physical stress in a laboratory were associated with psychotic reactivity to daily stress in first-degree relatives of patients with psychosis.

Gene-Environment Interactions (GXE): One study was found Met/Met genotype of patients with psychosis showed increases in psychotic symptoms and negative affect in relation to daily stressors. However, reviewers also found patients with Val/Val carriers reported feelings of paranoia in response to stress. Lastly, reviewers also found patients with COMT Val carriers reported an increase in hallucinations in response to cannabis use.

Eating Disorders:

Bulimia Nervosa: Reviews reported studies that examined proximal antecedents of behaviours of eating disorders. Reviews found daily levels of NA, such as anger, and daily levels of PA and dissociative experiences were associated with the precedence of a binge episode for people with bulimia nervosa and binge eating disorders. The review findings of EMA studies were mixed. First, the review found one study that found a deterioration of mood and self-perception after a binge episode, while another study found increases of PA and decreases of NA and lower anger after a binge or vomit episode in people with bulimia nervosa. Another study found the levels of NA were associated with the desire of eating in people with bulimia nervosa. Some findings were reported in the review study that found binge episodes related to social experiences and interactions and self-esteem issues in people with bulimia. Furthermore, review findings suggest self-criticism was the result of negative social interactions among people with bulimia. Other

known behaviours include an association between dietary restraint and binge cravings, and cravings were associated with actual binge episode.

Subtypes of Bulimia: Reviewers reported study findings on the eating behaviours and affect levels of people with particular subtypes of bulimia nervosa. Reports on people with interpersonal-emotional subtypes found daily increase levels of binge and purging behaviours. Other reports also found people with multi-impulsive bulimia were associated with impulsive and self-damaging behaviours than other subtypes of bulimia. Findings also suggest that childhood maltreatment, such as sexual abuse, were associated with levels of purging and self-destructive behaviours, and childhood maltreatment, such as emotional abuse, was associated with anger.

Anorexia Nervosa: Review findings found physical activity were associated with changes in emotional experiences and weight reoccupation in people with anorexia nervosa. Another reported study found body mass index were associated with levels of the urge to physical activity. These findings may also suggest that changes in affect levels, such as PA and NA, and restrictive eating behaviours were related to stressful events.

Anxiety Disorders:
Reviewers reported on findings related the panic attacks, time spent in public places and at home, anxiety levels, senses of danger, helplessness, avoidance, distress, and catastrophic thoughts. Findings suggest there was no difference in time spent in public places between people with agoraphobia or without agoraphobia. However, people with acrophobia spent more time alone. Other findings suggest an expectation of panic attack did not predict anxiety levels, threat, or experiences of control. However, panic attacks were associated with elevated danger, helplessness, avoidance, and catastrophic thought. Levels of distress and anticipated feelings of the attack were high in expected panic attacks.

Attention Deficit Hyperactivity Disorder (ADHD):

			EMA studies on ADHD found inattentive symptoms were associated with general distress. However, hyperactive-impulsive symptoms were not associated with overall affective states and concentration but associated with reduced sensitivity to the context of perceptions of situations. Another study found children with ADHD experience child behaviour problems, and mothers of ADHD experienced NA and argumentative interactions when daily living tasks are especially challenging. Other findings suggest mothers of children with ADHD experience lower parenting esteem and more anger in the company of children. One study found the people with ADHD experiences reductions in nicotine-related ADHD symptoms during the day. ***Pervasive Developmental Disorder:*** Reviewer reported on one study that investigated autism spectrum disorders. The study examined a small sample of three people. The study found two people reported inner experiences, with the remainder person did not experience any inner experiences. Furthermore, inner thoughts were reported as images with no features of inner experiences.
Cain et al. (2009)	14 studies: 14 uncontrolled and controlled studies 26 studies not included because of a non-clinical population	Psychopathology Age: Adults aged 50 years and over Gender: Not Specified	***Mood Disorders:*** <u>Affective States:</u> Reviewers reported low social rhythm stability and activity level were not associated with experiences of bereavement among older people with MDD. Reviewers found PA after bereavement reduced stress and depression in older people with depression. Reviewers reported on the association of PA with positive events among older people with MDD. Reviewers found a study that found an adverse impact of Parkinson's Disease (PD) symptoms on PA and NA among older people with PD. Reviewers found less NA than continuous experiences of NA and less or continuous experiences of PA among people in a long-term care facility.

11. APPENDIX C

Summary of Review Findings of Evaluation Studies of Interventions using EMA

Review Studies	*Included Evaluation Studies*	*Population Characteristics*	*Findings of Evaluation Studies (under themes)*
Wenze & Miller (2010)	2 studies: N/A	Anxiety disorder, and alcohol problems Age: Not Specified Gender: Not Specified	Anxiety Disorder: One studies were reported in the systematic review that showed a palmtop-computer based CBT intervention for panic disorder with six sessions of psychotherapy with a therapist improved therapeutic outcomes when compared to control group or psychotherapy without EMA. Alcohol Problems: Another study on college students showed a Portable Device Assistant based self-monitoring intervention with subsequent messages addressing negative consequences of alcohol consumption reduced alcohol consumptions on days that they consume alcohol with lower expectation for getting in trouble as a result of drinking than those with PDA without messages.
aan het Rot et al. (2012)	1 study: N/A	Bipolar Age: Not Specified Gender: Not Specified	Bipolar: Reviewers reported on one studies on EMI. One study showed a PDA-based intervention providing real-time personalized health promotional behaviours showed a decrease in depression scores among people with BD. Furthermore, patients with BD reported the continuing use of PDA would be helpful to them.
Telford et al. (2012)	2 studies: N/A	Anxiety disorder and MDD Age: Not Specified	Anxiety Disorder: One study showed a palmtop-based computer that prompted people to complete breathing retraining exercises or to alter their thinking while in a situation resulted in clinically significant improvements in symptoms among people with panic disorders.

		Gender: Not Specified	Depression: Another study found EMA with mindfulness-based cognitive therapy showed people with MDD was about to create awareness of negative thinking patterns and disengagement from the ruminative depressive cycle.
Ehrenreich et al. (2011)	8 studies:8 RCTs	People with smoking addictions, and panic disorder Age: Not Specified Gender: Not Specified	Smoking Cessation: The review findings reported that majority of mobile phone interventions with personalized text messaging along or personalized messages via internet, voice response, or email had significant results in abstinence rates when compared to control groups (approximately 2 to 3 times more likely to achieving abstinence). It was reported in the review findings that retention rates were very high (ranged from 74.2% to 92%). Furthermore, reviewers reported the user satisfaction of mobile phone interventions were generally high. Additionally, reviewers found CBT telephone interventions were more than 5 times more likely to achieving abstinence compared to usual care. Anxiety Disorders: Reviewers found a study on CBT with a handheld computer that delivered self-monitoring and treatment modules did not significantly reduce panic symptoms than standard CBT with a therapist. However, another study showed CBT with a handheld computer that delivered treatment significantly reduced panic symptoms than the control group. A second study showed group CBT did not significantly reduce symptoms when therapy with handheld computer modules was compared with waitlist control group.
Whittaker et al. (2009)	5 studies: 5 RCTs	Smoking addictions Age: Not Specified Gender: Not Specified	Smoking Addiction: Meta-analysis of the review showed mobile phone interventions increased long timer quit rates than the control group (RR = 1.71, 95% CI: 1.47 to 1.99, P = .001, over 9000 participants total).

Heron & Smyth (2010)	17 studies (mental health related):8 RCTs, 9 others * 10 studies not included because not mental health related.	Smoking addiction, weight loss problems, anxiety disorder, eating disorder, and alcohol problems Age: Not Specified Gender: Not Specified	Smoking Addiction: Reviewers found mobile phone-based interventions to help people quit smoking improved in self-abstinence of smoking and more efficacious in quitting smoking than a standard cessation intervention alone. Reviewers found little evidence of the effects of mobile phone interventions on objective measures, such as salivary cotinine levels. Anxiety Disorder: Reviewers reported on RCT studies that demonstrate mobile device based CBT treatment supplemented with psychotherapy delivered by the therapist produced similar (and some statistical significant results) statistical significant reduction of symptoms when compared with usual of care for people with panic disorders and social anxiety. Cost-effectiveness was not examined in the included studies on anxiety disorders. Eating Disorder: Pre-post studies were reported for mobile text message interventions for people with bulimia nervosa. One study found an 'after care' text messaging intervention showed some improvements in self-reported binge eating and purging behaviours for two participants; however, they experience 'dysfunctional' levels of body dissatisfaction. Alcohol Problems: The review found one study that showed a palmtop computer intervention for students to reduce negative consequences of alcohol consumption. The results showed students receiving a palmtop intervention for 2 weeks reported reductions in the consumption of alcoholic drinks than people just receiving EMA monitoring without feedback.

12. APPENDIX D

List of Specific Search Terms for Systematic Review of EMIs for Stress and Anxiety

Cochrane Library for Randomised Controlled Trials
("mental health" OR "mental disorder*" OR "mental disease" OR "neuropsychiatric disorder*" OR psychopathology OR fear OR stress OR "stress disorder" OR neurosis OR neurotic OR anxiety OR "anxiety disorder*" OR panic OR agoraphobi* OR "social phobia" OR "generalized anxiety disorder" OR GAD OR "obsessive compulsive" OR OCD OR "adjustment disorder" OR "separation anxiety" OR "post-traumatic stress" OR PTSD OR phobi* OR neurasthenia OR "anxious personality" OR "social anxiety disorder*") AND ("ecological momentary*" OR "experience sampl*" OR "ambulatory assessment*" OR "context-aware experience*" OR *diary OR self-monitor* OR self-regulat* OR self-aware* OR "daily task*" OR "daily activit*" OR "daily life" OR *context* OR *environment* OR *experience* OR "event-contingent*" OR "signal-contingent*" OR tailor* OR *monitor* OR contingen* OR adjunct*) AND (mobile OR phone OR handheld OR "cell* phone" OR PDA OR mHealth OR (pen AND paper) OR biofeedback OR actigraphy OR "palmtop computer*" OR "hand-held") *Filters: study type = Trials*
PubMed
("mental health" OR "mental disorder*" OR "mental disease" OR "neuropsychiatric disorder*" OR psychopathology OR fear OR stress OR "stress disorder" OR neurosis OR neurotic OR anxiety OR "anxiety disorder*" OR panic OR agoraphobi* OR "social phobia" OR "generalized anxiety disorder" OR GAD OR "obsessive compulsive" OR OCD OR "adjustment disorder" OR "separation anxiety" OR "post-traumatic stress" OR PTSD OR phobi* OR neurasthenia OR "anxious personality" OR "social anxiety disorder*") AND ((ecological AND momentary*) OR experience sampl* OR ambulatory assessment* OR (context-aware AND experience*) OR *diary OR self-monitor OR self-regulat* OR self-aware* OR "daily activity" OR "daily activities" OR "daily life" OR *context* OR *environment* OR *experience* OR "event-contingent*" OR "signal-contingent*" OR tailor* OR *monitor* OR contingen* OR adjunct*) AND (mobile OR phone OR handheld OR "cell* phone" OR PDA OR "mHealth" OR (paper AND pen) OR biofeedback OR actigraphy OR "palmtop computer*" OR "hand-held") *Filters: study type = Clinical Trial, Controlled Clinical Trial, Pragmatic Clinical Trial, Randomized Controlled Trial, and Journal Article*
OvidSP (including Medline and PsycInfo)
("mental health" or "mental disorder*" or "mental disease" or "neuropsychiatric disorder*" or psychopathology or fear or stress or "stress disorder" or neurosis or neurotic or anxiety or "anxiety disorder*" or panic or agoraphobi* or "social phobia" or "generalized anxiety disorder" or GAD or "obsessive compulsive" or OCD or "adjustment disorder" or "separation anxiety" or "post-traumatic stress" or PTSD or phobi* or neurasthenia or "anxious personality" or "social anxiety disorder*") AND ("ecological momentary" or "experience sampl*" or "ambulatory assessment*" or "context-aware experience*" or self-monitor or self-regulat* or self-aware* or "daily

task*" or "daily activity" or "daily activities" or "event-contingent*" or "signal-contingent*" or diary or tailor* or "*monitor*" or contingen* or context or environment or experience or adjunct*) AND (mobile or phone or handheld or "cell* phone" or PDA or mHealth or (pen and paper) or biofeedback or actigraphy OR "palmtop computer*" OR "hand-held") *Filters: study type = Randomised Controlled Trail, and Clinical Trial*
Science Direct
("mental health" OR "mental disorder*" OR "mental disease" OR "neuropsychiatric disorder*" OR psychopathology OR fear OR stress OR "stress disorder" OR neurosis OR neurotic OR anxiety OR "anxiety disorder*" OR panic OR agoraphobi* OR "social phobia" OR "generalized anxiety disorder" OR GAD OR "obsessive compulsive" OR OCD OR "adjustment disorder" OR "separation anxiety" OR "post-traumatic stress" OR PTSD OR phobi* OR neurasthenia OR "anxious personality" OR "social anxiety disorder*") AND (“ecological momentary*” OR “experience sampl*” OR “ambulatory assessment*” OR “context-aware experience*” OR *diary OR self-monitor* OR self-regulat* OR self-aware* OR “daily task*” OR “daily activit*” OR “daily life” OR *context* OR *environment* OR *experience* OR “event-contingent*” OR “signal-contingent*” OR tailor* OR *monitor* OR contingen* OR adjunct*) AND (mobile OR phone OR handheld OR "cell* phone" OR PDA OR mHealth OR (pen AND paper) OR biofeedback OR neurofeedback OR actigraphy OR “palmtop computer*” OR “hand-held”) *Filters: article type = Journals*

13. APPENDIX E

Detailed Summary of Included Studies in the Systematic Review of EMIs for Stress and Anxiety

Study Country Disorder or Symptoms targeted	**Participants (# randomised) (# analysed, if not ITT), Population Description, and Recruitment method**	**Age (M, SD) Sex (%F)**	**Intervention Description**	**Intervention Type**	**EMI Type**	**Distal**	**Human Contact**	**ITT**	**Primary outcome and Measuring points**	**Significant interaction between time and group favouring EMI group?**	**Between-group effect size (Cohen's *d*) at post-test**
Generalized Anxiety											
Riva et al. (2006) ITA Examination Anxiety	*Randomised*: *n*=33, I^1=11, I^2=11, C=11 Analysed sample size not reported *Population*: People travelling on a regional Italian train *Recruitment*: NR	M=23.82 SD=-0.72 F=51%	I^1=4 sessions of 6 minute audio and video of virtual desert tropical beach with narratives using relaxation techniques. I^2=4 samples of New Age	Universal	I^1=S I^2=S C=NA	I^1=Y I^2=Y C=NA	I^1=SA I^2=SA C=NA	NR	1. STAI 2. VAS 3. PANAS 4. ITC-Sopi • *Baseline* • *2 days*	2 days: 1. $I_1 > I_2$ $I_1 > C$ 2. NR 3. NR 4. NR	ND

			video and music C=NI								
Riva et al. (2007) ITA Examination Symptoms	*Randomised*: *n* =30, I^1=6, I^2=6, I^3=6, I^4=6, C=6 Analysed sample size not reported *Population*: People experiencing anxiety from university exams *Recruitment*: NR	M=23.48 SD=1.24 F=100%	I^1=6 sessions of audio and video relaxation training narratives I^2=6 sessions of audio only relaxation training content I^3=6 sessions of audio and video relaxation training content I^4=6 sessions of audio only relaxation training content	Universal	I^1=S I^2=S I^3=S I^4=S C=NR	I^1=Y I^2=Y I^3=Y I^4=Y C=NR	I^1=SA I^2=SA I^3=SA I^4=SA C=NR	NR	1. STAI 2. VAS 3. PANAS • *Baseline* • *Post-test: NR*	Post-test: 1. Y 2. Y	ND

			C=NR								
Grassi et al. (2009) ITA Anxiety Symptoms	*Randomised*: *n*=120, I^1=30, I^2=30, I^3=30, C= 30 Analysed sample size not reported *Population*: Urban train commuters at Milan who were traveling to University before class *Recruitment*: Prior to 70-minute local train trip between Varese to Milano	M=23.27 SD=1.38 F=50%	I^1=4 sessions of 10 minutes sessions of audio and video virtual island and relaxation training I^2=4 sessions of 10 minutes sessions of video only narrative I^3=4 sessions of 10 minutes sessions of audio only narrative C=NI	Universal	I^1=S I^2=S I^3=S C=NA	I^1=Y I^2=Y I^2=Y C=NA	I^1=SA I^2=SA I^2=SA C=NA	NR	1. STAI 2. VAS 3. PANAS • *Day 1: AM* • *Day 1: PM* • *Day 2: AM* • *Day 2: PM*	NIS	Day 2: PM: 1. I^1 vs C=0.73 I^2 vs C=-0.02 I^3 vs C=-0.02 2. I^1 vs C=1.05 I^2 vs C=0.43 I^3 vs C=0.08 3. I^1 vs C=-1.35 I^2 vs C=-0.20 I^3 vs C=-0.10

Mosso et al. (2009) MEX Anxiety Symptoms	*Randomised*: *n*=21, I^1=11, C= 10 Analysed sample size not reported *Population*: Hospital patients undergoing an ambulatory surgical operation and under local and regional anaesthesia *Recruitment*: NR	M=49.6 SD=18 F=67%	I^1=Virtual 3D world with relaxation music and visuals C=NI	Universal	I^1=S C=NA	I^1=CO C=NA	I^1=SA C=NA	NR	1. VAS • *Baseline* • *T1: 45 mins after operation* • *T2: 90 mins after operation*	T2: 90 mins: 1. Y	ND
Pallavicini et al. (2009) ITA GAD	*Randomised*: *n*=12, I^1=4, I^2=4, C=4 Analysed sample size not reported *Population*: People	I^1: M=41.25 SD=13.24 I^2: M=48.5 SD=12.66	I^1=8 sessions of audio-visual based relaxation and exposure training of virtual world	Treatment	I^1=IG I^2=S C=NA	I^1=CO I^2=CO C=NA	I^1=PSH I^2=PSH C=NA	NR	1. STAI-Y2 2. PSWQ 3. BAI 4. HAM 5. GAD7 • *Baseline* • *Post-test: NR*	Post-test: 1. I^1, I^2: N 2. I^1, I^2: N 3. I^1, I^2: N 4. I^1, I^2: N 5. I^1, I^2: N	Post-test: 1. I^1 vs C=0.18 I^2 vs C=0.44 2. I^1 vs C=0.27 I^2 vs C=-0.06 3. I^1 vs C=0.25 I^2 vs C=-0.35

	diagnosed with GAD *Recruitment*: Researchers targeted people seeking treatment through a public health-care institute.	C: M=51.2 SD=9.84 5 F=75%	*with* biofeedback. I^2=8 sessions of audio-visual based relaxation and exposure training of virtual world *without* biofeedback. C=WC								4. I^1 vs C=0.27 I^2 vs C=-0.06 5. I^1 vs C=0.48 I^2 vs C=0.11
Gorini et al. (2010) ITA GAD	*Randomised*: *n*=20, I^1=8, I^2=8, C=4 Analysed sample size not reported *Population*: Diagnosed with GAD *Recruitment*: NR	Age not reported Sex not reported	I^1=8 sessions of audio-visual based relaxation and exposure training of virtual island using mobile phone *with* interactive biofeedback I^2=8 sessions of audio-	Treatment	I^1=IG I^2=S C=NA	I^1=CO I^2=CO C=NA	I^1=PSH I^2=PSH C=NA	NR	1. PSWQ 2. BAI 3. STAI-Y 4. HAM • *Baseline* • *Post-test: NR*	Post-test: 1. I^1, I^2: N 2. I^1, I^2: N 3. I^1, I^2: N 4. I^1, I^2: N	ND

			visual based relaxation and exposure training of virtual island using mobile phone *without* interactive biofeedback C=WC								
Newman et al. (2013) USA GAD	*Randomised*: *n*=38, I^1=12, I^2=14, I^3=12 *Analysed*: *n*=34, I^1=11, I^2=14, I^3=9 *Population*: People diagnosed with GAD *Recruitment*: Flyers in local community and referrals from	M=42.08 SD=12.15 F=60%	I^1=6 weeks of 2 hours GCBT and mobile EMI-CBT (diary, relaxation training, and cognitive restructuring). I^2=6 weeks of 2 hours GCBT sessions. No mobile EMI-CBT. I^3=12 weeks of	Treatment	I^1=IG I^2=NA I^3=NA	I^1=CO I^2=N I^3=N	I^1=TA I^2=TA I^3=TA	N	1. STAI-T 2. PSWQ 3. HAM • *Baseline* • *12-13 weeks* • *6 months* • *1 Year*	12-13 weeks: 1. $I^1 > I^2$ $I^3 > I^1$ 2. $I^1 > I^2$ $I^3 > I^1$ 3. $I^1 > I^2$ $I^3 > I^1$ 6 months: 1. I^2, $I^3 > I^1$ 2. I^2, $I^3 > I^1$ 3. I^2, $I^3 > I^1$ 1 Year: 1. I^2, $I^3 > I^1$ 2. I^2, $I^3 > I^1$	12-13 weeks: 1. I^1 vs I^2=0.61 I^1 vs I^3=0.40 2. I^1 vs I^2=0.39 I^1 vs I^3=0.76 3. I^1 vs I^2=0.46 I^1 vs I^3=0.18

	mental health professionals.		2 hours GCBT sessions. No mobile EMI-CBT.							3. I^2, $I^3 > I^1$	
Anxiety and Stress											
Reid et al. (2011) AUS Anxiety and Stress	*Randomised*: *n*=118, I^1=69, C=49 *Analysed*: *n*=114, I^1=68, C=46 *Follow up*: *n*=86, I^1=48, C=38 *Population*: Young GP patients with mild to more severe mental	I^1: M=18.5 SD=3.2 F=77% C: M=17.4 SD=3.2 F=63%	I^1=Self-monitoring therapy that tracks mood, stress, coping strategies, daily activities, eating, sleeping, exercise patterns, and alcohol and cannabis use.	Indicated	I^1=IA C=IA	I^1=CO C=CO	I^1=PSH C=PSH	Y	1. DASS Stress 2. DASS Anxiety • *Baseline* • *2-4 weeks* • *6 weeks* • *6 months (not analysed)*	6 weeks: 1. N 2. N	6 weeks: 1. I^1 vs C=-0.08 2. I^1 vs C=-0.14

	health concerns in primary care and clinical setting. *Recruitment*: GPs were recruited via local Division of GP. Weekly fax reminders and nightly phone calls were used to update GPs on recruitment of study.		C=*Attention Control* - Self-monitoring using limited features of program (not including mood, stress, alcohol, and cannabis use monitoring modules) and received limited medical attention given by GP and researchers.								
Proudfoot et al. (2013) AUS Anxiety and Stress	*Randomised*: *n*=705, I^1=242, C^1=248, C^2=230 *Analysed*: *n*=519, I^1=126, C^1=195, C^2=198	I^1: M=39 SD=10.73 F=70% C^1: M=40 SD=11.42 F=70%	I^1=12 online CBT modules, SMS reminders, self-monitoring	Indicated	I^1=IG C^1=S C^2=NA	I^1=Y C^1=Y C^2=NA	I^1=SA C^1=SA C^2=NA	Y	1. DASS Stress 2. DASS Anxiety • *Baseline* • *7-8 weeks* Follow up: • *I^1, C^1: 3 months*	7-8 weeks: 1. $I^1 > C^1$ $I^1 > C^2$ 2. $I^1 > C^1$ $I^1 > C^2$ Follow up:	7-8 weeks: 1. I^1 vs C^1=0.21 I^1 vs C^2=0.34 2. I^1 vs C^1=0.37 I^1 vs C^2=0.44

	Follow up: *n*=350, I^1=100, C^1=167, C^2=83 *Population*: People with depression, anxiety, and stress in general community *Recruitment*: Facebook and Twitter social media, Black Dog Institute website, corporate and government organisations, national radio, and print media.	C^2: M=38 SD=10.26 F=70%	C^1=*Attention Control* - Factual information about depression, anxiety or stress via email and SMS. Weekly messages are sent as a reminder, motivational, and tips. C^2=WC						• *C^2: 19 weeks*	1. $C^2 > I^1, C^1$ 2. $I^1, C^1 > C^2$	
Stress											
Lemaire et al. (2011) CAN	*Randomised*: *n*=40, I^1=21, C=19	I^1: M=47.8 SD=8.5	I^1=Biofeedback stress management tool with	Universal	I^1=IA C=NA	I^1=CO C=NA	I^1=PSH C=NA	N	1. Perceived Stress Scale & POQA-R	28 days: 1. Y	28 days: 1. I^1 vs C=0.19

Work Stress	*Analysed*: *n*=38, I[1]=20, C=18 *Population*: Medical professionals *Recruitment*: Electronic mail, regular mail, and posters placed at physicians lounge and throughout the hospital.	F=43% C: M=44.8 SD=8.2 F=42%	rhythmic breathing training, self-generated positive emotion exercises, and self-help brochures for work-related stress. At extension phase, intervention participants were given full treatment *but received extra support from the research team.* C=*Attention Control* - Brochures for work-related stress and monitoring only measure						• *Baseline* • *28 days* • *56 days (Trial Extension)*	56 days: 1. N	

			of stress, well-being, heart rate and blood pressure. At extension phase, control participants were given full treatment but *did not received extra support from the research team.*								
Villani et al. (2013) ITA Work Stress	*Randomised*: *n*=30, I^1=15, C=15 Analysed sample size not reported *Population*: Medical oncology hospital staff *Recruitment*: Posting of flyers	M=43 SD=8.80 F=100%	I^1=8 sessions of SIT content using multimedia narrative based on a 4 SIT phase program. Participants used twice a week. C=*Attention Control* - 8	Indicated	I^1=S C=S	I^1=Y C=Y	I^1=SA C=SA	NR	1. STAI 2. COPE 3. JCQ • *Baseline* • *4 weeks*	4 weeks: 1. I^1 > C 2. NR 3. NR	ND

	and emails in a 6 day-hospital medical oncology ward		sessions of SIT content using *neutral* multimedia content (no narrative voice). Participants used twice a week.								
Lappalainen et al. (2013) FIN Work Stress	*Randomised*: *n*=23, I^1=11, C=12 *Analysed*: *n*=24, I^1=12, C=12 *Population*: People with full time employment, basic computer skills, stress symptoms, and sleeping problems *Recruitment*: Advertisement	I^1: M=39.4 SD=8.0 C: M=47.1 SD=4.7 F=0%	I^1=3 groups of face-to-face meetings including a mixture of electronic CBT and ACT. Website includes information, exercise modules, and peer support. Mobile application include self-monitoring, and fitness	Indicated	I^1=IG C=NA	I^1=CO C=NA	I^1=MC C=NA	Y	1. BBI (Burnout) 2. BBI (Exhaustion) 3. BBI (Cynicism) 4. BBI (Sense of Inadequacy) • *Baseline* • *3 months* • *6 months*	NIS	3 months: 1. I^1 vs C=0.50 2. I^1 vs C=0.21 3. I^1 vs C=0.63 4. I^1 vs C=0.36

	in a local newspaper		and relaxation training. C=WC								
Panic Disorder											
Newman et al. (1997) AUS and USA PD	*Randomised*: *n*=18, I^1=9, I^2=9 *Analysed*: *n*=18, I^1=9, I^2=9 *Population*: People diagnosed with PD *Recruitment*: Advertisements and screening were conducted on the phone.	M=38 SD=11.7 F=83%	I^1=4 weeks of 1-2 hours ICBT with EMI-CBT. I^2=12 weeks of 1 hour ICBT with EMI-CBT (*used as a diary only. No therapy component*).	Treatment	I^1=IG I^2=IA	I^1=CO I^2=CO	I^1=MC I^2=TA	N	1. MI-Acc 2. MI-Alone 3. ACQ 4. Panic Attacks 5. FQ-Ag 6. FQ-Phobia 7. BSQ • *Baseline* • *12-13 weeks* • *6 months*	12-13 weeks: Y 6 months: N	12-13 weeks: 1. I^1 vs I^2=-0.45 2. I^1 vs I^2=0.11 3. I^1 vs I^2=0.81 4. I^1 vs I^2=-0.92 5. I^1 vs I^2=0.33 6. I^1 vs I^2=0.01 7. I^1 vs I^2=-0.14
Kenardy et al. (2003) AUS and SCOT	*Randomised*: *n*=163, I^1=41, I^2=42, I^3=39, C=41	M=36.8 SD=10.0 F=75.5%	I^1=6 weeks of 1 hour ICBT with EMI-CBT.	Treatment	I^1=IG I^2=NA I^3=NA C=NA	I^1=CO I^2=N I^3=N C=NA	I^1=TA I^2=TA I^3=TA C=NA	Y	1. Composite • *Baseline* • *12 weeks* • *3-6 months*	12 weeks: 1. I^1 > C I^2, I^3 > I^1 3-6 months:	12 weeks: 1. I^1 vs C=2.00 I^1 vs I^2=-0.23 I^1 vs I^3=0.43

PD	*Analysed*: *n*=186, I^1=50, I^2=45, I^3=45, C=46 *Population*: People who have been diagnosed with PD *Recruitment*: Referrals by health professionals at an Adult Clinical Psychology Service, and Psychology Clinic that provides psychiatric treatments to patients.		I^2=12 weeks of 1 hour ICBT without EMI-CBT. I^3=6 weeks of 1 hour ICBT without EMI-CBT. C=WC						• *9 months*	1. I^1 > C	

Social Phobia											
Gruber et al. (2001) USA SP	*Randomised*: *n*=54, I^1=18, I^2=18, C=18 *Analysed*: N=53, I^1=15, I^2=14, C=17 *Follow-up*: N=26, I^1=13, I^2=13 *Population*: People who have been diagnosed with SP *Recruitment*: Newspaper advertisement offering free treatment to SP.	M=41.7 SD=8.2 F=48%	I^1=8 sessions of 2.5 hours GCBT over 12 weeks *with* EMI-CBT. I^2=12 sessions of 2.5 hours GCBT over 12 weeks *without* EMI-CBT C=WC	Treatment	I^1=IG I^2=NA C=NA	I^1=CO I^2=N C=NA	I^1=TA I^2=TA C=NA	NR	1. FNE 2. SPS 3. SPAI • *Baseline* • *12 weeks* • *6 months*	12 weeks: 1. C > I^1 I^2 > C 2. C > I^1 I^2 > C 3. C > I^1 I^2 > C 6 months: 1. I^2 > I^1 2. I^2 > I^1 3. I^2 > I^1	12 weeks: 1. I^1 vs C=0.81 I^1 vs I^2=-0.48 2. I^1 vs C=0.71 I^1 vs I^2=-0.34 3. I^1 vs C=0.68 I^1 vs I^2=-0.86

Notes: GAD = generalized anxiety disorder, PD = panic disorders, SP = social phobia, SA = self-administered therapy, PSH = predominantly self-help, MC = minimal-contact therapy, TA = predominantly therapist administered treatments, ICBT = individual cognitive behavioural therapy (face-to-face), GCBT = group cognitive behavioural therapy (face-to-face), EMI-CBT = EMI-based cognitive behavioural therapy (include diary and therapy components), SIT = stress inoculation training, ACT = acceptance and commitment therapy, GP = general practitioner, I^x = intervention groups, C = control group, WC = waitlist control, NI = no intervention control, M = mean, SD = standard deviation, F = females, CO = combined on-site and distal, Y

= yes, N = no, NR = not reported, ITT = Intention-to-treat, NA = not applicable, S = simple EMI type, IA = interactive EMI type, IG = integrative EMI type, ND = insufficient data to calculate effect size, NIS = insufficient information to determine between-group effects against each intervention and control, I^x > C = intervention group is superior to the control group.

Measures: PSWQ = Penn State Worry Questionnaire, BAI = Beck Anxiety Inventory, STAI - (S or T) = State Trait Anxiety Inventory - (State or Trait), HAM = Hamilton Anxiety Rating Scale, VAS = Visual Analogue Scale, PANAS = Positive Affect Negative Affect Scale, DASS = Depression, Anxiety, and Stress Scale, BBI = Bergen Burnout Indicator, POQA-R = Personal and Organisational Quality Assessment-Revised, MSP = Mesure du Stress Psychologique, COPE = Brief Coping Orientation to Problems Experienced, JCQ = Job Content Questionnaire, MI-Acc = Mobility Inventory - Accompanied subscale, MI-Alone = Mobility Inventory – Alone subscale, ACQ = Agoraphobic Cognitions Questionnaire, FQ-Ag = Fear Questionnaire – Agoraphobia subscale, FQ-Phobia = Fear Questionnaire – Total Phobia Rating, BSQ = Body Sensation Questionnaire, 💭= panic frequency, panic severity, BSQ, ACQ, STAI-T, MI-Acc, MI-Alone, FQ-Ag, FQ-Phobia, Fear Questionnaire - Blood/Injury subscale, FNE = Fear of Negative Evaluation, SPS = Social Phobia Scale, SPAI = Social Phobia and Anxiety Inventory.

14. APPENDIX F

Technical Features and Strategies of Mobile-Related Health Interventions

			Mobile technology characteristics (Klasnja and Pratt, 2012)									
Study author, year	**Devices**	**Device model**	**Technical features**					**Intervention strategies**				
			SMS	**CAM**	**SEN**	**WEB**	**NAV**	**THI**	**IHT**	**LSI**	**IAHI**	**ENT**
Hand-held computer												
Newman et al. (1997)	Palmtop Computer (software developed on MS-DOS)	Casio PB-1000	-	-	-	-	x	x	x	-	x	-
Gruber et al. (2001)	Palmtop Computer (software developed on MS-DOS)	Casio PB-1001										

Kenardy et al. (2003)	Palmtop Computer (software developed on MS-DOS)	Hewlett Packard 200LX										
Newman et al. (2013)	Palmtop Computer (software developed on MS-DOS)	Hewlett Packard 200LX										
Regular Ambulatory Biofeedback												
Lemaire et al. (2011)	Ambulatory Biofeedback (heart-rate) + PC (custom-built PC software)	emWavePSR (heart rate monitor) emWavePC (monitoring software)	-	-	x	-	x	x	x	-	-	-
Mobile phone & other devices												
Riva et al. (2006)	UMTS Mobile Phone (G&A programming libraries)	Motorola A925	-	-	-	-	x	-	-	-	x	x

	Audio CD (non-portable) + DVD (non-portable)	Standard Format										
Riva et al. (2007)	UMTS Mobile Phone (G&A programming libraries)	Nokia 6680	-	-	-	-	x	-	-	-	x	x
	Portable digital media player	MP3 Player (device model unknown)										
Grassi et al. (2009)	UMTS Mobile Phone (G&A programming libraries)	Motorola A925	-	-	-	-	x	-	-	-	x	x
	Portable digital media player	MP3 Player (device model unknown)										

Reid et al. (2011)	Mobile phone with JAVA software libraries support (SMS) + PC (internet) support	Sony Ericsson Z750i	x	-	-	x	x	x	x	-	-	-
Villani et al. (2013)	UMTS Mobile Phone (G&A programming libraries)	Nokia N70	-	-	-	-	x	-	-	-	x	x
Proudfoot et al. (2013)	Internet Mobile Phone with mobile and web support + PC (internet) support	Various device models	-	-	-	-	x	x	-	-	x	-
Smartphone												
Mosso et al. (2009)	Mobile Phone (G&A and network	Nokia N95	-	-	-	-	x	-	-	-	x	x

	programming libraries)											
	VR hardware	HMD Vuzix iWear AV 920 (VR headset)										
Pallavicini et al. (2009)	Smartphone (G&A and network programming libraries)	HTC touch pro T7272	-	-	x	-	x	x	x	-	x	x
	Laptop, VR and Gaming hardware	Vuzix iWear VR920 (VR hardware) + Xbox joystick + EEPC 100H - BK039X (therapist notebook)										
	Wearable sensors	GSR/HR Sensor Module (Skin Conductanc										

		e Response sensors and Blood Volume Pulse sensor)										
Gorini et al. (2010)	Smartphone (G&A and network programming libraries)	HTC touch pro	-	-	x	-	x	x	x	-	x	x
	VR and Gaming hardware	VR hardware model unknown + joystick										
	Wearable sensors	GSR/HR Sensor Module (Skin Conductanc e Response sensors and Blood										

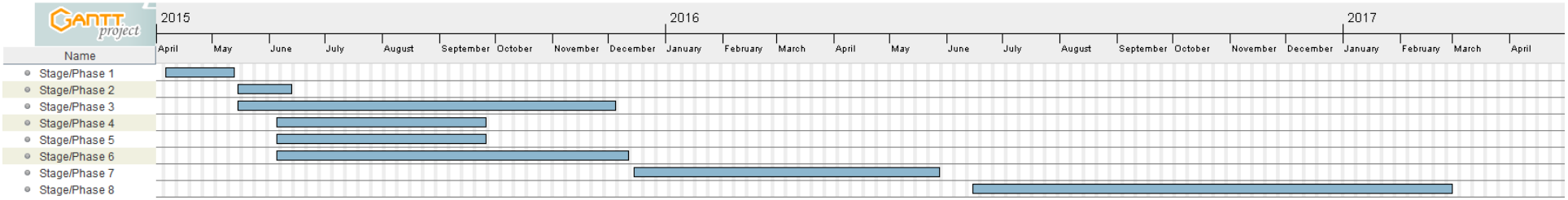
		Volume Pulse sensor)										
Lappalainen et al. (2013)	Smartphone (network programming libraries) + PC support	Nokia E15	-	-	x	x	x	x	x	-	x	-
	Wearable sensors	Suunto Memory Belt (heart rate monitor) + Omron Pedometer + Vivago Personal wellness manager (actigraph)										

Notes: G&A = Graphic and Audio, VR = Virtual Reality, **X** = yes, **-** = no, SMS = Text messaging , CAM = Cameras, SEN = Automated sensing, WEB = Internet access, NAV = Native applications, THI = Tracking health information, IHT = Involving the healthcare team, LSI = Leveraging social influence, IAHI = Increasing the access to health information, ENT = Using Entertainment

15. APPENDIX G

Gantt Chart Displaying the Time Schedule of Development Process

Dates presented in the timeline are traced back through the electronic archives of documents of the research project.



16. APPENDIX H

User Stories

User stories of EMI for social anxiety. Appendices contain individual user stories used for the development of the EMI for social anxiety.

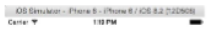
16.1. APPENDIX H.1

User Stories for Exposure Practice Steps

Main User Scenario: Practicing In-situ Exposure (Main Stages)

As a Consumer named Jerry

Step 1: Jerry will familiarise and learn about tasks for practicing exposure therapy



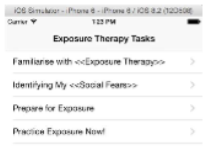
Step 2: Jerry will familiarise and learn about exposure therapy

Step 3: Jerry will identify his social fears

Step 4: Jerry will begin to prepare for exposure therapy before practicing

Step 5: Jerry will check for actioned tasks. If Jerry have not actioned all tasks, then do not allow Jerry to seek out a live situation to practice exposure therapy. If Jerry is not allowed to seek out a live situation to practice exposure therapy, then prompt Jerry to complete all tasks.

Step 6: Jerry will seek out a live situation to practice exposure therapy



Commented [JAL1]: Julia says that Jerry should be presented with information about each step. Julia want to know whether Jerry should select steps in sequence or all together? What is your opinion Kathy?

Commented [BLG2]: Present information about the tasks of exposure therapy.

Commented [BLG3]: Place a condition to check for completed exposure tasks

Commented [JAL4]: Julia think it is really important for Jerry to action the previous steps before continue with a live exposure.

16.2. APPENDIX H.2

User Stories for Learning about Exposure Practice

User Scenario: Familiarising with exposure therapy

As a Consumer named Jerry

Step 1.1: Jerry will choose and learn exposure therapy from a manual

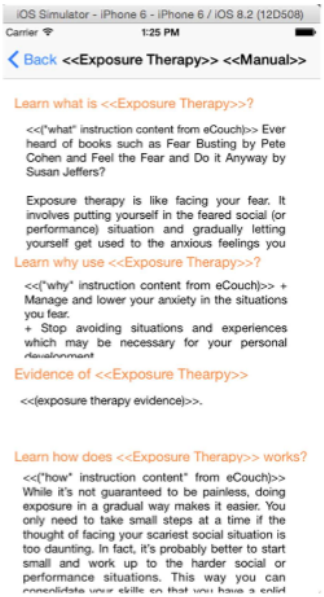
Step 1.2: Jerry will choose a topic of exposure therapy from a manual

Step 1.3: Jerry will open and read the instructional content of what exposure therapy is

Step 1.4: Jerry will open and read the instructional content of why use exposure therapy

Step 1.5: Jerry will open and read the instructional content of on the evidence of exposure therapy

Step 1.6: Jerry will open and read the instructional content of how does exposure therapy works



Step 1.5: Jerry will close the manual and proceed to the next stage

Commented [BLG1]: Is Jerry missing any steps for learning exposure therapy?

Commented [BLG2]: Before choosing content to read from a manual, Jerry will need to choose a topic of exposure therapy to learn.

Commented [BLG3]: Present a separate section for content relating to evidence around exposure therapy

Commented [JAL4]: Julia thinks that Jerry should be presented a "summary of the evidence" around exposure therapy". This content can be associated with "why" use exposure therapy

16.3. APPENDIX H.3

User Stories for Identifying My Social Anxieties

User Scenario: Identifying his social fears

As a Consumer named Jerry

Step 2.1: Jerry will learn and read content and instructions of what are fearful situations. Jerry will learn and read content on the types of fearful situation(s). Jerry will learn the four types which are easy, hard, difficult, and very hard.

Step 2.2: Jerry will review the current list of fearful situation(s) from his workbook. As Jerry just started to use exposure therapy, there is no situations that are displayed in his workbook

Step 2.3: Jerry will review and write down a fearful situation into his workbook. Jerry will require to recall and record a fearful situation which is of "Easy" difficulty before recalling and recording a fearful situation which is of "Harder" difficulty. Jerry will require to recall and record a fearful situation which is of "Difficult" difficulty before recalling and recording a fearful situation which is of "Very Difficult" difficulty.

Commented [BLG1]: Present information or a prompt that ensure the person record and think about easier fearful situations before harder situations.

Step 2.4: He will recall and record "Going to speak with friends" as a description of a fearful situation. He will recall and record "Easy" as the difficulty of that fearful situation.

Step 2.5: If a fearful situation, such as "Going to visit my father", is displayed in his workbook in which Jerry does not want anymore, then Jerry can erase a fearful situation from his workbook

Commented [BLG2]: Should Jerry recall and write his anxiety levels (from 0 -10)?

Should Jerry recall and write his anxious thoughts (such as "I feel stupid")?

Should Jerry recall and write his avoidance level (from 0 – 10)?

Are there other things Jerry should report on?

Commented [BL3]: In order to record the description of the fearful situation. Jerry will open an assessment for recording a fearful situation in a workbook.

Commented [JAL4]: Julia says Jerry should be able to record Subjective Unit of Discomfort (SUDS) for fearful situations.

Julia thinks Jerry can record "I feel stupid" as an anxious thought but it's not necessary. While information on cognitive change is not presented in this app, Julia thinks there should be some section for Jerry to read content on key cognitive problems in social anxiety, and where to get other help.

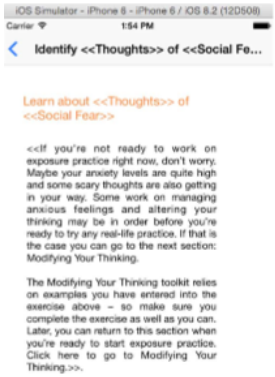
Julia still needs to think whether Jerry should need to record avoidance levels for situation (from 0-10).

Julia thinks Jerry should be given explicit prompts or signs to identify and record easier situations otherwise Jerry may start get confused with hard and easy situations.

Similar to eCouch, Julia thinks Jerry should record difficulty of a fearful situation in 4 quartiles (easier, harder, difficult, very hard).

Step 2.6: Jerry will read and learn content on thoughts of social fear.

Commented [BLG5]: Present information on cognitive/thought change for social anxiety



Step 2.7: Jerry can identify any safety behaviours, if he has behaviours.

Commented [BLG6]: Should Jerry be able to report his safety behaviours and situations together? Can they be done separately?

Step 2.8: Jerry will learn and read content and instructions on what safety behaviours are.

Step 2.9: Jerry will review the current list of safety behaviour(s) from his workbook. As Jerry just started to use exposure therapy, there is no safety behaviours that are display in his workbook.

Step 2.10: Jerry will recall and write down a safety behaviour, such as "Drinking a lot of beer when I am at a party", into his workbook.

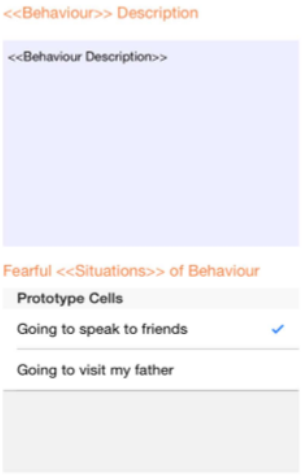
Step 2.11: Jerry can recall and write down a fearful situation, such as "Going to speak with friends", with a safety behaviour, such as "Drinking a lot of beer when I am at a party", into his workbook.

Commented [JAL7]: Julia think Jerry should be given an option to add situations to safety behaviours. Or, Jerry should be able to rate the difficulty of the situation with or without safety behaviour.

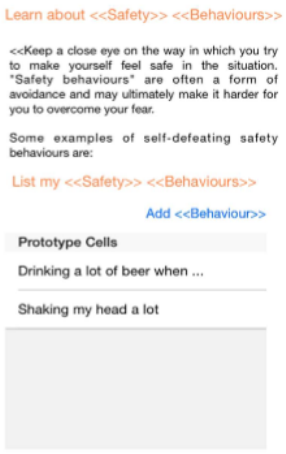
Commented [BLS8]: In order to record the description of the safety behaviour. Jerry will open an assessment for recording a safety behaviour in a workbook.

Commented [BLG9]: Give an option for recording a fearful situation with a safety behaviour.

Commented [BLG10]: Can Jerry select more than one fearful situations for a safety behaviour??



Step 2.12: If a safety behaviour, such as "Shaking my head a lot", is displayed in his workbook in which Jerry does not want anymore, then Jerry can erase this behaviour from his workbook



Step 2.13: Jerry will need to check if he has written a fearful situation for each difficulty ("Easy", "Hard", "Difficult", and "Very Difficult") before continuing with preparing and practicing exposure therapy.

Step 2.14: Jerry will close the workbook and proceed to the next stage.

Commented [BLG11]: Program should check if the person has recorded a situation for each difficulty before preparing and practicing exposure therapy.

Commented [BLG12]: Should Jerry identify any more things relating to his social fears?

Commented [JAL13]: Julia thinks Jerry should record at least one situation before continuing the next stage of the exposure therapy. Jerry should see a situation for each 4 quartile of difficulty before continuing.

16.4. APPENDIX H.4

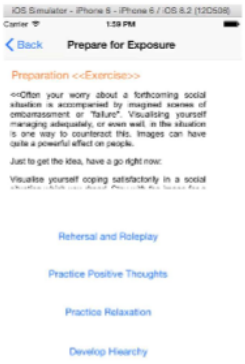
User Stories for Getting Ready for Exposure Practice

User Scenario: Prepare for exposure therapy

As a Consumer named Jerry

Step 3.1: Jerry will learn and read content and instructions of how to prepare for exposure therapy from a manual.

Step 3.2: Jerry will choose a preparation exercise from the workbook to prepare for exposure therapy (rehearsal and roleplay, develop hierarchy, practice positive thought, and learn and practice relaxation).



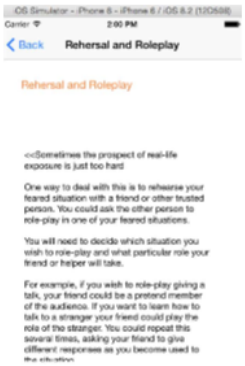
Step 3.3: Jerry will begin by learning and reading content and instructions of how to rehearse exposure exercises from a manual.

Commented [BLC1]: Allow people to choose a range of preparation exercises for preparing for exposure therapy.

Commented [BLC2]: Should Jerry be given a step-by-step guide to rehearsing exposure exercises? Or is it enough for Jerry to learn from informational content?

Commented [JAL3]: Lou said providing information about how to prepare themselves is enough.

Julia thinks a step-by-step guide to imaginal exposure could be optional. Julia and Lou believes the program can support various types of exposure therapies (imaginal, rehearsal, or in vivo) before starting a live exposure exercise.

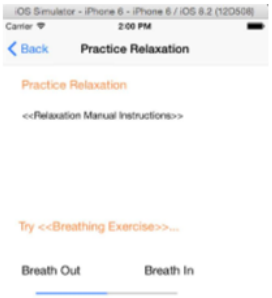


Step 3.4: Jerry will learn and read content and instructions of how to practice positive thoughts

Commented [BLC4]: Get people to learn about how to practice positive thoughts for social anxiety

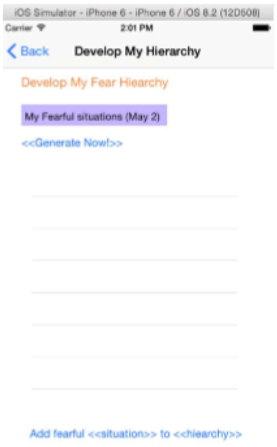
Step 3.5: Jerry will learn and read content and instructions of how to practice relaxation

Commented [BLC5]: Get people learn about how to practice relaxation during a socially anxious situation



Step 3.6: Jerry will able to identify and record images of "his son" into his workbook in order to practice relaxation

Commented [BLG6]: Get people to identify images and record them into their workbook for them better practice relaxation

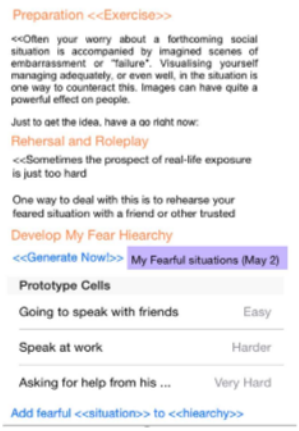


Step 3.7: Jerry will begin by developing a hierarchy from fearful situations titled "Jerry's fearful situation to practice (May 2/5/2015)" into his workbook.

Step 3.8: Jerry will review the list of fearful situations (ie. "Going to speak with friends", "Speak at work") from his workbook

Step 3.9: If a fearful situation is not in the hierarchy, then Jerry will add "Asking for help from his teacher" as a "Very Hard" fearful situation into the hierarchy,

Step 3.10: Jerry will sort the list of fearful situations by difficulty from a hierarchy from his workbook.



Step 3.11: Jerry will close the workbook and proceed to the next step.

Commented [BLG7]: How many hierarchy plans should the Jerry be able to develop? Can Jerry develop more than 1 hierarchy for himself?

Commented [JAL8]: Julia believes it is important for Jerry to develop multiple hierarchy but Jerry needs to be clear of the different hierarchies Jerry is creating in order to avoid confusion.

Commented [BLG9]: Should Jerry be able to manually manage his own hierarchy or should the system automatically generate this plan.

Commented [JAL10]: Julia and Lou believes this process should be automated by the computer

Commented [BLG11]: Should Jerry be able to schedule when to perform a particular hierarchy or exposure to a fearful situation?

Commented [JAL12]: Julia thinks Jerry should be able to opt in or out in relation to scheduling a hierarchy.

Commented [BLG13]: Should Jerry do more things before starting exposure therapy?

Commented [JAL14]: Julia strongly believes that Jerry should do more to prepare before exposing himself to a live fearful situation.

Some of the examples Julia mention includes providing motivational messages to Jerry to perform positive thought exercises, or to allow Jerry to load personal images of relaxation to calm himself down before and after enter a fearful situation.

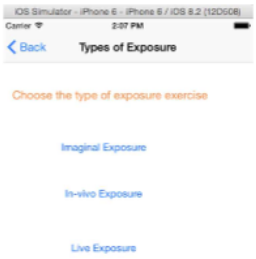
16.5. APPENDIX H.5

User Stories for Performing Exposure Now

User Scenario: Seek out a live situation to practice exposure exercise

As a Consumer named Jerry

Step 4.1: Jerry will decide a type of exposure exercise from a list of types of fearful situation in his manual. He will choose to do "live" exposure exercise.



Commented [BLC1]: A person will decide on the type of exposure exercise to do with the application

Step 4.2: Jerry will review a list of all fearful situations from his hierarchy in his workbook. Also, Jerry will be able to review fearful situations that he successfully completed.

Commented [BLC2]: A person should be able to review all situations from his hierarchy including situations that the person has successfully completed.

Step 4.3: Jerry will need to pick a fearful situation with the least difficulty, such as "Going to speak with friends" from a list of fearful situations from his hierarchy in his workbook.

Commented [BLC3]: Should Jerry be able to perform one or more hierarchy plans. For example, creating a separate hierarchy for "speaking in public". Personally, I can see so many smaller steps I can do before putting myself into the deep end.

Commented [JAL4]: Julia mentioned Jerry should be given some indication of successful situations.

Step 4.4: If Jerry have previously in-completed a fearful situation, such as "Speaking at work", then Jerry should be able to continue with practicing "Speaking at work".

Step 4.5: Jerry will need to seek an actual situation that entails "going to speak with friends".

Step 4.6: If Jerry cannot seek the actual situation of "going to speak with friends", then Jerry should choose another situation from his hierarchy in his workbook.

Step 4.7: if Jerry has no other easier situation to do, then Jerry should be presented a message to add more easy situations into his hierarchy before proceeding with practicing exposure exercise in a live situation.

Step 4.8: Jerry decides to "speak to his friend called Matthew". Jerry will record "speaking to Matthew" in his workbook as an action to complete.

Step 4.9: If Jerry does seek the time to "speak to Matthew", then Jerry should record and measure his anxiety levels using a Subjective Units of Distress Scale (SUDS) assessment in his workbook before "speaking to Matthew". Additionally, Jerry will record the approximate end time for "speaking to Matthew".

Commented [JAL5]: Julia and Lou thinks Jerry can choose to do different types of exposure exercises (ie. in vivo, imaginal, or live). However, Julia stresses that certain exposure exercises should be controlled by the system or clinician before allowing Jerry to practice one of them.

Commented [BLG6]: The person should be prompted message to think about easy situations before continuing with exposure exercises

Commented [JAL7]: Julia is concerned with Jerry performing harder situations before attempting easier situations if Jerry cannot find the actual situation of "going to speak with friends". As a clinician, she would usually instruct Jerry to think about carefully identify easy situations before starting live exposure practice.

Commented [JAL8]: Julia strongly believes the anxiety levels (or SUDS) should be recorded before and after Jerry exposure himself to speak with Matthew.

Julia and Lou thinks Jerry needs to record the expect time period of speaking to Matthew, and Jerry should not be interacting with the phone while speaking to Matthew.

Commented [BLG9]: Is it possible to add a time and date of this action??

Commented [BLG10]: Ensure person complete a SUDS assessment which is a numeric scale 0 to 10 that measures a subjective measure of current distress levels.

Commented [BLG11]: A person can record the approximate end time of exposure to the fearful situation

Step 4.10: Jerry's current SUDS anxiety levels is 9, then Jerry's anxiety levels are too high. If Jerry's SUDS anxiety levels are too high, then Jerry should choose to retreat or continue with "speaking to Matthew".

Commented [BLG12]: Person can record SUDS anxiety level before exposing themselves to fearful situation

Step 4.11: However, Jerry's current SUDS anxiety levels is 3, then Jerry's SUDS anxiety levels are ok to "speak to Matthew".

Commented [BLG13]: Person can record SUDS anxiety level before exposing themselves to fearful situation

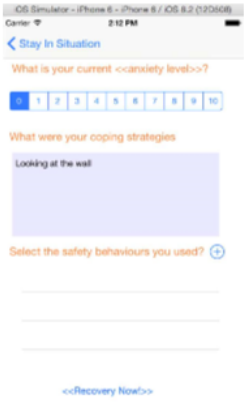
Step 4.12: Jerry should not be able to write or access workbook during "speaking to Matthew".

Commented [BLG14]: The program is on idle during exposure to the live situation.

Step 4.13: Jerry will need to record and measure his current SUDS anxiety levels using an assessment in his workbook after "speaking to Matthew".

Commented [BLG15]: Person can record SUDS anxiety level before exposing themselves to fearful situation

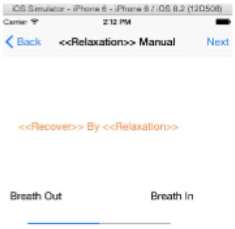
Step 4.14: Jerry will also record "Looking at the wall" as a coping strategy and "Drinking a lot of beer" as a safety behaviours after actually "speaking to Matthew".



Step 4.15: Jerry will need to recover from "speaking to Matthew". ~~Jerry will begin by reading instructional content of how to recover from "speaking to Matthew" from a manual. This is followed by reading the instructions,~~ Jerry will need to recover by practicing breathing exercises from relaxation manual.

Commented [BLG16]: Instead of learning form a manual after exposing a person from a fearful situation. The person can practice relaxation exercise.

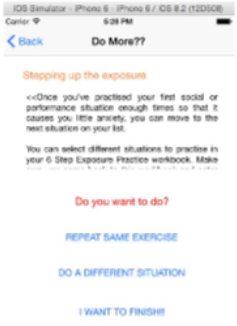
Commented [JAL17]: Julia strongly thinks Jerry should read and learn relaxation exercises before attempting to speak to Matthew. Julia believes Jerry should be well prepared before speaking to Matthew because Jerry should be focusing on "doing" relaxation.



Step 4.16: After relaxation, Jerry can continue with "speaking to Matthew" again. If Jerry continues with "speaking to Matthew" again, then Jerry should approach the situation again by recording his anxiety levels before "speaking to Matthew" again.

Step 4.17: After relaxation, Jerry can also start practicing "Speaking at work" which is a different fearful situation from his hierarchy in his workbook.

Step 4.18: After relaxation, Jerry might feel he wants to finish with exposure exercise, then Jerry should finish practicing "speaking to Matthew" and do something else.



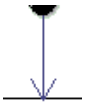
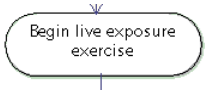
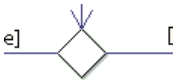
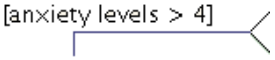
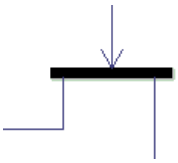
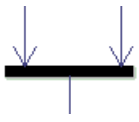
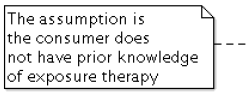
Step 4.19: Jerry will close the workbook and finish with exposure therapy.

Commented [JAL18]: Julia and Lou believes Jerry should be able to review their progress after speaking to Matthew. Jerry should be able to review how his anxiety has reduced after speaking to Matthew, and offer supportive decision making content about the next exposure.

Julia strongly believe there should be more reinforcement content – graphs, images of positive thoughts, or rewards of engagement.

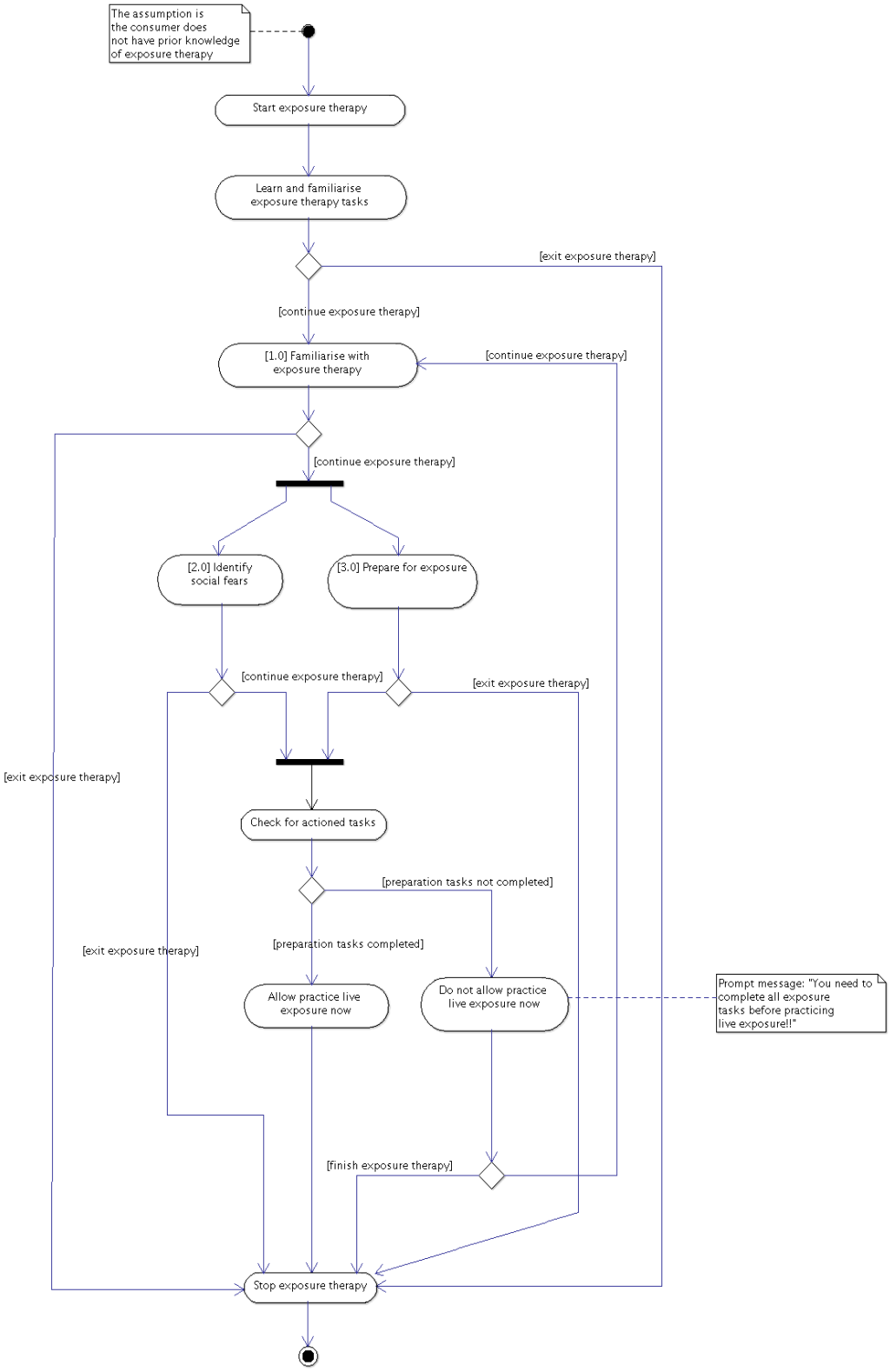
17. APPENDIX I

Notation, Name, and Description of UML Activity Diagrams used for the EMI for Social Anxiety

UML activity diagram notation	Name	Description
	Initial Node	This UML notation represents the first action or actions in the activity.
	Final Node	This UML notation represents the final action of activity.
	Control Flow	This UML notation represents the flow of control of the activity. Control flows are modelled based on verbs described in the user stories.
	Action	This UML notation represents a step or action of some task or activity. Description of action contains *nouns* and *verbs* modelled in the user stories.
	Decision Node	This UML notation represents a decision or condition in a flow. It has one input and two outputs. Decision flows are modelled based on verbs described in the user stories.
	Guard	This UML notation represents a condition of the flow from a connector. Description of guard parameters contains *nouns* and *verbs* modelled in the user stories.
	Fork Node	This UML notation represents a division of a single flow into concurrent flows.
	Join Node	This UML notation represents a combination of concurrent flows into a single flow.
	Note	This UML notation represents remarks or comments about elements of the model.

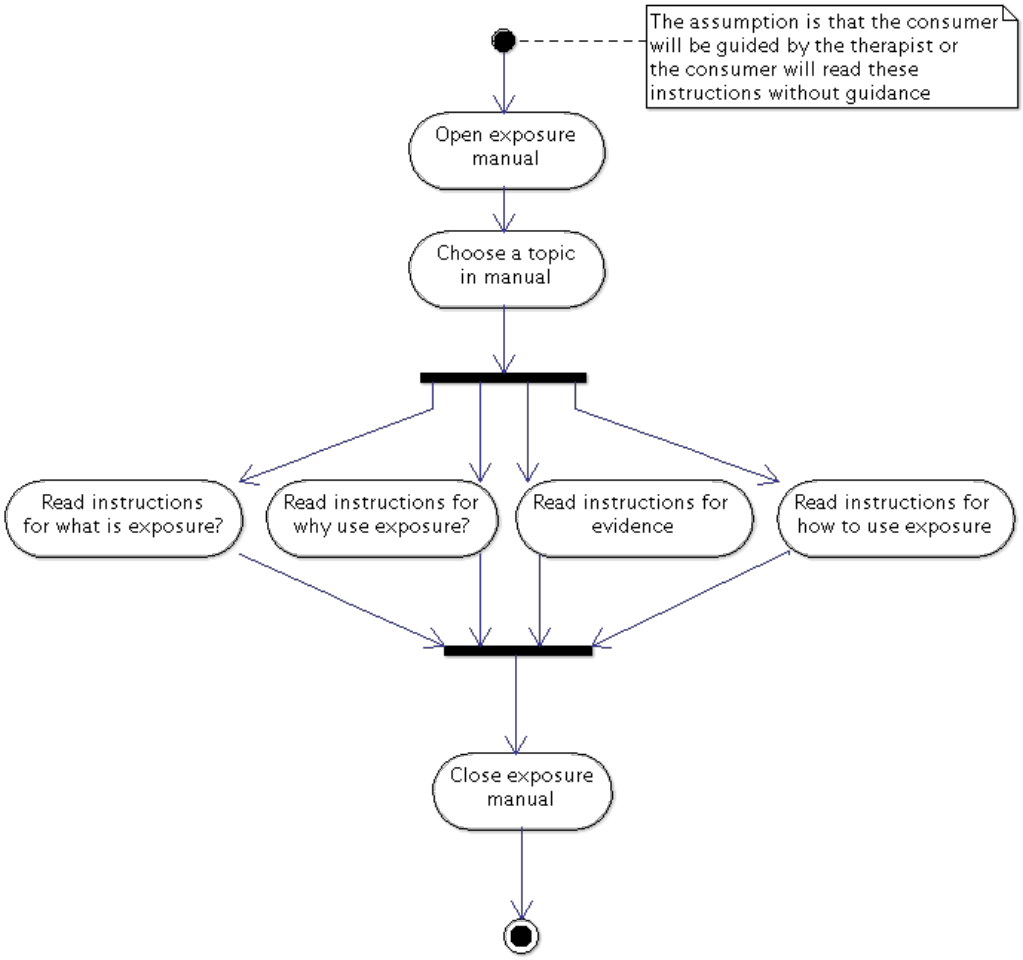
18. APPENDIX J

UML Activity Diagram for Exposure Practice Steps



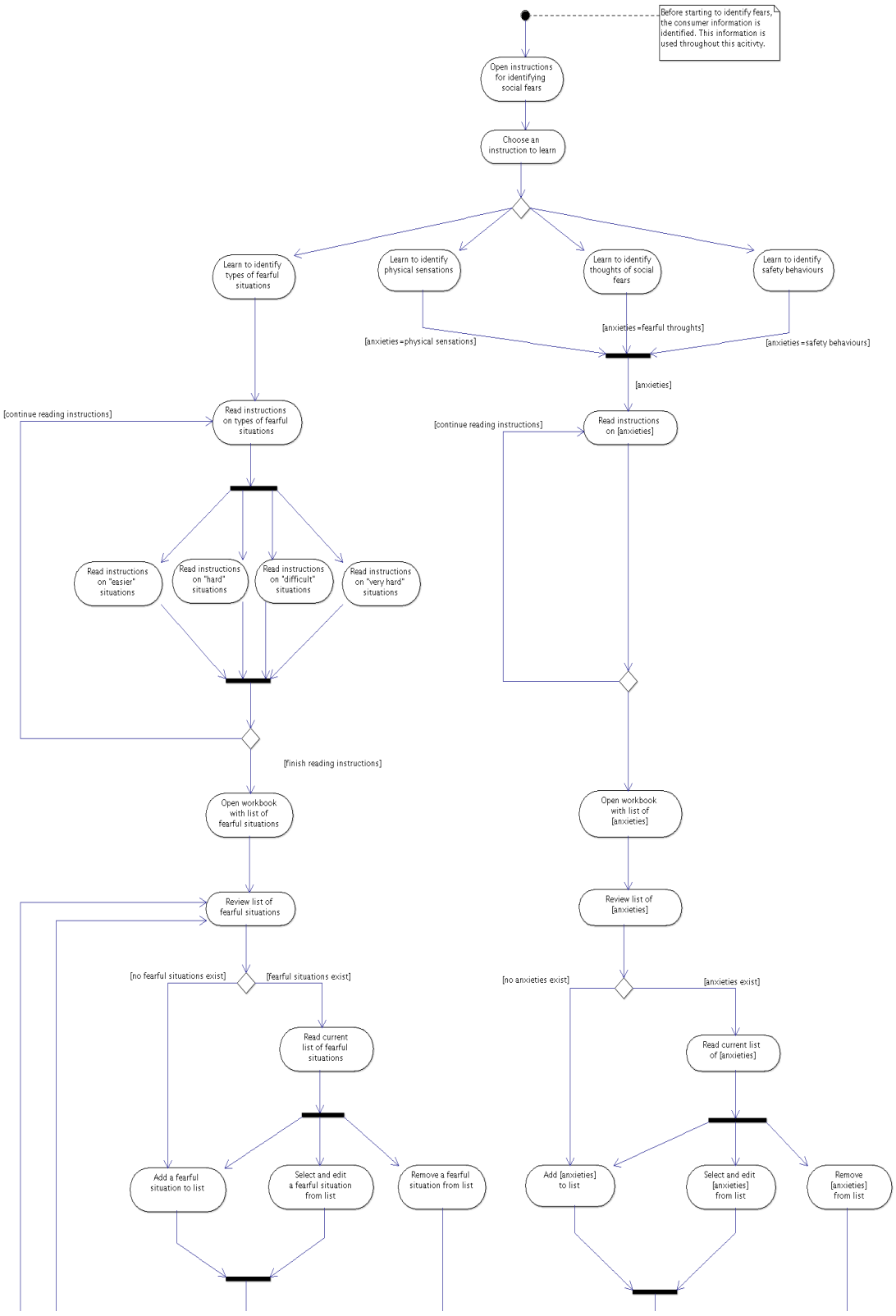
18.1. APPENDIX J.1

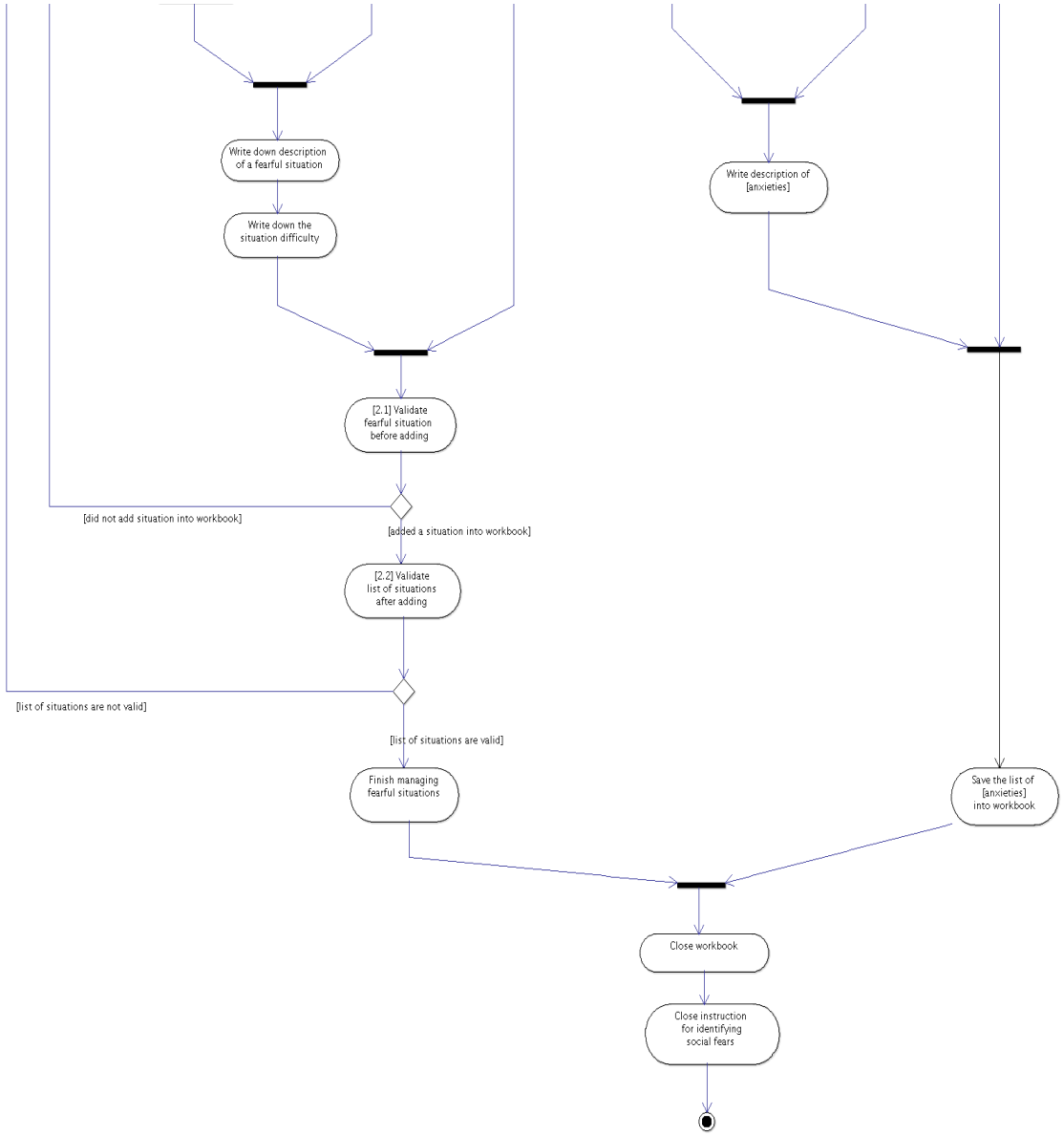
UML Activity Diagram for Exposure Practice Steps



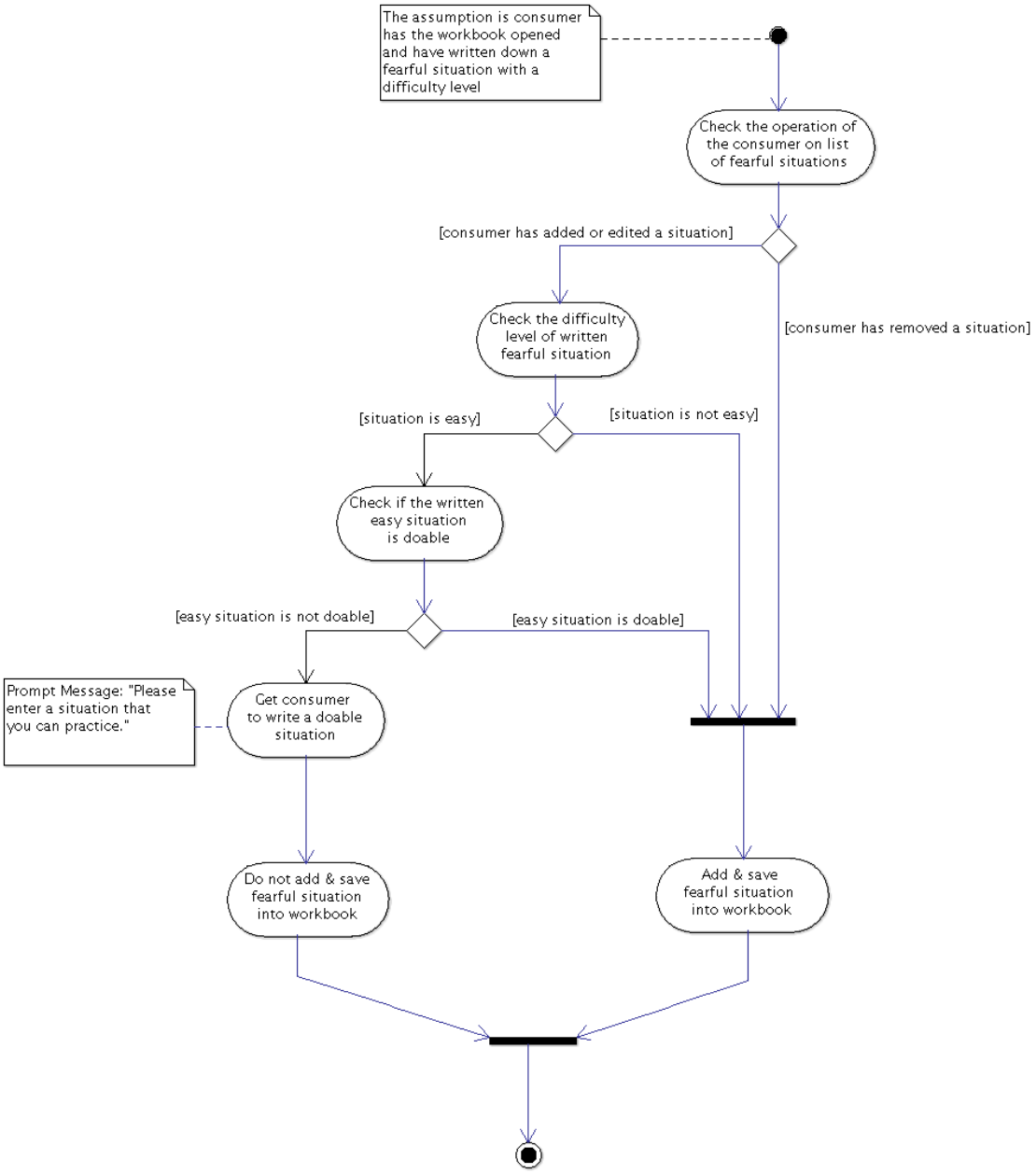
18.2. APPENDIX J.2

UML Activity Diagrams for Identifying My Social Anxieties [2, 2.1, 2.2]

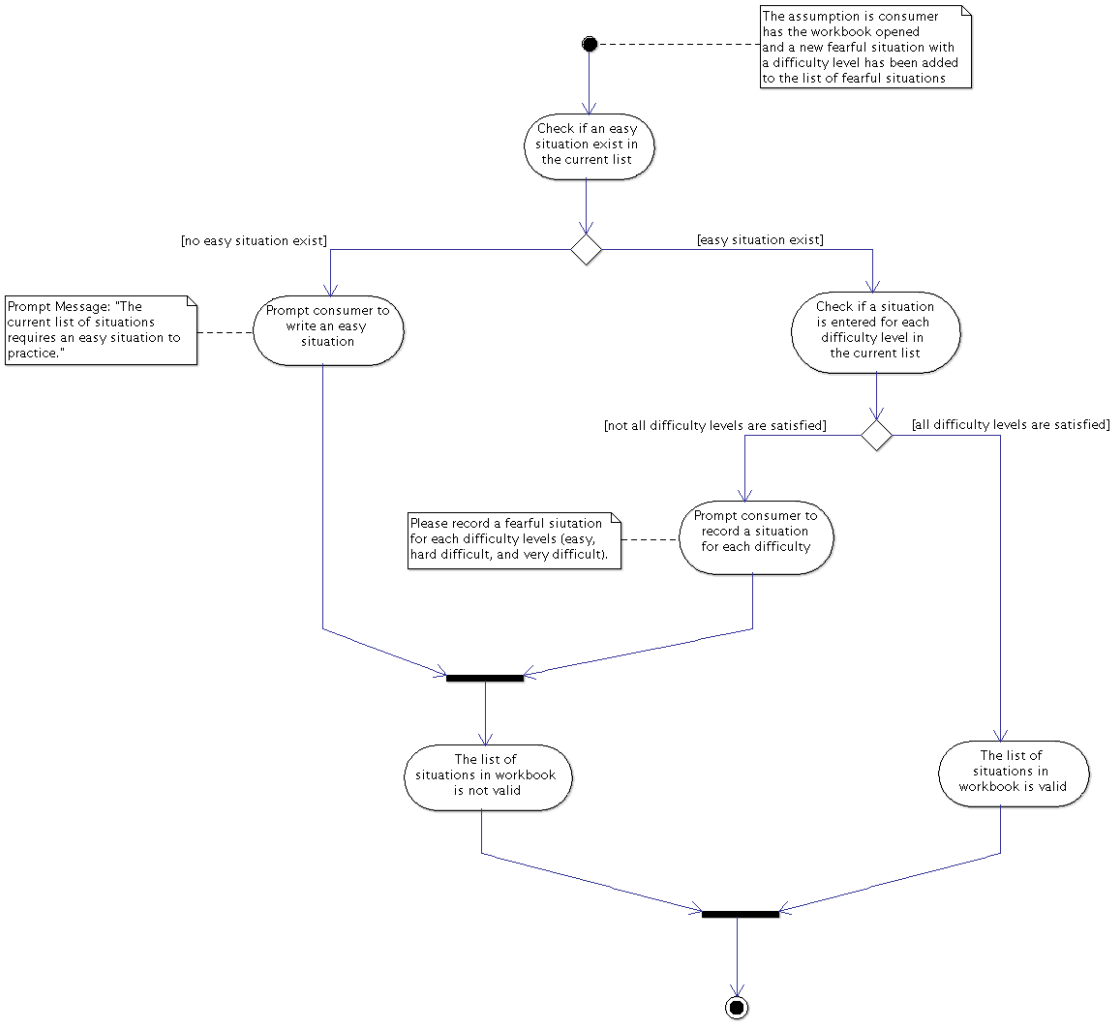




[2] Activities for identifying anxieties (i.e. situations, physical sensations, safety behaviours, and negative thoughts)



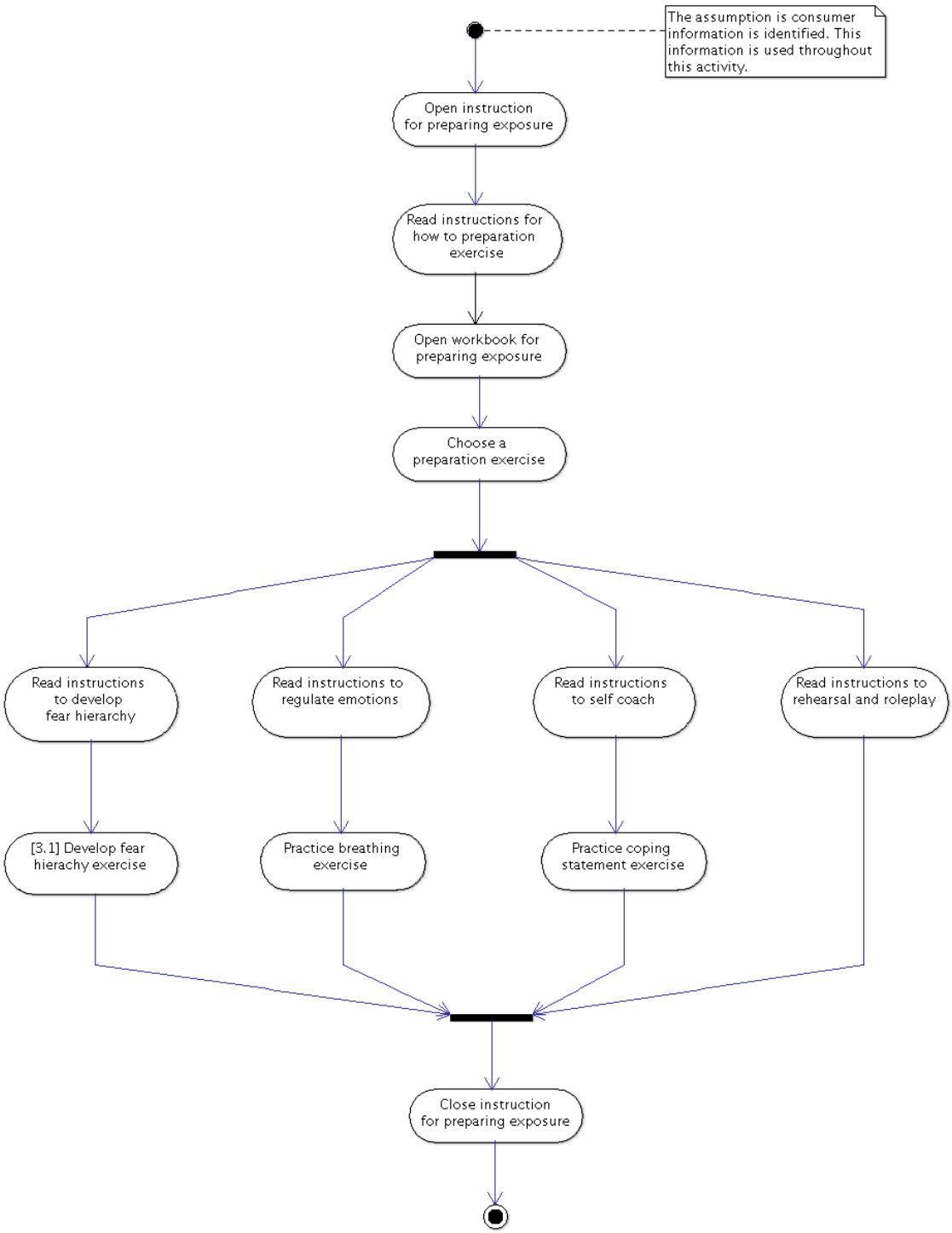
[2.1] Activities for validating fear before adding to workbook



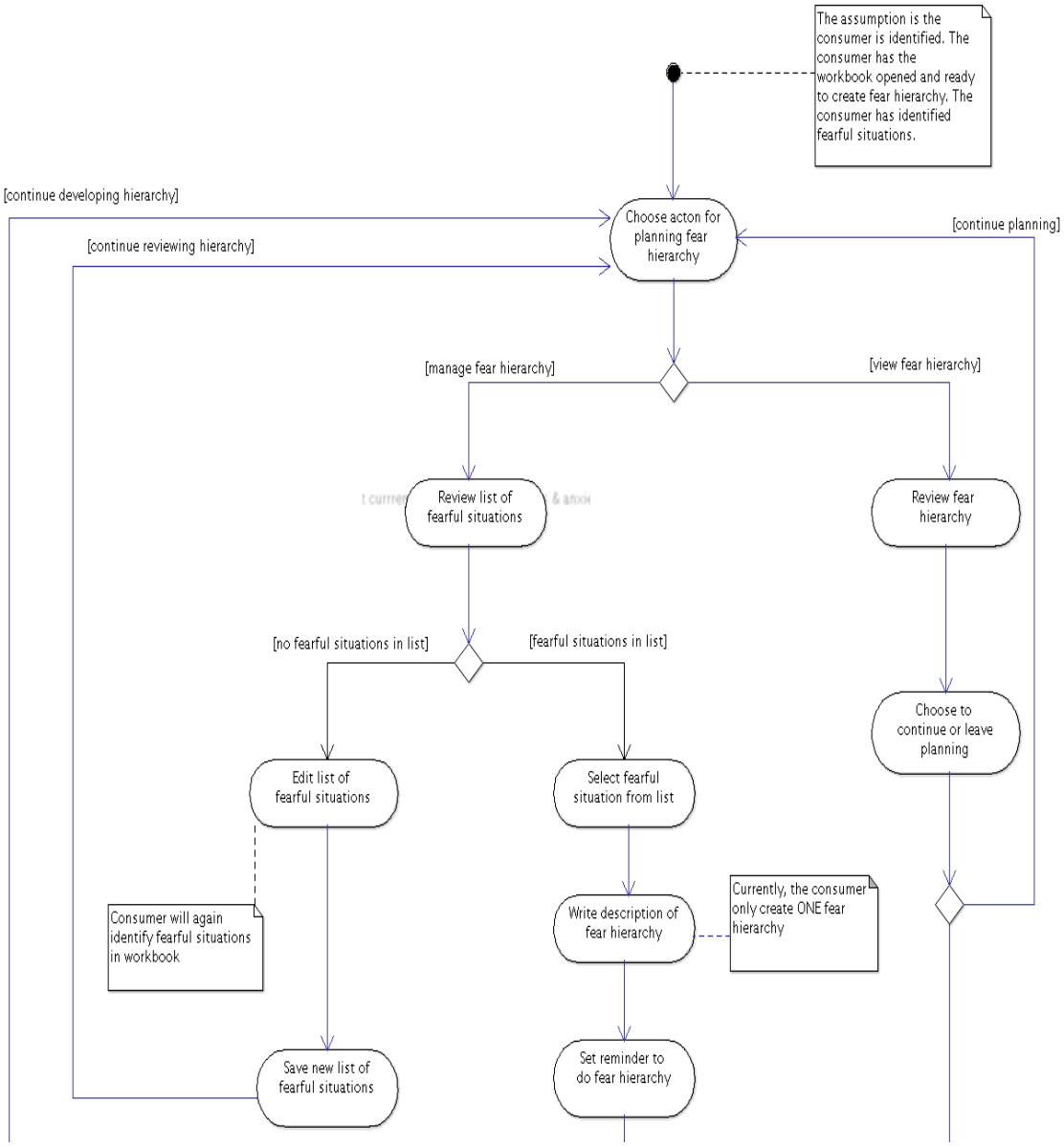
[2.2] Activities for validating a list of situations after adding to the workbook.

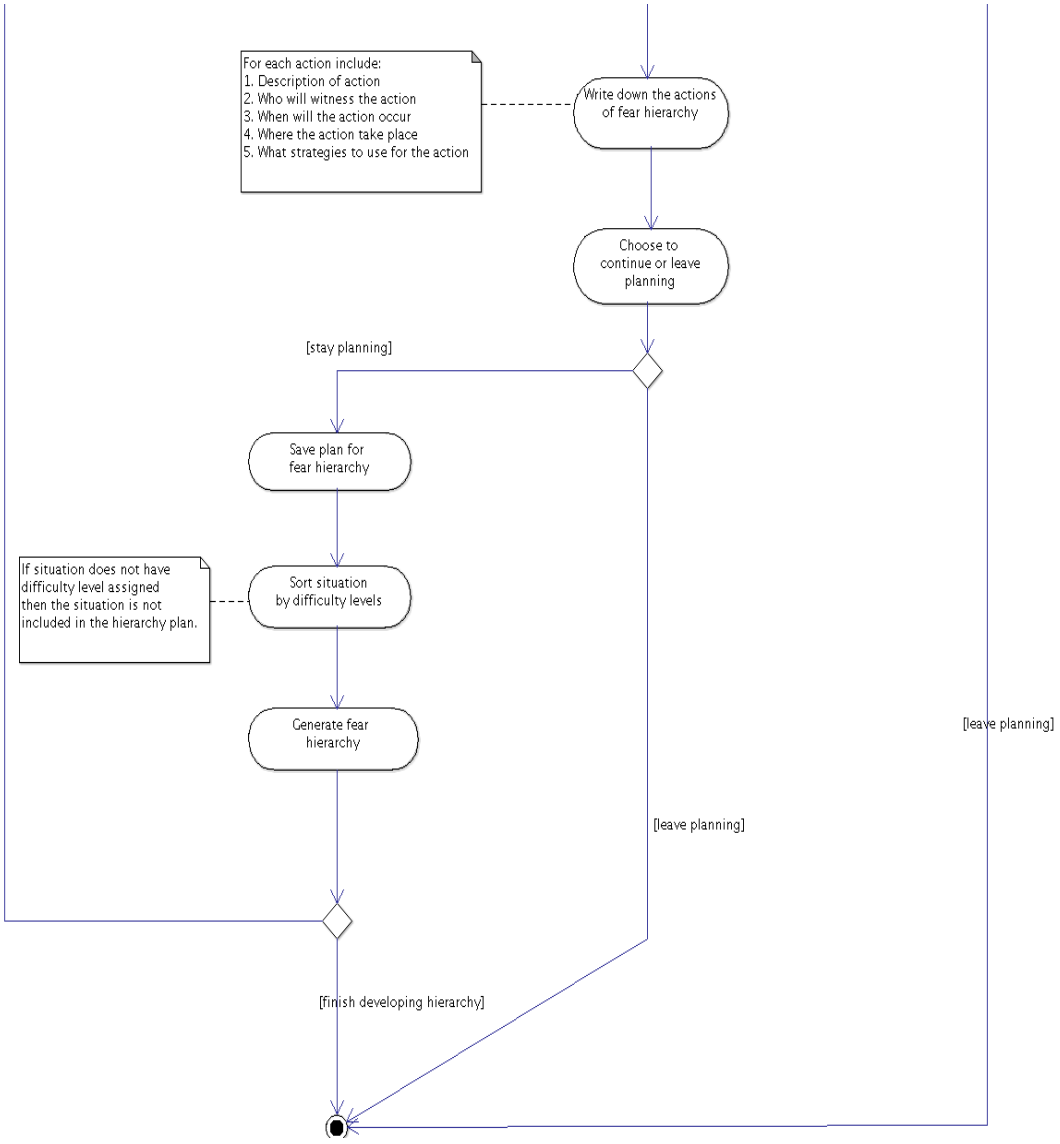
18.3. APPENDIX J.3

UML Activity Diagrams for Getting Ready for Exposure Practice [3, 3.1]



[3] Activities for getting ready for exposure practice

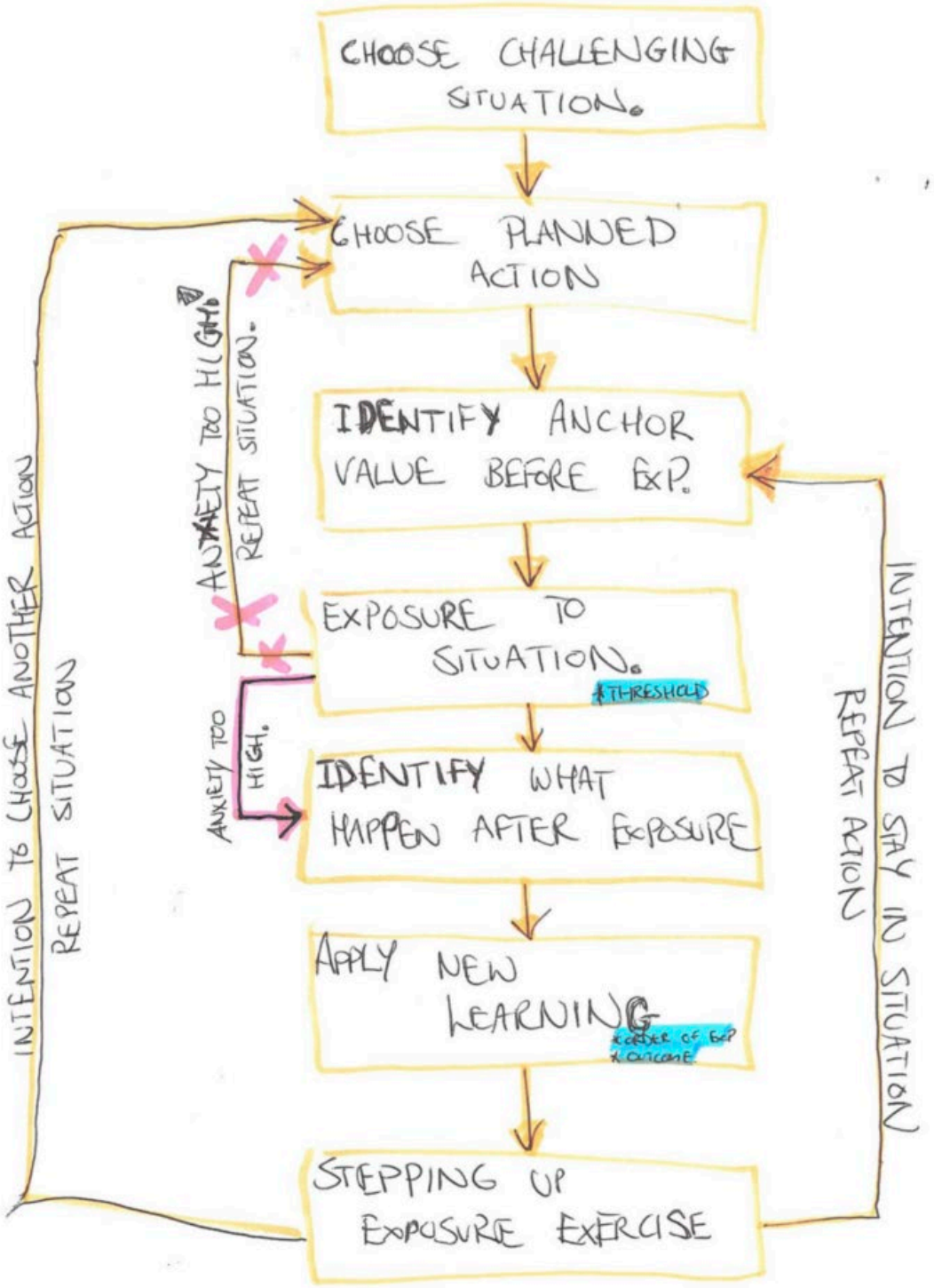




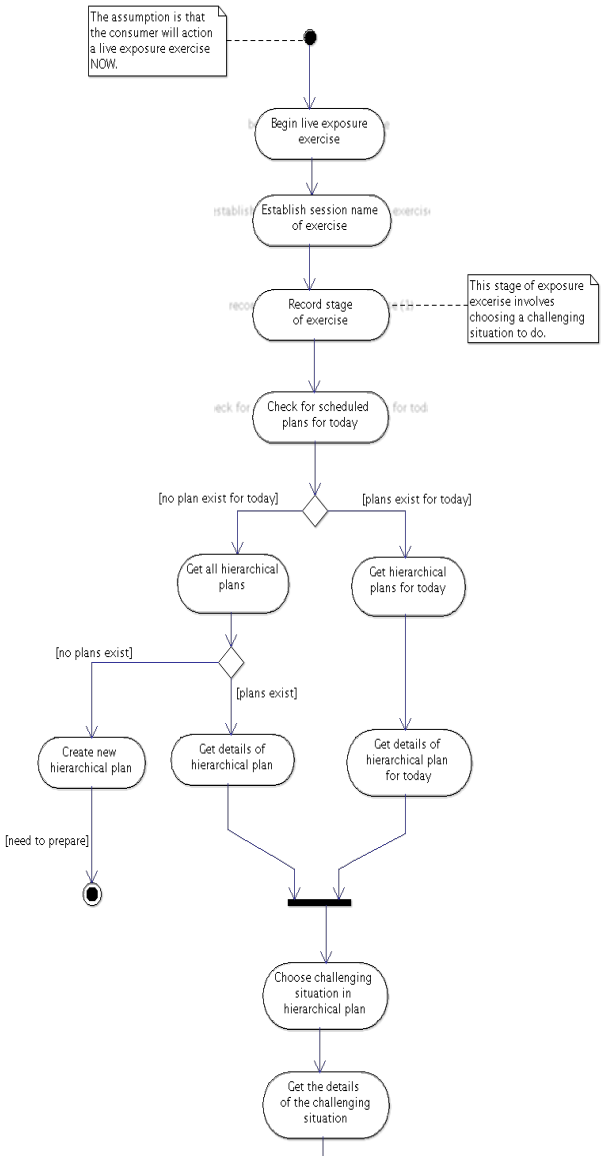
[3.1] Activities for developing fear hierarchy exercise

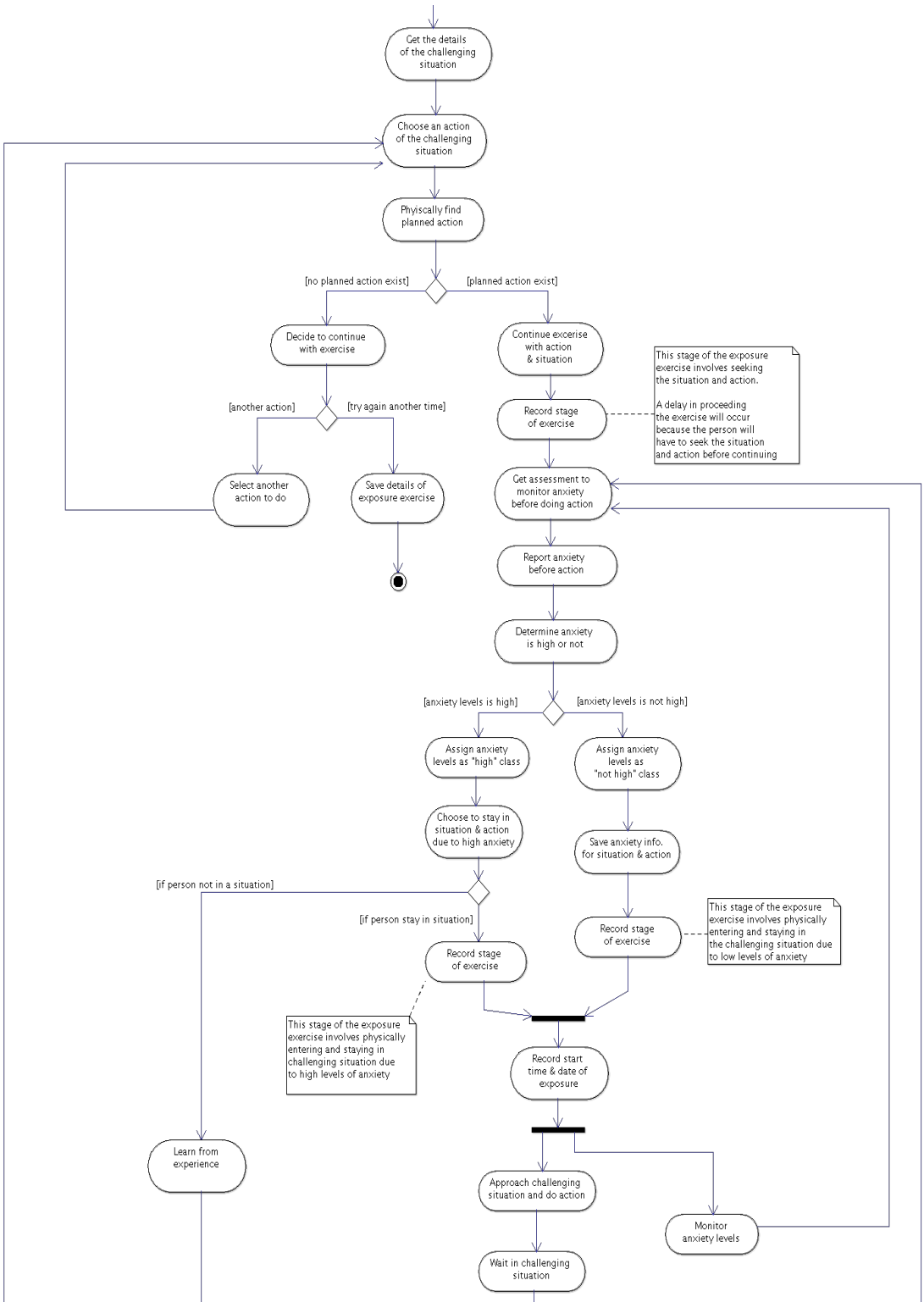
18.4. APPENDIX J.4

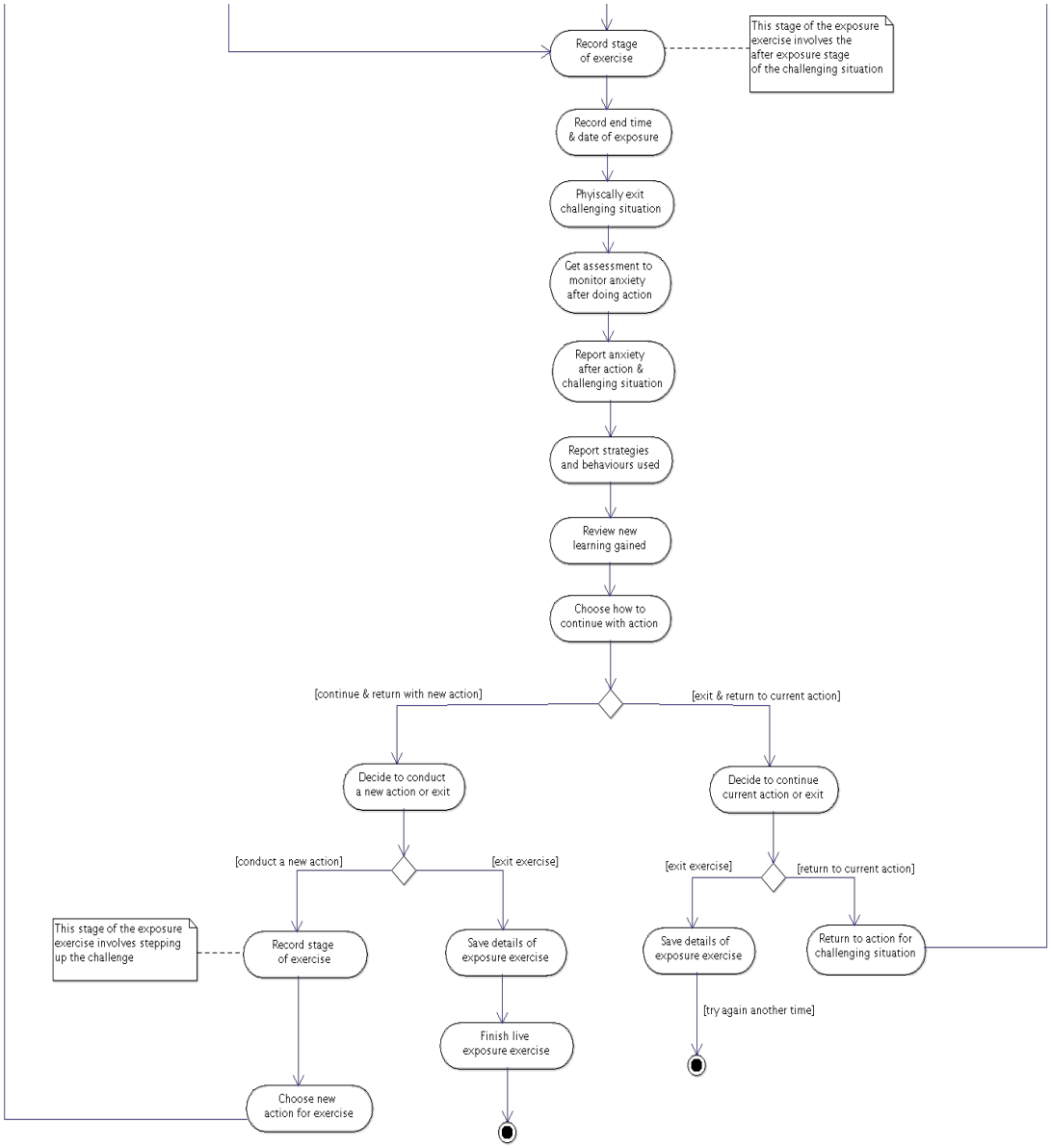
UML Activity Diagrams for Performing Exposure Now [a, b]



[a] Rough sketch of a high-level overview of activities for practising in-situ exposure.



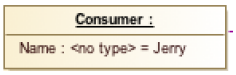
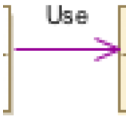

Get the details of the challenging situation
Choose an action of the challenging situation
Phyiscally find planned action
[no planned action exist]
[planned action exist]
Decide to continue with exercise
Continue excerise with action & situation
This stage of the exposure exercise involves seeking the situation and action.
A delay in proceeding the exercise will occur because the person will have to seek the situation and action before continuing
[another action]
[try again another time]
Record stage of exercise
Select another action to do
Save details of exposure exercise
Get assessment to monitor anxiety before doing action
Report anxiety before action
Determine anxiety is high or not
[anxiety levels is high]
[anxiety levels is not high]
Assign anxiety levels as "high" class
Assign anxiety levels as "not high" class
Choose to stay in situation & action due to high anxiety
Save anxiety info. for situation & action
[if person not in a situation]
[if person stay in situation]
Record stage of exercise
This stage of the exposure exercise involves physically entering and staying in the challenging situation due to low levels of anxiety
Record stage of exercise
This stage of the exposure exercise involves physically entering and staying in challenging situation due to high levels of anxiety
Record start time & date of exposure
Learn from experience
Approach challenging situation and do action
Monitor anxiety levels
Wait in challenging situation



[b] More detailed activity diagram for practicing in-situ exposure.

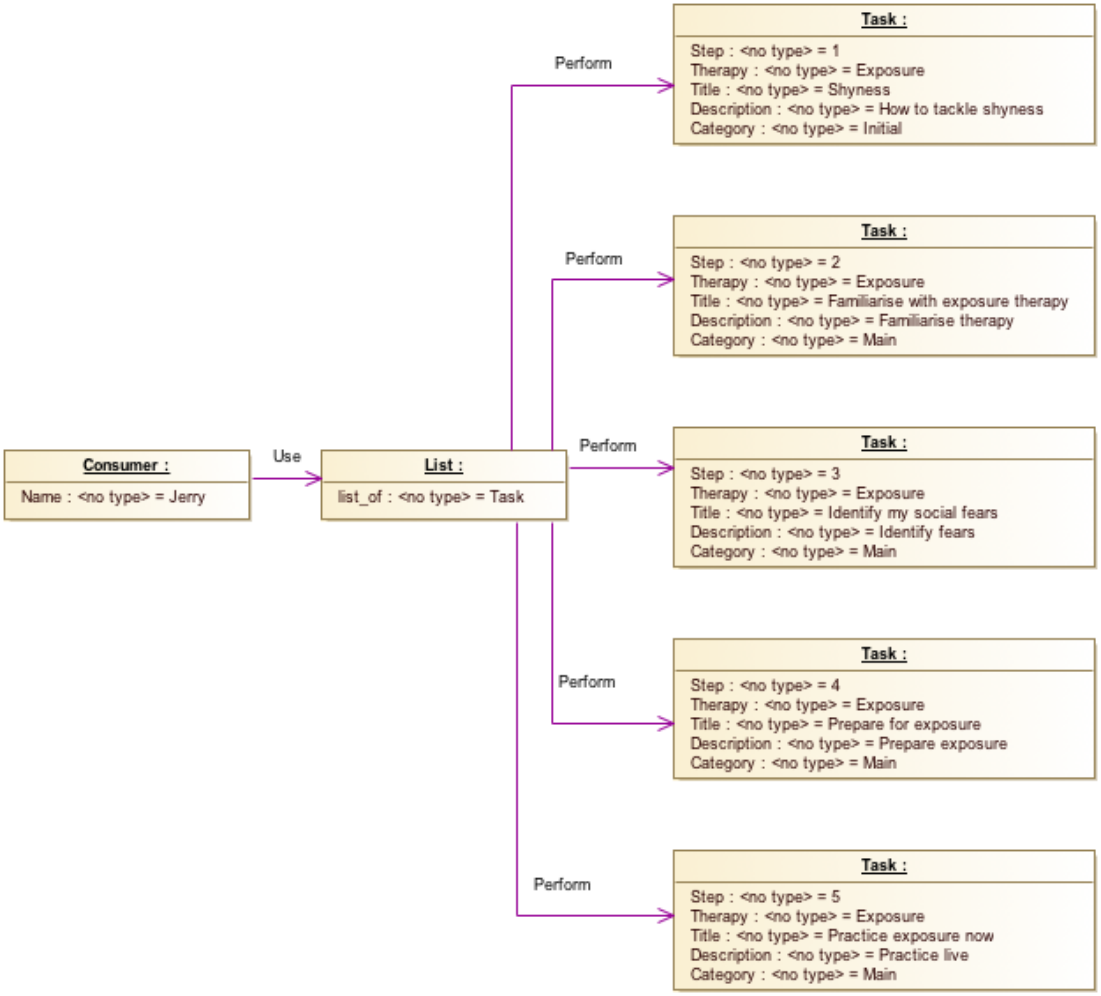
19. APPENDIX K

Notation, Name, and Description of UML Object Diagrams used for the EMI for Social Anxiety

UML object diagram notation	Name	Description
	Instance	This UML notation represents an instance specification of an entity in a therapy process. An instance partially describes the entity in an object diagram. Instances are modelled based on *nouns* described in the user stories and UML activity diagrams.
	Attribute	This UML notation represents the properties of an instance in a therapy process. A semicolon and the concrete value of the property follows the name of the attribute. For example, a property called “Name” is assigned the value “Jerry” for a “Consumer” instance.
	Association	This UML notation represents the relationship or link between one or more instances in a therapy process. The name of the instance is modelled based on the *verbs* described in the user stories and UML activity diagrams.
	Unidirectional association	This UML notation represents the direction of an association between one or more instances in a therapy process. The direction of the arrow represents how an instance interacts with another instance.

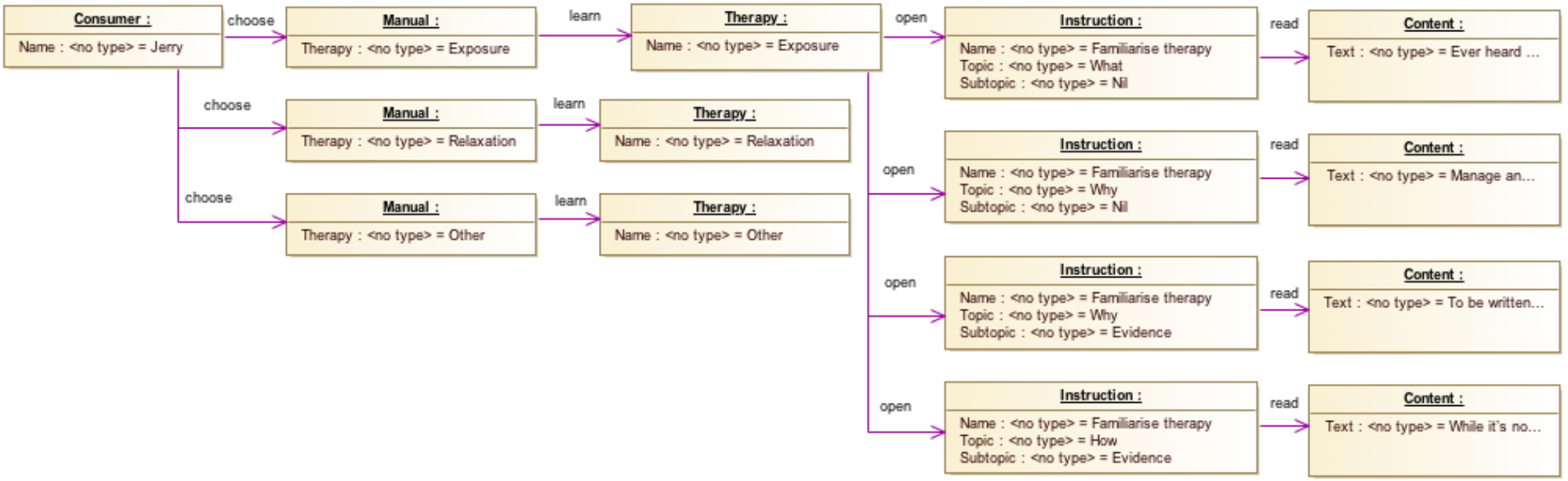
20. APPENDIX L

UML Object Diagram for Exposure Practice Steps



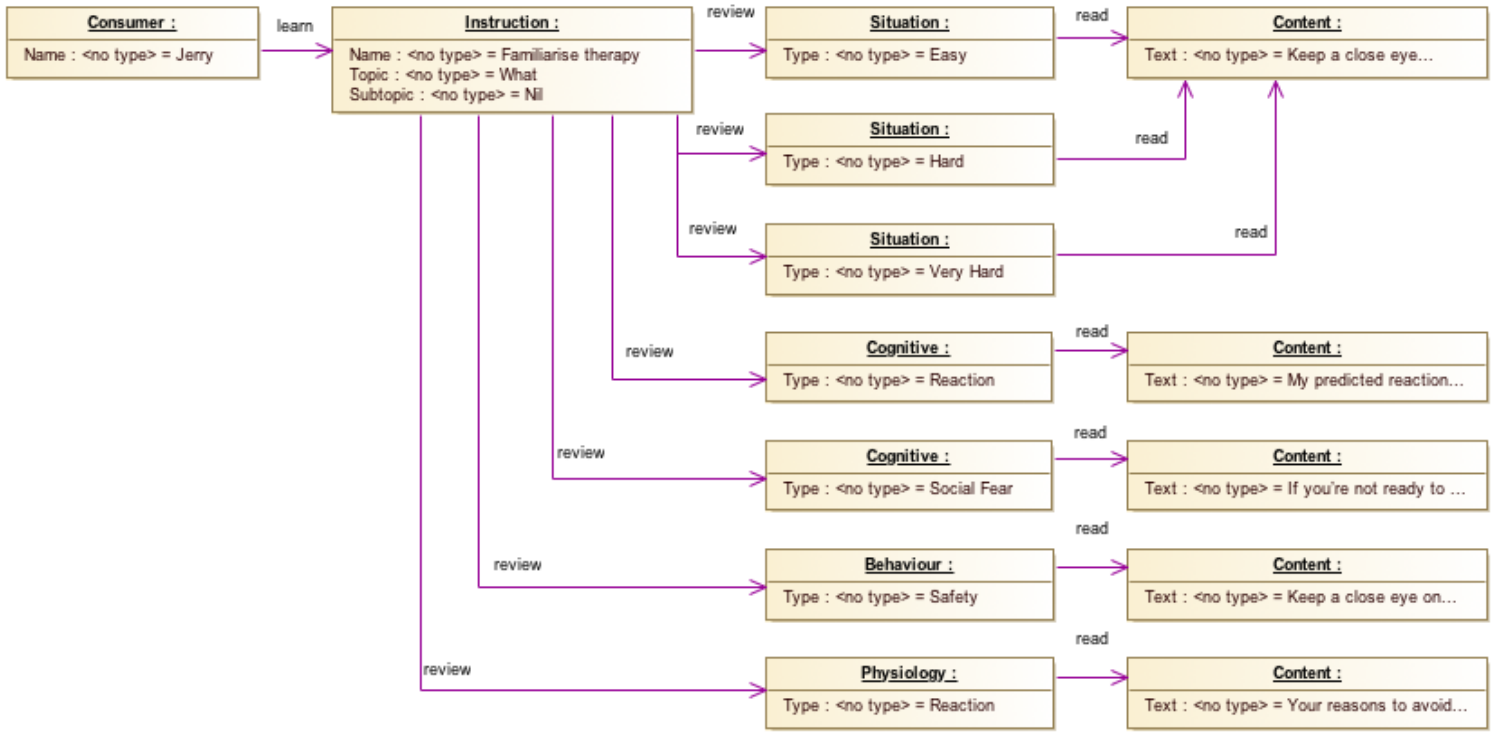
20.1. APPENDIX L.1

UML Object Diagram for Learning about Exposure Practice

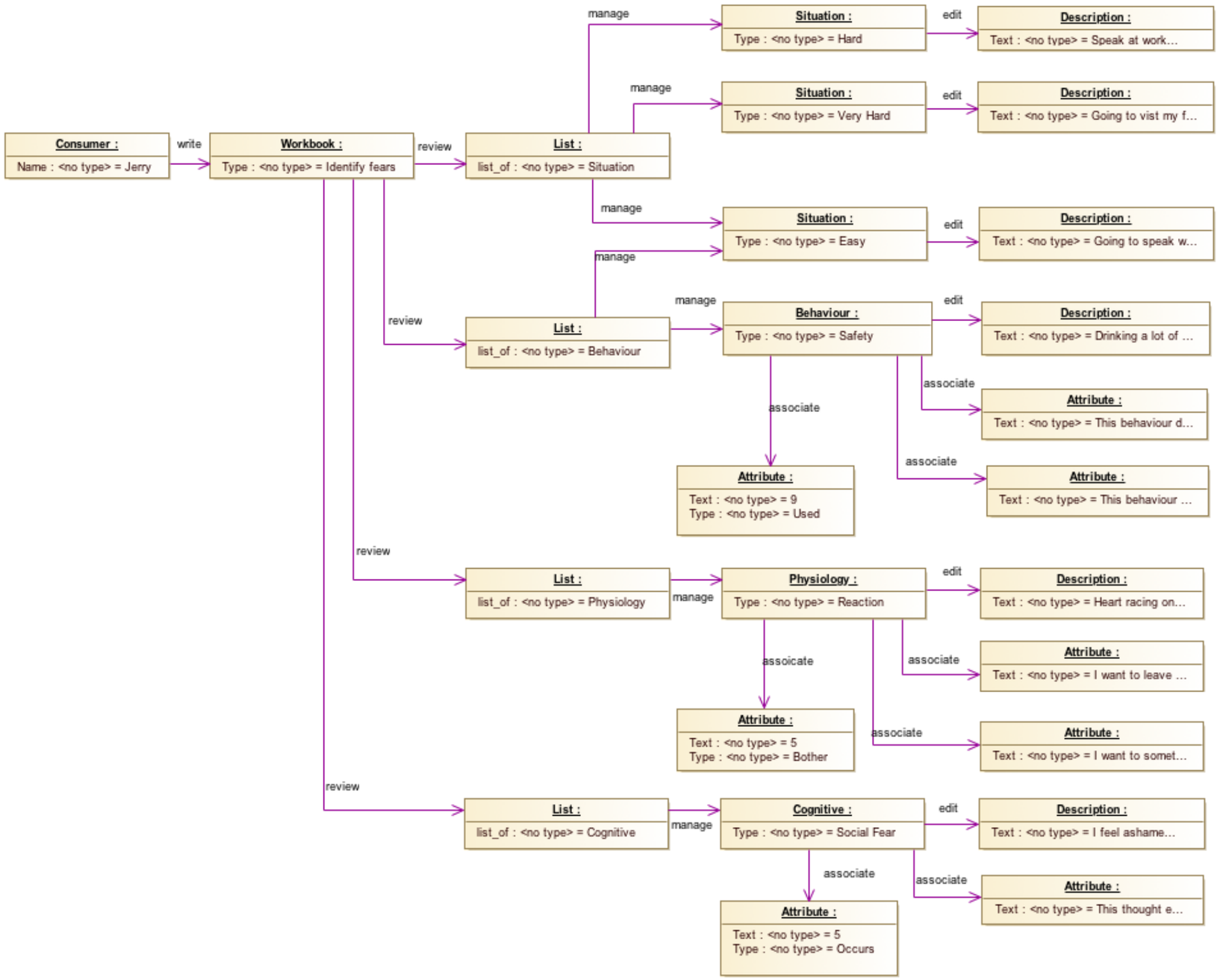


20.2.APPENDIX L.2

UML Object Diagrams for Identifying My Social Anxieties [a, b]



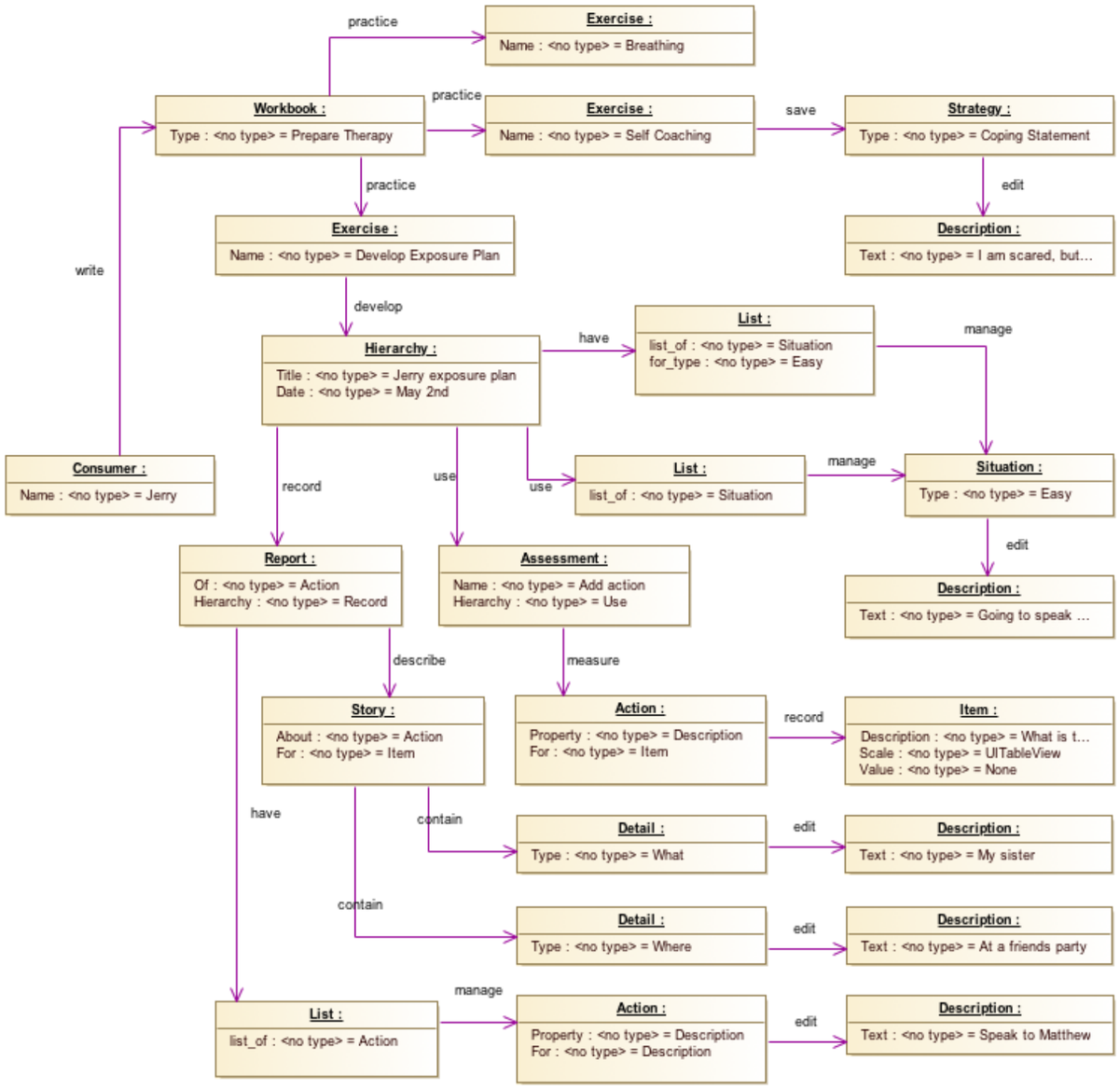
[a] Objects are representing the instructions for identifying my anxieties.



[b] Objects representing the workbook features for identifying my anxieties.

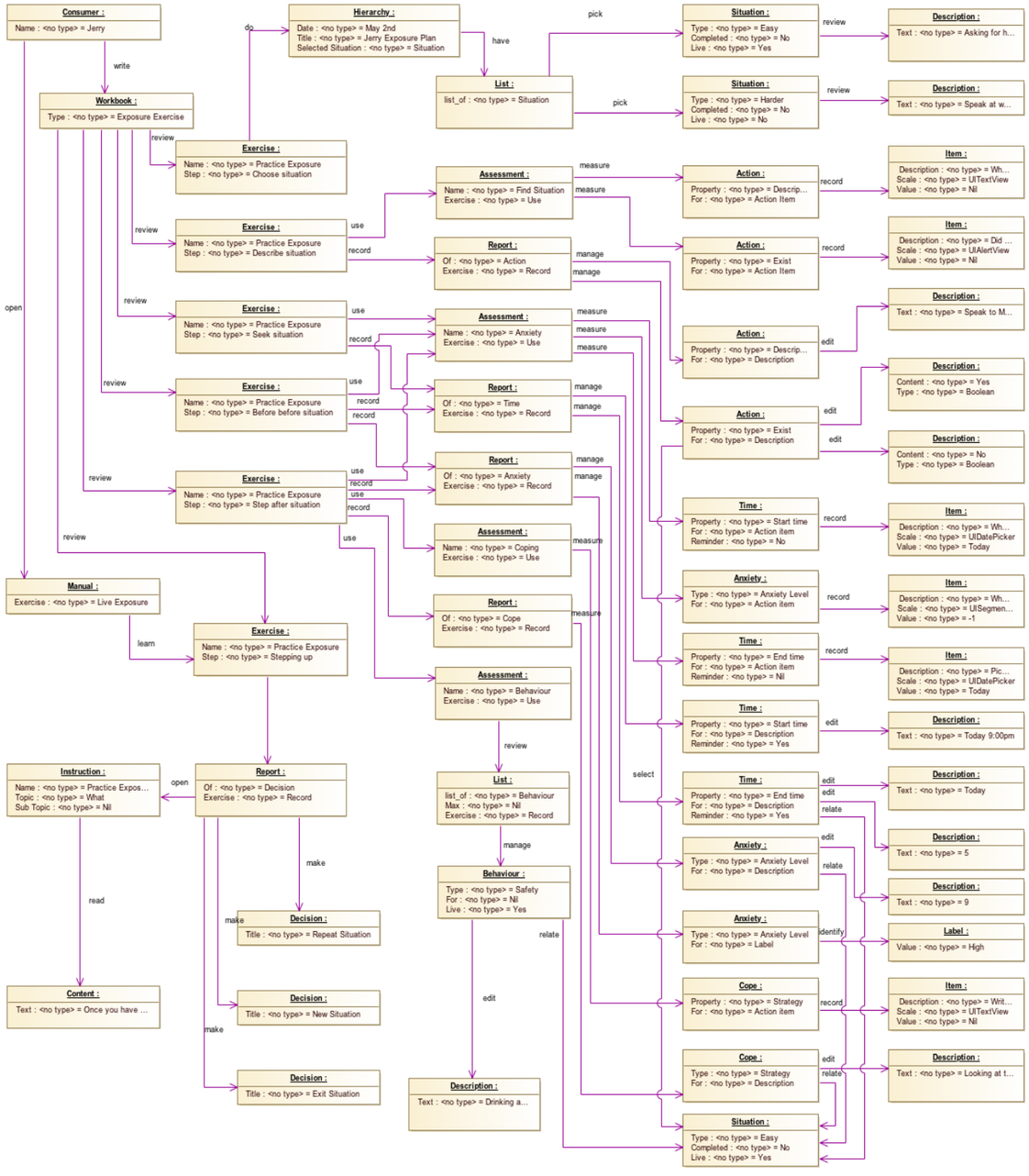
20.3. APPENDIX L.3

UML Object Diagram for Getting Ready for Exposure Practice



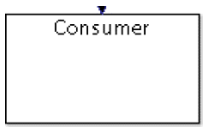
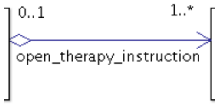
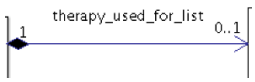
20.4.APPENDIX L.4

UML Object Diagram for Performing Exposure Now

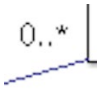
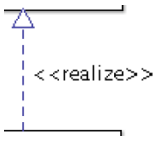


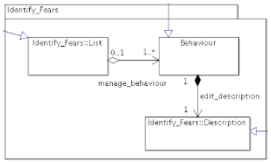
21. APPENDIX M

Notation, Name, and Description of UML Class Diagrams used for the EMI for Social Anxiety

UML class diagram notation	Name	Description
	Class	This UML notation represents a set of instances or objects that share the same specification of structures, properties, and operations. A class fully describes the entity in a therapy process. Classes are modelled based on *duplicate* instances described in UML object diagrams.
	Interface Class	This UML notation represents a set of operations that a class can inherit and implement. An interface is reusable in the domain. Interfaces have been used to represent platform-specific mechanisms used in the domain of an EMI. Additionally, it has been used to represent the implementation of the same instance of a class described across UML object diagrams.
	Utility Class	This UML notation represents a set of static properties and operations for classes.
	Aggregation Association	This UML notation represents the shared relationship or link between one or more classes in a therapy process. Aggregated associations are modelled based on *duplicate* associations between two instances described in UML object diagrams.
	Composition Association	This UML notation represents a whole and part relationship or link between one or more classes in a therapy process. Composite relationships are a type of aggregation that requires instantiated dependent classes to instantiate the target class in a therapy process. Hence, it applies a mandatory condition for an entity during the lifecycle of an object. Composite associations are modelled based on *duplicate* associations between two instances described in UML object diagrams.
	One-to-many Cardinality (1,N)	This UML notation represents an association that applies a condition for many instances of the class to exist (*), and at least *one* instance of the class to exist (1...)

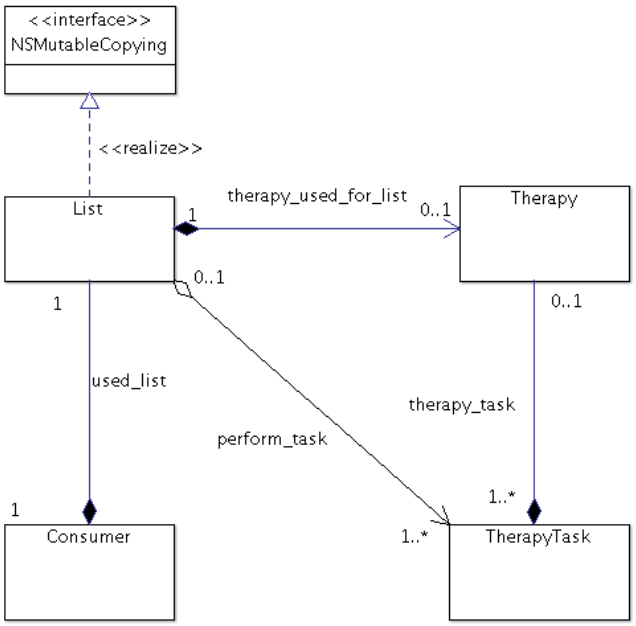
for the relationship to be valid. Cardinality values are modelled based on the number of instances of a class described in UML object diagrams.

	Nil-to-many Cardinality (0,N)	This UML notation represents an association that applies a condition for many instances of the class to exist (*), but instances of a class do *not* have to exist (0...) for the relationship to be valid. Cardinality values are modelled based on the number of instances of a class described in UML object diagrams.
	One-to-one Cardinality (1,1)	This UML notation represents an association that applies a condition for only one entity, and at least *one* entity must exist for the relationship to be valid (1). Cardinality value is modelled based on the number of instances of a class described in UML object diagrams.
	Nil-to-one Cardinality (0,1)	This UML notation represents an association that applies a condition for only one entity (1), but instances of a class do *not* have to exist (0...) for the relationship to be valid. Cardinality value is modelled based on the number of instances of a class described in UML object diagrams.
	Generalisation	This UML notation represents the relationship between a more general class and a more specific class. Generalisations are modelled based on the common instances of a class described in UML object diagrams.
	Realisation	This UML notation represents the dependent relationship between a class that supplies a specification for the implementation of a specific class. An interface class in a therapy process can supply this specification. Realisations are modelled based on the common instances of a class described in UML object diagrams.

	Package	This UML notation represents a group of classes and associations in a therapy process. It provides a namespace (i.e., Identify Fears) for all classes and associations in the group of UML notation. Packages are modelled based on a group of instances or modules described in UML object diagrams.

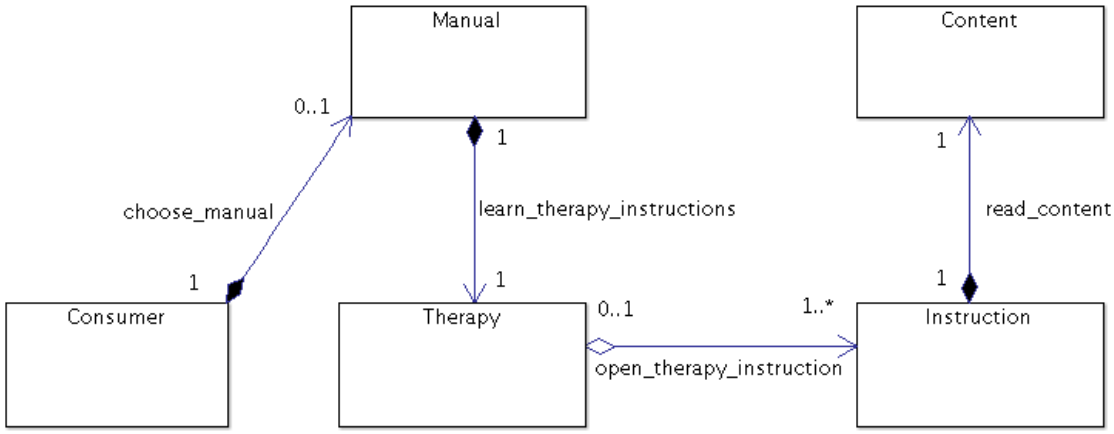
22. APPENDIX N

UML Class Diagram for Exposure Practice Steps



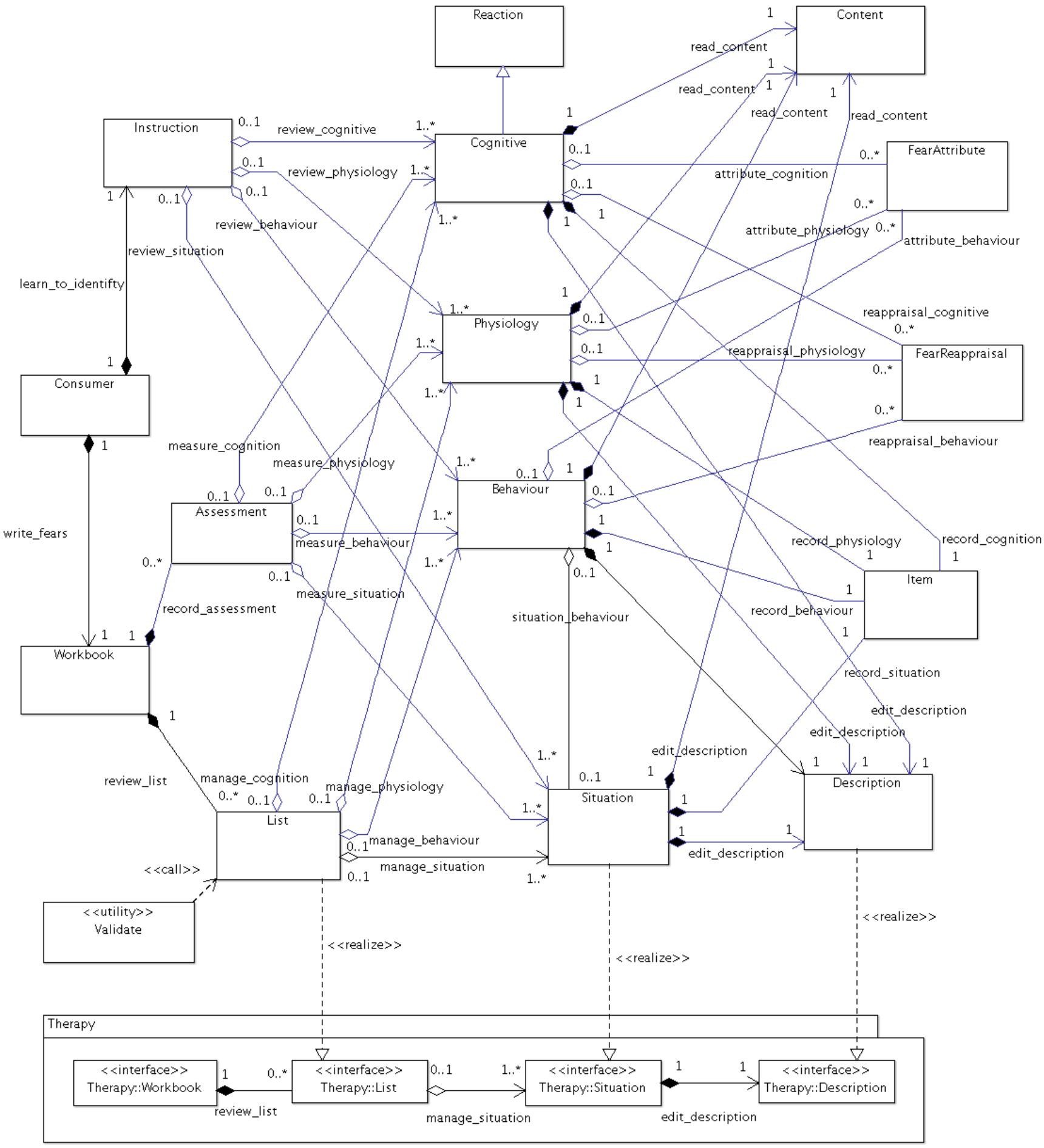
22.1. APPENDIX N.1

UML Class Diagram for Learning about Exposure Practice



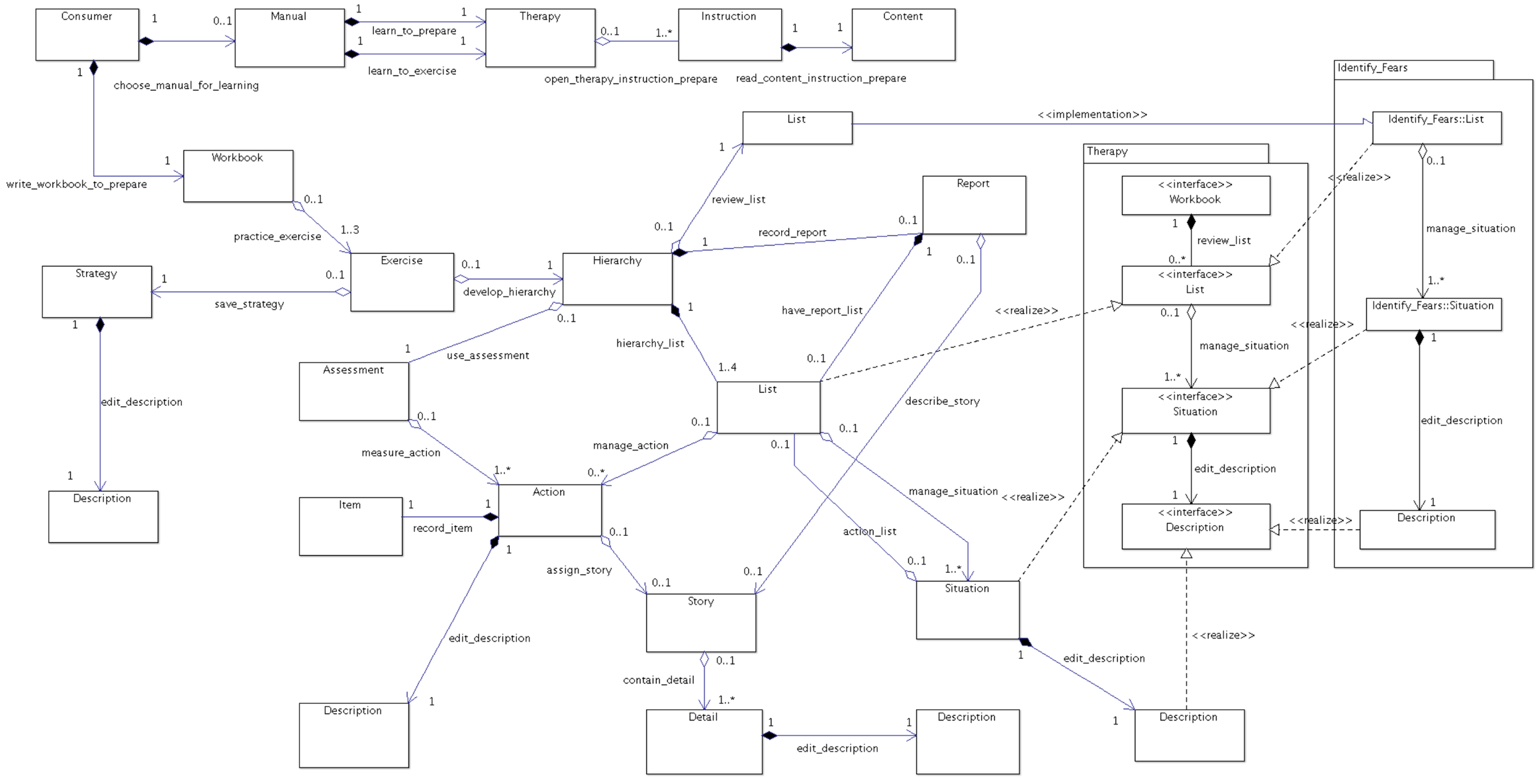
22.2. APPENDIX N.2

UML Class Diagram for Identifying My Social Anxieties



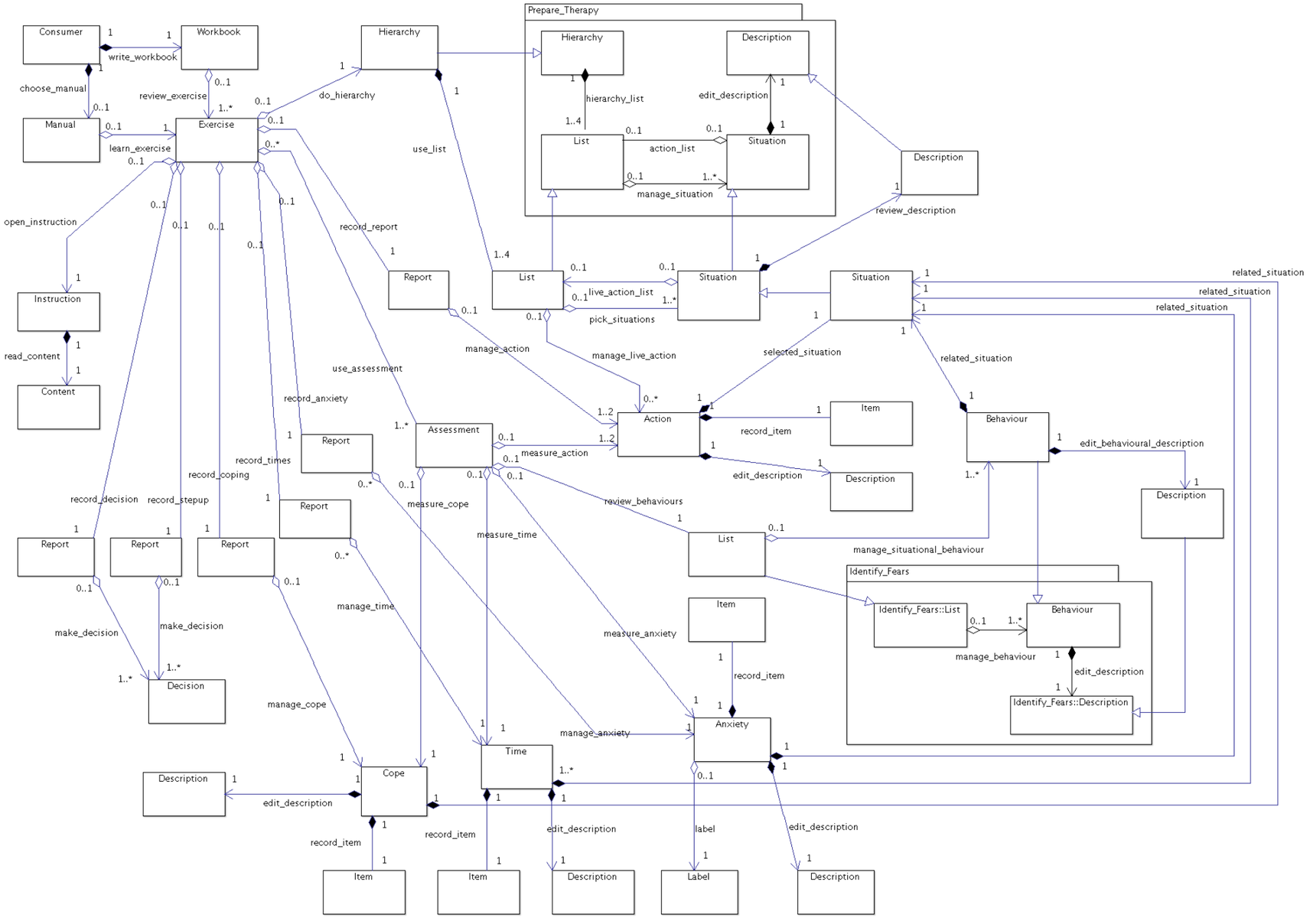
22.3. APPENDIX N.3

UML Class Diagram for Getting Ready for Exposure Practice



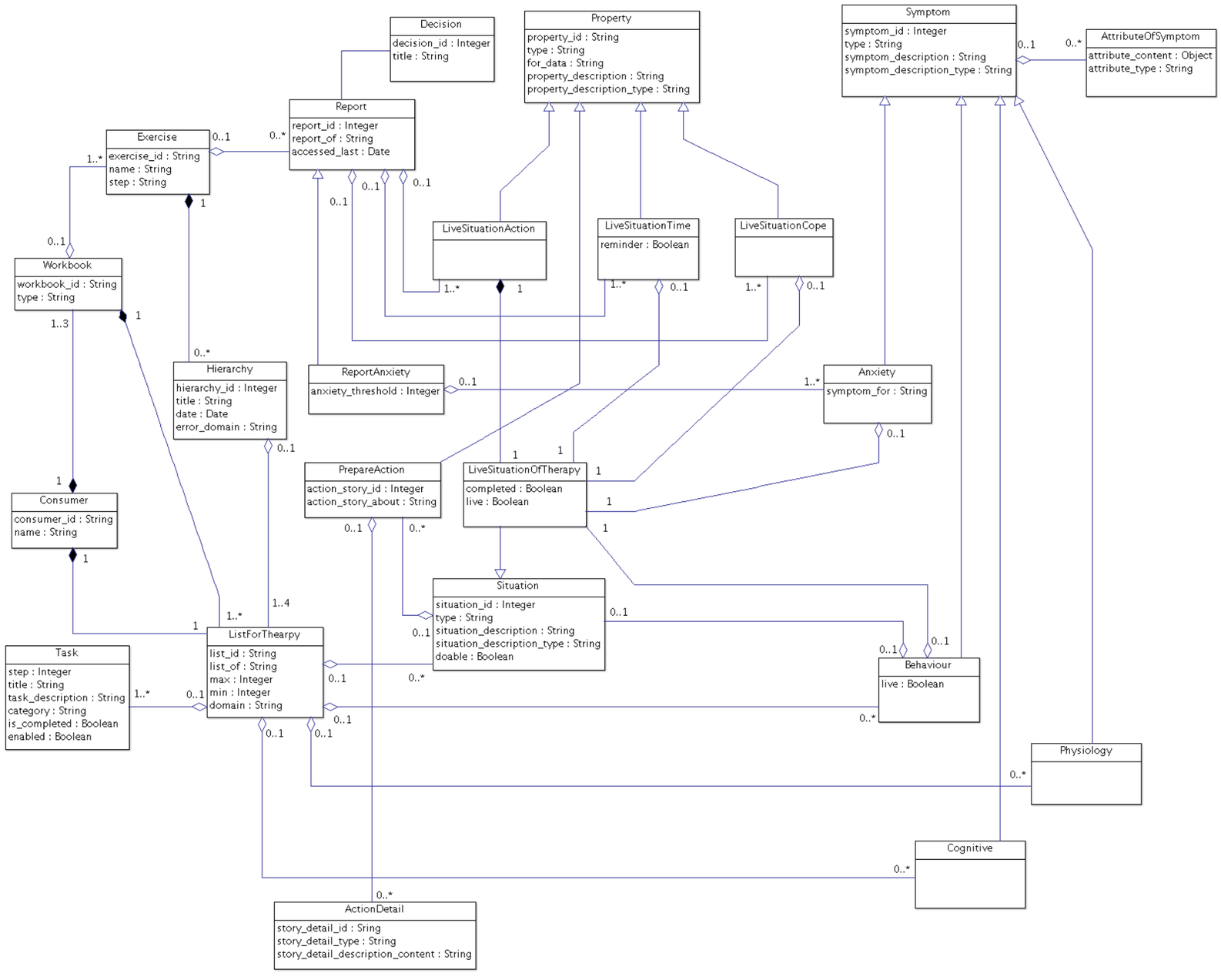
22.4. APPENDIX N.4

UML Class Diagram for Performing Exposure Now



23. APPENDIX O

UML Class Diagram of the Data Access Layer of the iOS Mobile App Delivering an EMI for Social Anxiety



24. APPENDIX P

Software Architectural Layer of the iOS Mobile App Delivering the EMI